

Eric I. Abraham  
Christina L. Saveriano  
**HILL WALLACK LLP**  
21 Roszel Road  
Princeton, New Jersey 08540  
Telephone: 609-924-0808

*Of Counsel:*

Jeffrey R. Gargano  
Peter M. Siavelis  
Wan-Shon Lo  
Zachary D. Miller  
**MCDERMOTT WILL & EMERY LLP**  
227 W Monroe Street, Suite 4400  
Chicago, Illinois 60606  
Telephone: 312-372-2000

Rebecca H. Duttry  
**MCDERMOTT WILL & EMERY LLP**  
500 North Capitol Street, N.W.  
Washington, DC 20005  
Telephone: 202-756-8000

*Attorneys for Plaintiff Elan Pharma  
International Ltd.*

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

\_\_\_\_\_  
ELAN PHARMA INTERNATIONAL LTD. )

Plaintiff, )

v. )

ACTAVIS LABORATORIES UT, INC., )  
ACTAVIS, INC. AND ACTAVIS PLC )

Defendants. )  
\_\_\_\_\_ )

Civil Action No. \_\_\_\_\_

**COMPLAINT FOR PATENT  
INFRINGEMENT**

## **COMPLAINT**

In this patent infringement action, Plaintiff Elan Pharma International Ltd. (“Elan”), for its complaint against Defendants Actavis Laboratories UT, Inc., Actavis, Inc. and Actavis plc, allege as follows:

### **NATURE OF THE ACTION**

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, in response to the filing by Actavis Laboratories UT, Inc. (“Actavis Labs”) of Abbreviated New Drug Application (“ANDA”) No. 208012 with the U.S. Food and Drug Administration (“FDA”) seeking approval to manufacture and sell a generic version of CLINDESSE® prior to the expiration of U.S. Patent No. 6,899,890.

### **THE PARTIES**

2. Plaintiff Elan is a corporation organized and existing under the laws of the Country of Ireland, having a place of business at Treasury Building, Lower Grand Canal Street, Dublin 2, Ireland.

3. On information and belief, Defendant Actavis Labs is a company organized and existing under the laws of the State of Delaware, having a place of business at 577 Chipeta Way, Salt Lake City, Utah.

4. On information and belief, Actavis Labs was formerly known as Watson Laboratories, Inc. On information and belief, Actavis Labs is a wholly owned subsidiary of Actavis, Inc.

5. On information and belief, Actavis, Inc. is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey. On information and belief, Actavis,

Inc. is registered as a manufacturer and wholesale drug distributor in the State of New Jersey under Registration Number 5003854. On information and belief, Actavis, Inc. is a wholly owned subsidiary of Actavis plc.

6. On information and belief, Actavis plc is a corporation organized and existing under the laws of the Country of Ireland, having a principal place of business at 1 Grand Canal Square Dublin 2, Docklands Dublin, 07054 Ireland.

7. On further information and belief, Actavis plc conducts its principal United States operations at the principal place of business of Actavis, Inc., namely, Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey.

8. On information and belief, Actavis Labs, Actavis, Inc. and Actavis plc are agents of each other and/or operate in concert as integrated parts of Actavis plc's generic pharmaceutical division. On further information and belief, the acts of Actavis Labs complained of herein were done at the direction, or with the authorization, or with the cooperation, participation or assistance, or at least in part for the benefit, of Actavis, Inc. and Actavis plc.

9. On information and belief, Actavis Labs and Actavis, Inc. are the alter egos of Actavis plc, where a unity of interest and ownership exists between Actavis Labs, Actavis, Inc. and Actavis plc, such that separate personalities of the three corporate entities in reality do not exist, and thus will be collectively referred to herein as "Defendants."

#### **JURISDICTION AND VENUE**

10. This action for patent infringement arises under 35 U.S.C. § 1 *et seq.* generally, and 35 U.S.C. § 271 specifically.

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

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

13. This Court has personal jurisdiction over each of the Defendants by virtue of, *inter alia*, their systematic and continuous contacts with New Jersey, the reasons set forth below, and for other reasons that will be developed and presented to the Court if personal jurisdiction is challenged. This Court has personal jurisdiction over Actavis, Inc. and Actavis plc by virtue of, *inter alia*, their presence in New Jersey.

14. On information and belief, Actavis plc is a global specialty pharmaceutical company engaged in the development, manufacturing, marketing, and distribution of generic, branded generic, brand name, biosimilar and over-the-counter pharmaceutical products. On information and belief, Actavis plc and its subsidiaries, including Actavis, Inc. and Actavis Labs, predominantly market their generic products to various drug wholesalers, mail order, government and national retail drug and food store chains. On information and belief, these generic products are marketed, distributed, and sold in the District of New Jersey and throughout the United States.

15. On information and belief, Defendants are the owner of ANDA No. 208012.

16. On information and belief, Defendants will market, distribute, and/or sell the generic products that are the subject of ANDA No. 208012 in the District of New Jersey.

17. Defendant Actavis Labs, whether known by that name or as Watson Laboratories Inc., has not contested, or has otherwise submitted to, the personal jurisdiction of the United States District Court for the District of New Jersey in numerous actions, such as at least *Jazz Pharmaceuticals, Inc. et al v. Watson Laboratories, Inc.*, Civil Action No. 14-cv-07757; *Janssen Pharmaceuticals, Inc., et al. v. Watson Laboratories, Inc.*, Civil Action No. 14-cv-04617; *Supernus Pharmaceuticals, Inc. v. Actavis, Inc., et al.*, Civil Action No. 14-cv-6102; *Horizon*

*Pharma Ireland Limited, et al. v. Actavis Laboratories UT, Inc.*, Civil Action No. 13-cv-07992; and *Auxilium Pharms., Inc. et al. v. Watson Labs., Inc., et al.*, Civil Action No. 12-cv-3084.

Actavis Labs purposefully availed itself of the rights and benefits of this District by asserting counterclaims in this Court in a number of the foregoing actions.

18. Defendant Actavis, Inc. has not contested, or has otherwise submitted to, the personal jurisdiction of the United States District Court for the District of New Jersey in several actions, such as at least *Supernus Pharmaceuticals, Inc. v. Actavis, Inc., et al.*, Civil Action No. 14-cv-6102 and *Otsuka Pharmaceutical Co., Ltd. v. Actavis Elizabeth LLC et al.*, Civil Action No. 14-cv-7106. Actavis, Inc. purposefully availed itself of the rights and benefits of this District by asserting counterclaims in this Court in these actions.

19. Defendant Actavis plc has not contested, or has otherwise submitted to, the personal jurisdiction of the United States District Court for the District of New Jersey in several actions, such as at least *Supernus Pharmaceuticals, Inc. v. Actavis, Inc., et al.*, Civil Action No. 14-cv-6102 and *Otsuka Pharmaceutical Co., Ltd. v. Actavis Elizabeth LLC et al.*, Civil Action No. 14-cv-7106. Actavis plc purposefully availed itself of the rights and benefits of this District by asserting counterclaims in this Court in these actions.

20. On information and belief, Defendants share common officers and directors.

21. On information and belief, Actavis Labs and Actavis, Inc. are within the control of Actavis plc for the purposes of responding to discovery in this action.

22. On information and belief, each Defendant, directly, or through related companies, have engaged in substantial and continuous contacts with New Jersey that satisfy due process and confer personal jurisdiction over each Defendant in New Jersey.

**GENERAL ALLEGATIONS**

23. On May 31, 2005, the United States Patent and Trademark Office duly and legally issued U.S. Patent No. 6,899,890 (“the ‘890 Patent”). A true and correct copy of the ‘890 patent is attached hereto as Exhibit A.

24. Plaintiff Elan owns all rights, title and interest in the ‘890 patent, including all rights needed to bring this action.

25. Plaintiff Elan is the current assignee of the ‘890 patent.

26. Plaintiff Elan holds New Drug Application (“NDA”) No. 050793 for the manufacture and sale of clindamycin phosphate vaginal cream, 2%, which is marketed under the name CLINDESSE<sup>®</sup> in the United States.

27. CLINDESSE is covered by one or more claims of the ‘890 Patent, which is listed in connection with CLINDESSE in the FDA’s publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the “Orange Book”) as a patent “with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of” clindamycin phosphate vaginal cream, 2%. *See* 21 U.S.C. § 355(b)(1).

28. On information and belief, Defendants filed ANDA No. 208012 with the FDA in the name of Actavis Labs seeking approval to market a generic copy of CLINDESSE (the “ANDA product”) prior to the expiration of the ‘890 Patent.

29. Defendants’ ANDA No. 208012 contains a “Paragraph IV” certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the ‘890 Patent is “invalid, unenforceable, or will not be infringed by the manufacture, use, or sale” of the ANDA product.

30. On or about February 24, 2015, Plaintiff received a letter dated February 23, 2015 (the “notice letter”) purporting to be notice of Defendants’ ANDA No. 208012 and “Paragraph IV” certification(s) under § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act.

31. This action is being commenced by Plaintiff within 45 days of Plaintiff’s receipt of the notice letter.

32. Defendants’ submission of ANDA No. 208012 is an act of infringement of the ‘890 Patent under 35 U.S.C. § 271(e)(2)(A).

**COUNT I: INFRINGEMENT OF THE ‘890 PATENT**

33. Plaintiff incorporates and realleges paragraphs 1 through 30 above, as if set forth in full herein.

34. Defendants had knowledge of the ‘890 Patent when it submitted and filed ANDA No. 208012.

35. Defendants’ filing of ANDA No. 208012 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, marketing, distributing, and/or importation of the ANDA product before the expiration date of the ‘890 Patent is an act of infringement of the ‘890 Patent under 35 U.S.C. § 271(e)(2)(A).

36. On information and belief, unless enjoined by this Court, Defendants plan and intend to engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of the ANDA product and its proposed labeling immediately following the FDA’s approval of ANDA No. 208012.

37. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of the ANDA product in the United States will infringe one or more claims of the ‘890 Patent under 35 U.S.C. § 271(a), (b) and/or (c).

38. Unless Defendants are enjoined from infringing the '890 Patent, actively inducing infringement of the '890 Patent, and/or contributing to the infringement of the '890 Patent, Plaintiff will suffer irreparable injury for which there is no adequate remedy at law.

39. Plaintiff is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Defendants ANDA No. 208012 to be a date which is not any earlier than the expiration date of the '890 Patent, including any lawful extensions of that date.

40. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

#### **JURY DEMAND**

41. Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Elan Pharma International Ltd. hereby respectfully requests a jury trial on all issues and claims so triable.

#### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff respectfully requests the following relief:

- A. The entry of judgment that the '890 Patent is valid and enforceable;
- B. The entry of judgment that one or more claims of the '890 Patent would be infringed by the ANDA product, either literally or under the doctrine of equivalents; that Defendants' submission of ANDA No. 208012 is an act of infringement of one or more claims of the '890 Patent; and that Defendants' making, using, offering to sell, selling, marketing, distributing, or importing the ANDA product, or any product that infringes the '890 Patent prior to the expiration of the '890 Patent would infringe, actively induce infringement, and contribute to the infringement of one or more claims of the '890 Patent;



C. The entry of an order pursuant to 35 U.S.C. § 271(e)(4) directing the FDA not to approve Defendants' ANDA No. 208012, or, as the case may be, to change the effective date of approval of Defendants' ANDA No. 208012 to a date not earlier than the expiration date of the '890 Patent, including any lawful extension of that date;

D. The entry of a permanent injunction enjoining each of the Defendants, their officers, directors, agents, servants, employees, successors and assigns, and all others in concert and privity with them, from making, using, offering to sell, selling, marketing, distributing, or importing the ANDA product, or any other products not colorably different, that infringe the '890 Patent, and from inducing or contributing to the infringement of the '890 Patent, until after its expiration, including any extensions.

E. Damages or other monetary relief, including prejudgment interest, if Defendants engage in the commercial manufacture, use, offering to sell, sale, marketing, distribution, or importation of the ANDA product, or any other products that infringe the '890 Patent, or the inducement or contribution of the foregoing, prior to the expiration of the '890 Patent, including any lawful extensions;

F. The entry of judgment that this case is an exceptional case under 35 U.S.C. § 285, entitling Plaintiff to an award of its reasonable attorneys' fees for bringing and prosecuting this action;

G. An award of pre-judgment and post-judgment interest on each and every award;

H. An award of Plaintiff's costs and expenses in bringing and prosecuting this action;  
and

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

Dated: April 8, 2015

HILL WALLACK LLP  
*Attorneys for Plaintiff Elan Pharma  
International, Ltd.*

/s/Eric I. Abraham

Eric I. Abraham  
Christina L. Saveriano  
21 Roszel Road  
Princeton, NJ 08540

Of Counsel:

Jeffrey R. Gargano  
Peter M. Siavelis  
Wan-Shon Lo  
Zachary D. Miller  
MCDERMOTT WILL & EMERY LLP  
227 W Monroe Street, Suite 4400  
Chicago, Illinois 60606  
Telephone: 312-372-2000

Rebecca Harker Duttry  
MCDERMOTT WILL & EMERY LLP  
The McDermott Building  
500 North Capitol Street, N.W.  
Washington, DC 20001  
Telephone: 202-756-8000

**LOCAL CIVIL RULE 11.2 CERTIFICATION**

I hereby certify pursuant to Local Civil Rule 11.2, that to the best of my knowledge, information and belief that U.S. Patent No. 6,899,890 asserted in the accompanying Complaint is not at issue in any other actions.

/s/ Eric I. Abraham

Eric. I. Abraham

Dated: April 8, 2015