

Charles M. Lizza
William C. Baton
SAUL EWING LLP
One Riverfront Plaza
Newark, New Jersey 07102-5490
(973) 286-6700
clizza@saul.com

*Attorneys for Plaintiffs King Pharmaceuticals
Inc., King Pharmaceuticals Research and
Development, Inc., Elan Corporation, plc and
Elan Pharma International Ltd.*

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**KING PHARMACEUTICALS INC., KING
PHARMACEUTICALS RESEARCH AND
DEVELOPMENT, INC., ELAN
CORPORATION, PLC and ELAN
PHARMA INTERNATIONAL LTD.,**

Plaintiffs,

v.

**ACTAVIS, INC. and ACTAVIS
ELIZABETH LLC,**

Defendants.

Civil Action No. _____

**COMPLAINT FOR PATENT
INFRINGEMENT**

(Filed Electronically)

Plaintiffs, King Pharmaceuticals Inc., King Pharmaceuticals Research and Development, Inc. (together, “King”), Elan Corporation, plc and Elan Pharma International Ltd. (together, “Elan”) (collectively, “Plaintiffs”), by their attorneys, for their Complaint against defendants, Actavis, Inc. and Actavis Elizabeth LLC (collectively, “Actavis”), allege as follows:

Nature of the Action

1. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.* and, more particularly, 35 U.S.C. §§ 271(e)(2) and 281. This action relates to an Abbreviated New Drug Application (“ANDA”) filed by Actavis with the

United States Food and Drug Administration (“FDA”) for approval to market generic versions of King’s Avinza[®] drug products.

The Parties

2. King Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Tennessee, and has a principal place of business at 501 Fifth Street, Bristol, Tennessee 37620.

3. King Pharmaceuticals Research and Development, Inc., a wholly owned subsidiary of King Pharmaceuticals Inc., is a corporation organized and existing under the laws of the State of Delaware, and has a principal place of business at 501 Fifth Street, Bristol, Tennessee 37620.

4. Elan Corporation, plc is a corporation organized and existing under the laws of Ireland, and has a principal place of business at Treasury Building, Lower Grand Canal St., Dublin 2, Ireland.

5. Elan Pharma International Ltd. is a corporation organized and existing under the laws of Ireland, and has a principal place of business at Monksland, Athlone County, Westmeath, Ireland. Elan Pharma International Ltd. is a subsidiary of Elan Corporation, plc.

6. Upon information and belief, defendant Actavis Elizabeth LLC is a corporation organized and existing under the laws of the State of Delaware, and has a principal place of business at 200 Elmora Avenue, Elizabeth, New Jersey 07207.

7. 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 07016.

8. Upon information and belief, defendant Actavis Elizabeth LLC is a subsidiary of defendant Actavis, Inc.

Jurisdiction and Venue

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

10. This Court has personal jurisdiction over defendants Actavis Elizabeth LLC and Actavis, Inc. because they reside in, and are doing business in New Jersey.

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

The Patent In Suit

12. United States Patent No. 6,066,339 (“the ’339 patent”) entitled “Oral Morphine Particulate Formulation” duly and legally issued on May 23, 2000 to inventors Paul Stark, Sean Cunningham and Jagathesan Moodly by the United States Patent and Trademark Office. The ’339 patent claims, *inter alia*, an oral morphine particulate formulation for once-daily administration to a patient. A copy of the ’339 patent is attached hereto as Exhibit A.

13. The ’339 patent is owned by Elan.

14. King has an exclusive license to market oral morphine drug products in the United States under the ’339 patent.

The Avinza® Drug Product

15. King Pharmaceuticals Inc. holds an approved New Drug Application (“NDA”) under Section 505(a) of the Federal Food Drug and Cosmetic Act (“FFDCA”), 21 U.S.C. § 355(a) for extended release capsules of morphine sulfate (NDA 21-260), which it markets under the trade name Avinza®. The claims of the ’339 patent cover formulations, including formulations of extended release morphine sulfate.

16. The ’339 patent is listed in the FDA publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluation” (“Orange Book”) as covering King’s

Avinza[®] 30mg, 60mg, 90mg and 120mg capsules.

Acts Giving Rise To This Action

17. Pursuant to Section 505 of the FFDCA, Actavis filed ANDA No. 79-040 for morphine sulfate extended release capsules, seeking approval to engage in the commercial manufacture, importation, use, sale or offer for sale of 30mg, 60mg, 90mg and 120mg Extended Release Capsules of Morphine Sulfate (“Actavis’s Proposed Morphine Product”).

18. In connection with its ANDA filing, Actavis provided written certification to the FDA, as called for by Section 505 of the FFDCA, alleging that the claims of the ’339 patent are invalid, unenforceable and/or will not be infringed by the activities described in Actavis’s ANDA.

19. No earlier than September 4, 2007, Actavis sent written notice of its ANDA filing to King and Elan (the “Notice Letter”). The Notice Letter alleged that the claims of the ’339 patent are invalid, unenforceable and/or will not be infringed by Actavis’s Proposed Morphine Product. Actavis’s Notice Letter also informed King and Elan that Actavis seeks approval to market Actavis’s Proposed Morphine Product prior to the expiration of the ’339 patent.

20. This action is being brought pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) within 45 days of King’s and Elan’s receipt of Actavis’s Notice Letter.

Infringement Count

21. Plaintiffs repeat and reallege the allegations of paragraphs 1-20 as though fully set forth herein.

22. Actavis’s submission of its ANDA No. 79-040 to obtain approval to engage in the commercial manufacture, importation, use, sale or offer for sale of Actavis’s Proposed Morphine Product, prior to the expiration of the ’339 patent, constitutes infringement of one or more of the claims of the ’339 patent under 35 U.S.C. § 271(e)(2).

23. There is a justiciable controversy between the parties hereto as to infringement of the '339 patent.

24. Upon information and belief, Actavis intends to engage and will engage in the commercial manufacture, importation, use, sale or offer for sale of Actavis's Proposed Morphine Product promptly upon receiving FDA approval to do so.

25. Unless enjoined by this Court, Actavis, upon FDA approval of Actavis's ANDA 79-040, will infringe the '339 patent by making, importing, using, selling and offering to sell Actavis's Proposed Morphine Product in the United States.

26. Plaintiffs will be substantially and irreparably damaged and harmed if Actavis's infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

27. Actavis had notice of the '339 patent at the time of its infringement. Actavis's infringement has been, and continues to be, willful and deliberate.

28. This case is an exceptional one and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Prayer For Relief

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) A Judgment declaring that Actavis has infringed and that Actavis's commercial manufacture, importation, use, sale or offer for sale of Actavis's Proposed Morphine Product will infringe the '339 patent;

(B) A Judgment that the effective date of any FDA approval for Actavis's commercial manufacture, importation, use, sale or offer for sale of Actavis's Proposed Morphine Product be no earlier than the date on which the '339 patent expires, including any applicable FDA exclusivities;

(C) A Judgment permanently enjoining Actavis from commercial manufacture,

importation, use, sale or offer for sale of Actavis's Proposed Morphine Product until after the expiration of the '339 patent, including any applicable FDA exclusivities;

(D) If Actavis engages in the commercial manufacture, importation, use, sale or offer to sell Actavis's Proposed Morphine Product prior to the expiration of the '339 patent, a Judgment awarding Plaintiffs damages resulting from such infringement, increased to treble the amount found or assessed, together with interest;

(E) Attorneys' fees in this action pursuant to 35 U.S.C. § 285;

(F) Costs and expenses in this action; and

(G) Such further and other relief as this Court may deem just and proper.

Date: October 18, 2007

Respectfully submitted,

OF COUNSEL:

F. Dominic Cerrito
Daniel L. Malone
Eric Stops
JONES DAY
222 East 41st Street
New York, New York 10017
(212) 326-3939

Attorneys for Plaintiffs King Pharmaceuticals Inc. and King Pharmaceuticals Research and Development, Inc.

OF COUNSEL:

Jack B. Blumenfeld
Maryellen Noreika
MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Chase Manhattan Center, 18th Floor
1201 North Market Street
Wilmington, Delaware 19899
(302) 658-9200

Attorneys for Plaintiffs Elan Corporation, plc and Elan Pharma International Ltd.

By: s/ Charles M. Lizza

Charles M. Lizza
William C. Baton
SAUL EWING LLP
One Riverfront Plaza
Newark, New Jersey 07102-5490
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