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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.** **SANDOZ INC.,** **Defendant.**	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 defendant, Sandoz Inc. ("Sandoz"), 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 Sandoz 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 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 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., a subsidiary of Elan Corporation, plc., is a corporation organized and existing under the laws of Ireland, and has a principal place of business at Monksland, Athlone County, Westmeath, Ireland.

6. Upon information and belief, defendant Sandoz Inc. is a corporation organized and existing under the laws of Colorado, and has a principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540. Upon information and belief, Sandoz is in the business of developing, manufacturing and marketing pharmaceutical products in the United States, including generic pharmaceutical products.

Jurisdiction and Venue

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

8. This Court has personal jurisdiction over Sandoz because it resides in, and is

doing business in New Jersey.

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

The Patent In Suit

10. 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 Moodley 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.

11. The '339 patent is owned by Elan.

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

The Avinza® Drug Product

13. 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.

14. 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

15. Pursuant to Section 505 of the FFDCA, Sandoz filed ANDA No. 91-290 for morphine sulfate extended release capsules, seeking approval to engage in the commercial

manufacture, importation, use, sale or offer for sale of 30mg and 120mg Morphine Sulfate Extended Release Capsules ("Sandoz's Proposed Morphine Product").

16. In connection with its ANDA filing, Sandoz 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 Sandoz's ANDA.

17. No earlier than June 11, 2009, Sandoz 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 Sandoz's Proposed Morphine Product. Sandoz's Notice Letter also informed King and Elan that Sandoz seeks approval to market Sandoz's Proposed Morphine Product prior to the expiration of the '339 patent.

18. In its Notice Letter, Sandoz offered to provide access to confidential information about its ANDA. Plaintiffs King and Elan accepted Sandoz's offer of confidential access and requested production of confidential information from Sandoz, including Sandoz's ANDA, to allow Plaintiffs to assess Sandoz's claim of non-infringement of the '339 patent. Nevertheless, Sandoz refused to produce its ANDA or related materials to either King or Elan.

19. 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 Sandoz's Notice Letter.

Infringement Count

20. Plaintiffs repeat and reallege the allegations of paragraphs 1-19 as though fully set forth herein.

21. Sandoz's submission of its ANDA No. 91-290 to obtain approval to engage in the commercial manufacture, importation, use, sale or offer for sale of Sandoz'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).

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

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

24. Unless enjoined by this Court, Sandoz, upon FDA approval of Sandoz's ANDA No. 91-290, will infringe the '339 patent by making, using, offering to sell, importing and selling Sandoz's Proposed Morphine Product in the United States.

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

26. 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 Sandoz has infringed and that Sandoz's commercial manufacture, importation, use, offer for sale or sale of Sandoz's Proposed Morphine Product will infringe the '339 patent;

(B) A Judgment that the effective date of any FDA approval for Sandoz's commercial manufacture, importation, use, sale or offer for sale of Sandoz'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 Sandoz from commercial manufacture, importation, use, offer for sale or sale of Sandoz's Proposed Morphine Product until after the

expiration of the '339 patent, including any applicable FDA exclusivities;

(D) If Sandoz engages in the commercial manufacture, importation, use, offer for sale, or sale of Sandoz'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.

Respectfully submitted,

Dated: July 21, 2009

s/ Charles M. Lizza

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2 & 40.1

I hereby certify that the matter captioned, *King Pharmaceuticals Inc., et al. v. Actavis, Inc., et al.*, Civil Action No. 07-5041 (JAG)(MCA), is a related action because it involves the same plaintiffs and the same patent as the matter in controversy.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Respectfully submitted,

Dated: July 21, 2009

s/ Charles M. Lizza

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