

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

*Attorneys for Plaintiffs
King Pharmaceuticals, Inc.,
King Pharmaceuticals Research and Development, Inc.
and Pharmaceutical IP Holding, Inc.*

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

_____)	
KING PHARMACEUTICALS, INC.,)	
KING PHARMACEUTICALS)	Civil Action No. _____
RESEARCH AND DEVELOPMENT,)	
INC. and PHARMACEUTICAL IP)	
HOLDING, INC.,)	COMPLAINT FOR PATENT
)	INFRINGEMENT
Plaintiffs,)	
)	
v.)	(Filed Electronically)
)	
SANDOZ INC.,)	
)	
Defendant.)	
_____)	

Plaintiffs King Pharmaceuticals, Inc., King Pharmaceuticals Research and Development, Inc. (together, “King”) and Pharmaceutical IP Holding, Inc. (“Pharmaceutical IP”) (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 under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from Sandoz's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of King's Skelaxin® drug product.

The Parties

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

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

4. Plaintiff Pharmaceutical IP Holding, Inc. is a wholly owned subsidiary of Mutual Pharmaceutical Company, Inc., organized and existing under the laws of Delaware, having a principal place of business at 1105 North Market Street, Suite 1300, Wilmington, DE 19801.

5. Upon information and belief, Sandoz is a corporation organized and existing under the laws of Colorado, having 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

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

7. This Court has personal jurisdiction over Sandoz because, *inter alia*, Sandoz has availed itself of the laws of New Jersey, conducts business in New Jersey and has a place of business in New Jersey.

8. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The Patent in Suit and the Skelaxin[®] Drug Product

9. United States Patent No. 7,122,566 (“the ‘566 patent”) entitled “Metaxalone Products, Method of Manufacture, and Method of Use,” duly and legally issued on October 17, 2006 to Mutual Pharmaceutical Company, Inc. (“Mutual”) as assignee of the inventors Jie Du and Richard H. Roberts. The ‘566 patent was subsequently assigned to Pharmaceutical IP. A copy of the ‘566 patent is attached hereto as Exhibit A.

10. King has an exclusive license to, *inter alia*, market and sell metaxalone pharmaceutical products in the United States under the ‘566 patent.

11. King markets and sells metaxalone tablets in the United States under the brand name Skelaxin[®]. The claims of the ‘566 patent cover methods of using metaxalone.

12. The ‘566 patent is listed in the FDA publication, “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”), with respect to Skelaxin[®].

Acts Giving Rise to this Suit

13. Upon information and belief, Sandoz filed ANDA No. 40-445 and amendments thereto with the FDA pursuant to § 505(j) of the Federal Food, Drug, and Cosmetic Act (“the FDCA”), 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use,

sale, or importation of 800 mg metaxalone tablets (“Sandoz’s Proposed Product”) prior to the expiration of the ‘566 patent.

14. Upon information and belief, in connection with its filing of ANDA No. 40-445, Sandoz filed a patent certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), commonly known as a “Paragraph IV Certification,” alleging that the claims of the ‘566 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Sandoz’s ANDA.

15. King has received a letter from Sandoz purporting to be a Notice of Certification under 21 U.S.C. §§ 355(j)(2)(B), informing King of Sandoz’s ANDA submission and corresponding certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The letter alleges that the claims of the ‘566 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Sandoz’s ANDA, and that Sandoz seeks approval to market Sandoz’s Proposed Product before the ‘566 patent expires.

Count for Infringement of the ‘566 Patent

16. Plaintiffs repeat and reallege the allegations of paragraphs 1-15 as though fully set forth herein.

17. Sandoz’s submission and amendment of ANDA No. 40-445 to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Sandoz’s Proposed Product, prior to the expiration of the ‘566 patent, constitutes infringement of one or more of the claims of the ‘566 patent under 35 U.S.C. § 271(e)(2)(A).

18. There is a justiciable controversy between the parties hereto as to the infringement of the ‘566 patent.

19. Unless enjoined by this Court, Sandoz, upon FDA approval of ANDA No. 40-445, will infringe the '566 patent under 35 U.S.C. § 271 by making, using, offering to sell, importing, and selling Sandoz's Proposed Product in the United States.

20. Plaintiffs will be substantially and irreparably damaged and harmed if Sandoz's infringement of the '566 patent is not enjoined.

21. Plaintiffs do not have an adequate remedy at law.

22. 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 be entered that Sandoz has infringed the '566 patent by submitting ANDA No. 40-445 and amendments thereto;

(B) A Judgment be entered that Sandoz's making, using, selling, offering to sell, or importing Sandoz's Proposed Product will infringe one or more claims of the '566 patent;

(C) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of FDA approval of ANDA No. 40-445 be a date which is not earlier than the later of the expiration of the '566 patent or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(D) Preliminary and permanent injunctions enjoining Sandoz and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, selling, offering to sell, or importing Sandoz's Proposed Product until after the expiration of the '566 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

(E) If Sandoz engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Sandoz's Proposed Product prior to the expiration of the

'566 patent, or any later expiration of exclusivity to which Plaintiffs are or become entitled, a Judgment awarding damages to Plaintiffs resulting from such infringement, together with interest;

- (F) Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;
- (G) Costs and expenses in this action; and
- (H) Such further and other relief as this Court may deem just and proper.

Dated: December 5, 2008

By: s/ Charles M. Lizza

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

OF COUNSEL:

F. Dominic Cerrito
Daniel L. Malone
Eric Stops
Evangeline Shih
JONES DAY
222 East 41st Street
New York, New York 10017-6702
(212) 326-3939

*Attorneys for Plaintiffs
King Pharmaceuticals, Inc.,
King Pharmaceuticals Research and Development,
Inc. and Pharmaceutical IP Holding, Inc.*

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

Thomas F. Poché
COOLEY GODWARD KRONISH LLP
777 6th Street, NW
Suite 1100
Washington, DC 20001
(202) 842-7839

*Attorney for Plaintiff
Pharmaceutical IP Holding, Inc.*