UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

KING PHARMACEUTICALS, INC. AND JONES PHARMA INC.,
Plaintiffs,

v.

MUTUAL PHARMACEUTICAL CO., INC.,
Defendant.

Civil Action No.

COMPLAINT

Plaintiffs, King Pharmaceuticals, Inc. and Jones Pharma Inc. (collectively, King), for their Complaint against defendant, Mutual Pharmaceutical Co., Inc. ("Mutual"), allege as follows:

Nature of the Action

1. This is an action for a judgment of patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.,* including, *inter alia*, §§ 271(e), 281, 283, and 285.

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. King Pharmaceuticals, Inc. is engaged in the business of researching, developing, marketing, acquiring, and selling pharmaceutical products throughout the world.

3. Jones Pharma Inc. is a corporation organized and existing under the laws of the state of Delaware, and has a principal place of business at 1945 Craig Road, St. Louis, Missouri 63146. Jones Pharma Inc. is a wholly owned subsidiary of King Pharmaceuticals, Inc.

4. Mutual is a corporation organized and existing under the laws of the state of Pennsylvania, and has a place of business at 1100 Orthodox Street, Philadelphia, Pennsylvania 19124. Upon information and belief, Mutual is engaged in the business of manufacturing and selling generic pharmaceuticals for distribution throughout the United States.

Jurisdiction and Venue

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

6. This Court has personal jurisdiction over Mutual by virtue of, *inter alia*, Mutual's place of business in Pennsylvania.

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

The Patent-In-Suit and the SKELAXIN® Drug Product

8. On January 27, 2004, the United States Patent and Trademark Office issued to King United States Patent No. 6,683,102 ("the '102 patent") (attached hereto as Exhibit 1), entitled "Methods of Using Metaxalone in the Treatment of Musculoskeletal Conditions."

9. King markets and sells metaxalone in the United States under the brand name SKELAXIN®, which is listed in the Food and Drug Administration's ("FDA") *Approved Drug Products With Therapeutic Equivalence Evaluations* ("Orange Book") (attached hereto as Exhibit 2).

10. The SKELAXIN® product label (attached hereto as Exhibit 3) instructs and informs healthcare practitioners and patients that the bioavailability of metaxalone may be increased by administering to a patient receiving metaxalone therapy a therapeutically effective amount of metaxalone in a pharmaceutical composition with food.

Count for Infringement of the '102 Patent

11. The King Plaintiffs incorporate by reference the averments of Paragraphs 1-10 as if set forth herein.

12. Mutual filed its ANDA seeking approval to engage in the commercial manufacture, use, sale, or importation of its generic metaxalone product in the United States prior to the expiration of the '102 patent.

13. Mutual filed with its ANDA a patent certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") alleging that none of the claims of the '102 patent will be infringed by the commercial manufacture, use, sale, or importation of Mutual's generic metaxalone product.

14. On or about February 2, 2004, King received a letter from Mutual purporting to be a Notice of Certification under 21 U.S.C. § 355(j)(2)(B)(ii), informing King of Mutual's ANDA submission and corresponding Paragraph IV Certification (attached hereto as Exhibit 4).

15. If an ANDA applicant is not seeking approval of its ANDA for a use claimed in a method of use patent listed in the Orange Book with respect to the reference listed drug, then the ANDA applicant must file a statement pursuant to 21 U.S.C. § 355(j)(2)(A)(viii) declaring that it is not seeking such a use.

16. Upon information and belief, Mutual did ***not*** file a statement pursuant to 21 U.S.C. § 355(j)(2)(A)(viii) with respect to the '102 patent.

17. Because Mutual filed a Paragraph IV Certification with respect to the '102 patent rather than a statement pursuant to 21 U.S.C. § 355(j)(2)(A)(viii), and upon information and belief, Mutual is necessarily seeking approval of its ANDA for its generic metaxalone product for the same uses approved by the FDA for SKELAXIN® and claimed in the '102 patent.

18. Because Mutual filed a Paragraph IV Certification against the '102 patent rather than a statement pursuant to 21 U.S.C. § 355(j)(2)(A)(viii), and upon information and belief, Mutual is seeking approval of proposed product labeling for Mutual's generic metaxalone product that necessarily reflects the same uses approved by the FDA for SKELAXIN® and claimed in the '102 patent.

19. Because Mutual is seeking approval of its ANDA, including the proposed product labeling, for its generic metaxalone product for the same uses approved by the FDA for SKELAXIN® and claimed in the '102 patent, and upon information and belief, Mutual's generic metaxalone product will be administered to human patients with food to increase bioavailability, in a therapeutically effective amount for the treatment of musculoskeletal disorders.

20. Pursuant to 35 U.S.C. § 271(e)(2)(A), Mutual's submission to the FDA of its ANDA, with the proposed product labeling, to obtain approval to engage in the commercial manufacture, use, sale, or importation of Mutual's generic metaxalone product, prior to the expiration of the '102 patent, constitutes infringement of the '102 patent.

21. Upon information and belief, Mutual intends to and will engage in the commercial manufacture, use, sale or importation of its generic metaxalone product promptly upon receiving FDA approval to do so.

22. Upon FDA approval of Mutual's generic metaxalone product, Mutual will infringe one or more claims of the '102 patent through its commercial manufacture, use, sale, or importation of its generic metaxalone product.

23. Upon information and belief, Mutual will actively induce, encourage, aid and abet healthcare practitioners and patients in infringing the '102 patent through the commercial manufacture, use, sale, or importation of its generic metaxalone product.

24. King will be substantially and irreparably damaged and harmed if Mutual's infringement is not enjoined. King does not have an adequate remedy at law.

Prayer for Relief

WHEREFORE, King demands judgment against Mutual as follows:

(a) a judgment that Mutual has infringed one or more claims of the '102 patent;

(b) a preliminary and permanent injunction against Mutual preventing the commercial manufacture, use, or sale within the United States or importation into the United States of Mutual's generic metaxalone product prior to the expiration of the '102 patent;

(c) an order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Mutual's generic metaxalone product will be a date that is not earlier than the date of the expiration of the '102 patent;

(d) an injunction pursuant to 35 U.S.C. § 271(e)(4)(B) against Mutual to prevent the commercial manufacture, use, or sale within the United States or importation into the United States of Mutual's generic metaxalone product;

(e) damages or other monetary relief pursuant to 35 U.S.C. § 271(e)(4)(C), increased to treble the amount found or assessed, together with interest, if Mutual engages in the commercial manufacture, use, or sale within the United States or importation into the United States of Mutual's generic metaxalone product;

(f) an order with respect to Mutual's ANDA directing Mutual to change its Paragraph IV Certification against the '102 patent to a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III) pursuant to 21 C.F.R. § 314.94(a)(12)(viii)(A); and

(g) attorneys' fees pursuant to 35 U.S.C. § 285, costs and expenses, and such further and other relief as this Court may deem just and proper.

Respectfully submitted,

Date: March 11, 2004

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