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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

DAIICHI PHARMACEUTICAL CO., LTD.

Plaintiff,

v.

HI-TECH PHARMACAL CO., INC.

Defendant.

Civ. Action No. 03-6006 (GEB)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Daiichi Pharmaceutical Co., Ltd. ("Daiichi"), by its attorneys, for its complaint against Hi-Tech Pharmacal, Co., Inc. ("Hi-Tech") alleges as follows:

The Parties

1. Plaintiff Daiichi is a corporation organized and existing under the laws of Japan and has its registered office at 14-10, Nihonbashi 3-chome, Chuo-ku, Tokyo, Japan.

2. Upon information and belief, Defendant Hi-Tech is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 369 Bayview Avenue, Amityville, N.Y., 11701, and is registered to do business and does business in New Jersey.

Jurisdiction and Venue

3. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, for infringement of United States Patent No. 5,053,407 ("the '407 patent"). This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

4. Hi-Tech is subject to personal jurisdiction in this judicial district.

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

Count 1: Patent Infringement

6. Plaintiff realleges paragraphs 1 through 5 above as if fully set forth herein.

7. On October 1, 1991, the United States Patent and Trademark Office ("the PTO") duly and legally issued the '407 patent, entitled "Optically Active Pyridobenzoxazine Derivatives And Anti-Microbial Use." A true and correct copy of the '407 patent is attached hereto as Exhibit A.

8. Daiichi is the owner of the '407 patent, which discloses and claims, inter alia, a drug known as "levofloxacin," and methods of using levofloxacin.

9. Santen Inc. ("Santen") is a sublicensee under the '407 patent, pursuant to an exclusive license agreement between Daiichi and Santen Pharmaceutical Co, Ltd. ("Santen Japan"), of the right to make, use and sell certain ophthalmic pharmaceutical preparations containing levofloxacin in the United States and other territories. Pursuant to that exclusive sublicense, Santen currently markets levofloxacin ophthalmic solution, 0.5% under the trademark QUIXIN® in the United States.

10. Levofloxacin is the active ingredient contained in QUIXIN® and is a broad spectrum antibacterial agent used to treat eye infections, as well as lung, sinus, skin and urinary tract infections. Levofloxacin and pharmaceutical preparations containing levofloxacin are widely sold throughout the world and have enjoyed worldwide commercial success.

11. Santen is the holder of Approved New Drug Application ("NDAs") No. 021199 under Section 505(a) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for a pharmaceutical preparation containing Levofloxacin Ophthalmic Solution, 0.5%.

12. Upon information and belief, Hi-Tech submitted an Abbreviated New Drug Application ("ANDA") No. 76-826 to the Food and Drug Administration ("FDA") under § 505(j) of the FFDCA, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale and sale of levofloxacin ophthalmic solution, 0.5% ("Levofloxacin Ophthalmic Solution") before the expiration of the '407 Patent. Defendant's manufacture, use, offer for sale or sale of Levofloxacin Ophthalmic Solution would infringe the claims of the '407 patent.

13. Daiichi and Santen received letters dated November 7, 2003 stating that Hi-Tech had filed ANDA No. 76-826 seeking approval to manufacture, use, offer for sale and sell Levofloxacin Ophthalmic Solution in the United States before the expiration of the '407 patent. The letter purports to notify Daiichi that ANDA 76-826 contains a certification pursuant to Title I of the Drug Price Competition and Patent Term Restoration Act of 1984, Section 505(j)(2)(B)(i) and (ii) and 21 U.S.C. §

355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") that the claims of the '407 patent are invalid, not enforceable or not infringed.

14. Hi-Tech has infringed the '407 patent under 35 U.S.C. § 271(e)(2)(A) by submitting a Paragraph IV certification with ANDA 76-826 and seeking FDA approval to make, use, offer for sale and sell Levofloxacin Ophthalmic Solution as identified above prior to expiration of the '407 patent.

15. Upon information and belief, Hi-Tech had actual and constructive notice of the '407 patent prior to filing ANDA 76-826 and Hi-Tech's infringement of the '407 patent has been, and continues to be, willful.

16. Plaintiff will be irreparably harmed if Hi-Tech is not enjoined from infringing or actively inducing or contributing to infringement of the '407 patent. Plaintiff does not have an adequate remedy at law.

Prayer For Relief

WHEREFORE, Plaintiff seeks the following relief:

A. A judgment that Hi-Tech has infringed the '407 patent under 35 U.S.C. § 271(e)(2)(A);

B. An Order pursuant to 35 U.S.C. §271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 76-826 be not earlier than the expiration date of the '407 patent;

C. A permanent injunction pursuant to 35 U.S.C. §271(e)(4)(B) restraining and enjoining Hi-Tech and its officers, agents, servants and employees, and those persons in active concert or participation with any of them, from engaging in the commercial manufacture, use, offer to sell or sale within the United States, or importation into the

United States, of any Levofloxacin Ophthalmic Solution described in ANDA No. 76-826 or any product including bulk levofloxacin that infringes or induces or contributes to the infringement of the '407 patent;

D. A finding that this is an exceptional case, and an award of 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 determines to be just and proper.

L.CIV.R. 11.2 CERTIFICATION

At the present time, there are several cases which involve the same matter as in this case: Ortho-McNeil Pharmaceutical, Inc., et al. v. Teva Pharmaceutical USA, District of New Jersey, Civil Action No. 02cv2794; Ortho-McNeil Pharmaceutical, Inc., et al. v. Ben Venue Laboratories, Inc., et al, District of New Jersey, Civil Action No. 03cv1268; Ortho McNeil Pharmaceutical, Inc., et al. v. Sicor Pharmaceuticals, Inc., et al., District of New Jersey, Civil Action No. 03cv1268; and in the Northern District of West Virginia, Civil Action No. 1:02cv32, Ortho-McNeil Pharmaceutical, Inc., et al. v. Mylan Laboratories, Inc., et al. Plaintiff knows of no other arbitration or lawsuit involving this matter, nor is any to Plaintiff's knowledge contemplated, and Plaintiff knows of no other person who should be joined in this action at this time.

Michael A. Lampert

Dated:

Dated: December___, 2003

Respectfully submitted on behalf of Plaintiff:

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