UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

ALZA CORPORATION)
Plaintiff,)
)
v.)
)
MYLAN LABORATORIES INC. and)
MYLAN PHARMACEUTICALS INC.,)
)
Defendants)

Civ. Action No. 1:03CV158

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Alza Corporation ("Alza") by its attorneys, for its complaint against Mylan Laboratories Inc. ("Mylan Laboratories") and Mylan Pharmaceuticals Inc. ("Mylan Pharmaceuticals") (collectively, "Defendants" or "Mylan") alleges as follows:

The Parties

1. Alza is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 1900 Charleston Road, Mountain View, California.

2. Upon information and belief, Mylan Laboratories is a corporation organized and existing under the laws of the State of Pennsylvania and has its principal place of business at 1500 Corporate Drive, Suite 400, Cannonsburg, Pennsylvania.

3. Upon information and belief, Mylan Pharmaceuticals is a corporation organized and existing under the laws of the State of West Virginia and has its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia. Upon information and belief, Mylan Pharmaceuticals is wholly owned and controlled by Mylan Laboratories.

Jurisdiction And Venue

4. This action is based upon the Patent Law of the United States, Title 35 of the United States Code, for infringement of United States Patent No. 6,124,355 ("the '355 patent"). This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a) and 1400(b).

5. Mylan Laboratories and Mylan Pharmaceuticals are subject to personal jurisdiction in this judicial district.

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

Count I: Patent Infringement

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

8. On September 26, 2000, the United States Patent and Trademark Office issued the '355 patent, entitled "Oxybutynin Therapy." A true and correct copy of the '355 patent is attached as Exhibit A.

9. Alza holds title to the '355 patent.

10. The United States Food & Drug Administration ("FDA") has approved a New Drug Application under § 505(a) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(a), for administering oxybutynin sold under the trade name Ditropan XL.

11. Pursuant to 21 U.S.C. § 355(b)(1), the '355 patent is identified in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), as covering Ditropan XL.

12. Upon information and belief, on or before March 31, 2003, Mylan submitted an Abbreviated New Drug Application ("ANDA") No. 76-702 to the United States

Food and Drug Administration ("FDA") under § 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), ("Mylan ANDA") seeking FDA approval to engage in the commercial manufacture, use, offer for sale and sale of oxybutynin chloride extended release tablets utilizing a 5mg dosage ("5mg oxybutynin extended release tablets").

13. On or about May 21, 2003, Mylan sent a letter to Alza stating it had filed the Mylan ANDA seeking approval to manufacture, use and sell 5mg oxybutynin extended release tablets before the expiration of the '355 patent ("the paragraph IV notice").

14. Upon information and belief, the Mylan ANDA was filed in the name of Mylan Pharmaceuticals Inc., but was also filed for the benefit of Mylan Laboratories Inc.

15. Upon information and belief, Mylan's paragraph IV notice was prepared at, signed at and sent from the Mylan Pharmaceuticals offices in Morgantown, West Virginia.

16. Upon information and belief, the factual and legal statement purportedly supporting the paragraph IV notice was prepared and signed by Shelly Monteleone, Esquire, an employee of Mylan Pharmaceuticals located at the Mylan Pharmaceuticals offices in Morgantown, West Virginia.

17. Upon information and belief, the officers and directors of Mylan Laboratories and/or Mylan Pharmaceuticals directed the preparation and filing of the Mylan ANDA with the FDA.

18. Mylan's paragraph IV notice states that the Mylan ANDA certifies, pursuant to 21 U.S.C. § 355(b)(2)(A)(iv), that the manufacture, use or sale of 5mg oxybutynin extended release tablets will not infringe the '355 patent and that the '355 patent is invalid ("paragraph IV certification").

19. Mylan Pharmaceuticals Inc. is liable for the infringement of the '355 patent under 35 U.S.C. § 271(e)(2)(A) by filing the Mylan ANDA which, upon information and belief, includes the paragraph IV certification.

20. Mylan Laboratories is liable for the infringement of the '355 patent because, upon information and belief, Mylan Laboratories caused or participated in, contributed to, aided, abetted, directed and induced the submission of the Mylan ANDA and its paragraph IV certification to the FDA.

21. Moreover, if Mylan manufactures, uses, or sells 5mg oxybutynin extended release tablets, it would further infringe the '355 patent, or induce or contribute to such conduct, under 35 U.S.C. § 271(a), (b) and/or (c).

22. Mylan had actual and constructive notice of the '355 patent prior to filing the Mylan ANDA.

23. Mylan's infringement of the '355 patent has been, and continues to be, willful.

24. Alza will be irreparably harmed if Mylan is not enjoined from infringing or actively inducing or contributing to infringement of the '355 patent. Alza does not have an adequate remedy at law.

Prayer For Relief

WHEREFORE, Alza prays for:

A. A judgment providing that the effective date of any FDA approval for the making, using, selling, offering for sale, or importing of 5mg oxybutynin extended release tablets described in ANDA No. 76-702 by Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc. be no earlier than the date on which Mylan will not infringe the '355 patent;

B. A judgment declaring that the making, using, selling, offering to sell, or importing of the 5mg oxybutynin extended release tablets described in ANDA No. 76-702 would constitute infringement of the '355 patent, or inducing or contributing to such conduct, by Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc. pursuant to 35 U.S.C. § 271(a), (b) and (c);

C. A judgment permanently enjoining Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc. and each of their officers, agents, servants and employees, and those persons in active concert or participation with any of them, from making, using, selling, offering to sell, or importing the 5 mg oxybutynin extended release tablets described in ANDA No. 76-702 or any product that infringes or induces or contributes to the infringement of the '355 patent;

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

E. Costs and expenses in this action; and

F. Such further and other relief as this Court determines to be just and proper.

Dated: June 26th, 2003

SIMMERMAN LAW OFFICE, PLLC

Frank E. Simmerman, Jr., Esq. (WV Bar #3403)
254 East Main Street
Clarksburg, West Virginia 26301
(304) 623-4900

Counsel for Plaintiff Alza Corporation

Of Counsel

PATTERSON, BELKNAP, WEBB & TYLER LLP
Jeffrey I.D. Lewis
Jeb Harben
Richard J. McCormick
Scott M. Brown
1133 Avenue of the Americas
New York, New York 10036-6710
(212) 336-2000