

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SCIELE PHARMA, INC. and SCIELE
PHARMA CAYMAN LTD.,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS, INC.
and MYLAN LABORATORIES, INC.,

Defendants.

Civil Action No.

JURY TRIAL DEMANDED

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Sciele Pharma, Inc. and Sciele Pharma Cayman Ltd. (collectively, “Sciele” or “Plaintiffs”), by their attorneys, Fish & Richardson P.C., for their complaint against Defendants Mylan Pharmaceuticals, Inc. and Mylan Laboratories, Inc. (collectively, “Mylan” or “Defendants”) allege as follows:

The Nature of the Action

1. This is an action for infringement of United States Patent No. 4,892,741 (“the ‘741 patent”) under 35 U.S.C. § 271(e)(2).

The Parties

2. Plaintiff Sciele Pharma, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 5 Concourse Parkway, Suite 1800, Atlanta, Georgia 30328.

3. Plaintiff Sciele Pharma Cayman Ltd. is a corporation organized and existing under the laws of the Cayman Islands with a principal place of business at Ugland House, South Church Street, Georgetown, Grand Cayman, Cayman Islands.

4. On information and belief, defendant Mylan Pharmaceuticals, Inc. (“Mylan Pharmaceuticals”) is a corporation organized and existing under the laws of the State of West

Virginia, with a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

5. On information and belief, Mylan Pharmaceuticals manufactures and sells numerous generic pharmaceutical products for use throughout the United States, including this judicial district.

6. On information and belief, defendant Mylan Laboratories, Inc. (“Mylan Laboratories”) is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a principal place of business at 1500 Corporate Drive, Suite 400, Canonsburg, Pennsylvania 15317.

7. On information and belief, Mylan Laboratories is the parent company of Mylan Pharmaceuticals, and Mylan Pharmaceuticals is a wholly-owned subsidiary of Mylan Laboratories.

8. On information and belief, Mylan Pharmaceuticals and Mylan Laboratories collaborate in the manufacture, marketing, and sale of many generic pharmaceutical products, including numerous products that are marketed and sold in Delaware.

9. Mylan Laboratories states in its 2007 Annual Report that “Mylan Pharmaceuticals, Inc., Mylan’s flagship generic subsidiary, once again ranked as one of the nation’s leading providers of pharmaceutical products overall, and pharmacists filled over 257 million prescriptions with products from Mylan.” On information and belief, a proportionate number of those prescriptions were filled in Delaware.

Jurisdiction and Venue

10. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq.* This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331 and 1338.

11. Based on the facts and causes alleged herein, this Court has personal jurisdiction over defendants Mylan Pharmaceuticals and Mylan Laboratories.

12. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

Background

13. The '741 patent, entitled "Press Coated DHP Tablets," issued on January 9, 1990 to Andreas Ohm, Helmut Luchtenberg, Shinji Maegata and Wolfgang Opitz. A copy of the '741 patent is attached to this complaint as Exhibit A.

14. Sciele is the exclusive licensee of the '741 patent and possesses all substantial rights in the '741 patent, including the right to enforce the patent.

15. Sciele is the holder of approved New Drug Application ("NDA") No. 20-356 for nisoldipine extended release tablets in 10mg, 20mg, 30mg, and 40mg dosages, all sold under the Sular® trademark.

16. In conjunction with NDA No. 20-356, Sciele has listed the '741 patent, which covers various aspects of the approved formulations of Sular®, in the Orange Book.

17. On September 10, 2007, Sciele received a letter ("Paragraph IV Letter"), dated September 7, 2007, signed on behalf of Mylan. The Paragraph IV Letter represented that Mylan had filed Abbreviated New Drug Application No. 79-051 ("ANDA No. 79-051") with the United States Food and Drug Administration ("FDA") under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") seeking approval to engage in the commercial manufacture, use, or sale of a proposed generic version of Sciele's Sular® tablets 40mg, before the expiration of the '741 patent.

18. After receiving the Paragraph IV Letter, Sciele filed suit against Mylan for infringement of the '741 patent on October 22, 2007. That case is captioned *Sciele Pharma, Inc. and Sciele Pharma Cayman Ltd. v. Mylan Pharmaceuticals, Inc. and Mylan Laboratories, Inc.*, No. 07-664-GMS (D. Del.).

19. On November 7, 2007, Sciele received a second letter ("Second Paragraph IV Letter"), dated November 6, 2007, signed on behalf of Mylan. The Second Paragraph IV Letter represented that Mylan had amended ANDA No. 79-051 to seek the FDA's approval to engage in the commercial manufacture, use, or sale of proposed generic versions of Sciele's Sular® tablets 20mg and 30mg, before the expiration of the '741 patent.

20. The Second Paragraph IV Letter also stated that ANDA No. 79-051 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '741 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Mylan's proposed generic versions of Sciele's Sular® tablets 20mg and 30mg.

21. Mylan's Second Paragraph IV Letter claims that Mylan's proposed generic versions of 20mg and 30mg Sular® would not infringe the '741 patent, but contains extremely limited information about those proposed generic versions. For example, although the Second Paragraph IV Letter purports to list various ingredients in the proposed generic version, it does not list the amounts of the various ingredients or provide any information about the method by which the proposed generic version is manufactured. In total, the Second Paragraph IV Letter contains fewer than 15 lines of information about Mylan's proposed generic versions of 20 mg and 30mg Sular®.

22. Along with the Second Paragraph IV Letter, Mylan sent to Sciele a document entitled "Offer of Confidential Access to ANDA No. 79-051" that it requested Sciele sign before providing access to any portion of Mylan's ANDA No. 79-051. This document contained various restrictions on who could view the ANDA that effectively eliminated Sciele's ability to meaningfully access ANDA No. 79-051 and process the information contained therein. For example, this Offer barred any access to in-house counsel, and substantially limited the fields of practice of outside counsel who might view the ANDA.

23. Under 21 U.S.C. § 355(j)(5)(C)(i)(III), an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information."

24. Since receiving the Second Paragraph IV Letter and the accompanying "Offer of Confidential Access," Sciele has attempted to negotiate with Mylan to procure a copy of ANDA No. 79-051 under restrictions "as would apply had a protective order been issued." These

negotiations have been unsuccessful. For example, Mylan has continued to insist on inappropriate restrictions on the fields of practice of counsel that might review the ANDA.

25. By requiring these inappropriate restrictions, Mylan has effectively refused to provide information that would allow Sciele to confirm that Mylan's proposed generic versions of Sciele's Sular® tablets 20mg and 30mg are within the lawful scope of one or more claims of the '741 patent.

26. Sciele is not aware of any other means of obtaining information regarding Mylan's proposed generic versions of Sciele's Sular® tablets 20mg and 30mg within the 45-day statutory period. In the absence of such information, Sciele resorts to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm its allegations of infringement and to present to the Court evidence that Mylan's proposed generic versions of Sciele's Sular® tablets 20mg and 30mg fall within the scope of one or more claims of the '741 patent.

27. On information and belief, in filing ANDA No. 79-051, Mylan has requested the FDA's approval to market generic copies of Sciele's Sular® tablets 20mg and 30mg throughout the United States, including Delaware.

28. On information and belief, if the FDA approves ANDA No. 79-051, Mylan will attempt to sell the approved proposed generic versions of Sciele's Sular® tablets 20mg and 30mg throughout the United States, including Delaware, before the expiration of the '741 patent.

Count I

(Infringement of the '741 Patent Under 35 U.S.C. § 271(e)(2) by Mylan's proposed generic nisoldipine extended release tablets 20mg)

29. Paragraphs 1 to 28 are incorporated herein as set forth above.

30. On information and belief, Mylan submitted an ANDA to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, or sale of proposed generic nisoldipine extended release tablets 20mg throughout the United States. By

submitting the application, Mylan has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

31. While Mylan denied infringement of the '741 patent in its Second Paragraph IV Letter, that Letter provides insufficient information on which Sciele may evaluate that claim. Mylan has also, to date, failed to provide ANDA No. 79-051 to allow Sciele to review the necessary information. In the absence of such information, Sciele resorts to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm its allegations of infringement and to present to the Court evidence that Mylan's proposed generic version of Sciele's Sular® tablets 20mg falls within the scope of one or more claims of the '741 patent.

32. On information and belief, Sciele is entitled to a declaration whether the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's proposed generic nisoldipine extended release tablets 20mg constitutes or will constitute an act of infringement of the '741 patent under 35 U.S.C. § 271.

33. Sciele will be irreparably harmed by Mylan's infringing activities unless those activities are enjoined by a Court of law. Sciele does not have an adequate remedy at law.

Count II

(Infringement of the '741 Patent Under 35 U.S.C. § 271(e)(2) by Mylan's proposed generic nisoldipine extended release tablets 30mg)

34. Paragraphs 1 to 33 are incorporated herein as set forth above.

35. On information and belief, Mylan submitted an ANDA to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use, or sale of proposed generic nisoldipine extended release tablets 30mg throughout the United States. By submitting the application, Mylan has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

36. While Mylan denied infringement of the '741 patent in its Second Paragraph IV Letter, that Letter provides insufficient information on which Sciele may evaluate that claim.

Mylan has also, to date, failed to provide ANDA No. 79-051 to allow Sciele to review the necessary information. In the absence of such information, Sciele resorts to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information as is required to confirm its allegations of infringement and to present to the Court evidence that Mylan's proposed generic version of Sciele's Sular® tablets 30mg falls within the scope of one or more claims of the '741 patent.

37. On information and belief, Sciele is entitled to a declaration whether the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's proposed generic nisoldipine extended release tablets 30mg constitutes or will constitute an act of infringement of the '741 patent under 35 U.S.C. § 271.

38. Sciele will be irreparably harmed by Mylan's infringing activities unless those activities are enjoined by a Court of law. Sciele does not have an adequate remedy at law.

Prayer For Relief

Plaintiffs respectfully pray for the following relief:

a. That judgment be entered that Mylan has infringed the '741 patent under 35 U.S.C. § 271(e)(2)(A) by submitting an ANDA under section 505(j) of the Federal Food Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, sale and/or importation of Mylan's proposed generic nisoldipine extended release tablets 20mg will constitute an act of infringement of the '741 patent;

b. That judgment be entered that Mylan has infringed the '741 patent under 35 U.S.C. § 271(e)(2)(A) by submitting an ANDA under section 505(j) of the Federal Food Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, sale and/or importation of Mylan's proposed generic nisoldipine extended release tablets 30mg will constitute an act of infringement of the '741 patent;

c. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Mylan's ANDA shall be a date which is not earlier than the expiration date of the '741 patent;

d. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Mylan, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the '741 patent before the expiration of said patent;

e. That damages or other monetary relief be awarded to Sciele under 35 U.S.C. § 271(e)(4)(C) as appropriate, including an accounting for any damages not included in any judgment entered after trial;

f. That this is an exceptional case under 35 U.S.C. § 285, and that Sciele be awarded reasonable attorneys' fees and costs; and


g. That this Court award such other and further relief as it may deem just and proper.

Demand for Jury Trial

Sciele demands a trial by jury on all issues appropriately tried to a jury.

Dated: December 14, 2007

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