

Judge Pauley

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

PFIZER INC., PFIZER PRODUCTS INC.,
and C.P. PHARMACEUTICALS
INTERNATIONAL C.V.,

Plaintiffs,

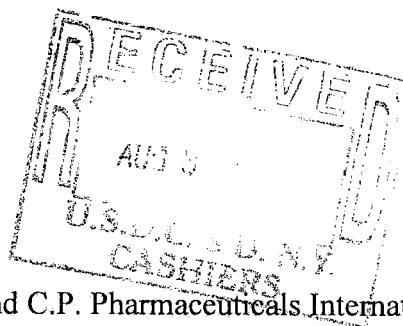
v.

MYLAN INC. and
MYLAN PHARMACEUTICALS INC.,

Defendants.

10 CIV 6469

COMPLAINT



Plaintiffs Pfizer Inc., Pfizer Products Inc. and C.P. Pharmaceuticals International C.V.

(collectively, "Pfizer"), by its attorneys, White & Case LLP, for its Complaint against
Defendants Mylan Inc. and Mylan Pharmaceuticals Inc. (collectively, "Mylan"), allege:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Mylan's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Pfizer's pharmaceutical product Chantix[®] prior to the expiration of United States Patent Nos. 7,265,119 ("the '119 patent") and 6,890,927 ("the '927 patent"), which cover Chantix[®] or its use.

THE PARTIES

2. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 235 East 42nd Street, New York, New York.

3. Plaintiff Pfizer Products Inc. is a corporation organized and existing under the laws of the State of Connecticut, having a place of business at Eastern Point Road, Groton, Connecticut. Pfizer Inc. is the ultimate parent of Pfizer Products Inc.

4. Plaintiff C.P. Pharmaceuticals International C.V. is a limited partnership organized and existing under the laws of the Netherlands, having a place of business at 235 East 42nd Street, New York, New York. Pfizer Inc. is the ultimate parent of C.P. Pharmaceuticals International C.V.

5. Upon information and belief, Defendant Mylan Inc., formerly known as Mylan Laboratories Inc., is a corporation organized under the laws of the Commonwealth of Pennsylvania, having a principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317. Mylan Inc. is in the business of making and selling generic pharmaceutical products, which it distributes in the State of New York and throughout the United States. Mylan Inc. has previously consented to the jurisdiction of this Court and has purposely availed itself of the jurisdiction of this Court by filing lawsuits and asserting counterclaims in lawsuits filed in this judicial district.

6. Upon information and belief, Defendant Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia, having a principal place of business at 781 Chestnut Ridge Rd., Morgantown, West Virginia 26505. Upon information and belief, Mylan Pharmaceuticals Inc., is a wholly-owned subsidiary of Mylan Inc.

Upon information and belief, Mylan Pharmaceuticals Inc. is registered to do business in the State of New York, and does business in this judicial district. Mylan Pharmaceuticals Inc. is registered to distribute drugs in the State of New York, and is in the business of making and selling generic pharmaceutical products, which it distributes in the State of New York and throughout the United States. Mylan Pharmaceuticals Inc. has previously consented to the jurisdiction of this Court and has purposely availed itself of the jurisdiction of this Court by filing lawsuits and asserting counterclaims in lawsuits filed in this judicial district.

JURISDICTION AND VENUE

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

8. This court has personal jurisdiction over Mylan by virtue of, *inter alia*: (1) its presence in New York, having conducted business in New York, (2) its systematic and continuous contacts with New York, including its substantial and ongoing sale of generic drugs in New York; and (3) its prior consent to personal jurisdiction in this judicial district and its filing of suit and counterclaims in this judicial district, having availed itself of the rights and benefits of New York law.

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

THE PATENTS-IN-SUIT

10. On September 4, 2007, the United States Patent and Trademark Office issued the '119 patent, entitled "Tartrate Salts of 5,8,14-Triazatetracyclo[10.3.1.0^{2,11}.0^{4,9}]-Hexadeca-2(11),3,5,7,9-Pentaene and Pharmaceutical Compositions Thereof." At the time of its issue, the '119 patent was assigned to Pfizer Inc., and Pfizer Inc. currently holds title to the '119

patent. A copy of the '119 patent is attached as Exhibit A.

11. The '119 patent is directed to and claims, inter alia, salts and polymorphs of 5,8,14-triazatetracyclo[10.3.1.0^{2,11}.0^{4,9}]-hexadeca-2(11),3,5,7,9-pentaene, including varenicline tartrate, and their use in the treatment of nicotine dependency, addiction, and withdrawal.

12. Pfizer Inc. has exclusively licensed the '119 patent to C.P. Pharmaceuticals International C.V.

13. On May 10, 2005, the United States Patent and Trademark Office issued the '927 patent, entitled "Tartrate Salts of 5,8,14-Triazatetracyclo[10.3.1.0^{2,11}.0^{4,9}]-Hexadeca-2(11),3,5,7,9-Pentaene and Pharmaceutical Compositions Thereof." At the time of its issue, the '927 patent was assigned to Pfizer Inc. and Pfizer Products Inc., and Pfizer Inc. and Pfizer Products Inc. currently hold title to the '927 patent. A copy of the '927 patent is attached as Exhibit B.

14. The '927 patent is directed to and claims, inter alia, salts and polymorphs of 5,8,14-triazatetracyclo[10.3.1.0^{2,11}.0^{4,9}]-hexadeca-2(11),3,5,7,9-pentaene, including varenicline tartrate, and their use in the treatment of nicotine dependency, addiction, and withdrawal.

15. Pfizer Inc. has exclusively licensed the '927 patent to C.P. Pharmaceuticals International C.V.

CHANTIX[®]

16. Pfizer Inc. holds an approved New Drug Application (the "Chantix[®] NDA") for varenicline tartrate tablets, in 0.5 mg and 1.0 mg dosages, which Pfizer sells under the trade name Chantix[®].

17. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '119 and '927 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Chantix®.

MYLAN'S ANDA

18. On information and belief, Mylan submitted ANDA No. 20-2019 (the "Mylan ANDA") to the FDA, pursuant to 21 U.S.C. §§ 355(j), seeking approval to market varenicline tartrate tablets, in 0.5 mg and 1.0 mg dosages (the "Mylan Product").

19. The Mylan ANDA refers to and relies upon the Chantix® NDA and contains data that, according to Mylan, demonstrates the bioequivalence of the Mylan Product and Chantix®.

20. Pfizer received from Mylan a letter and attached memorandum, dated August 3, 2010 (collectively, the "Mylan Notification"), stating that Mylan had included in its ANDA a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '119 and '927 patents are invalid, unenforceable, or would not be infringed by the manufacture, use, or sale of the Mylan Product (the "Paragraph IV Certification").

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 7,265,119

21. Pfizer realleges and incorporates by reference the allegations of paragraphs 1-20 of this Complaint.

22. Mylan has infringed the '119 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Mylan ANDA, by which Mylan seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale or importation of the Mylan Product prior to the expiration of the '119 patent.

23. If Mylan commercially makes, uses, offers to sell, or sells the Mylan

Product within the United States, or imports the Mylan Product into the United States, or induces or contributes to any such conduct during the term of the '119 patent, it would further infringe the '119 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

24. Pfizer will be substantially and irreparably harmed if Mylan is not enjoined from infringing the '119 patent.

25. Pfizer does not have an adequate remedy at law.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 6,890,927

26. Pfizer realleges and incorporates by reference the allegations of paragraphs 1-25 of this Complaint.

27. Mylan has infringed the '927 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Mylan ANDA, by which Mylan seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale or importation of the Mylan Product prior to the expiration of the '927 patent.

28. If Mylan commercially makes, uses, offers to sell, or sells the Mylan Product within the United States, or imports the Mylan Product into the United States, or induces or contributes to any such conduct during the term of the '927 patent, it would further infringe the '927 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

29. Pfizer will be substantially and irreparably harmed if Mylan is not enjoined from infringing the '927 patent.

30. Pfizer does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Pfizer prays for a judgment in its favor and against Mylan, as follows:

A. That Mylan has infringed U.S. Patent Nos. 7,265,119 and 6,890,927;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(B), Mylan, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from making, using, selling, offering to sell the Mylan Product within the United States, or importing the Mylan Product into the United States prior to the expiration of the '119 and '927 patents;

C. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 20-2019 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration dates of the '119 and '927 patents, including any extensions;

D. That Pfizer be awarded monetary relief if Mylan commercially makes, uses, sells, or offers to sell the Mylan Product within the United States, or imports the Mylan Product into the United States, prior to the expiration of the '119 and '927 patents, including any extensions, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest; and

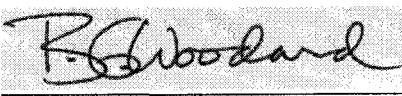
E. That Pfizer be awarded such other relief as the Court deems just and proper.

Dated: August 30, 2010
New York, NY

Respectfully submitted,

WHITE & CASE LLP

1155 Avenue of the Americas
New York, New York 10036
Phone: (212) 819-8200
Facsimile: (212) 354-8113

By: 

Dimitrios T. Drivas (DD 8891)

Jeffrey J. Oelke (JO 2534)

Adam Gahtan (AG 8802)

Brendan G. Woodard (BW 6194)

R. Gregory Parker (RP 2121)

Attorneys for Plaintiffs

Pfizer Inc., Pfizer Products Inc. and

C.P. Pharmaceuticals International C.V.