

MARCH 5, 2008
MICHAEL W. DOBBINS
CLERK, U.S. DISTRICT COURT

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS**

08 C 1343

ORTHO-MCNEIL PHARMACEUTICAL, INC.,)	Case No.
)	
Plaintiff,)	
)	
vs.)	
)	
MYLAN PHARMACEUTICALS INC., and ALPHAPHARM)	
)	
Defendants.)	

**JUDGE ANDERSEN
MAGISTRATE JUDGE ASHMAN**

COMPLAINT

In this patent infringement action, Plaintiff Ortho-McNeil Pharmaceutical, Inc., for its complaint against Defendants Mylan Pharmaceuticals Inc. and Alphapharm, alleges as follows:

PARTIES

1. Plaintiff Ortho-McNeil Pharmaceutical, Inc. ("Ortho-McNeil") is a corporation incorporated under the laws of the State of Delaware with its principal place of business at 1000 U.S. Route 202, Raritan, New Jersey 08869.

2. Upon information and belief, Defendant Mylan Pharmaceuticals Inc. ("MPI") is a West Virginia corporation with its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

3. Upon information and belief, Alphapharm is an Australian corporation with its principal place of business at Chase Building 2, Wentworth Park Road, Glebe NSW 2037.

JURISDICTION AND VENUE

4. This action for patent infringement arises under 35 U.S.C. § 100 *et seq.* generally, and 35 U.S.C. § 271(e)(2) specifically.

5. This Court has subject matter jurisdiction over this dispute pursuant to 28 U.S.C. §§ 1331 and 1338.

6. MPI is subject to personal jurisdiction in this district because MPI does business in the State of Illinois. The Northern District of Illinois ruled that MPI is subject to personal jurisdiction in this district in *Abbott Laboratories v. Mylan Pharmaceuticals, Inc.*, No. 05 C 6561, 2006 WL 850916 (N.D. Ill. March 28, 2006).

7. Alphapharm has designated MPI as Alphapharm's authorized agent, thereby consenting to personal jurisdiction for this matter where its authorized agent, MPI, is subject to personal jurisdiction. MPI is subject to personal jurisdiction in this district as stated in Paragraph 6, which is incorporated herein, and therefore Alphapharm is subject to personal jurisdiction in this district.

8. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(c) and (d) and 1400 because Alphapharm is an alien, because Alphapharm has designated MPI as its authorized agent, and because MPI and consequently Alphapharm are subject to personal jurisdiction in this judicial district.

GENERAL ALLEGATIONS

9. On August 1, 2006, the United States Patent and Trademark Office ("USPTO") granted Reissue Patent No. RE39,221 ("the RE221 Patent"). A true and correct copy of the RE221 Patent is attached as Exhibit A.

10. Ortho-McNeil is the current assignee of the RE221 Patent.

11. Ortho-McNeil owns all rights, title, and interest in the RE221 Patent.

12. Ortho-McNeil markets the drug covered by New Drug Application ("NDA") No. 21-123 under the tradename Ultracet®, the active ingredients of which are tramadol hydrochloride and acetaminophen (hereinafter, "Ultracet®" or "the Ultracet® drug product").

13. On information and belief, Alphapharm is an Australian company that manufactures generic pharmaceuticals in Australia.

14. On information and belief, prior to October 2, 2007, Alphapharm was a subsidiary of Merck Generics Group B.V.

15. On information and belief, as of October 2, 2007, Merck Generics Group B.V. was acquired by Mylan Inc., a Pennsylvania corporation with its principal place of business in Pennsylvania, and as a consequence of that acquisition Alphapharm became a subsidiary of Mylan Inc.

16. On information and belief, Alphapharm initially filed Abbreviated New Drug Application ("ANDA") No. 77-858 with the Food and Drug Administration ("FDA") including a certification under § 505(j)(2)(A)(vii)(III) of the Federal Food Drug and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(b)(2)(A)(iii)) ("the Paragraph III Certification"), stating the date upon which the RE221 Patent would expire, such that the ANDA would not be approved until that date.

17. On information and belief, at some point following its original filing, Alphapharm amended the Paragraph III Certification in ANDA No. 77-858 to a certification under § 505(j)(2)(A)(vii)(IV) of the FDCA (codified at 21 U.S.C. § 355(b)(2)(A)(iv)) ("the Paragraph IV Certification") asserting that the RE221 Patent is invalid or will not be infringed

and seeking approval to engage in the commercial manufacture, use, sale, or offer for sale of a pharmaceutical composition containing tramadol hydrochloride and acetaminophen at a dosage ratio of 325 mg/37.5 mg in oral tablets prior to the expiration of the RE221 Patent.

18. On information and belief, Alphapharm, through its authorized agent MPI, notified Ortho-McNeil of this certification via a letter bearing the date February 25, 2008 ("Paragraph IV notice").

19. According to the letter bearing the date February 25, 2008, Alphapharm asserts that its tramadol hydrochloride/acetaminophen product would not infringe claims 6, 21, or 55-66 of the RE221 Patent. The letter bearing the date February 25, 2008 does not contest infringement of the other 49 claims of the RE221 Patent by Alphapharm's product as detailed in ANDA No. 77-858.

20. On information and belief, MPI is also a subsidiary of Mylan Inc.

21. On information and belief, MPI is a U.S.-based generic pharmaceutical manufacturer with production facilities in three states and Puerto Rico.

22. On information and belief, MPI also distributes generic pharmaceuticals that are manufactured by other subsidiaries of Mylan Inc.

COUNT I

(Infringement of the RE221 Patent against Defendant Alphapharm)

23. Ortho-McNeil incorporates and realleges Paragraphs 1 through 22 above, as if set forth in full herein.

24. Because Alphapharm seeks approval of ANDA No. 77-858, and, on information and belief, with such approval seeks to engage in the manufacture, use, offer for sale, import, or sale of the pharmaceutical composition and its method of use claimed by the RE221 Patent before the patent's expiration, Alphapharm has infringed one or more claims of the

RE221 Patent pursuant to 35 U.S.C. § 271(e)(2)(A), entitling Ortho-McNeil to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for Alphapharm's ANDA be a date which is not earlier than the expiration date of the RE221 Patent, a date which is currently September 6, 2011.

COUNT II

(Infringement of the RE221 Patent against Defendant MPI)

25. Ortho-McNeil incorporates and realleges Paragraphs 1 through 24 above, as if set forth in full herein.

26. MPI has acted as Alphapharm's authorized agent with respect to ANDA No. 77-858, and on information and belief, MPI is Alphapharm's sister subsidiary of Mylan Inc., MPI is a generic drug manufacturer in the United States with the capability to manufacture, use, offer for sale, import, and/or sell the tramadol hydrochloride and acetaminophen product covered by ANDA No. 77-858, and if ANDA No. 77-858 is approved MPI is likely to manufacture, use, offer for sale, import, and/or sell the tramadol hydrochloride and acetaminophen product covered by ANDA No. 77-858 under an arrangement with Alphapharm. MPI has therefore infringed one or more claims of the RE221 Patent pursuant to 35 U.S.C. § 271(e)(2)(A), entitling Ortho-McNeil to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for Alphapharm's ANDA be a date which is not earlier than the expiration date of the RE221 Patent, a date which is currently September 6, 2011.

COUNT III

(Induced Infringement of the RE221 Patent against Defendant MPI)

27. Ortho-McNeil incorporates and realleges Paragraphs 1 through 24 above, as if set forth in full herein.

28. MPI has acted as Alphapharm's authorized agent with respect to ANDA No. 77-858 and, on information and belief, has aided and abetted at least the amendment of

ANDA No. 77-858 to contain a Paragraph IV certification, MPI is Alphapharm's sister subsidiary of Mylan Inc., MPI is a generic drug manufacturer in the United States with the capability to manufacture, use, offer for sale, import, and/or sell the tramadol hydrochloride and acetaminophen product covered by ANDA No. 77-858, and if ANDA No. 77-858 is approved MPI is likely to manufacture, use, offer for sale, import, and/or sell the tramadol hydrochloride and acetaminophen product covered by ANDA No. 77-858 under an arrangement with Alphapharm.

29. Upon information and belief, MPI knew that Alphapharm's ANDA No. 77-858 and the product covered by that ANDA would infringe the RE221 Patent, MPI knowingly induced Alphapharm's infringement of the RE221 Patent, and MPI specifically intended to encourage Alphapharm's infringement of the RE221 Patent.

30. MPI has therefore aided and abetted in and intentionally induced Alphapharm's infringement of one or more claims of the RE221 Patent pursuant to 35 U.S.C. § 271(e)(2)(A), entitling Ortho-McNeil to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for Alphapharm's ANDA be a date which is not earlier than the expiration date of the RE221 Patent, a date which is currently September 6, 2011.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Ortho-McNeil requests that:

A. Judgment be entered that Alphapharm has infringed one or more claims of the RE221 Patent;

B. Judgment be entered that MPI has infringed or induced the infringement of one or more claims of the RE221 Patent;

C. Judgment be entered that the manufacture, use, sale, or offer to sell within the United States, or importation into the United States of the generic copy of Ultracet® described in Alphapharm's ANDA No. 77-858 infringes one or more claims of the RE221 Patent;

D. An order be entered directing the FDA not to approve Alphapharm's ANDA No. 77-858 any earlier than the expiration date of the RE221 Patent;

E. A permanent injunction be granted preventing Alphapharm, its officers, directors, agents, attorneys, employees, successors and assigns, and those acting in privity or concert with it, and MPI, its officers, directors, agents, attorneys, employees, successors and assigns, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States of a pharmaceutical composition claimed in the RE221 Patent;

F. Ortho-McNeil be awarded its costs and expenses in bringing and prosecuting this action; and

G. Ortho-McNeil be granted such other and further relief as the Court may deem just and proper.

Respectfully submitted,

By: s/ Linda R. Friedlieb

One of the Attorneys for Plaintiff
Ortho-McNeil Pharmaceutical, Inc.

David T. Pritikin
Lisa A. Schneider
Linda R. Friedlieb
SIDLEY AUSTIN LLP
One South Dearborn Street
Chicago, Illinois 60603
(312) 853-7000

-and-

Jeffrey P. Kushan (*pro hac vice* application
pending)
David A. Steffes (*pro hac vice* application
pending)
SIDLEY AUSTIN LLP
1501 K Street N.W.
Washington, D.C. 20005
(202) 736-8000

-and-

Michael D. Hatcher (*pro hac vice* application
pending)
SIDLEY AUSTIN LLP
717 North Harwood, Suite 3400
Dallas, Texas 75201
(214) 981-3300

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