

FILED

JULY 18, 2007

MICHAEL W. DOBBINS
CLERK, U.S. DISTRICT COURT

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

**JUDGE PALLMEYER
MAGISTRATE JUDGE KEYS**

_____)	
ORTHO-MCNEIL PHARMACEUTICAL,)	Case No.
INC.,)	
)	Judge
Plaintiff,)	
)	
vs.)	
)	Jury Trial Requested
APOTEX, INC.,)	WAH
)	
Defendant.)	

07 C 4050

COMPLAINT

In this patent infringement action, Plaintiff Ortho-McNeil Pharmaceutical, Inc., for its complaint against Defendant Apotex, Inc., 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 Apotex, Inc. ("Apotex") is a Canadian corporation with its principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M91-1T9

JURISDICTION AND VENUE

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

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

5. Apotex has designated Robert B. Breisblatt, Welsh and Katz, Ltd, 120 South Riverside Plaza, Chicago, IL 60606 as Apotex's agent authorized to accept service of process for Apotex, thereby consenting to personal jurisdiction in this judicial district.

6. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(c) and (d) and 1400 because Apotex is an alien and because Apotex is subject to personal jurisdiction in this judicial district.

INFRINGEMENT OF THE RE221 PATENT

7. 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.

8. Ortho McNeil is the current assignee of the RE221 Patent.

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

10. 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").

11. On information and belief, Apotex has filed an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA") including a certification under § 505(j)(2)(A)(vii)(IV) of the Federal Food Drug and Cosmetic Act (codified at 21 U.S.C. § 355(b)(2)(A)(iv)) ("the Paragraph IV Certification") for approval to engage in the commercial manufacture, use, sale or offer for sale of a therapeutic composition containing tramadol hydrochloride and acetaminophen. Apotex notified Ortho-McNeil of this certification via a letter bearing the date June 5, 2007.

12. Because, on information and belief, Apotex seeks approval of its ANDA referenced in Paragraph 11, and with such approval to engage in the manufacture, use, offer for sale, or sale of the therapeutic composition and its method of use claimed by the RE221 patent before the patent's expiration, Apotex 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 Apotex'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.

13. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Ortho-McNeil's reasonable attorney's fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Ortho-McNeil requests that:

A. Judgment be entered that Apotex has infringed, either literally or under the doctrine of equivalents, one or more claims of the RE221 Patent;

B. 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 Apotex's ANDA infringes one or more claims of the RE221 Patent;

C. An order be entered directing the FDA not to approve Apotex's ANDA effective any earlier than the expiration date of the RE221 Patent;

D. A permanent injunction be granted preventing Apotex, 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 therapeutic composition claimed in the RE221 Patent;

E. Judgment be entered that this case is an exceptional case under 35 U.S.C. § 285, entitling Ortho-McNeil to an award of its reasonable attorneys' fees;

F. Ortho-McNeil be awarded its reasonable attorneys' fees;

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

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

JURY DEMAND

Plaintiff Ortho-McNeil hereby demands a trial by jury of all issues so triable pursuant to Rule 38 of the Federal Rules of Civil Procedure.

Respectfully submitted,

By: s/ Lisa A. Schneider

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