

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION**

PHARMACIA & UPJOHN COMPANY LLC, and )  
PFIZER ASIA-PACIFIC PTE. LTD., )

Plaintiffs, )

v. )

APOTEX INC., and )  
APOTEX CORP. )

Defendants. )

C.A. No. \_\_\_\_\_

**COMPLAINT**

Plaintiffs Pharmacia & Upjohn Company LLC and Pfizer Asia-Pacific Pte. Ltd., (collectively "Pharmacia"), for their Complaint against Defendants Apotex Inc. and Apotex Corp., (collectively "Apotex"), allege as follows:

**NATURE OF THE ACTION**

1. This is an action for infringement of U.S. Patent No. 5,688,792 ("the '792 patent"). This action arises out of Apotex's filing of Abbreviated New Drug Application ("ANDA") No. 20-4260 seeking approval to sell a generic copy of Pharmacia's highly successful Zyvox® product prior to the expiration of the '792 patent owned by Pharmacia.

**THE PARTIES**

2. Pharmacia & Upjohn Company LLC is a limited liability company organized and existing under the laws of Delaware with offices located at 7000 Portage Road, Kalamazoo, Michigan 49001.

3. Pfizer Asia Pacific PTE. LTD. is a private limited company organized and existing under the laws of Singapore with a principal place of business located at 31 Tuas South Avenue 6, Singapore 637578.

4. Pharmacia has all right, title and interest in the '792 patent and the right to sue for infringement thereof.

5. On information and belief, Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

6. On information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware with a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. On information and belief, Apotex Corp. has an office located at 3601 N Sacramento Ave, Fl 2, Chicago, Illinois 60618.

7. On information and belief, Apotex Inc. manufactures numerous drug products for sale and use in the United States including this judicial district.

8. On information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Inc.

9. On information and belief, Apotex Corp. is the United States marketing and sales affiliate for Apotex Inc.

10. On information and belief, Apotex Corp. markets and sells drug products, including generic drug products manufactured by Apotex Inc., in the United States including this judicial district. On information and belief, Apotex Corp. distributes and/or has distributed pharmaceutical products in the United States, including the state of Illinois.

**JURISDICTION AND VENUE**

11. This action arises under the patent laws of the United States, Title 35, United States Code. This Court has subject matter jurisdiction over this action pursuant to the provisions of 28 U.S.C. §§ 1331, 1338, 2201 and 2202.

12. Venue is proper in this judicial district as to each Defendant pursuant to the provisions of 28 U.S.C. §§ 1391 and 1400(b).

13. This Court has personal jurisdiction over Defendant Apotex Corp. by virtue of the fact that, *inter alia*, on information and belief it has an office located within this judicial district.

14. This Court has personal jurisdiction over each Defendant by virtue of, *inter alia*, their presence in the State of Illinois through their continuous and systemic contacts with Illinois. On information and belief: (1) Apotex directly or indirectly distributes, markets, sells and offers to sell its drug products in Illinois; (2) Apotex regularly conducts other business activities in Illinois; (3) Apotex derives substantial revenue from its sales of drug products and other business activities in Illinois; (4) Apotex has availed itself of the jurisdiction of this Court by (i) bringing actions in this district, (ii) regularly and routinely litigating ANDA cases in this District, including through the filing of counterclaims in such actions; and (iii) consenting to jurisdiction in this Court in multiple previous litigations; (5) Apotex has also moved other courts to transfer ANDA litigations to this district; (6) Apotex has, directly or through an agent, filed ANDA No. 20-4260, and/or has been actively involved in the preparation and submission of that ANDA, for the purpose of seeking regulatory approval to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of a generic version of Pharmacia's Zyvox® product in the United States, including in Illinois; and (7) upon receiving FDA approval, Apotex Inc. intends to offer to sell, sell, distribute, market, and import its generic Zyvox® product throughout the United States, including in Illinois primarily through Apotex Corp.

15. On information and belief, Apotex Inc. has further availed itself of the laws of the State of Illinois and engaged in a course of conduct in the State of Illinois, at least by designating Robert B. Breisblatt, Katten Muchin Rosenman LLP, 525 W. Monroe St., Chicago, IL 60661-3693, as its agent authorized to accept service of process for Apotex Inc. in this action.

16. Apotex has consented to jurisdiction in this Court for the purposes of this case.

### **BACKGROUND**

17. On November 18, 1997, the United States Patent and Trademark Office ("the PTO") duly and legally issued the '792 patent entitled "Substituted Oxazine and Thiazine Oxazolidinone Antimicrobials," based on an application filed by Michael R. Barbachyn, Steven J. Brickner and Douglas K. Hutchinson. That application had been duly and legally assigned to Pharmacia & Upjohn Company. A copy of the '792 patent is attached hereto as Exhibit A.

18. Pharmacia holds an approved New Drug Application on Linezolid tablets, which it sells under the registered name Zyvox®. Zyvox® is approved for the treatment of various microbial infections. The Zyvox® product and its use are covered by one or more claims of the '792 patent. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA promulgated pursuant thereto, the '792 patent is listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") for Zyvox®.

19. The Orange Book lists the '792 patent's expiration date as November 18, 2014.

20. Patents associated with Zyvox®, including the '792 patent, have been granted a further period of pediatric exclusivity under section 505(a) of the Federal Food, Drug and Cosmetic Act ("FDCA").

21. The pediatric exclusivity period associated with the '792 patent will expire May 18, 2015.

22. By letter dated January 30, 2013 (the "Notice Letter"), Apotex Inc. notified Pharmacia & Upjohn Company that it had filed ANDA No. 20-4260 with the FDA, seeking approval under the FDCA to market and sell its Linezolid Tablets, 600 mg ("Apotex's ANDA Product"), a generic copy of Zyvox®, prior to the expiration of the '792 patent.

23. The Notice Letter states that in its ANDA No. 20-4260 Apotex certifies that the '792 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of Apotex's ANDA Product.

24. On information and belief, Apotex Corp. participated in, contributed to, aided, abetted, acted in concert with, and/or induced Apotex Inc.'s preparation and/or submission of ANDA 20-4260 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA. Such collaboration was done, at least in part, for the benefit of Apotex Inc. and Apotex Corp.

25. On information and belief, the acts of Apotex Inc. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of, Apotex Corp.

26. This action is being commenced before the expiration of forty-five days from the date of the receipt of the Notice Letter.

#### **COUNT I**

#### **CLAIM FOR RELIEF: INFRINGEMENT OF THE '792 PATENT**

27. Plaintiffs reallege paragraphs 1 through 26 above as if fully set forth herein.

28. Apotex's ANDA Product and its use are covered by one or more claims of the '792 patent.

29. Apotex had knowledge of the '792 patent when it submitted ANDA No. 20-4260 to the FDA.

30. Apotex's submission of ANDA 20-4260 to the FDA, seeking approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Apotex's ANDA Product before the expiration date of the '792 patent is an act of infringement of the '792 patent under 35 U.S.C. § 271(e)(2)(A).

31. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product would infringe one or more claims of the '792 patent literally or under the doctrine of equivalents.

32. On information and belief, the use of Apotex's ANDA Product in accordance with and as directed by Apotex's proposed labeling for that product would infringe one or more claims of the '792 patent literally or under the doctrine of equivalents.

33. On information and belief, Apotex will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA product with its proposed labeling immediately and imminently upon approval of ANDA 20-4260.

34. On information and belief Apotex Corp. will be the entity that offers for sale, sells, markets, distributes, and/or imports Apotex's ANDA product.

35. On information and belief, Apotex plans and intends to, and will, actively induce infringement of the '792 patent when ANDA No. 20-4260 is approved by the FDA, and plans and intends to, and will do so immediately and imminently upon such approval.

36. On information and belief, Apotex knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '792 patent, and that its ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Apotex plans and intends to, and will, contribute to the infringement of the '792 patent immediately and imminently upon approval of ANDA 20-4260.

37. The foregoing actions by Apotex constitute and/or would constitute infringement of the '792 patent, active inducement of infringement of the '792 patent, and/or contribute to the infringement of the '792 patent by others.

38. Pharmacia will be substantially and irreparably damaged and harmed if Apotex's infringement is not enjoined. Pharmacia does not have an adequate remedy at law.

39. This is an exceptional case warranting imposition of attorney fees against Defendants under 35 U.S.C. § 285.

### **REQUEST FOR RELIEF**

WHEREFORE, Pharmacia prays that this Court grant the following relief:

1. A judgment that Apotex's submission of ANDA 20-4260 was an act of infringement and that Apotex's making, using, offering to sell, selling, marketing, distributing, or importing Apotex's ANDA Product prior to the expiration of the '792 patent will infringe, actively induce infringement, and/or contribute to the infringement of the '792 patent;

2. A judgment ordering that the effective date of any FDA approval for Apotex to make, use, offer for sale, sell, market, distribute, or import Apotex's ANDA Product, or any product or compound that infringes the '792 patent, be no earlier than the expiration date of the '792 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

3. A preliminary and permanent injunction enjoining Apotex, their officers, agents, servants and employees, and all persons acting in concert or participation with any of them, from making, using, selling, offering for sale, marketing, distributing, or importing Apotex's ANDA Product, or any product or compound that infringes the '792 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '792 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

4. The entry of judgment that this case is an exceptional case under 35 U.S.C. § 285, entitling Plaintiffs to an award of their reasonable attorneys' fees for bringing and prosecuting this action;

5. An award of Plaintiffs' costs and expenses in this action; and

6. Such further and additional relief as this Court deems just and proper.

Dated: March 15, 2013

*/s/ Marcus E. Sernel*

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**LOCAL RULE 3.2 STATEMENT**

Pursuant to Local Rule 3.2, Plaintiffs submit the following statements:

(1) Pharmacia & Upjohn Company LLC (“PUC”) is a wholly owned, indirect subsidiary of Pfizer Inc. Its direct parent is Pharmacia & Upjohn LLC. PUC has numerous affiliates and subsidiaries within the Pfizer Inc. family.

(2) Pfizer Asia Pacific PTE. LTD. (“PAPL”) is a wholly owned, indirect subsidiary of Pfizer Inc. Its direct parent is PF Prism C.V. PAPL has the following subsidiaries: Pfizer Asia Manufacturing Pte. Ltd. and Pfizer Asia Contract Operations Pte. Ltd.

Dated: March 15, 2013

*/s/ Marcus E. Sernel*

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**NOTICE OF CLAIMS INVOLVING PATENTS**

Pursuant to Local Rule 3.4, the Plaintiffs hereby give notice that the complaint includes claims for patent infringement and further provide the information required by 35 U.S.C. § 290. The names and addresses of the parties are: (1) Pharmacia & Upjohn Company LLC, 7000 Portage Road, Kalamazoo, Michigan 49001; (2) Pfizer Asia Pacific PTE. LTD., 31 Tuas South Avenue 6, Singapore 637578; (3) Apotex Inc., 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9; and (4) Apotex Corp., 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. The patent is U.S. Patent No. 5,688,792. The inventors on the patent are Michael R. Barbachyn, Steven J. Brickner and Douglas K. Hutchinson.

Dated: March 15, 2013

*/s/ Marcus E. Sernel*

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