IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

NYCOMED GmbH and WYETH Plaintiffs, v. APOTEX Inc. and APOTEX Corp. Defendants.	CIVIL ACTION NO._____

COMPLAINT FOR PATENT INFRINGEMENT

1. Nycomed GmbH is a corporation incorporated and existing under the laws of Germany, having its principal place of business at Byk-Gulden-Str. 2, 78467 Konstanz, Germany.

2. Wyeth is a Delaware corporation with offices at Five Giralda Farms, Madison, NJ 07940.

3. Nycomed GmbH is at times referred to hereinafter as "Nycomed."

4. Upon information and belief, Defendant Apotex Inc. is a corporation incorporated and existing under the laws of Canada and having a principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

5. Upon information and belief, Defendant Apotex Corp. is a corporation organized under the laws of the State of Delaware and having a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

6. Upon information and belief, Apotex Corp. is the agent, affiliate, representative and/or alter ego of, and/or acts in concert with, Apotex Inc. for the purposes of

marketing, distributing, and/or selling generic pharmaceutical products within the United States, including this district.

7. Apotex Inc. and Apotex Corp. are at times referred to hereinafter as "Apotex."

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States of America, and jurisdiction exists under 28 U.S.C. §§ 1331 and 1338(a).

9. Upon information and belief, Apotex Inc. develops and manufactures generic drugs for sale and use in the United States and does business throughout the United States, including in this district.

10. Upon information and belief, Apotex Corp. is the United States marketing and sales affiliate for Apotex Inc. and does business throughout the United States, including in this district.

11. Apotex, Inc. has designated Steven E. Feldman of Husch Blackwell Sanders Welsh & Katz, 120 South Riverside Plaza, 22nd Floor, Chicago, Illinois 60606, as its agent authorized to accept service of process in this action, and has thereby consented to personal jurisdiction in this district.

12. Upon information and belief, Apotex has maintained continuous and systematic contacts with the State of Illinois and this district.

13. Upon information and belief, Apotex has previously submitted to personal jurisdiction in this district.

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

BACKGROUND FOR CLAIM FOR RELIEF UNDER 35 U.S.C. § 271 (e)

15. Wyeth Pharmaceuticals Inc., a wholly-owned subsidiary of Wyeth, is the holder of New Drug Application ("NDA") No. 20-987, by which the United States Food & Drug Administration ("USFDA") granted approval for pantoprazole sodium 20 mg and 40 mg delayed-release tablets, which are marketed and sold by Plaintiffs in the United States under the trade name PROTONIX®.

16. Nycomed is the owner of United States Patent No. 4,758,579 ("the '579 patent"), which was duly and legally issued on July 19, 1988, and discloses and claims certain compounds useful for inhibiting gastric acid secretion, including pantoprazole sodium, the active ingredient of PROTONIX®.

17. Wyeth is the exclusive licensee of the '579 patent in the United States.

18. A copy of the '579 patent is attached as Exhibit A.

19. The expiration date of the '579 patent is July 19, 2010.

20. Plaintiffs have been awarded a period of pediatric exclusivity that extends their exclusive rights under the '579 patent until January 19, 2011.

21. Upon information and belief, Apotex filed in the USFDA an Abbreviated New Drug Application ("ANDA"), No. 90-807, including a certification with respect to the '579 patent under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355), seeking approval to engage in the commercial manufacture, use, importation, sale and/or offer for sale of pantoprazole sodium 20 mg and 40 mg delayed-release tablets, prior to expiration of the '579 patent.

22. Upon information and belief, pantoprazole sodium is the active ingredient of the products for which Apotex is seeking regulatory approval in ANDA No. 90-807.

23. Upon information and belief, the pantoprazole sodium drug substance and the pantoprazole sodium delayed-released tablets that are the subject of ANDA No. 90-807 will be manufactured by Apotex.

24. Upon information and belief, Apotex intends to — directly or indirectly — market, sell, offer for sale, and distribute the products that are the subject of ANDA No. 90-807, including within this district, upon regulatory approval.

25. By letter dated July 3, 2009, Apotex sent a notice to Nycomed and Wyeth in which Apotex represented that it had filed an ANDA for pantoprazole sodium delayed-release tablets, including the certification with respect to the '579 patent, and that it sought approval of its ANDA prior to the expiration of that patent.

26. Nycomed received notice of the Apotex certification no earlier than July 7, 2009.

27. Wyeth received notice of the Apotex certification no earlier than July 7, 2009.

CLAIM FOR RELIEF UNDER 35 U.S.C. § 271 (e)

28. Because Apotex seeks approval of ANDA No. 90-807 to engage in the commercial manufacture, use, importation, sale and/or offer for sale of a drug claimed in the '579 patent before its expiration, Apotex has infringed the '579 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

29. Apotex actively and knowingly submitted, caused to be submitted, assisted with, participated in, contributed to and/or directed the submission of ANDA No. 90-807 and the § 505(j)(2)(A)(vii)(IV) certification to the FDA.

30. Apotex's active and knowing participation in, contribution to, aiding, abetting and/or inducement of the submission to the FDA of ANDA No. 90-807 and the § 505(j)(2)(A)(vii)(IV) certification constitutes infringement of the '579 patent under 35 U.S.C. § 271(e)(2)(A).

31. Nycomed and Wyeth are entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of ANDA No. 90-807 be a date that is not earlier than the expiration date of the '579 patent and all exclusivities that have been granted, including pediatric exclusivity, or any later expiration of exclusivity for the '579 patent to which Nycomed and/or Wyeth is or becomes entitled.

32. Upon information and belief, Apotex was aware of the existence of the '579 patent and was aware that the filing of its ANDA and certification with respect to the '579 patent constituted an act of infringement of that patent.

PRAYER FOR RELIEF

33. Plaintiffs request that:

a. Judgment be entered that Apotex has infringed the '579 patent by submitting the aforesaid ANDA;

b. Judgment be entered that Apotex has infringed the '579 patent under 35 U.S.C. 271;

c. A permanent injunction be issued, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283, restraining and enjoining Apotex and its directors, officers, agents,

attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of compounds claimed in the '579 patent;

d. An order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 90-807 be a date that is not earlier than the expiration date for the '579 patent and all exclusivities that have been granted, including pediatric exclusivity, or any later expiration of exclusivity for the '579 patent to which Plaintiffs are or become entitled; and

e. For such other and further relief as the Court may deem just and proper under the circumstances, including reasonable attorney fees.

Dated: August 14, 2009

/s/ James B. Coughlan

James B. Coughlan (6201004)
Paul, Hastings, Janofsky & Walker LLP
191 North Wacker Drive, 30th floor
Chicago, IL 60606
Phone: (312) 499-6018
Facsimile: (312) 499-6100

Joseph M. O'Malley, Jr. *(Pro Hac to be Filed)*
Bruce M. Wexler *(Pro Hac to be Filed)*
Eric W. Dittmann *(Pro Hac to be Filed)*
Isaac S. Ashkenazi *(Pro Hac to be Filed)*
Paul, Hastings, Janofsky & Walker LLP
75 East 55th Street
New York, New York 10022
Phone: (212) 318-6000
Facsimile: (212) 319-4090

William F. Lee *(Pro Hac to be Filed)*
Wilmer Cutler Pickering Hale and Dorr LLP
60 State Street
Boston, Massachusetts 02109
Phone: (617) 526-6000
Facsimile: (617) 526-5000

William G. McElwain *(Pro Hac to be Filed)*
Amy Kreiger Wigmore *(Pro Hac to be Filed)*
Wilmer Cutler Pickering Hale and Dorr LLP
1875 Pennsylvania Avenue, N.W.
Washington, DC 20006
Phone: (202) 663-6000
Facsimile: (202) 663-6363

Attorneys for Plaintiffs
Nycomed GmbH and Wyeth