UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA
Case No. _____

GENENTECH, INC. and
ROCHE PALO ALTO LLC,

Plaintiffs,

v.

APOTEX INC.

Defendant.

COMPLAINT

Plaintiffs Genentech, Inc. and Roche Palo Alto LLC, by their attorneys, for their Complaint in this action allege:

PARTIES

1. Genentech, Inc. ("Genentech") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1 DNA Way, South San Francisco, California 94080-4990.

2. Roche Palo Alto LLC ("Roche Palo Alto") is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 3431 Hillview Avenue, Palo Alto, California 94304-1397.

3. On information and belief, Apotex Inc. ("Apotex") is a company

organized and existing under the laws of Canada, having a place of business at 150 Signet Drive, Toronto, Ontario, Canada.

JURISDICTION

4. This action arises under the Patent Act of 1952, as amended, 35 U.S.C. §§ 1-376.

5. This Court has subject matter jurisdiction to hear this action under 28 U.S.C. §§ 1331 and 1338(a).

THE PATENT IN SUIT

6. On July 4, 2000, the United States Patent and Trademark Office issued U.S. Patent No. 6,083,953 (the "'953 patent"), entitled "2- (2-amino-1,6-dihydro-6-oxo-purin-9-yl) methoxy-1,3-propanediol Derivative." Roche Palo Alto is the owner by assignment of all right, title and interest in the '953 patent. A copy of the '953 patent is attached hereto as Exhibit A.

7. Genentech markets and sells an FDA-approved pharmaceutical product, called VALCYTE®, in the form of tablets containing 450 mg of the active pharmaceutical ingredient, valganciclovir hydrochloride in crystalline form. The '953 patent is listed in the FDA's publication of approved drugs, Approved Drug Products with Therapeutic Equivalence Evaluations (known as the "Orange Book"), as covering VALCYTE® 450 mg tablets and their use.

APOTEX'S ANDA AND NOTICE LETTER

8. By letter to Roche Palo Alto and certain of its affiliates dated April 6, 2011 (the "Notice Letter"), Apotex gave notice under Section 505(j)(2)(B) of the Food, Drug and Cosmetic Act ("FDCA") that it had submitted Abbreviated New Drug Application ("ANDA") No. 202785 to the FDA, seeking the FDA's approval to manufacture, use and sell valganciclovir hydrochloride 450 mg tablets prior to expiration of the '953 patent.

9. In the Notice Letter, Apotex notified Roche Palo Alto that its ANDA contained a "Paragraph IV Certification" that the claims of the '953 patent will not be infringed by the commercial manufacture, use, offer for sale and sale of certain valganciclovir hydrochloride 450 mg tablets (the "Apotex Generic Product"). The Apotex Notice Letter asserts that such commercialization will not infringe the '953 patent because the Apotex Generic Product purportedly will comprise "amorphous," rather than crystalline, valganciclovir hydrochloride.

10. In truth and in fact, amorphous valganciclovir hydrochloride is hygroscopic and prone to conversion to crystalline form during use by patients, e.g. upon exposure to ambient conditions of temperature and humidity.

11. Apotex has provided Roche Palo Alto and its affiliates with confidential access to a portion of its ANDA but has refused to provide physical samples of the Apotex Generic Product and related materials for testing.

12. On information and belief, Apotex threatens to market and sell the Apotex Generic Product in Florida and elsewhere in the United States and thereby to cause massive infringement of the '953 patent in Florida, in this district, and elsewhere in the United States. On information and belief, Apotex has appointed an agent in Weston, Florida with authority to accept service of process, limited to a patent infringement action based on Apotex's notice of its Paragraph IV Certification.

13. On information and belief, Apotex is not qualified to do business in any State of the United States. On information and belief, Apotex is not subject to jurisdiction in any state court of general jurisdiction in the United States. On information and belief, Apotex derives substantial revenue from sales of pharmaceutical products in Florida, in this district, and elsewhere in the United States.

14. This complaint is being filed before the expiration of forty-five days from the date Roche Palo Alto and its affiliates received the Apotex Notice Letter. On May 17, 011, Genentech and Roche Palo Alto commenced a first action against Apotex in the Northern District of California, Case No. CV11-2410-DMR, asserting the same claims for relief that are stated herein. This case is filed here in an abundance of caution as a protective action to preserve the procedural rights of Genentech and Roche Palo Alto in the event that Apotex were to assert that the

United States District Court for the Northern District of California lacks jurisdiction over the person of Apotex and the Northern District of California were to agree with such an assertion by Apotex.

FIRST CLAIM FOR RELIEF
INFRINGEMENT OF THE '953 PATENT

15. Each of the preceding paragraphs 1 to 14 is incorporated herein as if set forth in full.

16. Plaintiffs believe and expect that following receipt of relevant Apotex physical materials, investigation will confirm that the valganciclovir hydrochloride active ingredient in the proposed Apotex Generic Product will comprise or convert to crystalline valganciclovir hydrochloride at least during use by patients, e.g. upon exposure to ambient atmospheric humidity during storage in pill trays.

17. On information and belief, Apotex's commercial use, offer for sale, and sale of the proposed Apotex Generic Product would infringe the '953 patent at least under 35 U.S.C. §§ 271(b) and (c).

18. On information and belief, Apotex infringed the '953 patent under 35 U.S.C. § 271(e)(2) by filing ANDA No. 202785.

SECOND CLAIM FOR RELIEF
DECLARATORY AND EQUITABLE RELIEF
AGAINST THREATENED PATENT INFRINGEMENT

19. Each of the preceding paragraphs 1 to 18 is incorporated herein as if set forth in full.

20. Apotex has proposed and threatens to market, sell, and actively induce use of the Apotex Generic Product throughout the United States including in California and this federal judicial district.

21. On information and belief, Apotex's proposed and threatened use, offer for sale, and sale of the Apotex Generic Product will infringe or actively induce or contribute to infringement of the '953 patent.

22. An actual controversy exists between Plaintiffs and Apotex concerning whether offer for sale, sale, or use of the Apotex Generic Product in the United States will infringe the '953 patent.

23. Offer for sale, sale or use of the Apotex Generic Product in the United States would cause injury to Plaintiffs for which there is no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE Plaintiffs pray that the Court:

(i) declare, adjudge, and decree that Apotex has infringed the '953 patent by submitting ANDA No. 202785;

(ii) declare, adjudge, and decree that Apotex's commercial use, offer for sale and sale of the Apotex Generic Product will infringe the '953 patent;

(iii) issue an Order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of the Apotex Generic Product be no earlier than the

expiration date of the '953 patent, or any later expiration of exclusivity to which Roche Palo Alto is or becomes entitled;

(iv) issue a permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), 35 U.S.C. § 283, and 28 U.S.C. § 1331 restraining and enjoining Apotex and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in commercial activity that would directly or indirectly infringe the '953 patent; and

(v) award such other and further relief as the Court may deem just and proper.

Dated: May 19, 2011

STEPHEN S. RABINOWITZ
srabinowitz@friendfrank.com
RANDY C. EISENSMITH
randy.eisensmith@friedfrank.com
FRIED, FRANK, HARRIS, SHRIVER & JACOBSON LLP
ONE NEW YORK PLAZA
NEW YORK, NEW YORK 10001
Telephone: 212-859-8000
Facsimile: 212-859-4000

Of counsel

EDWARD A. MAROD, P.A.
Counsel for Plaintiffs Genentech, Inc., and Roche Palo Alto LLC
P.O. Box 3606
West Palm Beach, Florida 33402
ed.marod@marod.com
(561) 832-0050
(561) 832-6324 Fax

By: /s/ Edward A. Marod
Edward A. Marod, Esq.
Fla. Bar No. 238961