UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No. **1:11-cv- - -**

GENENTECH, INC., a Delaware corporation, and
ROCHE PALO ALTO LLC, a Delaware limited liability company,

Plaintiffs,

v.

SANDOZ INC, a Colorado corporation,

Defendant.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Genentech, Inc. and Roche Palo Alto LLC, through their attorneys Fried, Frank, Harris, Shriver & Jacobson LLP and Levine Sullivan Koch & Schulz, L.L.P., for their Complaint in this action against Defendant Sandoz Inc., allege as follows:

PARTIES AND JURISDICTION

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, Sandoz Inc. ("Sandoz") is a company organized and existing under the laws of the State of Colorado, having its principal place of business at 506 Carnegie Center, Princeton, New Jersey 08540.

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. §§ 331 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, and incorporated as a part of the pleadings, 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.

SANDOZ'S ANDA AND NOTICE LETTER

8. By letter to Genentech and certain of its affiliates dated March 9, 2011 (the "Notice Letter"), Sandoz gave notice that it had submitted Abbreviated New Drug Application ("ANDA") No. 202575 to the FDA under Section 505(j)(2)(B) of the Food, Drug and Cosmetic

Act ("FDCA"), 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, Sandoz notified Genentech that its ANDA contained a "Paragraph IV Certification" that the claims of the '953 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale and sale of certain valganciclovir hydrochloride 450 mg tablets (the "Sandoz Generic Product"). The Sandoz Notice letter asserts that such commercialization will not infringe the '953 patent because the Sandoz 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 upon exposure to ambient conditions of temperature and humidity, as typically happens when VALCYTE® is used by patients.

11. Since March 9, 2011, Sandoz has failed and, on information and belief, willfully refused to respond to numerous telephonic, e-mail, and written communications seeking access to the Chemistry, Manufacturing and Controls (CMC) section of the Sandoz ANDA and physical samples relating to the Sandoz Generic Product that Sandoz has proposed to sell in Colorado and elsewhere in the United States.

12. This complaint is being filed before the expiration of forty-five days from the date Genentech and its affiliates received the Sandoz Notice Letter.

FIRST CLAIM FOR RELIEF
INFRINGEMENT OF THE '953 PATENT

13. Each of the preceding paragraphs 1 to 12 is incorporated herein as if set forth in full.

14. Plaintiffs believe and expect that following receipt of relevant Sandoz documents and physical materials, investigation will confirm that the valganciclovir hydrochloride active ingredient in the Sandoz 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.

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

16. On information and belief, Sandoz infringed the '953 patent under 35 U.S.C. § 271(e)(2) by filing ANDA No. 202575.

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

17. Each of the preceding paragraphs 1 to 16 is incorporated herein as if set forth in full.

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

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

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

21. Offer for sale, sale or use of the Sandoz 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 Sandoz has infringed the '953 patent by submitting ANDA No. 202575;

(ii) declare, adjudge, and decree that Sandoz's commercial use, offer for sale and sale of the Sandoz 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 Sandoz 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 Sandoz 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.

Respectfully submitted this 22nd day of April, 2011

By: */s Christopher P. Beall*

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