IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ROCHE PALO ALTO LLC, Plaintiff, v. ENDO PHARMACEUTICALS, INC., Defendant.	Civil Action No._____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, Roche Palo Alto LLC by its attorneys, for its Complaint in this action alleges:

PARTIES AND JURISDICTION

1. 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.

2. On information and belief, Endo Pharmaceuticals, Inc. ("Endo") is a company organized and existing under the laws of the State of Delaware, having its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317.

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

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

THE PATENT-IN-SUIT

5. 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.

6. Roche Palo Alto's affiliates market and sell 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.

ENDO'S ANDA AND NOTICE LETTER

7. By letter dated February 22, 2010 (the "Notice Letter"), Endo gave notice that it had submitted Abbreviated New Drug Application ("ANDA") No. 200790 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.

8. In the Notice Letter, Endo notified Roche Palo Alto that its ANDA contained a "Paragraph IV Certification" asserting that the commercial manufacture, use, offer for sale and sale of Endo valganciclovir hydrochloride 450 mg tablets will not infringe any valid and enforceable claim of the '953 patent.

9. This complaint is being filed before the expiration of forty-five days from the date Roche Palo Alto received the Endo Notice Letter.

FIRST CLAIM FOR RELIEF
INFRINGEMENT OF THE '953 PATENT

10. Each of the preceding paragraphs 1 to 9 is incorporated herein as if set forth in full.

11. In the Notice Letter Endo contends that the active pharmaceutical ingredient in Endo's valganciclovir product exists only in amorphous form and that the commercial manufacture, use, offer for sale and sale of Endo valganciclovir hydrochloride 450 mg tablets purportedly will not infringe the '953 patent.

12. In truth and in fact, amorphous valganciclovir hydrochloride is inherently unstable and hygroscopic, readily converting to crystalline form upon exposure to ambient conditions of temperature and humidity, as typically happens when VALCYTE® is used by patients.

13. Although requests were made promptly following receipt of the Notice Letter, Roche Palo Alto did not receive samples of Endo's proposed dosage form, active ingredient, and excipients for testing until March 25, 2010. Roche Palo Alto accordingly will not have sufficient opportunity to complete its investigation of the manufacture and behavior(s) of Endo's proposed valganciclovir hydrochloride 450 mg tablets before the expiration of the statutory forth-five day period following receipt of the Endo Notice Letter; however, Roche Palo Alto believes and expects that further investigation will confirm that the valganciclovir hydrochloride active ingredient in Endo's proposed product will comprise or convert to crystalline valganciclovir hydrochloride at least during use by patients, upon exposure to ambient atmospheric humidity

during storage in pill trays, upon exposure to gastric contents upon administration to patients, or both.

14. On information and belief, Endo's commercial manufacture, use, offer for sale and sale of its valganciclovir hydrochloride 450 mg tablets would infringe the '953 patent at least under 35 U.S.C. §§ 271(b) and (c).

15. On information and belief, Endo infringed the '953 patent under 35 U.S.C. § 271(e)(2) by filing ANDA No. 200790.

SECOND CLAIM FOR RELIEF
DECLARATORY JUDGMENT OF PATENT INFRINGEMENT

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

17. On information and belief, upon FDA approval of Endo's ANDA No. 200790, Endo will further infringe the '953 patent under at least 35 U.S.C. §§ 271(b) and (c) by the commercial manufacture, use, offer for sale and sale of its valganciclovir hydrochloride 450 mg tablets

18. If Endo's infringement of the '953 patent is not enjoined, plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE Roche Palo Alto prays that the Court:

(i) declare, adjudge, and decree that Endo has infringed the '953 patent by submitting ANDA No. 200790;

(ii) declare, adjudge, and decree that Endo's commercial manufacture, use, offer for sale and sale of its valganciclovir hydrochloride 450 mg tablets 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 Endo's product be no earlier than the expiration date of the '953 patent, or any later expiration of exclusivity for the '953 patent to which Roche Palo Alto is or becomes entitled; and

(iv) issue a permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Endo and its officers, agents, attorneys 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 that are claimed or whose use is claimed in the '953 patent; and

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

DATED: March 31, 2010

FISH & RICHARDSON P.C.

By: /s/ *Douglas E. McCann*

Douglas E. McCann (#3852)
dmccann@fr.com
222 Delaware Avenue, 17th floor
P.O. Box 1114
Wilmington, DE 19899-1114
(302) 652-5070

Counsel for Plaintiff Roche Palo Alto LLC

Of Counsel:

Stephen S. Rabinowitz
Randy C. Eisensmith
Fried, Frank, Harris, Shiver
& Jacobson LLP
One New York Plaza
New York, NY 10004
(212) 859-8000