IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ROCHE PALO ALTO LLC and GENENTECH, INC.,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
MYLAN PHARMACEUTICALS INC.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

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

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 1 DNA Way, South San Francisco, California 94080-4990.

2. 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.

3. On information and belief, Mylan Pharmaceuticals Inc. ("Mylan Pharmaceuticals") is a corporation organized and existing under the laws of the State of West Virginia, having its principal place of business at 781 Chestnut Ridge, Morgantown, West Virginia 26505.

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

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

THE PATENT-IN-SUIT

6. Roche Palo Alto is the owner by assignment of 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," which the United States Patent and Trademark Office duly and legally issued on July 4, 2000. A true and correct copy of the '953 patent is attached hereto as Exhibit A.

7. Under an exclusive license under the '953 patent, Genentech and its 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.

MYLAN'S ANDA AND NOTICE LETTER

8. By letter to Roche Palo Alto and certain of its affiliates dated July 22, 2013 (the "Notice Letter"), Mylan Pharmaceuticals gave notice under Section 505(j)(2)(B) of the Food, Drug and Cosmetic Act ("FDCA") that it had submitted ANDA No. 20-5151 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, Mylan Pharmaceuticals notified Plaintiffs that its ANDA contained a "Paragraph IV Certification" alleging 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 Mylan's proposed valganciclovir hydrochloride 450 mg tablets (the "Mylan Generic Product"). The Notice Letter asserts that such commercialization will not infringe the '953 patent because the active pharmaceutical ingredient in the Mylan Generic Product purportedly will contain amorphous valganciclovir hydrochloride and will not contain any crystalline

valganciclovir hydrochloride.

10. On information and belief, the amorphous valganciclovir hydrochloride contained in the Mylan Generic Product is hygroscopic and prone to conversion to crystalline form during manufacture, storage, or use by patients as directed, e.g., upon exposure to ambient conditions of temperature and humidity or to fluid gastric contents.

11. Despite requests made by Plaintiffs after receiving the Notice Letter, Plaintiffs have not yet received physical samples of the Mylan Generic Product and its active pharmaceutical ingredient and excipients for testing. Accordingly, Plaintiffs have not been able to complete their investigation of Mylan's Generic Product and its active pharmaceutical ingredient within forty-five days following receipt of the Notice Letter. In the absence of such samples and information, Plaintiffs resort to the judicial process and the aid of discovery to obtain under appropriate judicial safeguards such information and samples as are required to obtain and to present to the Court evidence that the defendant has infringed and will infringe one or more claims of the '953 patent. Plaintiffs believe that further investigation will confirm that the active pharmaceutical ingredient in the Mylan Generic Product will comprise valganciclovir hydrochloride in crystalline form when sold or used, or will convert to valganciclovir hydrochloride in crystalline form at least during use by patients, upon exposure to ambient atmospheric humidity during storage in pill tray organizers, and/or upon exposure to gastric contents upon administration to patients.

12. On information and belief, Defendant threatens to market and sell the Mylan Generic Product in Delaware and thereby cause massive infringement of the '953 patent in this federal judicial district.

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

FIRST CLAIM FOR RELIEF
INFRINGEMENT OF THE '953 PATENT

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

15. On information and belief, Defendant's commercial manufacture, use, offer for sale, sale, and importation of the Mylan Generic Product will infringe the '953 patent under 35 U.S.C. § 271(a).

16. When it filed the Paragraph IV Certification in ANDA No. 20-5151, Defendant had knowledge of the '953 patent.

17. On information and belief, patients, caregivers, and other end users who use the Mylan Generic Product in accordance with the directions in the label will directly infringe the '953 patent.

18. On information and belief, Defendant intends to actively induce infringement of the '953 patent as demonstrated by its inclusion of instructions in the label of the Mylan Generic Product that will cause patients, caregivers, and other end users to infringe the '953 patent.

19. On information and belief, Defendant's commercial manufacture, use, offer for sale, sale, and importation of the Mylan Generic Product will actively induce or contribute to infringement of the '953 patent under 35 U.S.C. §§ 271(b) and (c).

20. On information and belief, Defendant's manufacture, use, offer for sale, or sale of the Mylan Generic Product in the United States or importation of the Mylan Generic Product into the United States prior to the expiration of the '953 patent or any additional patent exclusivity to which Roche Palo Alto is or becomes entitled would cause injury to the Plaintiffs for which there is no adequate remedy at law.

21. On information and belief, Defendant infringed the '953 patent under 35 U.S.C.

§ 271(e)(2) by filing ANDA No. 20-5151.

SECOND CLAIM FOR RELIEF
DECLARATORY JUDGMENT OF PATENT INFRINGEMENT

22. Each of the proceeding paragraphs 1 to 21 is incorporated herein as if set forth in full.

23. On information and belief, Defendant's manufacture, use, offer for sale, sale, or importation of the Mylan Generic Product prior to the expiration of the '953 patent or any additional patent exclusivity to which Roche Palo Alto is or becomes entitled will infringe the '953 patent.

24. Defendant will have knowledge of any ruling by this Court that patients, caregivers, or other end users who use the Mylan Generic Product in accordance with the directions in the product label will infringe the '953 patent.

25. On information and belief, Defendant's manufacture, use, offer for sale, sale, or importation of the Mylan Generic Product following such a ruling and prior to the expiration of the '953 patent or any additional patent exclusivity to which Roche Palo Alto is or becomes entitled will actively induce or contribute to infringement of the '953 patent.

26. An actual controversy exists between Plaintiffs and Defendant concerning whether manufacture, use, offer for sale, sale of the Mylan Generic Product in the United States or importation of the Mylan Generic Product into the United States will infringe the '953 patent.

PRAYER FOR RELIEF

WHEREFORE Plaintiffs pray that the Court:

(i) declare, adjudge, and decree that Defendant has infringed the '953 patent by submitting ANDA No. 20-5151;

(ii) declare, adjudge, and decree that Defendant's commercial manufacture, use, offer

for sale, sale, and importation of the Mylan Generic Product will directly or indirectly 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 Mylan Generic 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;

(iv) issue a permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B), 35 U.S.C. § 283 restraining and enjoining Defendant, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the 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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Mary B. Graham

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