

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

ROCHE PALO ALTO LLC and  
GENENTECH, INC.,

Plaintiffs,

v.

DR. REDDY'S LABORATORIES, LTD. and  
DR. REDDY'S LABORATORIES, INC.,

Defendants.

Civil Action No. \_\_\_\_\_

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Roche Palo Alto LLC and Genentech, Inc., 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, Dr. Reddy's Laboratories, Ltd. ("DRL Ltd.") is a company organized and existing under the laws of India, having its principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Andhra Pradesh 500034, India.

4. On information and belief, Dr. Reddy's Laboratories, Inc. ("DRL Inc.") is a company organized and existing under the laws of the State of New Jersey, having its principal

place of business at 200 Somerset Corporate Boulevard, Bridgewater, NJ 08807-2862. On information and belief, DRL Inc. is a wholly-owned subsidiary of DRL Ltd.

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

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

### **THE PATENT-IN-SUIT**

7. On July 4, 2000, the United States Patent and Trademark Office issued United States 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.

8. Genentech markets and sells an FDA-approved pharmaceutical product, called VALCYTE<sup>®</sup>, 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<sup>®</sup> 450 mg tablets and their use.

### **DRL LTD. AND DRL INC.’S NOTICE LETTER AND ANDA**

9. By letter to Roche Palo Alto, Genentech, and certain of their affiliates dated November 4, 2011 (the “Notice Letter”), DRL Ltd. and DRL Inc. gave notice under Section 505(j)(2)(B) of the Food, Drug and Cosmetic Act (“FDCA”) that DRL Ltd. and DRL Inc. had collectively submitted Abbreviated New Drug Application (“ANDA”) No. 203511 to the FDA, seeking the FDA’s approval to manufacture, use and sell oral tablets containing valganciclovir

hydrochloride, equivalent to 450 mg base (the “Proposed Generic Product”) prior to expiration of the ’953 patent.

10. In the Notice Letter, DRL Ltd. and DRL Inc. notified Plaintiffs and their affiliates that the ANDA filed by DRL Ltd. and DRL Inc. contained a “Paragraph IV Certification” that the ’953 patent is invalid, unenforceable or will not be infringed by the manufacture, use, sale, offer to sell or importation into the United States of their Proposed Generic Product.

11. DRL Ltd. and DRL Inc. have provided Plaintiffs and their affiliates with confidential access to a portion of their ANDA, but have refused to provide physical samples of their Proposed Generic Product and related materials for testing even though Plaintiffs requested that such physical samples be provided.

12. On information and belief, DRL Ltd. and DRL Inc. threaten to market and sell their Proposed Generic Product in Delaware and elsewhere in the United States and thereby to cause infringement of the ’953 patent throughout the United States, including in Delaware and consequently in this district.

13. On information and belief, DRL Ltd. is not subject to jurisdiction in any state court of general jurisdiction in the United States. On information and belief, DRL Ltd. derives substantial revenue from sales of pharmaceutical products in Delaware 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, Genentech and their affiliates received the Notice Letter.

**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 physical materials from DRL Ltd. and DRL Inc., investigation will confirm that the valganciclovir hydrochloride active ingredient in the Proposed Generic Product will either comprise crystalline valganciclovir hydrochloride 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, DRL Ltd. and DRL Inc.'s commercial use, offer for sale, and sale of their Proposed Generic Product would infringe the '953 patent at least under 35 U.S.C. §§ 271(b) and (c).

18. On information and belief, DRL Ltd. and DRL Inc. infringed the '953 patent under 35 U.S.C. § 271(e)(2) by filing ANDA No. 203511.

**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. DRL Ltd. and DRL Inc. have proposed and threatened to market, sell, and actively induce use of the Proposed Generic Product throughout the United States including in Delaware and consequently this federal judicial district.

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

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

23. Offer for sale, sale, or use of the Proposed 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 DRL Ltd. and DRL Inc. have infringed the '953 patent by submitting ANDA No. 203511;

(ii) declare, adjudge, and decree that DRL Ltd. and DRL Inc.'s commercial use, offer for sale and sale of the Proposed 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 Proposed 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 DRL Ltd. and DRL Inc. and their 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: December 20, 2011

FISH & RICHARDSON P.C.

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