IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENZYME CORPORATION and SANOFI-AVENTIS U.S. LLC, Plaintiffs, v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC., Defendants.	)	C.A. No._____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs, Genzyme Corporation ("Genzyme") and sanofi-aventis U.S. LLC ("Sanofi"), by their attorneys, for their complaint against Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL"), hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement of U.S. Patent Nos. RE42,152 ("the '152 patent"), 7,897,590 ("the '590 patent"), and 6,987,102 ("the '102 patent") arising under the Patent Laws of the United States, Title 35, United States Code, Sections 100 *et seq*.

2. This action relates to the following Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA"): ANDA No. 205182 filed by DRL for approval to market Plerixafor Injection 20 mg/mL, a proposed generic version of Genzyme's Mozobil® drug product.

THE PARTIES

3. Plaintiff Genzyme is a corporation organized and existing under the laws of the State of Massachusetts, having its principal place of business at 500 Kendall Street, Cambridge, MA 02142.

4. Plaintiff Sanofi is a Delaware corporation with its principal place of business in Bridgewater, NJ.

5. On information and belief, Defendant Dr. Reddy's Laboratories Inc. ("DRL Inc.") is a corporation organized and existing under the laws of the New Jersey having a place of business at 200 Somerset Corporate Blvd., Bridgewater, NJ 08807.

6. On information and belief, Defendant Dr. Reddy's Laboratories Ltd. ("DRL Ltd.") is a company organized and existing under the laws of India having a place of business at 7-1-27, Amerpeet, Hyderabad, 500 016, India.

7. On information and belief, DRL Inc. is a wholly owned subsidiary of DRL Ltd., and is controlled by DRL Ltd.

8. On information and belief, the acts of DRL Inc. complained of herein were done at the direction of, and with the authorization, cooperation, participation, and assistance of DRL Ltd. On information and belief, the acts of DRL Inc. complained of herein were done at least in part for the benefit of DRL Ltd.

JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 1400(b), 2201, and 2202.

10. On information and belief, DRL Inc. and DRL Ltd. are subject to personal jurisdiction in this district.

11. On information and belief, DRL Inc. and DRL Ltd. are in the business of developing and manufacturing generic and branded pharmaceutical products.

12. On information and belief, DRL Inc. and DRL Ltd. directly, or indirectly through subsidiaries and/or distributors, market, distribute, and sell their generic and branded pharmaceutical products within and throughout the United States, including the State of Delaware.

13. On information and belief, DRL Inc. and DRL Ltd. have purposefully availed themselves of the privilege of doing business in the State of Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including the State of Delaware, and/or by selling, directly or through their agents, pharmaceutical products in the State of the Delaware.

14. In the alternative, DRL Inc. and DRL Ltd. are subject to the jurisdiction of the Court pursuant to 10 *Del. C.* § 3104. Specifically, DRL Inc. and DRL Ltd. cause tortious injury in Delaware, namely from the tort of patent infringement, and DRL Inc. and DRL Ltd. regularly conduct or solicit business, engage in a persistent course of conduct in Delaware and this District, and derive substantial revenue from things used or consumed in Delaware and this District.

15. On information and belief, personal jurisdiction over DRL Inc. and DRL Ltd. is also proper because DRL Inc. and DRL Ltd. have sought affirmative relief in this jurisdiction by answering Complaints and filing counterclaims in at least four cases since 2004, and because DRL Inc. and DRL Ltd. have employed Delaware counsel to assist in obtaining that relief.

16. In one of those cases, *Merck & Co. v. Dr. Reddy's Laboratories, Ltd.,* 04-cv-131 (GMS), DRL Ltd. admitted that it was "subject to personal jurisdiction in this district," i.e. the District of Delaware.

17. Venue is proper in this judicial District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

18. Genzyme is the holder of New Drug Application ("NDA") No. 022311, which relates to Plerixafor solution 20 mg/mL for subcutaneous injection. On December 15, 2008, the FDA approved the marketing of the drug product described in NDA No. 022311 for use in combination with granulocyte-colony stimulating factor ("G-CSF") to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma and multiple myeloma. This drug product is prescribed and sold in the United States using the trademark Mozobil®. Genzyme and Sanofi both share in the profits from the sale of Mozobil®.

19. United States Patent No. RE42,152 (a true and accurate copy of which is attached hereto as Exhibit A) was duly and legally issued on February 15, 2011 to inventors Gary J. Bridger, Sreenivasan Padmanbhan, Renato Skerlj, and David M. Thornton. With patent term extension, the '152 patent will expire on December 10, 2018. At all times from the issuance of the '152 patent to the present, Genzyme has been the owner of the '152 patent.

20. United States Patent No. 7,897,590 (a true and accurate copy of which is attached hereto as Exhibit B) was duly and legally issued on March 1, 2011 to inventors Gary J. Bridger, Michael J. Abrams, Geoffrey W. Henson, Ronald Trevor MacFarland, Gary B. Calandra, Hal E. Broxmeyer, and David C. Dale. With patent term adjustment, the '590 patent will expire on July

22, 2023. At all times from the issuance of the '590 patent to the present, Genzyme has been the owner of the '590 patent.

21. United States Patent No. 6,987,102 (a true and accurate copy of which is attached hereto as Exhibit C) was duly and legally issued on January 17, 2006 to inventors Gary J. Bridger, Michael J. Abrams, Geoffrey W. Henson, Ronald Trevor MacFarland, Gary B. Calandra, Hal E. Broxmeyer, and David C. Dale. The '102 patent was assigned to Anormed, Inc., which then assigned the '102 patent to Genzyme in 2008. With patent term adjustment, the '102 patent will expire on July 22, 2023. Since 2008, Genzyme has been the owner of the '102 patent.

22. By letter dated July 19, 2013, purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B) (the "Notice Letter"), DRL notified Genzyme that DRL had submitted ANDA No. 205182 to the FDA under section 505(j) of the Federal Food Drug and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, importation, use, and sale of 20 mg/mL Plerixafor injection ("Plerixafor ANDA Injection Product") as a generic version of Genzyme's Mobozil® drug product.

23. On information and belief and as stated in the Notice Letter, the FDA received ANDA No. 205182 from DRL Inc. and DRL Ltd.

24. On information and belief, both DRL Inc. and DRL Ltd. participated in the preparation and/or filing of ANDA No. 205182.

25. On information and belief, DRL stated in its ANDA that its Plerixafor ANDA Injection Product is bioequivalent to Genzyme's Mobozil® drug product.

26. DRL's ANDA was submitted to obtain FDA approval to engage in the commercial manufacture, importation, use, and sale of DRL's Plerixafor ANDA Injection

Product prior to the expiration of the '152 patent, the '590 patent, and the '102 patent, all of which are listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluation" (the "Orange Book") as being applicable to Genzyme's Mozobil® drug product.

27. On information and belief, DRL intends to engage in the commercial manufacture, importation, use, and sale of its Plerixafor ANDA Injection Product promptly upon receiving FDA approval to do so.

28. In the Notice Letter, DRL notified Genzyme that its ANDA contained a "paragraph IV" certification that in DRL's opinion the '152 patent, and '590 patent, and the '102 patent are invalid or will not be infringed by the commercial manufacture, use, sale, offer to sell, or importation of DRL's Plerixafor ANDA Injection Product.

COUNT I
INFRINGEMENT BY DRL OF U.S. PATENT NO. RE42,152

29. Plaintiffs repeat and reallege the allegations of paragraphs 1-28 as if fully set forth herein.

30. DRL's submission of its ANDA to obtain approval from the FDA to engage in the commercial manufacture, importation, use, or sale of its Plerixafor ANDA Injection Product prior to the expiration of the '152 patent constitutes infringement of one or more of the claims of the '152 patent, including but not limited to Claim 37, under 35 U.S.C. § 271(e)(2).

31. DRL's commercial manufacture, importation, use, offer to sell, or sale of its Plerixafor ANDA Injection Product in/into the United States, prior to the expiration of the '152 patent, would constitute infringement of one or more claims of the '152 patent under 35 U.S.C. § 271.

32. DRL's ANDA and DRL's intent to engage in the commercial manufacture, importation, use, or sale of its Plerixafor ANDA Injection Product upon receiving FDA approval create an actual case or controversy with respect to infringement of one or more claims of the '152 patent.

33. Upon FDA approval of DRL's ANDA, DRL will infringe one or more claims of the '152 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing its Plerixafor ANDA Injection Product in/into the United States, unless enjoined by this Court.

34. Upon FDA approval of DRL's ANDA, DRL will infringe one or more claims of the '152 patent under 35 U.S.C. § 271(b) and (c) by actively inducing and contributing to infringement by others, unless enjoined by this Court.

35. Plaintiffs will be substantially and irreparably harmed if DRL's infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

COUNT II
INFRINGEMENT BY DRL OF U.S. PATENT NO. 7,897,590

36. Plaintiffs repeat and reallege the allegations of paragraphs 1-28 as if fully set forth herein.

37. DRL's submission of its ANDA to obtain approval from the FDA to engage in the commercial manufacture, importation, use, or sale of its Plerixafor ANDA Injection Product prior to the expiration of the '590 patent constitutes infringement of one or more of the claims of the '590 patent, including but not limited to Claim 8, under 35 U.S.C. § 271(e)(2).

38. DRL's commercial manufacture, importation, use, offer to sell, or sale of its Plerixafor ANDA Injection Product in/into the United States, prior to the expiration of the '590

patent, would constitute infringement of one or more claims of the '590 patent under 35 U.S.C. § 271.

39. DRL's ANDA and DRL's intent to engage in the commercial manufacture, importation, use, or sale of its Plerixafor ANDA Injection Product upon receiving FDA approval create an actual case or controversy with respect to infringement of one or more claims of the '590 patent.

40. Upon FDA approval of DRL's ANDA, DRL will infringe one or more claims of the '590 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing its Plerixafor ANDA Injection Product in/into the United States, unless enjoined by this Court.

41. Upon FDA approval of DRL's ANDA, DRL will infringe one or more claims of the '590 patent under 35 U.S.C. § 271(b) and (c) by actively inducing and contributing to infringement by others, unless enjoined by this Court.

42. Plaintiffs will be substantially and irreparably harmed if DRL's infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

COUNT III
INFRINGEMENT BY DRL OF U.S. PATENT NO. 6,987,102

43. Plaintiffs repeat and reallege the allegations of paragraphs 1-28 as if fully set forth herein.

44. DRL's submission of its ANDA to obtain approval from the FDA to engage in the commercial manufacture, importation, use, or sale of its Plerixafor ANDA Injection Product prior to the expiration of the '102 patent constitutes infringement of one or more of the claims of the '102 patent, including but not limited to Claim 8, under 35 U.S.C. § 271(e)(2).

45. DRL's commercial manufacture, importation, use, offer to sell, or sale of its Plerixafor ANDA Injection Product in/into the United States, prior to the expiration of the '102 patent, would constitute infringement of one or more claims of the '102 patent under 35 U.S.C. § 271.

46. DRL's ANDA and DRL's intent to engage in the commercial manufacture, importation, use, or sale of its Plerixafor ANDA Injection Product upon receiving FDA approval create an actual case or controversy with respect to infringement of one or more claims of the '102 patent.

47. Upon FDA approval of DRL's ANDA, DRL will infringe one or more claims of the '102 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing its Plerixafor ANDA Injection Product in/into the United States, unless enjoined by this Court.

48. Upon FDA approval of DRL's ANDA, DRL will infringe one or more claims of the '102 patent under 35 U.S.C. § 271(b) and (c) by actively inducing and contributing to infringement by others, unless enjoined by this Court.

49. Plaintiffs will be substantially and irreparably harmed if DRL's infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that DRL has infringed, and that DRL's making, using, selling, offering to sell, or importing its Plerixafor ANDA Injection Product will infringe one or more claims of the '152 patent;

(b) A judgment declaring that DRL has infringed, and that DRL's making, using, selling, offering to sell, or importing its Plerixafor ANDA Injection Product will infringe one or more claims of the '590 patent;

(c) A judgment declaring that DRL has infringed, and that DRL's making, using, selling, offering to sell, or importing its Plerixafor ANDA Injection Product will infringe one or more claims of the '102 patent;

(d) A judgment under 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of DRL's ANDA No. 205182 under Section 505(j) of the Federal Food, Drug, and Cosmetic Action (21 U.S.C. § 355(j)) be a date no earlier than July 22, 2023, the date on which the '590 patent and the '102 patent expire, or the expiration of any other exclusivity to which Plaintiffs become entitled;

(e) Injunctive relief under 35 U.S.C. § 271(e)(4)(B) permanently enjoining DRL from making, using, selling, offering to sell, or importing its Plerixafor ANDA Injection Product in/into the United States until after July 22, 2023, the date on which the '590 patent and the '102 patent expire, or the expiration of any other exclusivity to which Plaintiffs become entitled;

(f) Damages under 35 U.S.C. § 271(e)(4)(C), which this Court should treble pursuant to 35 U.S.C. § 284, if DRL infringes the '152 patent, the '590 patent, or the '102 patent by engaging in the commercial manufacture, importation, use, offer to sell, or sale of its Plerixafor ANDA Injection Product in/into the United States prior to the expiration of any of the above patents, or the expiration of any other exclusivity to which Plaintiffs become entitled;

(g) An award of reasonable attorney fees in this action pursuant to 35 U.S.C. § 285;

(h) Costs and expenses in this action; and

(i) Such further and other relief as this Court may deem just and proper.

DATED: August 29, 2013

NOVAK DRUCE CONNOLLY BOVE + QUIGG LLP

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