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Attorneys for Plaintiffs
Genzyme Corporation and
Southern Research Institute

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

GENZYME CORPORATION and SOUTHERN RESEARCH INSTITUTE, Plaintiffs, v. DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, LTD., Defendants.	Civil Action No. _____ **COMPLAINT** *Electronically Filed*

Plaintiffs Southern Research Institute ("Southern Research") and Genzyme Corporation ("Genzyme"), by their attorneys, for their Complaint against Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL") allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Patent Laws of the United States, Title 35, United States Code, Sections 100 *et seq*. This action relates to an

Abbreviated New Drug Application ("ANDA") filed by DRL with the United States Food and Drug Administration ("FDA") for approval to market a generic version of Genzyme's Clolar® drug product.

THE PARTIES

2. Southern Research is a corporation organized and existing under the laws of Alabama, having its principal place of business at 2000 Ninth Avenue South, P.O. Box 55305, Birmingham, Alabama 35205-5305.

3. Genzyme is a corporation organized and existing under the laws of Massachusetts, having its principal place of business at 500 Kendall Street, Cambridge, Massachusetts 02142. Genzyme sells drug products containing clofarabine in the United States under the trademark Clolar®.

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

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

6. On information and belief, DRL Inc. is a wholly owned subsidiary of DRL Ltd. and is controlled and/or dominated by DRL Ltd.

7. On information and belief, DRL Ltd. operates in the United States through DRL Inc.

8. On information and belief, DRL Inc. and DRL Ltd. have common officers and directors, and DRL Ltd. and DRL Inc. have represented to the public that they are a unitary entity.

9. On information and belief, the acts of DRL Inc. complained of herein were done at the direction of, with the authorization of, and/or with the 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.

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

JURISDICTION AND VENUE

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

12. On information and belief, DRL Inc. and DRL Ltd. are in the business of developing, formulating, manufacturing, offering to sell, selling, commercializing, and marketing pharmaceutical products.

13. On information and belief, DRL Inc. and DRL Ltd. operate as an integrated, unitary business.

14. On information and belief, DRL Inc. and DRL Ltd. directly, or indirectly through subsidiaries and/or distributors, develop, manufacture, market, distribute, and sell pharmaceutical products within and throughout the United States, including in the State of New Jersey.

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

16. On information and belief, DRL Inc. and DRL Ltd. have generated significant revenue from purchases made by DRL's pharmaceutical product customers, who are located throughout the United States, including within the State of New Jersey.

17. On information and belief, DRL Inc. and DRL Ltd. acted in concert to develop DRL's generic copy of Genzyme's Clolar® drug product, and to seek approval from the FDA to sell DRL's generic copy of Genzyme's Clolar® drug product throughout the United States and within the State of New Jersey.

18. On information and belief and as stated in the letter dated September 25, 2013, purporting to be a notice pursuant to 21 U.S.C. § C.F.R. § 314.95 (the "Notice Letter"), DRL Inc. and DRL Ltd. submitted ANDA No. 205375 to the FDA.

19. On information and belief and as stated in the Notice Letter, DRL Inc. and DRL Ltd. notified Plaintiffs that DRL Inc. and DRL Ltd. had submitted ANDA No. 205375, seeking approval to market DRL's generic copy of Genzyme's Clolar® drug product, and that DRL Inc. and DRL Ltd. were providing information to Plaintiffs pursuant to § 505(j)(2)(B)(ii) of the Food, Drug and Cosmetic Act and § 314.95 of Title 21 of the Code of Federal Regulations.

20. In the Notice Letter, DRL Inc. and DRL Ltd. stated that the name and address of their agent in the United States authorized to accept service of process for DRL for purposes of

an infringement action based upon its Notice Letter is Mr. Lee Banks at DRL Inc. in Bridgewater, New Jersey.

21. On information and belief, DRL Inc. and DRL Ltd. have previously been sued in this district and have not challenged personal jurisdiction. *See, e.g., Astrazeneca AB v. Dr. Reddy's Labs. Inc. and Dr. Reddy's Labs. Ltd.*, Civ. Action No. 3:11-cv-02317-JAP-DEA (D.N.J.); *Wyeth LLC v. Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs., Inc.*, Civ. Action No. 3:10-cv-04551-FLW-DEA (D.N.J.); *Albany Molecular Research, Inc. v. Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs., Inc.*, Civ. Action No. 2:09-cv-04638-GEB-MCA (D.N.J.).

22. On information and belief, both DRL Inc. and DRL Ltd. have admitted that each is subject to personal jurisdiction in this district. *See, e.g., AstraZeneca UK Ltd. and AstraZeneca Pharms. LP v. Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs., Inc.*, 3:08-cv-03237-MLC-TJB (D.N.J.), Answer to Complaint ¶ 8 (Jul. 11, 2008).

23. On information and belief, both DRL Inc. and DRL Ltd. have availed themselves of the jurisdiction of this Court by initiating litigation in this district. *See, e.g., Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs, Inc. v. Eli Lilly & Co.*, Civ. Action No. 3:09-cv-0192-GEB-LHG (D.N.J.); *Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs., Inc., v. AstraZeneca AB et al.*, Civil Action No. 3:08-cv-02496-JAP-TJP (D.N.J.).

24. On information and belief, DRL Ltd. has continuous and systematic contacts with New Jersey, including, but not limited to, ongoing communications and contacts with DRL Inc.

25. On information and belief, separate and apart from its relationship with DRL Inc., DRL Ltd. has availed itself of the laws of the State of New Jersey and engaged in a course of conduct in the State of New Jersey, at least by incorporating its U.S. subsidiary, DRL Inc., under New Jersey law.

26. On information and belief, by virtue of, *inter alia*, the sales-related activities of DRL Ltd. in New Jersey, including but not limited to the substantial, continuous, and systematic distribution, marketing, and/or sales of pharmaceutical products to residents of New Jersey; DRL Ltd.'s relationship with DRL Inc., including in connection with the preparation and/or filing of ANDA No. 205375; DRL Ltd.'s designation of Mr. Lee Banks at DRL Inc. in Bridgewater, New Jersey as its agent for service of process; and DRL Ltd.'s continuous and systematic contacts with New Jersey, this Court has personal jurisdiction over DRL Ltd. These activities satisfy due process and confer personal jurisdiction over DRL consistent with New Jersey law.

27. This Court has personal jurisdiction over DRL Inc. by virtue of its presence and incorporation in New Jersey.

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

THE PATENT

29. United States Patent No. 5,661,136 ("'136 patent") was duly and legally issued on August 26, 1997 to inventors Drs. John A. Montgomery and John A. Secrist, III. The '136 patent was assigned to Southern Research. With patent term extension, the '136 patent will expire on January 14, 2018. At all times from the issuance of the '136 patent to the present, Southern Research has been the owner of the '136 patent. Genzyme holds exclusive rights from Southern Research under the '136 patent.

ACTS GIVING RISE TO THIS ACTION

30. By the Notice Letter dated September 25, 2013, purporting to be a notice pursuant to section 505(j)(2)(B)(ii) of the Federal Food Drug and Cosmetic Act and 21 C.F.R. § 314.95, DRL notified plaintiffs that DRL had submitted ANDA No. 205375 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 20mg/20ml clofarabine injection ("Clofarabine ANDA Injection") as a generic version of Genzyme's Clolar® drug product.

31. On information and belief, DRL asserted in its ANDA that its Clofarabine ANDA Injection is bioequivalent to Genzyme's 20 mL clofarabine Clolar® drug product.

32. DRL's ANDA was submitted to obtain FDA approval to engage in the commercial manufacture, importation, use, and sale of DRL's Clofarabine ANDA Injection prior to the expiration of the '136 patent, which is listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluation" (the "Orange Book") as being applicable to Genzyme's Clolar® drug product.

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

34. In the Notice Letter, DRL notified plaintiffs that its ANDA contained a "Paragraph IV" certification that in DRL's opinion the '136 patent is invalid or will not be infringed by the commercial manufacture, use, sale, offer to sell, or importation of DRL's Clofarabine ANDA Injection.

COUNT I
INFRINGEMENT BY DRL OF U.S. PATENT NO. 5,661,136

35. Plaintiffs repeat and reallege the allegations of paragraphs 1-34 as if fully set forth herein.

36. DRL's submission of its ANDA to obtain approval from the FDA to engage in the commercial manufacture, importation, use, or sale of its Clofarabine ANDA Injection prior to the

expiration of the '136 patent constitutes infringement of one or more of the claims of the '136 patent, including but not limited to Claim 1, under 35 U.S.C. § 271(e)(2)(A).

37. DRL had notice of the '136 patent at the time of its infringement. DRL's infringement has been, and continues to be, deliberate.

38. 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
DECLARATORY JUDGMENT OF INFRINGEMENT BY DRL OF U.S. PATENT NO. 5,661,136

39. Plaintiffs repeat and reallege the allegations of paragraphs 1-38 as if fully set forth herein.

40. This claim arises under the Patent Laws, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, based upon an actual controversy between the parties. DRL has taken immediate and active steps, through DRL's submission of its ANDA, to obtain approval from the FDA and, after obtaining FDA approval, to engage in the commercial manufacture, importation, use, or sale of its Clofarabine ANDA Injection in the United States prior to the expiration date of the '136 patent. There is a real and actual controversy between the parties with respect to DRL's intent to engage in the commercial manufacture, importation, use, or sale of its Clofarabine ANDA Injection upon receiving FDA approval and infringement of the '136 patent.

41. DRL's commercial manufacture, importation, use, offer to sell, or sale of its Clofarabine ANDA Injection in/into the United States, prior to the expiration of the '136 patent, would constitute infringement of one or more of the claims of the '136 patent, including but not limited to Claim 1, under 35 U.S.C. §§ 271(a), (b) and/or (c).

42. Upon FDA approval of DRL's ANDA, DRL will infringe one or more of the claims of the '136 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell or importing its Clofarabine ANDA Injection in/into the United States, unless enjoined by this Court.

43. Upon FDA approval of DRL's ANDA, DRL will infringe one or more of the claims of the '136 patent under 35 U.S.C. § 271(b) and (c) by actively inducing and contributing to infringement by others, unless enjoined by this Court.

44. DRL had notice of the '136 patent at the time of its infringement. DRL's infringement has been, and will continue to be, deliberate.

45. 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 one or more claims of the '136 patent by the filing of ANDA No. 205375;

(b) A judgment declaring that DRL's commercial making, using, selling, offering to sell, or importing its Clofarabine ANDA Injection in/into the United States will infringe one or more claims of the '136 patent;

(c) A judgment under 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 205375 under Section 505(j) of the Federal Food, Drug, and Cosmetic Action (21 U.S.C. § 355(j)) be a date no earlier than January 14, 2018, the date on which the '136 patent expires, or the expiration of any other exclusivity to which Genzyme or Southern Research becomes entitled;

(d) Injunctive relief under 35 U.S.C. § 271(e)(4)(B) permanently enjoining DRL from making, using, selling, offering to sell, or importing its Clofarabine ANDA Injection in/into the United States until after expiration of the '136 patent or the expiration of any other exclusivity to which Genzyme or Southern Research becomes entitled;

(e) 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 '136 patent by engaging in the commercial manufacture, importation, use, sale, offer to sell or import its Clofarabine ANDA Injection in/into the United States prior to the expiration of the '136 patent or the expiration of any other exclusivity to which Genzyme or Southern Research becomes entitled;

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

(g) Costs and expenses in this action; and

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

DATED: November 8, 2013

CONNELL FOLEY LLP

s/ Liza M. Walsh

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RULE 11.2 CERTIFICATION

I hereby certify that the matter in controversy is related to the following action pending before the Honorable Joseph E. Irenas, U.S.D.J. in the United States District Court, District of New Jersey: *Southern Research Institute and Genzyme Corp. v. Abon Pharmas. LLC*, Civil Action No. 12-4709.

I certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding other than the above referenced matter, nor are there any non-parties known to Plaintiffs that should be joined to this action. In addition, I recognize a continuing obligation during the course of this litigation to file and to serve on all other parties and with the Court an amended certification if there is a change in the facts stated in this original certification.

DATED: November 8, 2013

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RULE 201.1 CERTIFICATION

We hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the plaintiffs seek, *inter alia*, injunctive relief.

DATED: November 8, 2013

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