IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENZYME CORP. and THE REGENTS OF THE UNIVERSITY OF MICHIGAN, Plaintiffs, v. DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, LTD., Defendants.	)	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Genzyme Corp. ("Genzyme") and The Regents of the University of Michigan ("U of M") (collectively, "Plaintiffs"), by way of their Complaint against Defendants Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, "DRL" or "Defendants"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of U.S. Patent No. 7,196,205 (the "'205 patent") under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, including § 271, and for a declaratory judgment of infringement of the '205 patent under 28 U.S.C. §§ 2201 and 2202. This action arises out of DRL's submission of Abbreviated New Drug Application ("ANDA") No. 212449 seeking approval to manufacture, use and/or sell a generic version of the pharmaceutical product CERDELGA® (eliglustat) capsules (84 mg) ("DRL's ANDA product" or "Defendants' ANDA Product") prior to the expiration of the '205 patent. Plaintiffs seek injunctive relief against infringement, attorneys' fees, and any other relief the Court deems just and proper.

PARTIES

2. Plaintiff Genzyme is a corporation organized and existing under the laws of the Commonwealth of Massachusetts, having its principal place of business at 50 Binney Street, Cambridge, Massachusetts 02142. Genzyme is engaged in the business of research, development, manufacture, and sale of pharmaceutical products.

3. The Regents of the University of Michigan is a constitutional corporation of the State of Michigan, having a principal place of business at 1600 Huron Parkway, 2nd Floor, Ann Arbor, MI 48109.

4. Upon information and belief, Defendant Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 107 College Road East, Princeton, New Jersey 08540.

5. Upon information and belief, Defendant Dr. Reddy's Laboratories, Ltd. is a corporation organized and existing under the laws of India. Its principal place of business is located at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500034, India.

6. Upon information and belief, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. Upon further information and belief, Defendants are agents of one another and/or operate in concert as integrated parts of the same business group. Upon further information and belief, Dr. Reddy's Laboratories, Ltd. is the ultimate parent of Dr. Reddy's Laboratories, Inc.

7. Upon information and belief, Defendants caused ANDA No. 212449 to be submitted to the United States Food and Drug Administration ("FDA") and seek FDA approval of ANDA No. 212449.

8. Upon information and belief, Defendants regularly act in concert to transact business throughout the United States and within Delaware, including but not limited to marketing, distribution, sales, and/or offers to sell generic drugs.

JURISDICTION AND VENUE

9. This action arises under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

10. This Court has jurisdiction over Dr. Reddy's Laboratories, Inc. because, *inter alia*, upon information and belief, Dr. Reddy's Laboratories, Inc. has substantial, continuous, and systematic contacts with the State of Delaware, and directly or indirectly manufactures, imports, markets, and sells generic drugs throughout the United States, including Delaware, and Delaware would be a destination of Defendants' ANDA product. Upon information and belief, Dr. Reddy's Laboratories, Inc. acted in concert with and/or with the assistance of Dr. Reddy's Laboratories, Ltd. to file ANDA No. 212449. Upon information and belief, Defendants, acting in concert and/or as agents of one another, will market, distribute, and/or sell Defendants' ANDA product in the United States, including in Delaware, upon approval of ANDA No. 212449, and will derive substantial revenue from the use or consumption of Defendants' ANDA product in the State of Delaware.

11. This Court has jurisdiction over Dr. Reddy's Laboratories, Ltd. because, *inter alia*, upon information and belief, Dr. Reddy's Laboratories, Ltd. has substantial, continuous, and systematic contacts with the State of Delaware, and directly or indirectly manufactures, imports, markets, and sells generic drugs throughout the United States, including Delaware, and Delaware would be a destination of Defendants' ANDA product. Upon

information and belief, Dr. Reddy's Laboratories, Ltd. acted in concert with and/or with the assistance of Dr. Reddy's Laboratories, Inc. to file ANDA No. 212449. Upon information and belief, Defendants, acting in concert and/or as agents of one another, will market, distribute, and/or sell Defendants' ANDA product in the United States, including in Delaware, upon approval of ANDA No. 212449, and will derive substantial revenue from the use or consumption of Defendants' ANDA product in the State of Delaware.

12. In the alternative, this Court has jurisdiction over Dr. Reddy's Laboratories, Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met. This Court has jurisdiction over Dr. Reddy's Laboratories, Ltd. because, *inter alia*, this action arises under federal law, Dr. Reddy's Laboratories, Ltd. is a foreign defendant not subject to personal jurisdiction in the courts of any state, and Dr. Reddy's Laboratories, Ltd. has sufficient contacts with the United States as a whole, including but not limited to filing ANDAs with the FDA and manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Dr. Reddy's Laboratories, Ltd. satisfies due process.

13. This Court also has jurisdiction over Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. because, *inter alia*, upon information and belief, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. have previously been sued in this district without objecting on the basis of lack of personal jurisdiction and have availed themselves of Delaware courts through the assertions of counterclaims in suits brought in Delaware. *See e.g.*, *Viiv Healthcare Co., Shionogi & Co., Ltd., and Viiv Healthcare UK (No. 3) Ltd. v. Dr. Reddy's Labs., Inc. and Dr. Reddy's Labs., Ltd.*, Civil Action No. 17-1678-MSG (D. Del.); *Viiv Healthcare Co., Shionogi & Co., Ltd., and Viiv Healthcare UK (No. 3) Ltd. v. Dr. Reddy's Labs.,*

Inc. and Dr. Reddy's Labs., Ltd., Civil Action No. 17-1737-MSG (D. Del.); *Onyx Therapeutics, Inc. v. Dr. Reddy's Labs., Inc. and Dr. Reddy's Labs., Ltd.*, Civil Action No. 17-1811-LPS (D. Del.).

14. Venue is proper in this district for Dr. Reddy's Laboratories, Inc. under 28 U.S.C. §§ 1391(b), (c) and 1400(b).

15. Venue is proper in this district for Dr. Reddy's Laboratories, Ltd. under 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Dr. Reddy's Laboratories, Ltd. is a corporation organized and existing under the laws of India, and may be sued in any judicial district. 28 U.S.C. § 1391(c).

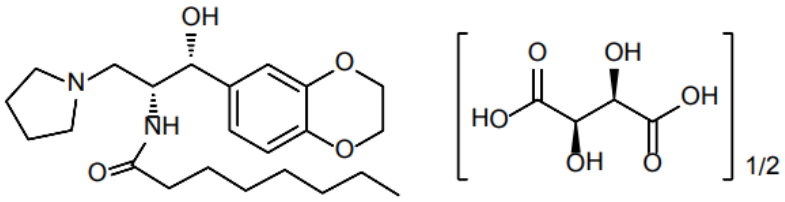
CERDELGA®

16. Genzyme is the holder of an approved New Drug Application ("NDA") No. 205494 for CERDELGA®, which the FDA approved on August 19, 2014.

17. CERDELGA® is a medication marketed and sold by Genzyme as 84 mg capsules for oral use. Genzyme received FDA approval to market CERDELGA® (eliglustat) for the long-term treatment of adult patients with Gaucher disease type 1 who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an FDA-cleared test.

18. Eliglustat is the active ingredient in CERDELGA®. Eliglustat is a novel small molecule inhibitor of glucosylceramide synthase.

19. CERDELGA® capsules contain eliglustat as a hemitartrate salt (eliglustat tartrate), which can be referred to by the chemical name N-((1*R*,2*R*)-1-(2,3-dihydrobenzo[b][1,4]dioxin-6-yl)-1-hydroxy-3-(pyrrolidin-1-yl)propan-2-yl)octanamide (2*R*,3*R*)-2,3-dihydroxysuccinate, and has the following chemical structure:



20. CERDELGA® was granted Orphan Drug Exclusivity for long-term treatment of adult patients with Gaucher disease type 1 who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an FDA-cleared test.

THE PATENT-IN-SUIT

21. On March 27, 2007, the '205 patent, titled "Synthesis of UDP-Glucose: *N*-Acylsphingosine Glucosyltransferase Inhibitors," was issued by the United States Patent and Trademark Office ("PTO"). A true and correct copy of the '205 patent is attached as Exhibit A.

22. Eliglustat is covered by one or more of the claims of the '205 patent, which is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for NDA No. 205494.

23. The '205 patent is owned by Genzyme and U of M.

DRL'S ANDA NO. 212449

24. Plaintiffs received a letter dated October 8, 2018 from Defendants notifying Plaintiffs that Defendants had submitted ANDA No. 212449 to the FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") seeking approval to commercially manufacture, use, sell, and/or import DRL's ANDA product prior to the expiration of the '205 patent.

25. According to applicable regulations, the purpose of Defendants' October 8, 2018 letter was to notify Plaintiffs that ANDA No. 212449 included a certification

under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") alleging that the claims of the '205 patent are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, sale, offer for sale, and/or importation of Defendants' ANDA product.

26. Included in the October 8, 2018 letter was a "Detailed Factual and Legal Basis" for Defendants' Paragraph IV Certification, alleging that the claims of the '205 patent were invalid as obvious under 35 U.S.C. § 103.

27. Upon information and belief, Defendants were aware of the '205 patent when Defendants notified Plaintiffs of their Paragraph IV Certification regarding the '205 patent.

28. Plaintiffs commenced this action within 45 days of receipt of Defendants' October 8, 2018 letter.

COUNT I
INFRINGEMENT OF THE '205 PATENT

29. Plaintiffs incorporate and reallege paragraphs 1-28 above, as if set forth specifically here.

30. Upon information and belief, Defendants submitted ANDA No. 212449 to the FDA under the provisions of 21 U.S.C. § 355(j).

31. Upon information and belief, Defendants' ANDA No. 212449 seeks FDA approval to engage in the commercial manufacture, use, sale, and/or importation of DRL's ANDA product (generic eliglustat in 84 mg capsules for oral use) before the expiration of the '205 patent.

32. Plaintiffs received a letter from Defendants dated October 8, 2018, purporting to be a Notice of Certification for ANDA No. 212449 under Section 505(j)(2)(B) of the FDCA, 21 U.S.C. § 355(j)(2)(B), and 21 C.F.R. § 314.95.

33. Defendants' October 8, 2018 letter states that the active ingredient in Defendants' ANDA product for which it seeks approval is eliglustat.

34. Upon information and belief, Defendants made and included in their ANDA a Paragraph IV Certification stating that, in Defendants' opinion, the '205 patent is invalid, unenforceable and/or not infringed.

35. Defendants' submission of ANDA No. 212449 to obtain approval to engage in the commercial manufacture, use, sale, and/or importation of Defendants' ANDA product prior to the expiration of the '205 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

36. Defendants' commercial manufacture, use, sale, and/or importation of Defendants' ANDA product would infringe, either literally or under the doctrine of equivalents, at least claims 1 and 3-9 of the '205 patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 212449, Defendants will make, use, offer to sell, or sell Defendants' ANDA product within the United States, or will import Defendants' ANDA product into the United States, and will thereby infringe at least claims 1 and 3-9 of the '205 patent.

37. Defendants had actual knowledge of the '205 patent prior to submission of ANDA No. 212449, and were aware that the filing of ANDA No. 212449 with the request for FDA approval prior to the expiration of the '205 patent would constitute an act of infringement of the '205 patent. Defendants had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Defendants' ANDA product will not infringe at least claims 1 and 3-9 of the '205 patent.

38. Defendants' "Detailed Factual and Legal Basis" in their October 8, 2018 letter lacks any contention that Defendants' ANDA product will not infringe at least claims 1 and 3-9 of the '205 patent.

39. On information and belief, Defendants' statement of the factual and legal bases for its opinions regarding invalidity of the '205 patent lacks an objective good faith basis.

40. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

41. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '205 patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, injunctive relief is warranted. Further, the public interest favors entry of an injunction.

COUNT II
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '205 PATENT

42. Plaintiffs incorporate and reallege paragraphs 1-41 above, as if set forth specifically here.

43. Upon information and belief, if ANDA No. 212449 is approved, Defendants' ANDA product will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Defendants and their affiliates. Defendants will therefore infringe at least claims 1 and 3-9 of the '205 patent under 35 U.S.C. § 271.

44. Defendants' "Detailed Factual and Legal Basis" in their October 8, 2018 letter lacks any contention that Defendants' ANDA product will not infringe at least claims 1 and 3-9 of the '205 patent.

45. Upon information and belief, Defendants' infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Defendants' ANDA product complained of herein will begin immediately after the FDA approves ANDA No. 212449. Any such conduct before the '205 patent expires will infringe at least claims 1 and 3-9 of the '205 patent under 35 U.S.C. § 271.

46. There is a real, substantial, and continuing justiciable controversy between Plaintiffs and Defendants concerning liability for the infringement of the '205 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

47. Plaintiffs will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

48. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that the claims of the '205 patent were infringed by Defendants' submission of ANDA No. 212449 under 35 U.S.C. § 271 (e)(2)(A), and that the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' ANDA product prior to the expiration of the '205 patent will constitute an act of infringement of at least claims 1 and 3-9 of the '205 patent;

B. A declaratory judgment that under 35 U.S.C. § 271, Defendants' commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of

Defendants' ANDA product would constitute infringement of at least claims 1 and 3-9 of the '205 patent;

C. An order permanently enjoining Defendants, their affiliates, subsidiaries, and each of their officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States, Defendants' ANDA product until after the expiration of the '205 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

D. An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 212449 shall be a date that is not earlier than the expiration date of the '205 patent, inclusive of any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

E. A declaration under 28 U.S.C. § 2201 that if Defendants, their officers, agents, servants, employees, licensees, representatives, and attorneys, and any other persons acting or attempting to act in active concert or participation with them or acting on their behalf, engages in the commercial manufacture, use, offer for sale, sale, and/or importation of the product described in ANDA No. 212449, it will constitute an act of infringement of the '205 patent;

F. A judgment that the claims of the '205 patent are valid and enforceable;

G. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendants engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' ANDA product, or any product that infringes the '205 patent,

prior to the expiration of the '205 patent, inclusive of any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

H. A declaration that this is an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and awarding Plaintiffs' costs, expenses, and disbursements in this action, including reasonable attorney fees; and

I. An award of such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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November 20, 2018