IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENZYME CORPORATION and SANOFI-AVENTIS U.S. LLC, Plaintiffs, v. ZYDUS PHARMACEUTICALS (USA) INC., Defendant.	)	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 Zydus Pharmaceuticals (USA) Inc. ("Zydus"), hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement of U.S. Patent Nos. 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. 208980 filed by Zydus for approval to market Plerixafor Injection 20 mg/mL, 1.2mL, 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, Massachusetts 02142.

4. Plaintiff Sanofi is a limited liability company organized and existing under the laws of the State of Delaware with its principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807.

5. On information and belief, Defendant Zydus is a corporation organized and existing under the laws of the State of New Jersey having a place of business at 73 Route 31 N., Pennington, New Jersey 08534. Upon information and belief, Defendant Zydus manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this District.

JURISDICTION AND VENUE

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

7. This Court has personal jurisdiction over Zydus pursuant to 10 Del. C. § 3104. Specifically, Zydus's filing of ANDA No. 208980 has caused tortious injury in Delaware, namely from the tort of patent infringement under 35 U.S.C. § 271(e)(2), and Zydus intends a future course of conduct that includes acts of patent infringement in Delaware. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in this District. For example, on information and belief, following approval of ANDA No. 208980, Zydus will make, use, sell, offer for sale, and/or import its generic product at issue in this suit in/into the United States, including the state of Delaware, prior to the expiration of the '590 patent and the '102 patent.

Further, Zydus maintains substantial, systematic, and continuous contacts with the state of Delaware as it regularly does or solicits business in the state and this District through its marketing and distribution of generic products and has acknowledged these marketing and distribution activities in this District in its pleadings in at least the following litigations in this Court: 1:09-cv-00239-JJF, 1:10-cv-00581-KAJ, 1:12-cv-00818-SLR and 1:14-cv-00200-LPS. Zydus has and continues engaging in a persistent course of conduct in Delaware and this District, and derives substantial revenue from things used or consumed in Delaware and this District.

8. Personal jurisdiction over Zydus is also proper because Zydus has availed itself of the benefits and protections of the Court and has sought affirmative relief in this jurisdiction by filing counterclaims in at least the following litigations in this Court: 1:09-cv-00239-JJF, 1:10-cv-00581-KAJ, 1:12-cv-00818-SLR and 1:14-cv-00200-LPS.

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

THE PATENTS AND ACTS GIVING RISE TO THIS ACTION

10. Genzyme is the holder of New Drug Application ("NDA") No. 022311, which relates to Plerixafor solution 20 mg/mL for subcutaneous injection (the "Mozobil® NDA"). 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 (the "Approved Indication"). This drug product is prescribed and sold in the United States using the trademark Mozobil®. Usage of this drug product and the Approved Indication are described in

the Mozobil® Prescribing Information (a true and accurate copy of which is attached hereto as Exhibit A). Genzyme and Sanofi both share in the profits from the sale of Mozobil®.

11. 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. Sanofi is Genzyme's exclusive licensee under the '590 patent.

12. 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. Sanofi is Genzyme's exclusive licensee under the '102 patent.

13. The '590 patent and '102 patent cover the use of Mozobil® according to its Approved Indication.

14. By letter dated May 17, 2016, purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B) ("Notice Letter"), Zydus notified Genzyme that Zydus had submitted ANDA No. 208980 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 Mozobil® drug product prior to the expiration of the '590 and '102 patents.

15. In addition to the information provided to Plaintiffs in the Notice Letter, counsel for Plaintiffs reviewed the portions of ANDA No. 208980 voluntarily provided by Zydus under the terms of a confidentiality agreement.

16. On information and belief, the active ingredient of the Plerixafor ANDA Injection Product is plerixafor, which is the same active ingredient in Mozobil® and the same active ingredient used in the methods of one or more claims of the '590 and '102 patents, including, but not limited to, claim 19 of the '590 patent and claim 1 of the '102 patent.

17. On information and belief, Zydus stated in its ANDA No. 208980 that its Plerixafor ANDA Injection Product is bioequivalent to Genzyme's Mozobil® drug product. On information and belief, Zydus's ANDA No. 208980 refers to and relies upon the Mozobil® NDA and contains data that, according to Zydus, demonstrate the bioequivalence of Zydus's Plerixafor ANDA Injection Product and Mozobil®.

18. On information and belief, Zydus is seeking approval to market its Plerixafor ANDA Injection Product for the same Approved Indication as Genzyme's Mozobil® drug product.

19. On information and belief, Zydus will knowingly accompany its Plerixafor ANDA Injection Product with prescribing information that is substantially similar to the Mozobil® Prescribing Information.

20. Upon information and belief, Zydus's prescribing information for its Plerixafor ANDA Injection Product will instruct users to administer Zydus's Plerixafor Injection Product to human patients to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation.

21. Upon information and belief, Zydus's prescribing information for its Plerixafor ANDA Injection Product will instruct users to administer its Plerixafor Injection Product to human patients after the patients have received granulocyte-colony stimulating factor (G-CSF).

22. Upon information and belief, Zydus has knowledge and/or an expectation that its Plerixafor ANDA Injection Product will be used in accordance with its prescribing information.

23. On information and belief, Zydus knows that the prescribing information for its Plerixafor ANDA Injection Product will induce and/or contribute to others using the Plerixafor ANDA Injection Product in the manner set forth in the prescribing information.

24. On information and belief, physicians, health care providers, and/or patients will directly infringe one or more claims of the '590 patent and the '102 patent, including, but not limited to, claim 19 of the '590 patent and claim 1 of the '102 patent, by using Zydus Plerixafor ANDA Injection Product in accordance with the prescribing information provided by Zydus after the FDA approves ANDA No. 208980.

25. On information and belief, Zydus specifically intends that physicians, health care providers, and/or patients will use the Plerixafor ANDA Injection Product in accordance with the prescribing information provided by Zydus to directly infringe one or more claims of the '590 patent and the '102 patent, including, but not limited to, claim 19 of the '590 patent and claim 1 of the '102 patent.

26. On information and belief, Zydus designed the Plerixafor ANDA Injection Product for use in a way that would infringe the '590 patent and the '102 patent and will instruct users of the Plerixafor ANDA Injection Product to use the Plerixafor ANDA Injection Product in a way that would infringe one or more claims of the '590 patent and the '102 patent, including, but not limited to, claim 19 of the '590 patent and claim 1 of the '102 patent.

27. On information and belief, the Plerixafor ANDA Injection Product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

28. On information and belief, Zydus knowingly has taken and intends to take active steps to induce and/or contribute to physicians, health care providers, and/or patients using the Plerixafor ANDA Injection Product in a manner that directly infringes one or more claims of the '590 patent and the '102 patent, including but not limited to by providing instructions for administering the Plerixafor ANDA Injection Product as claimed in one or more claims of the '590 patent and the '102 patent, including, but not limited to, claim 19 of the '590 patent and claim 1 of the '102 patent.

29. Zydus has knowledge of the '590 patent and the '102 patent.

30. Zydus's ANDA was submitted to obtain FDA approval to engage in the commercial manufacture, importation, use, and sale of Zydus's Plerixafor ANDA Injection Product prior to the expiration of the '590 and '102 patents, both 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.

31. On information and belief, Zydus intends to engage in the commercial manufacture, importation, use, sale, and/or offering for sale of its Plerixafor ANDA Injection Product in/into the United States and/or induce or contribute to such acts promptly upon receiving FDA approval to do so and during the terms of the '590 and '102 patents.

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

33. Zydus is aware of the decision issued on May 11, 2016 (Docket No. 215) in *Genzyme Corporation and Sanofi-Aventis U.S. LLC v. Dr. Reddy's Laboratories, Ltd and Dr. Reddy's Laboratories, Inc. and Teva Pharmaceuticals USA, Inc.,* 1:13-cv-1506-GMS, finding claim 19 of the '590 patent not invalid. Upon information and belief, the bases for Zydus's opinion that the '590 and '102 patents are invalid, as set forth in Zydus's Notice Letter, are substantially similar to those addressed in the decision issued by this Court in 1:13-cv-1506-GMS, Docket No. 215.

34. Plaintiffs commenced this action within 45 days of receiving the Notice Letter.

COUNT I
INFRINGEMENT BY ZYDUS OF U.S. PATENT NO. 7,897,590

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

36. Zydus'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 in/into the United States 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 claims 1-8, 16-19, and 21-22, under 35 U.S.C. § 271(e)(2).

37. Upon FDA approval, Zydus'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 will infringe one or more claims of the '590 patent, including but not limited to claims 1-8, 16-19, and 21-22, under 35 U.S.C. §§ 271(a), (b), and/or (c), unless enjoined by the Court.

38. Zydus's ANDA and Zydus's intent to engage in the commercial manufacture, importation, use, sale, or offer for sale of its Plerixafor ANDA Injection Product in/into the United States upon receiving FDA approval and prior to the expiration of the '590 patent create an actual case or controversy with respect to infringement of one or more claims of the '590 patent, including but not limited to claims 1-8, 16-19, and 21-22.

39. Upon FDA approval of Zydus's ANDA, use of the Zydus ANDA Plerixafor Injection in accordance with the prescribing information to be provided by Zydus will directly infringe one or more claims of the '590 patent, including but not limited to claims 1-8, 16-19, and 21-22, under 35 U.S.C. § 271(a), unless enjoined by this Court.

40. Upon FDA approval of Zydus's ANDA, Zydus will infringe one or more claims of the '590 patent, including but not limited to claims 1-8, 16-19, and 21-22, under 35 U.S.C. § 271(b) and (c) by actively inducing and contributing to infringement by others, unless enjoined by this Court.

41. Zydus has knowledge of the '590 patent and, by the prescribing information it will include with its Plerixafor ANDA Injection Product, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '590 patent, including but not limited to claims 1-8, 16-19, and 21-22.

42. Zydus's offering for sale, sale, and/or importation of the Plerixafor ANDA Injection Product in/into the United States with the prescribing information for the Plerixafor ANDA Injection Product will actively induce infringement of at least one of the claims of the '590 patent, including but not limited to claims 1-8, 16-19, and 21-22, under 35 U.S.C. § 271(b).

43. Use of the Plerixafor ANDA Injection Product constitutes a material part of at least one of the claims of the '590 patent; Zydus knows that the Plerixafor ANDA Injection

Product is especially made or adapted for use in infringing at least one of the claims of the '590 patent, including but not limited to claims 1-8, 16-19, and 21-22; and Zydus knows that the Plerixafor ANDA Injection Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

44. Zydus's manufacture, use, offering for sale, sale, and/or importation of the Plerixafor ANDA Injection Product in/into the United States will contributorily infringe at least one of the claims of the '590 patent, including but not limited to claims 1-8, 16-19, and 21-22, under 35 U.S.C. § 271(c).

45. Zydus had and will have notice of the '590 patent at the time of its infringement. Zydus also had notice of the decision issued by this Court in 1:13-cv-1506-GMS, Docket No. 215 holding that claim 19 of the '590 patent is not invalid. Zydus's infringement has been, continues to be and will be deliberate and willful.

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

47. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorney fees.

COUNT II
INFRINGEMENT BY ZYDUS OF U.S. PATENT NO. 6,987,102

48. Plaintiffs repeat and reallege the allegations of paragraphs 1-47 as if fully set forth herein.

49. Zydus'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 in/into the United States 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 claims 1-8, 12-13, 15-16, and 21-22, under 35 U.S.C. § 271(e)(2).

50. Upon FDA approval, Zydus'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 will infringe one or more claims of the '102 patent, including but not limited to claims 1-8, 12-13, 15-16, and 21-22, under 35 U.S.C. § 271(a), (b), and/or (c), unless enjoined by the Court.

51. Zydus's ANDA and Zydus's intent to engage in the commercial manufacture, importation, use, sale, or offer for sale of its Plerixafor ANDA Injection Product in/into the United States upon receiving FDA approval and prior to the expiration of the '102 patent create an actual case or controversy with respect to infringement of one or more claims of the '102 patent, including but not limited to claims 1-8, 12-13, 15-16, and 21-22.

52. Upon FDA approval of Zydus's ANDA, use of the Zydus ANDA Plerixafor Injection in accordance with the prescribing information to be provided by Zydus will directly infringe one or more claims of the '102 patent, including but not limited to claims 1-8, 12-13, 15-16, and 21-22, under 35 U.S.C. § 271(a), unless enjoined by this Court.

53. Upon FDA approval of Zydus's ANDA, Zydus will infringe one or more claims of the '102 patent, including but not limited to claims 1-8, 12-13, 15-16, and 21-22, under 35 U.S.C. § 271(b) and (c) by actively inducing and contributing to infringement by others, unless enjoined by this Court.

54. Zydus has knowledge of the '102 patent and, by the prescribing information it will include with its Plerixafor ANDA Injection Product, knows or should know that it will aid

and abet another's direct infringement of at least one of the claims of the '102 patent, including but not limited to claims 1-8, 12-13, 15-16, and 21-22.

55. Zydus's offering for sale, sale, and/or importation of the Plerixafor ANDA Injection Product in/into the United States with the prescribing information for the Plerixafor ANDA Injection Product will actively induce infringement of at least one of the claims of the '102 patent, including but not limited to claims 1-8, 12-13, 15-16, and 21-22, under 35 U.S.C. § 271(b).

56. Use of the Plerixafor ANDA Injection Product constitutes a material part of at least one of the claims of the '102 patent; Zydus knows that the Plerixafor ANDA Injection Product is especially made or adapted for use in infringing at least one of the claims of the '102 patent, including but not limited to claims 1-8, 12-13, 15-16, and 21-22; and Zydus knows that the Plerixafor ANDA Injection Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

57. Zydus's manufacture, use, offering for sale, sale, and/or importation of the Plerixafor ANDA Injection Product in/into the United States will contributorily infringe at least one of the claims of the '102 patent, including but not limited to claims 1-8, 12-13, 15-16, and 21-22, under 35 U.S.C. § 271(c).

58. Zydus had and will have notice of the '102 patent at the time of its infringement. Zydus also had notice of the decision issued by this Court in 1:13-cv-1506-GMS, Docket No. 215 holding that claim 19 of the '590 patent is not invalid. Zydus's infringement has been, continues to be, and will be deliberate and willful.

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

60. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorney fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that Zydus has infringed, and that Zydus's making, using, selling, offering to sell, or importing its Plerixafor ANDA Injection Product in/into the United States will infringe one or more claims of the '590 patent;

(b) A judgment declaring that Zydus has infringed, and that Zydus's making, using, selling, offering to sell, or importing its Plerixafor ANDA Injection Product in/into the United States will infringe one or more claims of the '102 patent;

(c) A judgment under 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Zydus's ANDA No. 208980 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (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;

(d) Injunctive relief under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Zydus 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;

(e) Damages under 35 U.S.C. § 271(e)(4)(C), which this Court should treble pursuant to 35 U.S.C. § 284, if Zydus infringes 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 the '590 patent and the '102 patent, or the expiration of any other exclusivity to which Plaintiffs become entitled;

(f) A determination that Zydus's infringement is deliberate and willful;

(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: June 29, 2016

RATNERPRESTIA

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