IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENZYME CORPORATION and SANOFI-AVENTIS U.S. LLC, Plaintiffs, v. FRESENIUS KABI USA, LLC, 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 Fresenius Kabi USA, LLC ("Fresenius Kabi") 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. 212395 filed by Fresenius Kabi for approval to engage in the marketing, commercial manufacture, use, or sale of Plerixafor Injection, 24 mg / 1.2 mL, a proposed generic version of Genzyme's Mozobil® drug product ("Fresenius Kabi's ANDA product").

THE PARTIES

3. 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.

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, Fresenius Kabi is a corporation organized and existing under the laws of Delaware, having its corporate offices and principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047.

6. On information and belief, Fresenius Kabi is in the business of, inter alia: (a) the development and manufacture of generic pharmaceutical products for sale and distribution throughout the world, including throughout the United States and, more specifically, throughout the State of Delaware; (b) the preparation, submission, and filing of ANDAs seeking FDA approval to market generic drugs throughout the United States, including throughout the State of Delaware; and (c) the distribution of generic pharmaceutical products for sale and use throughout the United States, including throughout the State of Delaware.

JURISDICTION AND VENUE

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

8. On information and belief, this Court has personal jurisdiction over Fresenius Kabi pursuant to 10 Del. C. § 3104. Specifically, Fresenius Kabi's filing of ANDA No. 212395 has caused tortious injury in Delaware, namely from the tort of patent infringement under 35

U.S.C. § 271(e)(2), and Fresenius Kabi 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. 212395, Fresenius Kabi 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, a product that infringes at least some claims of the '590 patent and the '102 patent. Moreover, Plaintiff Sanofi is a Delaware limited liability company, and so not only are the injuries and consequences suffered in Delaware, but Fresenius Kabi has purposefully directed its activities towards a Delaware entity. Because defending against a patent infringement lawsuit such as this one is an inherent and expected part of a generic ANDA filer's business, Fresenius Kabi reasonably anticipates being sued in Delaware. Further, Fresenius Kabi maintains substantial, systematic, and continuous contacts with the State of Delaware as it regularly does or solicits business in Delaware and this District through its marketing and distribution of generic products. Fresenius Kabi has engaged and continues to engage 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.

9. On information and belief, this Court has personal jurisdiction over Fresenius Kabi because, *inter alia*: (a) Fresenius Kabi prepared, filed, and submitted ANDA No. 212395 for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Fresenius Kabi's ANDA Product throughout the United States, including in Delaware; (b) upon any approval of ANDA No. 212395, Fresenius Kabi will market, distribute, offer for sale, and/or sell Fresenius Kabi's ANDA Product throughout the United States, including Delaware, and will derive substantial revenue from the use or sale of Fresenius

Kabi's ANDA Product in Delaware; (c) upon any approval of ANDA No. 212395, Fresenius Kabi's ANDA Product would be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and/or used by patients in Delaware; and (d) the resolution of this action will directly affect when ANDA No. 212395 can be approved to allow the marketing of Fresenius Kabi's ANDA Product in or directed at Delaware, and when such marketing can lawfully take place.

10. This Court also has personal jurisdiction over Fresenius Kabi because, *inter alia*: (a) Fresenius Kabi has purposefully directed its activities at corporate entities and residents within the State of Delaware; (b) the claims set forth herein arise out of or relate to those activities; (c) Fresenius Kabi's contacts with the State of Delaware are continuous and systematic; and (d) it is reasonable and fair for this Court to exercise personal jurisdiction over Fresenius Kabi.

11. This Court also has jurisdiction over Fresenius Kabi because, *inter alia*, Fresenius Kabi has been previously sued in this District without contesting personal jurisdiction and has availed itself of the legal protections of the State of Delaware by asserting counterclaims in suits brought in the State of Delaware. *See, e.g.*, *Teva Pharm. Int'l GmbH et al. v. Fresenius Kabi USA, LLC et al.*, C.A. No. 18-cv-01586, D.I. 9 (D. Del. Nov. 6, 2018); *Pharmacyclics LLC et al. v. Fresenius Kabi USA, LLC et al.*, C.A. No. 18-00192-CFC, D.I. 12 (D. Del. Mar. 12, 2018); *Onyx Therapeutics, Inc. v. Fresenius Kabi USA, LLC et al.*, C.A. No. 16-01012-LPS, D.I. 19 (D. Del. Jan. 6, 2017); *Teva Pharm. Int'l GmbH et al. v. Fresenius Kabi USA, LLC*, C.A. No. 17-01201-CFC, D.I. 10 (D. Del. Sept. 15, 2017); *Astellas Pharma Inc. et al. v. Fresenius Kabi USA, LLC*, C.A. No. 15-00080-LPS, D.I. 7 (D. Del. Feb. 13, 2015).

12. Fresenius Kabi has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of Delaware by having filed suits in this jurisdiction. *See, e.g.*, *Fresenius Kabi USA, LLC v. Sagent Pharm., Inc.*, C.A. No. 17-00011-LPS, D.I. 1 (D. Del. Jan. 4, 2017); *Fresenius Kabi USA, LLC v. B. Braun Med. Inc.*, C.A. No. 16-00250-RGA, D.I. 1 (D. Del. Apr. 11, 2016); *Fresenius Kabi USA, LLC v. Maia Pharm., Inc.*, C.A. No. 16-00237-GMS, D.I. 1 (D. Del. Apr. 7, 2016); *Fresenius Kabi USA, LLC v. Dr. Reddy's Labs., Inc. et al.*, C.A. No. 16-00169-GMS, D.I. 1 (D. Del. Mar. 17, 2016); *Fresenius Kabi USA, LLC v. Mylan Labs. Ltd.*, C.A. No. 14-01438-RGA, D.I. 1 (D. Del. Nov. 26, 2014); *Fresenius Kabi USA, LLC v. Dr. Reddy's Labs., Ltd. et al*, C.A. No. 14-00160-RGA, D.I. 1 (D. Del. Feb. 6, 2014).

13. 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

14. 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®.

15. The ’590 patent (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.

16. The ’102 patent (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.

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

18. By letter dated October 25, 2018, purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B) (“Notice Letter”), Fresenius Kabi notified Genzyme that Fresenius Kabi had submitted ANDA No. 212395 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) to seek approval to engage in the commercial manufacture, use, or sale of Fresenius Kabi’s ANDA Product as a generic version of Genzyme’s Mozobil® drug product prior to the expiration of the ’590 and ’102 patents.

19. On information and belief, the active ingredient of Fresenius Kabi’s ANDA Product is plerixafor, which is the same active ingredient in Mozobil® and the same active

ingredient used in the claims of the ’590 patent and the ’102 patent, including, but not limited to, Claims 8 and 19 of the ’590 patent and Claim 8 of the ’102 patent.

20. On information and belief, Fresenius Kabi stated in its ANDA No. 212395 that Fresenius Kabi’s ANDA Product is bioequivalent to Genzyme’s Mozobil® drug product. On information and belief, Fresenius Kabi’s ANDA No. 212395 refers to and relies upon the Mozobil® NDA and contains statements that, according to Fresenius Kabi, Fresenius Kabi’s ANDA Product is a bioequivalent of Mozobil®.

21. On information and belief, Fresenius Kabi is seeking approval to market Fresenius Kabi’s ANDA Product for the same Approved Indication as Genzyme’s Mozobil® drug product.

22. On information and belief, Fresenius Kabi will knowingly accompany Fresenius Kabi’s ANDA Product with prescribing information that is substantially similar to the Mozobil® Prescribing Information.

23. On information and belief, Fresenius Kabi’s prescribing information for Fresenius Kabi’s ANDA Product will instruct users to administer Fresenius Kabi’s ANDA Product to human patients to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation.

24. On information and belief, Fresenius Kabi’s prescribing information for Fresenius Kabi’s ANDA Product will instruct users to administer Fresenius Kabi’s ANDA Product to human patients after the patients have received granulocyte-colony stimulating factor (G-CSF).

25. On information and belief, Fresenius Kabi has knowledge and/or an expectation that Fresenius Kabi’s ANDA Product will be used in accordance with its prescribing information.

26. On information and belief, Fresenius Kabi knows that the prescribing information for Fresenius Kabi's ANDA Product will induce and/or contribute to others using Fresenius Kabi's ANDA Product in the manner set forth in the prescribing information.

27. On information and belief, physicians, health care providers, and/or patients will directly infringe one or more claims of the '590 patent and/or the '102 patent, including, but not limited to, Claims 8 and 19 of the '590 patent and Claim 8 of the '102 patent, by using Fresenius Kabi's ANDA Product in accordance with the prescribing information provided by Fresenius Kabi upon FDA approval of ANDA No. 212395.

28. On information and belief, Fresenius Kabi specifically intends that physicians, health care providers, and/or patients will use Fresenius Kabi's ANDA Product in accordance with the prescribing information provided by Fresenius Kabi to directly infringe one or more claims of the'590 patent and/or the '102 patent, including, but not limited to, Claims 8 and 19 of the '590 patent and Claim 8 of the '102 patent.

29. On information and belief, Fresenius Kabi designed Fresenius Kabi's ANDA Product for use in a way that would infringe the '590 patent and the '102 patent and will instruct users of Fresenius Kabi's ANDA Product to use the Fresenius Kabi's ANDA Product in a way that would infringe one or more claims of the '590 patent and/or the '102 patent, including, but not limited to, Claims 8 and 19 of the '590 patent and Claim 8 of the '102 patent.

30. On information and belief, Fresenius Kabi's ANDA Product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

31. On information and belief, Fresenius Kabi knowingly has taken and intends to take active steps to induce and/or contribute to physicians, health care providers, and/or patients using Fresenius Kabi's ANDA 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 Fresenius Kabi's ANDA Product as claimed in one or more claims of the '590 patent and the '102 patent, including, but not limited to, Claims 8 and 19 of the '590 patent and Claim 8 of the '102 patent.

32. Fresenius Kabi has knowledge of the '590 patent and the '102 patent.

33. Fresenius Kabi submitted its ANDA to obtain FDA approval to engage in the commercial manufacture, importation, use, and sale of the Fresenius Kabi ANDA Product prior to the expiration of the '590 patent and the '102 patent, each of which is 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.

34. On information and belief, Fresenius Kabi intends to engage in the commercial manufacture, importation, use, sale, and/or offering for sale of Fresenius Kabi's ANDA 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 patent and the '102 patent.

35. In the Notice Letter, Fresenius Kabi notified Genzyme that ANDA No. 212395 was submitted with Paragraph IV certifications to the '590 patent and the '102 patent based on Fresenius Kabi's contention that the '590 patent and the '102 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer to sell, or importation of Fresenius Kabi's ANDA Product in/into the United States.

36. On information and belief, Fresenius Kabi is aware of the Federal Circuit's affirmance of a previous decision from this District finding Claim 19 of the '590 patent not invalid. *Genzyme Corp. v. Dr. Reddy's Labs., Ltd*., 716 F. App'x 1006 (Fed. Cir. Dec. 18, 2017)

affirming *Genzyme Corp. v. Dr. Reddy's Labs., Ltd*., 13-cv-1506-GMS, 2016 WL 2757689 (D. Del. May 11, 2016).

37. On information and belief, Fresenius Kabi is aware of this Court's decision finding Claims 8 and 19 of the '590 patent and Claim 8 of the '102 patent not invalid and infringed. *Genzyme Corp. et al. v. Zydus Pharm. (USA) Inc.*, C.A. No. 16-cv-00540-KAJ, D.I. 105 (D. Del. Aug. 8, 2018).

38. On information and belief, Fresenius Kabi is aware that a third case involving a challenge to the validity of the '590 patent and the '102 patent is pending before this District in C.A. No. 18-cv-01071-KAJ.

39. On information and belief, the bases for Fresenius Kabi's opinion that the '590 patent and the '102 patent are invalid, as set forth in Fresenius Kabi's Notice Letter, are substantially similar to those presented in the previous cases, C.A. 13-cv-1506-GMS and C.A. No. 1:16-CV-0540-KAJ.

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

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

41. Plaintiffs repeat and reallege the allegations of paragraphs 1-40 as if fully set forth herein.

42. Fresenius Kabi's submission of ANDA No. 212395 to obtain approval from the FDA to engage in the commercial manufacture, importation, use, or sale of Fresenius Kabi's ANDA 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 8 and 19, under 35 U.S.C. § 271(e)(2).

43. Upon FDA approval of ANDA No. 212395, Fresenius Kabi's commercial manufacture, importation, use, offer to sell, or sale of Fresenius Kabi's ANDA 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 8 and 19, under 35 U.S.C. §§ 271(a), (b), and/or (c), unless enjoined by the Court.

44. Fresenius Kabi's filing of ANDA No. 212395 and Fresenius Kabi's intent to engage in the commercial manufacture, importation, use, sale, or offer for sale of Fresenius Kabi's ANDA 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 8 and 19.

45. Upon FDA approval of ANDA No. 212395, use of Fresenius Kabi's ANDA Product in accordance with the prescribing information to be provided by Fresenius Kabi will directly infringe one or more claims of the '590 patent, including but not limited to Claims 8 and 19, under 35 U.S.C. § 271(a), unless enjoined by this Court.

46. Upon FDA approval of ANDA No. 212395, Fresenius Kabi will infringe one or more claims of the '590 patent, including but not limited to Claims 8 and 19, under 35 U.S.C. § 271(b) and (c) by actively inducing and contributing to infringement by others, unless enjoined by this Court.

47. Fresenius Kabi has knowledge of the '590 patent and, by the prescribing information Fresenius Kabi will include with Fresenius Kabi's ANDA Product, Fresenius Kabi 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 8 and 19.

48. Fresenius Kabi's offering for sale, sale, and/or importation of Fresenius Kabi's ANDA Product in/into the United States with the prescribing information for Fresenius Kabi's ANDA Product will actively induce infringement of at least one of the claims of the '590 patent, including but not limited to Claims 8 and 19, under 35 U.S.C. § 271(b).

49. Use of Fresenius Kabi's ANDA Product constitutes a material part of at least one of the claims of the '590 patent; Fresenius Kabi knows that Fresenius Kabi's ANDA 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 8 and 19; and Fresenius Kabi knows that Fresenius Kabi's ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial non-infringing use.

50. Fresenius Kabi's manufacture, use, offering for sale, sale, and/or importation of Fresenius Kabi's ANDA 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 8 and 19, under 35 U.S.C. § 271(c).

51. Fresenius Kabi had and will have notice of the '590 patent at the time of its infringement. Fresenius Kabi also has notice of the decision by this Court in 1:13-CV-1506-GMS and affirmed by the Federal Circuit, holding that Claim 19 of the '590 patent is not invalid after considering invalidity arguments that are substantially similar to those that Fresenius Kabi made in its Notice Letter with respect to Claims 8 and 19 of the '590 patent. Fresenius Kabi also has notice of the decision by this Court in *Genzyme Corp. et al. v. Zydus Pharm. (USA) Inc.*, C.A. No. 16-cv-00540-KAJ, D.I. 105 (D. Del. Aug. 8, 2018), holding that Claims 8 and 19 of the '590 patent and Claim 8 of the '102 patent are not invalid and infringed after considering invalidity arguments that are substantially similar to those that Fresenius Kabi made in its Notice

Letter with respect to Claims 8 and 19 of the '590 patent. Fresenius Kabi's infringement has been, continues to be, and will be deliberate and willful.

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

53. 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 FRESENIUS KABI OF U.S. PATENT NO. 6,987,102

54. Plaintiffs repeat and reallege the allegations of paragraphs 1-53 as if fully set forth herein.

55. Fresenius Kabi's submission of ANDA No. 212395 to obtain approval from the FDA to engage in the commercial manufacture, importation, use, or sale of Fresenius Kabi's ANDA 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 Claim 8, under 35 U.S.C. § 271(e)(2).

56. Upon FDA approval of ANDA No. 212395, Fresenius Kabi's commercial manufacture, importation, use, offer to sell, or sale of Fresenius Kabi's ANDA 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 Claim 8, under 35 U.S.C. §§ 271(a), (b), and/or (c), unless enjoined by the Court.

57. Fresenius Kabi's filing of ANDA No. 212395 and Fresenius Kabi's intent to engage in the commercial manufacture, importation, use, sale, or offer for sale of Fresenius Kabi's ANDA 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 Claim 8.

58. Upon FDA approval of ANDA No. 212395, use of Fresenius Kabi’s ANDA Product in accordance with the prescribing information to be provided by Fresenius Kabi will directly infringe one or more claims of the ’102 patent, including but not limited to Claim 8, under 35 U.S.C. § 271(a), unless enjoined by this Court.

59. Upon FDA approval of ANDA No. 212395, Fresenius Kabi will infringe one or more claims of the ’102 patent, including but not limited to Claim 8, under 35 U.S.C. § 271(b) and (c) by actively inducing and contributing to infringement by others, unless enjoined by this Court.

60. Fresenius Kabi has knowledge of the ’102 patent and, by the prescribing information Fresenius Kabi will include with Fresenius Kabi’s ANDA Product, Fresenius Kabi 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 Claim 8.

61. Fresenius Kabi’s offering for sale, sale, and/or importation of Fresenius Kabi’s ANDA Product in/into the United States with the prescribing information for Fresenius Kabi’s ANDA Product will actively induce infringement of at least one of the claims of the ’102 patent, including but not limited to Claim 8, under 35 U.S.C. § 271(b).

62. Use of Fresenius Kabi’s ANDA Product constitutes a material part of at least one of the claims of the ’102 patent; Fresenius Kabi knows that Fresenius Kabi’s ANDA 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 Claim 8; and Fresenius Kabi knows that Fresenius Kabi’s ANDA

Product is not a staple article of commerce or commodity of commerce suitable for substantial non-infringing use.

63. Fresenius Kabi's manufacture, use, offering for sale, sale, and/or importation of Fresenius Kabi's ANDA Product in/into the United States will contributorily infringe at least one of the claims of the '102 patent, including but not limited to Claim 8, under 35 U.S.C. § 271(c).

64. Fresenius Kabi had and will have notice of the '102 patent at the time of its infringement. Fresenius Kabi also has notice of the decision by this Court in 1:13-CV-1506-GMS and affirmed by the Federal Circuit, holding that Claim 19 of the '590 patent is not invalid after considering invalidity arguments that are substantially similar to those that Fresenius Kabi made in its Notice Letter with respect to Claim 8 of the '102 patent. Fresenius Kabi also has notice of the decision by this this Court in *Genzyme Corp. et al. v. Zydus Pharm. (USA) Inc.*, C.A. No. 16-cv-00540-KAJ, D.I. 105 (D. Del. Aug. 8, 2018), holding that Claims 8 and 19 of the '590 patent and Claim 8 of the '102 patent are not invalid and infringed after considering substantially the same invalidity arguments that Fresenius Kabi made in its Notice Letter with respect to Claim 8 of the '102 patent. Fresenius Kabi's infringement has been, continues to be, and will be deliberate and willful.

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

66. 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 Fresenius Kabi has infringed, and that

Fresenius Kabi's making, using, selling, offering to sell, or importing of Fresenius Kabi's ANDA Product in/into the United States will infringe one or more claims of the '590 patent;

(b) A judgment declaring that Fresenius Kabi has infringed, and that Fresenius Kabi's making, using, selling, offering to sell, or importing of Fresenius Kabi's ANDA 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 Fresenius Kabi's ANDA No. 212395 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 Fresenius Kabi from making, using, selling, offering to sell, or importing Fresenius Kabi's ANDA 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 Fresenius Kabi infringes the '590 patent or the '102 patent by engaging in the commercial manufacture, importation, use, offer to sell, or sale of Fresenius Kabi's ANDA 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 Fresenius Kabi'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.

Respectfully submitted,

RATNERPRESTIA

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