IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENZYME CORPORATION and SANOFI-AVENTIS U.S. LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No._____
TEVA PHARMACEUTICALS USA, INC.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs, Genzyme Corporation ("Genzyme") and sanofi-aventis U.S. LLC ("Sanofi"), by their attorneys, for their complaint against Teva Pharmaceuticals USA, Inc. ("Teva"), 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. 205197 filed by Teva 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 Teva Pharmaceuticals USA, Inc. ("Teva USA") is a corporation organized and existing under the laws of the State of Delaware having a place of business at 1090 Horsham Road, North Wales, PA 19454.

JURISDICTION AND VENUE

6. 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.

7. This Court has personal jurisdiction over the person of Teva because Teva is incorporated in Delaware and is therefore subject to the jurisdiction of this Court. As a domestic corporation, Teva is registered to do business with the Delaware Department of State, Division of Corporations.

8. In the alternative, and to the extent that Teva is not subject to the jurisdiction of this Court as a resident of Delaware, it is subject to the jurisdiction of the Court pursuant to 10 *Del. C.* § 3104. Specifically, Teva causes tortious injury in Delaware, namely from the tort of patent infringement, and Teva regularly does or solicits business, engages 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, personal jurisdiction over Teva is also proper because Teva has availed itself of the benefits and protections of the court in this judicial District and has sought affirmative relief in this jurisdiction by filing counterclaims. Such cases include *Bristol Myers Squibb Co. v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd,* 10-cv-805-CJB.

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

BACKGROUND

11. 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®.

12. 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.

13. 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.

14. 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.

15. By letter dated July 16, 2013, purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B) (the "Notice Letter"), Teva notified Genzyme that Teva had submitted ANDA No. 205197 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.

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

17. Teva's ANDA was submitted to obtain FDA approval to engage in the commercial manufacture, importation, use, and sale of Teva'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.

18. On information and belief, Teva 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.

19. In the Notice Letter, Teva notified Genzyme that its ANDA contained a "paragraph IV" certification that in Teva'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 Teva's Plerixafor ANDA Injection Product.

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

20. Plaintiffs repeat and reallege the allegations of paragraphs 1-19 as if fully set forth herein.

21. Teva'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).

22. Teva'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.

23. Teva's ANDA and Teva'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.

24. Upon FDA approval of Teva's ANDA, Teva 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.

25. Upon FDA approval of Teva's ANDA, Teva 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.

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

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

27. Plaintiffs repeat and reallege the allegations of paragraphs 1-19 as if fully set forth herein.

28. Teva'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).

29. Teva'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.

30. Teva's ANDA and Teva'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.

31. Upon FDA approval of Teva's ANDA, Teva 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.

32. Upon FDA approval of Teva's ANDA, Teva 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.

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

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

34. Plaintiffs repeat and reallege the allegations of paragraphs 1-19 as if fully set forth herein.

35. Teva'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).

36. Teva'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.

37. Teva's ANDA and Teva'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.

38. Upon FDA approval of Teva's ANDA, Teva 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.

39. Upon FDA approval of Teva's ANDA, Teva 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.

40. Plaintiffs will be substantially and irreparably harmed if Teva'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 Teva has infringed, and that Teva'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 Teva has infringed, and that Teva'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 Teva has infringed, and that Teva'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 Teva's ANDA No. 205197 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 Teva 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 Teva 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

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