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

SANOFI-AVENTIS DEUTSCHLAND GMBH, AVENTIS PHARMA S.A., ABBOT GMBH & CO. KG, ABBOTT LABORATORIES, and ABBOTT LABORATORIES, INC., Plaintiffs, v. GLENMARK PHARMACEUTICALS INC., USA, and GLENMARK PHARMACEUTICALS LTD., Defendants.	Civil Action No. 07-CV-5855 **FIRST AMENDED COMPLAINT** JURY TRIAL DEMANDED

Plaintiffs sanofi-aventis Deutschland GmbH and Aventis Pharma S.A. (collectively "sanofi-aventis"), Abbott GmbH & Co. KG ("Abbott Germany"), Abbott Laboratories and Abbott Laboratories Inc. (collectively "Abbott"), by their attorneys, for their First Amended Complaint against Defendants, Glenmark Pharmaceuticals Inc., USA ("Glenmark USA") and Glenmark Pharmaceuticals Ltd. ("Glenmark Ltd.") (collectively "Glenmark"), 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.*, and, more particularly, 35 U.S.C. §§ 271,271(e)(2) and 281. This action relates to the Abbreviated New Drug Application No. 79- 135 ("Glenmark's ANDA") filed by Glenmark with the United States Food and Drug Administration ("FDA") for approval to market a generic version of Abbott's TARKA® drug product.

The Parties

2. Sanofi-aventis Deutschland GmbH is a corporation organized and existing under the laws of Germany, having a principal place of business at Industriepark Hoechst, Frankfurt am Main, Germany.

3. Aventis Pharma S.A. is a corporation organized and existing under the laws of France, having a principal place of business at 20, avenue Raymond Aron, 92160, Antony, France.

4. Abbott GMBH & Co. KG is a corporation organized and existing under the laws of Germany, having a principal place of business at Max-Planck-Ring 2, 65205 Wiesbaden, Germany.

5. Abbott Laboratories is a corporation organized and existing under the laws of the state of Illinois, having its headquarters and principal place of business at Abbott Park, Illinois, 60064. Abbott Germany is a wholly-owned subsidiary of Abbott Laboratories.

6. Abbott Laboratories Inc. is a corporation organized and existing under the laws of the state of Delaware, having its headquarters and principal place of business at 100 Abbott Park Rd., Abbott Park, Illinois, 60064. Abbott Laboratories Inc. is a wholly-owned subsidiary of Abbott Laboratories.

7. On information and belief, Glenmark USA is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 750 Corporate Drive, Mahwah, New Jersey 07430.

8. On information and belief, Glenmark Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at Glenmark House, HDO-Corporate Building, Wing-A, B. D. Sawant Marg, Chakala, Off Western Express Highway Andheri [East], Mumbai 400099, India.

9. Glenmark Ltd. states on its website that it "has generic formulation and API [active pharmaceutical ingredients] business interests in over 85 countries across the world including the regulated markets of USA and Europe." *See* Exhibit A, a true and correct copy of http://www.glenmarkpharma.com/about/index.html. The website further states that Glenmark Ltd. "incorporated subsidiaries in the regulated markets of USA in FY 2003 and EU in FY 2005 and is making significant investments to build a strong API and generic formulations business in these markets." *Id.* On a separate page within the website, under the heading "Glenmark, USA," Glenmark Ltd. states, "The Glenmark US subsidiary, Glenmark Pharmaceuticals Inc., USA [GPJ], was established in 2003 with a view to enter into the world's largest pharmaceutical market and establish a significant generic presence by 2007 through a multi-pronged strategy. GPI is responsible for sales and marketing of Generic drug formulations in the USA ...." *See* Exhibit B, a true and correct copy of http://www.glenmarkpharma.com/business/america/index.html.

10. On information and belief, Glenmark USA is a wholly-owned subsidiary, agent and alter-ego of Glenmark Ltd.

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

Jurisdiction and Venue

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

13. This Court has personal jurisdiction over Glenmark USA by virtue of its presence in New Jersey, and its systematic and continuous contacts with New Jersey.

14. This Court has personal jurisdiction over Glenmark Ltd. by virtue of its presence in New Jersey, including presence through its subsidiary, agent and alter-ego, Glenmark USA, and its systematic and continuous contacts with New Jersey, including contacts through its subsidiary, agent and alter-ego, Glenmark USA.

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

The Patent in Suit

16. United States Patent No. 5,721,244 ("the '244 patent") entitled "Combination of Angiotensin-Converting Enzyme Inhibitors with Calcium Antagonists as well as Their Use in Drugs" duly and legally issued on February 24, 1998 to inventors Reinhard Becker *et al.* by the United States Patent and Trademark Office. A copy of the '244 patent is attached hereto as Exhibit C. The '244 patent covers, *inter alia*, a combination of trandolapril and verapamil hydrochloride.

17. The '244 patent was assigned to Hoechst Aktiengesellschaft, which subsequently assigned its rights to Aventis Pharma Deutschland GmbH, which later changed its name to sanofi-aventis Deutschland GmbH. At all times from the issuance of the '244 patent to the

present, sanofi-aventis Deutschland GmbH or one of its predecessors in interest has been the owner of the '244 patent.

18. Aventis Pharma S-A. was granted an exclusive license, *inter alia*, to manufacture, use and sell pharmaceutical products containing trandolapril and verapamil hydrochloride under the '244 patent.

19. Aventis Pharma S.A., in turn, granted Abbott Germany an exclusive license, *inter alia*, to manufacture, use and sell pharmaceutical products containing trandolapril and verapamil hydrochloride under the '244 patent.

20. Abbott Germany, in turn, granted Abbott Laboratories an exclusive license, *inter alia*, to manufacture, use and sell pharmaceutical products containing trandolapril and verapamil hydrochloride under the '244 patent.

21. Abbott Laboratories, in turn, granted Abbott Laboratories Inc. an exclusive sublicense, *inter alia*, to use and sell pharmaceutical products containing trandolapril and verapamil hydrochloride under the '244 patent.

22. Abbott Laboratories is the owner of the New Drug Application ("NDA") No. 20-591, which the FDA approved on October 22, 1996. Pursuant to this approved NDA, Abbott Laboratories through its fully owned subsidiary Abbott Laboratories Inc. sells drug products containing the trandolapril/verapamil hydrochloride combination in the United States under the trademark TARKA®. The drug products are manufactured by Abbott Germany. Abbott Laboratories, through its relationships with its fully owned subsidiaries Abbott Germany and Abbott Laboratories Inc., serves as the sole, exclusive seller and distributor of these drug products in the United States.

23. The '244 patent is listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluation" ("Orange Book") as being applicable to Abbott Laboratories' aforementioned NDA for its TARKA® tablets.

Acts Giving Rise to this Action

24. No earlier than October 29, 2007, plaintiffs received a letter ("the Notification Letter") from Glenmark notifying them that Glenmark had submitted Glenmark's ANDA to the FDA pursuant to 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use and sale of 4 mg trandolapril/240 mg verapamil hydrochloride extended release tablets prior to the expiration of the '244 patent.

25. No earlier than November 16, 2007, plaintiffs received a second letter ("the Second Notification Letter") from Glenmark notifying them that Glenmark had submitted "a gratuitous amendment" to Glenmark's ANDA pursuant to 21 U.S.C. § 355(j) seeking approval to also engage in the commercial manufacture, use and sale of 2 mg trandolapril/240 mg verapamil hydrochloride and 2 mg trandolapril/180 mg verapamil hydrochloride extended release tablets prior to the expiration of the '244 patent.

26. Glenmark's 4 mg trandolapril/240 mg verapamil hydrochloride, 2 mg trandolapril/240 mg verapamil hydrochloride and 2 mg trandolapril/180 mg verapamil hydrochloride extended release tablets are collectively referred to herein as "Glenmark's Tablets."

27. In both the Notification Letter and the Second Notification Letter, Glenmark stated that Glenmark's ANDA contained a "Paragraph IV" certification (*i.e.*, a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV)) that, in Glenmark's opinion, the '244 patent is invalid or unenforceable, or will not be infringed by the commercial manufacture, use or sale of Glenmark's Tablets.

28. The submission of Glenmark's ANDA and Glenmark's intention to engage in the commercial manufacture, importation, use, offer for sale or sale of Glenmark's Tablets upon receiving FDA approval create an actual case or controversy with respect to infringement of the '244 patent.

29. On information and belief, on or about June 8, 2010, Glenmark initiated its commercial launch of Glenmark's Tablets engaging in the commercial manufacture, importation, use, offer for sale or sale of Glenmark's Tablets in the United States.

30. Plaintiffs have been and continue to be injured and damaged by Glenmark's commercial manufacture, importation, use, offer for sale or sale of Glenmark's Tablets in the United States.

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

Count I: Direct Infringement by Glenmark (First Count)

32. Plaintiffs repeat and reallege the allegations of paragraphs 1-31 as if fully set forth herein.

33. Glenmark's submission of Glenmark's ANDA to obtain approval to engage in the commercial manufacture, importation, use, offer for sale or sale of Glenmark's Tablets, prior to the expiration of the '244 patent, constitutes infringement of one or more claims of that patent under 35 U.S.C. § 271(e)(2).

34. Glenmark USA's parent corporation, Glenmark Ltd., is jointly and severally liable with Glenmark USA for this direct infringement of the '244 patent. This is so because, upon information and belief, Glenmark Ltd. directed, participated in, contributed to, aided and abetted the submission of Glenmark's ANDA, including its Paragraph IV allegation, to the FDA.

Count II: Direct Infringement by Glenmark (Second Count)

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

36. On information and belief, Glenmark intends to engage and will engage in the commercial manufacture, importation, use, offer for sale and sale of Glenmark's Tablets promptly upon receiving FDA approval to do so.

37. On information and belief, on or about June 8, 2010, Glenmark initiated its commercial launch of Glenmark's Tablets engaging in the commercial manufacture, importation, use, offer for sale or sale of Glenmark's Tablets in the United States.

38. Glenmark's actual commercial manufacture, importation, use, offer for sale or sale of Glenmark's Tablets prior to the expiration of the '244 patent constitutes direct infringement of the '244 patent under 35 U.S.C. § 271(a).

39. Glenmark USA's parent corporation, Glenmark Ltd., is jointly and severally liable with Glenmark USA for this direct infringement of the '244 patent. This is so because, upon information and belief, Glenmark Ltd. will direct, participate in, contribute to, aid and abet Glenmark's acts of manufacturing, importing, using, offering for sale and selling Glenmark's Tablets prior to the expiration of the '244 patent.

Count III: Inducement of Infringement by Glenmark Ltd.

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

41. On information and belief, Glenmark Ltd. has infringed the '244 patent under 35 U.S.C. § 271(b) by actively inducing Glenmark USA to submit Glenmark's ANDA, including its Paragraph IV allegation, which submission constitutes infringement of the '244 patent.

Count IV: Inducement and Contributory Infringement by Glenmark

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

43. Glenmark's actual commercial manufacture, importation, use, offer for sale or sale of Glenmark's Tablets prior to the expiration of the "244 patent actively induces and/or contributes to infringement by others of the '244 patent under 35 U.S.C. § 271(b) and (c), respectively.

44. Glenmark USA's parent corporation, Glenmark Ltd., is jointly and severally liable with Glenmark USA for this indirect infringement of the '244 patent. This is so because, upon information and belief, Glenmark Ltd. will direct, participate in, contribute to, aid and, abet Glenmark's acts of manufacturing, importing, using, offering for sale and selling Glenmark's Tablets prior to the expiration of the '244 patent.

Willfulness

45. Glenmark had notice of the '244 patent at the time of submitting Glenmark's ANDA, and, on information and belief, had notice that its actual commercial manufacture, importation, use, offer for sale or sale of Glenmark's Tablets, prior to the expiration of the '244 patent, would constitute infringement of this patent under 35 U.S.C. § 271.

46. Glenmark's acts of infringement were, and will be, objectively reckless, willful and deliberate.

Prayer for Relief

WHEREFORE, plaintiffs respectfully request the following relief;

(a) A judgment declaring that Glenmark has infringed, and that Glenmark's making, using, selling, offering to sell and importing Glenmark's Tablets infringes the '244 patent;

(b) A judgment ordering that the effective date of any FDA approval for Glenmark to make, use or sell Glenmark's Tablets be no earlier than the date on which the '244 patent expires as extended by any FDA exclusivities relating to Abbott's TARKA® drug products;

(c) A judgment permanently enjoining Glenmark from making, using, selling, offering to sell, or importing Glenmark's Tablets until after the expiration of the '244 patent and expiration of any FDA exclusivities relating to Abbott's TARKA® drug products;

(d) A judgment awarding plaintiffs damages resulting from Glenmark's importation, commercial manufacture, use, offer to sell or sale of Glenmark's Tablets prior to the expiration of the '244 patent,, increased to treble the amount found or assessed, together with interest;

(e) Attorneys' fees in this action pursuant to 35 U.S.C. § 285;

(f) Costs and expenses in this action; and

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

Date: September 20, 2010

Respectfully submitted

By: Brian M. English

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DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a jury trial.

Dated: September 20, 2010

Brian M. English

LOCAL RULE 11.2 CERTIFICATION

I hereby certify that the matter in controversy is not the subject of any other action pending in this or any other court, or of any pending arbitration or administrative proceeding.

Dated: September 20, 2010

Brian M. English

LOCAL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the plaintiffs seek, *inter alia*, injunctive relief, and the damages recoverable exceed the sum of $150,000 exclusive of interest and costs.

Dated: September 20, 2010

Brian M. English