

FILED

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

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CLERK US DISTRICT COURT
ALEXANDRIA, VIRGINIA

PFIZER INC., PFIZER LIMITED, and PFIZER
IRELAND PHARMACEUTICALS,

Plaintiffs,

v.

TIGER PHARMACEUTICALS, LLC,

Defendant.

Civil Action No.

1:14 CV 1501
AJT/TRJ

COMPLAINT

Pfizer Inc., Pfizer Limited, and Pfizer Ireland Pharmaceuticals (collectively, “Plaintiffs” or “Pfizer”), by their attorneys, for their complaint against Tiger Pharmaceuticals, LLC (“Defendant” or “Tiger”), allege as follows:

NATURE OF THE ACTION

1. Pfizer has all right, title and interest in United States Patent No. 6,124,363 (the “’363 patent”), and the right to sue for infringement thereof. This is an action by Pfizer against Defendant for patent infringement of the ’363 patent arising from Defendant’s filing of Abbreviated New Drug Application (“ANDA”) No. 207058 with the United States Food and Drug Administration (“FDA”) seeking approval to market generic versions of Pfizer’s Tikosyn[®] (dofetilide) capsules prior to expiration of the ’363 patent.

2. On information and belief, Defendant intends to market generic versions of Pfizer’s Tikosyn[®] capsules prior to the expiration of the ’363 patent. This will cause Pfizer to suffer irreparable harm—inflicting incalculable damage by causing Pfizer to lose substantial market share, to experience massive price erosion, and to lose goodwill and customers. This

irreparable harm to Pfizer will occur even if Defendant's generic versions of Tikosyn are subsequently removed from the market due to a later judicial determination that the '363 patent is valid, enforceable, and infringed. Accordingly, in the event that Pfizer is unable to obtain a full adjudication on the merits prior to launch of Defendant's generic versions of Tikosyn, Pfizer will need to seek a preliminary injunction to prevent such irreparable and irreversible harm.

THE PARTIES

Plaintiffs

3. Pfizer Inc. is a corporation organized under the laws of the State of Delaware and having its principal place of business located at 235 East 42nd Street, New York, New York 10017. Pfizer Inc. owns and licenses the '363 patent. Pfizer Inc. invests extensively in designing, developing, and evaluating new and innovative pharmaceutical products and sells pharmaceutical products to the public throughout the United States.

4. Pfizer Limited is a company organized under the laws of England and has its principal place of business at Ramsgate Road, Sandwich, Kent CT13 9NJ, England.

5. Pfizer Ireland Pharmaceuticals is a private unlimited liability company organized under the laws of Ireland and has its registered office at Operations Support Group, Ringaskiddy, Co. Cork, Ireland.

6. Pfizer has all right, title, and interest in the '363 patent and the right to sue for infringement thereof.

Defendant

7. On information and belief, Tiger Pharmaceuticals, LLC, is a limited liability company organized under the laws of the Commonwealth of Virginia and has its principal place of business at 1655 North Fort Myer Drive, Suite 700, Arlington, Virginia 22209. Tiger has

designated National Registered Agents, Inc., 4701 Cox Road, Suite 285, Glen Allen, Virginia 23060, as its registered agent in Virginia.

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States, Title 35, United States Code. The Court has subject matter jurisdiction over this action pursuant to the provisions of 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

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

10. Tiger is subject to personal jurisdiction in the Eastern District of Virginia because it is a limited liability company organized under the laws of the Commonwealth of Virginia with a principal place of business at 1655 North Fort Myer Drive, Suite 700, Arlington, Virginia 22209, and because it has designated National Registered Agents, Inc., 4701 Cox Road, Suite 285, Glen Allen, Virginia 23060, as its registered agent in Virginia.

BACKGROUND

The '363 Patent

11. On September 26, 2000, the United States Patent and Trademark Office (“USPTO”) issued the '363 patent, titled “Dofetilide Polymorphs.”

12. The '363 patent discloses and claims, *inter alia*, certain dofetilide polymorphs, processes for preparing certain dofetilide polymorphs, pharmaceutical compositions comprising certain dofetilide polymorphs, and methods of treating heart failure and cardiac arrhythmia by administering certain dofetilide polymorphs.

Orange Book Listing for Tikosyn

13. Pfizer holds an approved New Drug Application (“NDA”), No. 20-931, for dofetilide capsules, 0.125 mg, 0.25 mg, and 0.5mg dosage strengths, under the registered name

Tikosyn[®]. As stated in the FDA approved label for Tikosyn (“Pfizer’s Tikosyn Label”), Tikosyn is indicated for “the maintenance of normal sinus rhythm (delay in time to recurrence of atrial fibrillation/atrial flutter [AF/AFL]) in patients with atrial fibrillation/atrial flutter of greater than one week duration who have been converted to normal sinus rhythm” and “for the conversion of atrial fibrillation and atrial flutter to normal sinus rhythm.”

14. The FDA lists the ’363 patent in the FDA publication titled “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”) in connection with NDA No. 20-931 and Tikosyn (dofetilide) capsules.

15. The Orange Book states that the ’363 patent’s expiration date is October 9, 2018.

Tiger’s ANDA

16. By letter dated September 26, 2014 (“ANDA Notice Letter”), Defendant notified Pfizer that it had filed ANDA No. 207058 with the FDA seeking approval under the Federal Food, Drug and Cosmetic Act (“FDCA”) to market and sell generic copies of Pfizer’s Tikosyn capsules, 0.125 mg, 0.25 mg, and 0.50 mg dofetilide capsules (collectively, “Defendant’s ANDA Products”), prior to the expiration of the ’363 patent. Pfizer received the ANDA Notice Letter on September 29, 2014.

17. The ANDA Notice Letter stated that ANDA No. 207058 contains a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a “Paragraph IV” certification) alleging that “the claims of the ’363 patent are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, offer for sale, sale or importation of the proposed drug product that is the subject of Tiger’s ANDA.”

18. On information and belief, Defendant intends, conditioned upon the FDA granting approval of ANDA No. 207058, to market Defendant’s ANDA Products prior to expiration of the ’363 patent. On information and belief, Defendant also intends for doctors to prescribe, and

for patients to use, Defendant's ANDA Products in accordance with and as directed by Defendant's proposed labeling for Defendant's ANDA Products, which copies some or all of the indications in the label for Pfizer's Tikosyn capsules.

COUNT I: Defendant's ANDA Filing Infringes the '363 Patent
(Patent Infringement)

19. The allegations of paragraphs 1 through 18 above are repeated and re-alleged as if set forth fully herein.

20. Pursuant to 35 U.S.C. § 271(e)(2)(A), Defendant's filing of ANDA No. 207058 seeking approval to market Defendant's ANDA Products prior to expiration of the '363 patent is an act of infringement of one or more claims of the '363 patent, and entitles Pfizer to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 207058 be a date which is not earlier than the expiration date of the '363 patent, including any exclusivity to which Pfizer is or becomes entitled.

21. Upon information and belief, the labeling and/or package insert submitted with ANDA No. 207058 states that Defendant's ANDA Products are indicated for the treatment of one or more disorders included in Pfizer's Tikosyn label.

22. Upon information and belief, Defendant, conditioned upon the FDA granting approval of ANDA number 207058, intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Defendant's ANDA Products with the proposed labeling prior to expiration of the '363 patent.

23. Upon information and belief, Defendant's manufacture, use, offer for sale, sale, and/or importation of Defendant's ANDA Products with the proposed labeling prior to expiration of the '363 patent would infringe one or more claims of the '363 patent.

24. Upon information and belief, the use of Defendant's ANDA Products in accordance with and as directed by Defendant's proposed labeling would infringe one or more claims of the '363 patent.

25. Upon information and belief, Defendant intends to actively induce infringement of one or more claims of the '363 patent prior to expiration of the '363 patent.

26. Upon information and belief, Defendant knows that Defendant's ANDA Products and the proposed labeling are especially made or adapted for use in infringing one or more claims of the '363 patent and that Defendant's ANDA Products and the proposed labeling are not suitable for any substantial noninfringing use.

27. Upon information and belief, Defendant intends to contribute to the infringement of one or more claims of the '363 patent prior to expiration of the '363 patent.

28. The foregoing actions by Defendant constitute and/or would constitute infringement of one or more claims of the '363 patent, active inducement of infringement of one or more claims of the '363 patent, and/or contribution to the infringement by others of one or more claims of the '363 patent.

29. Pfizer will be substantially and irreparably harmed if Defendant is not enjoined from infringing the '363 patent. Pfizer has no adequate remedy at law.

COUNT II: Declaratory Judgment that Defendant will Infringe the '363 Patent
(Declaratory Judgment of Infringement)

30. Pfizer repeats and re-alleges paragraphs 1 through 29 above as if fully set forth herein.

31. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, based upon an actual controversy between the parties.

32. Upon information and belief, Defendant has taken active steps relating to importing, using, selling, or offering for sale in the United States, including in the Eastern District of Virginia, the Defendant's ANDA Products with the proposed labeling immediately following FDA approval of ANDA No. 207058. Defendant's active steps include, among other things, filing ANDA No. 207058 and challenging the validity of the '363 patent by its Paragraph IV certification and ANDA Notice Letter to Pfizer. As a result, Defendant is committed to selling Defendant's ANDA Products prior to expiration of the '363 patent.

33. Upon information and belief, the labeling and/or package insert submitted with ANDA No. 207058 states that Defendant's ANDA Products are indicated for the treatment of one or more indications included in the label for Pfizer's Tikosyn capsules.

34. Upon information and belief, Defendant intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Defendant's ANDA Products with the proposed labeling prior to expiration of the '363 patent.

35. Upon information and belief, Defendant's manufacture, use, offer for sale, sale, and/or importation of Defendant's ANDA Products with the proposed labeling prior to expiration of the '363 patent would infringe one or more claims of the '363 patent.

36. Upon information and belief, the use of Defendant's ANDA Products in accordance with and as directed by Defendant's proposed labeling would infringe one or more claims of the '363 patent.

37. Upon information and belief, Defendant intends to actively induce infringement of one or more claims of the '363 patent prior to expiration of the '363 patent.

38. Upon information and belief, Defendant knows that Defendant's ANDA Products and the proposed labeling are especially made or adapted for use in infringing one or more

claims of the '363 patent and that Defendant's ANDA Products and the proposed labeling are not suitable for any substantial noninfringing use.

39. Upon information and belief, Defendant intends to contribute to the infringement of one or more claims of the '363 patent prior to expiration of the '363 patent.

40. The foregoing actions by Defendant constitute and/or would constitute infringement of one or more claims of the '363 patent, active inducement of infringement of one or more claims of the '363 patent, and/or contribution to the infringement by others of one or more claims of the '363 patent.

41. Pfizer will be substantially and irreparably harmed if Defendant is not enjoined from infringing the '363 patent. Pfizer has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

- A. A judgment declaring that Defendant's submission and maintenance of ANDA No. 207058 was an act of infringement and that Defendant's making, using, offering to sell, selling, or importing Defendant's ANDA Products prior to the expiration of the '363 patent will infringe, actively induce infringement, and/or contribute to the infringement of the '363 patent and that the '363 patent remains valid and enforceable;
- B. A judgment declaring that the effective date of any approval for Defendant to make, use, offer for sale, sell, market, distribute, or import Defendant's ANDA Products be no earlier than the expiration of the '363 patent;

- C. A permanent injunction against Defendant, its respective officers, agents, servants, and employees, and those persons in active concert or participation with any of them, making using, selling, offering for sale, marketing, distributing, or importing Defendant's ANDA Products, or any other infringement of the '363 patent, and enjoining Defendant from inducing or contributing to any of the foregoing, prior to the expiration of the '363 patent;
- D. A declaratory judgment that Defendant's making, using, offering to sell, selling, or importing Defendant's ANDA Products prior to the expiration of the '363 patent will infringe, actively induce infringement, and/or contribute to the infringement of the '363 patent;
- E. If Defendant commercially manufactures, uses, offers to sell or sells Defendant's ANDA Products within the United States, or imports Defendant's ANDA Products into the United States, prior to the expiration of the '363 patent, including any extensions, a judgment awarding Plaintiffs monetary relief together with interest;
- F. A judgment that this case is an exceptional case under 35 U.S.C. § 285, entitling Plaintiffs to an award of its reasonable attorneys' fees for bringing and prosecuting this action;
- G. An award of Plaintiffs' costs and expenses in this action; and
- H. Such further and additional relief as this Court deems just and proper.

Dated: November 10, 2014



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