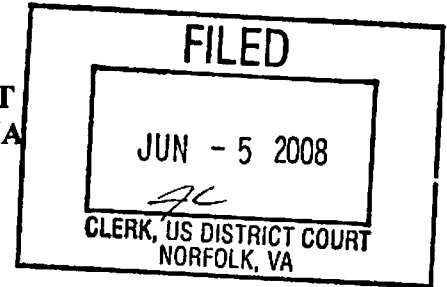


IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA



LUPIN LIMITED and)
LUPIN PHARMACEUTICALS, INC.,)
)
Plaintiffs,)
)
v.)
)
SANOFI-AVENTIS DEUTSCHLAND GMBH)
and KING PHARMACEUTICALS, INC.,)
)
Defendants.)
)
)

Civil Action No. *J:08cv758*

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiffs Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, "Lupin") bring this action against Defendants Sanofi-Aventis Deutschland GmbH ("Aventis") and King Pharmaceuticals, Inc. ("King") for a declaration that Lupin has not infringed, does not infringe, and will not infringe any valid and enforceable claim of U.S. Patent No. 7,368,469 ("the '469 patent").

The Parties

1. Plaintiff Lupin Limited is a corporation organized and existing under the laws of the Sovereign Nation of India, having a place of business at Laxmi Towers, "B" Wing, 5th Floor, Bandra Kurla Complex, Mumbai 400 051, India. Lupin Limited develops and manufactures prescription pharmaceutical drugs, including quality, affordable generic medicines.

2. Plaintiff Lupin Pharmaceuticals, Inc. ("LPI") is a corporation organized and existing under the laws of the Commonwealth of Virginia, having a principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. LPI is the United States marketing and sales affiliate for Lupin Limited.

3. On information and belief, Defendant Aventis is a corporation organized and existing under the laws of Germany, having a place of business at Industriepark Hoechst, Frankfurt am Main, Germany. On information and belief, Aventis manufactures and sells pharmaceutical products throughout the United States, including within the State of Virginia and this District. On information and belief, Aventis has also invoked and consented to the jurisdiction of this Court by suing Lupin in this District in a related case.

4. On information and belief, Defendant King is a corporation organized and existing under the laws of Tennessee, having a place of business at 501 Fifth Street, Bristol, Tennessee 37620. On information and belief, King manufactures and sells pharmaceutical products throughout the United States, including within the State of Virginia and this District. On information and belief, King has also invoked and consented to the jurisdiction of this Court by suing Lupin in this District in a related case.

Jurisdiction and Venue

5. This action arises under, *inter alia*, the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

6. The Court has original jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a), because this action involves substantial claims arising under the United States Patent Act (35 U.S.C. § 1 *et seq.*), and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, because this action involves an actual controversy concerning the infringement and validity of the patent-in-suit.

7. Venue is appropriate in this District under 28 U.S.C. §§ 1391(b) and 1400(b).

8. This Court has personal jurisdiction over Defendants because they regularly conduct business in, and have regular and systematic contact with, the State of Virginia, including this District, and because they have invoked and consented to the jurisdiction of this Court by suing Lupin in this District in a related case involving the subject matter of this suit.

Background Allegations Common to All Counts

King's Altace[®] (Ramipril) Capsules

9. King holds approved New Drug Application ("NDA") No. 19-901 for Altace[®] (Ramipril) Capsules 1.25 mg, 2.5 mg, 5 mg and 10 mg.

10. Altace[®] (Ramipril) is a so-called "ACE Inhibitor" that is indicated for, among other things, the treatment of hypertension.

11. On information and belief, King markets and sells Altace[®] (Ramipril) Capsules 1.25 mg, 2.5 mg, 5 mg and 10 mg throughout the United States, including within the State of Virginia and this District.

12. On information and belief, King markets and sells Altace[®] (Ramipril) Capsules 1.25 mg, 2.5 mg, 5 mg and 10 mg throughout the United States, including within the State of Virginia and this District, under and pursuant to a license from Aventis.

13. On information and belief, Aventis has licensed to King the right to market and sell Altace[®] (Ramipril) Capsules 1.25 mg, 2.5 mg, 5 mg and 10 mg throughout the United States, including within the State of Virginia and this District.

14. King's 2007 sales for Altace[®] (Ramipril) Capsules were approximately \$646 million.

Patent-in-Suit

15. On or about May 6, 2008, the United States Patent and Trademark Office (“PTO”) issued the ‘469 patent, entitled “Use of inhibitors of the renin-angiotensin system in the prevention of cardiovascular events.” A true and correct copy of the ‘469 patent as it issued is attached to this Complaint as Exhibit A.

16. According to the records of the PTO, Aventis is the assignee and record owner of the ‘469 patent.

17. On information and belief, Aventis purports and claims to own, and to have the right to enforce, the ‘469 patent.

18. On information and belief, King is the exclusive licensee of the ‘469 patent.

19. On information and belief, King purports and claims to have the right to enforce the ‘469 patent.

20. On information and belief, King asserts and claims that the ‘469 patent covers or protects the use of Altace® (Ramipril) Capsules from generic competition.

Lupin’s Generic Ramipril Capsules

21. Lupin has filed an Abbreviated New Drug Application (“ANDA”) seeking U.S. Food and Drug Administration (“FDA”) approval for a generic version of Ramipril Capsules 1.25 mg, 2.5 mg, 5 mg and 10 mg.

22. On May 12, 2008, FDA tentatively approved Lupin’s ANDA for generic Ramipril Capsules. On information and belief, FDA intends to grant final approval of Lupin’s ANDA imminently.

23. Lupin intends to manufacture, use, sell, and offer for sale in, and import into, the United States generic Ramipril Capsules before the expiration of the '469 patent.

24. Lupin has made substantial preparation to manufacture, use, sell, offer to sell in, or import into, the United States its generic Ramipril Capsules, including within the State of Virginia and this District, prior to the expiration of the '469 patent.

25. The commercial launch of Lupin's generic Ramipril Capsules in the United States is imminent.

26. The commercial manufacture, use, sale, offer for sale and importation of Lupin's generic Ramipril Capsules, which are the subject of Lupin's ANDA No. 77-626, have not infringed, do not infringe, and will not infringe any valid and enforceable claim of the '469 patent.

King's And Aventis' Threats And Litigious Conduct

27. King and Aventis are extremely litigious, and have previously exhibited an intent and willingness to aggressively assert and enforce their purported patent rights against companies seeking to market competing generic versions of ramipril. King and Aventis previously sued Lupin in this District alleging that Lupin's generic Ramipril Capsules, which are the subject of Lupin's ANDA No. 77-626, infringes another ramipril patent, which this Court and the United States Court of Appeals for the Federal Circuit subsequently invalidated. Given the invalidation of that patent and the expiration of all other relevant ramipril patents, Lupin is legally entitled to manufacture, use, sell, offer to sell and import ramipril in the United States.

28. King and Aventis, however, intend to assert the '469 patent against Lupin in order to protect King's Altace[®] (Ramipril) Capsules from generic competition. In fact, King has already threatened and expressed its intent to sue Lupin for infringement of the '469 patent.

29. Lupin is under a reasonable apprehension that it will face suit for alleged infringement of the '469 patent by manufacturing, using, selling, offering for sale, or importing its generic Ramipril Capsules.

30. There is an actual, substantial, and continuing justiciable case or controversy between Defendants and Lupin regarding the non-infringement and invalidity of the '469 patent.

COUNT I

(Declaratory Judgment of Non-Infringement of the '469 Patent)

31. Lupin repeats each of the foregoing paragraphs as if fully set forth herein.

32. There is an actual, substantial, and continuing justiciable case or controversy between Defendants and Lupin regarding the non-infringement of the '469 patent.

33. The manufacture, use, sale, offer for sale, or importation of Lupin's generic Ramipril Capsules, which are the subject of ANDA No. 77-626, have not infringed, do not infringe, and will not infringe any valid and/or enforceable claim of the '469 patent.

34. Lupin is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of Lupin's generic Ramipril Capsules, which are the subject of ANDA No. 77-626, have not infringed, do not infringe, and will not infringe any valid and/or enforceable claim of the '469 patent.

COUNT II

(Declaratory Judgment of Invalidity of the '469 Patent)

35. Lupin repeats each of the foregoing paragraphs as if fully set forth herein.

36. There is an actual, substantial, and continuing justiciable case or controversy between Defendants and Lupin regarding the invalidity of the '469 patent.

37. The claims of the '469 patent are invalid at least for failure to satisfy one or more of the conditions for patentability in 35 U.S.C. § 1 *et seq.*

38. Lupin is entitled to a judicial declaration that the claims of the '469 patent are invalid.

PRAYER FOR RELIEF

Wherefore, Lupin respectfully requests entry of judgment:

- A. Declaring that the manufacture, use, sale, offer for sale, or importation of Lupin's generic Ramipril Capsules have not infringed, do not infringe, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily) any valid or enforceable claim of the '469 patent;
- B. Declaring that the claims of the '469 patent are invalid;
- C. Declaring this an exceptional case and awarding Lupin its reasonable attorneys' fees under 28 U.S.C. § 285;
- D. Awarding Lupin its reasonable costs and expenses of this action; and
- E. Awarding Lupin such further necessary or proper relief as the Court may deem just.

JURY DEMAND

The Plaintiffs, Lupin Limited and Lupin Pharmaceuticals, Inc., hereby demand a trial by jury on all issues so triable.

Dated: June 5, 2008

Respectfully submitted,

LUPIN LIMITED and
LUPIN PHARMACEUTICALS, INC.

By: 
One of their attorneys

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