

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

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BARR LABORATORIES, INC.,

*Plaintiffs,*

v.

AVENTIS PHARMACEUTICALS INC.,

*Defendant.*

Civil Action No. 06CV5605 (JAG)

**COMPLAINT FOR DECLARATORY JUDGMENT**

Plaintiff Barr Laboratories, Inc. ("Barr") for their Complaint against Aventis Pharmaceuticals Inc. ("Aventis") allege on personal beliefs as to themselves and on information and beliefs as to the conduct of Aventis as follows:

**THE PARTIES**

1. Plaintiff Barr is a Delaware corporation having a principal place of business located at 2 Quaker Road, Pomona, New York 10970, and has a regular and established place of business located at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677.

2. On information and belief, defendant Aventis is a corporation organized and existing under the laws of Delaware, having its principal place of business at 300 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807. On information and belief, Aventis is a wholly owned subsidiary of sanofi-Aventis S.A.

3. On information and belief, Aventis owns U.S. Patent No. 7,138,524 ("the '524 patent"), entitled "Processes for Preparing Anhydrous and Hydrate Forms of Antihistaminic Piperidine Derivatives, Polymorphs and Pseudomorphs Thereof" issued November 21, 2006.

4. On information and belief, Aventis holds New Drug Application ("NDA") 20-872 for Allegra<sup>®</sup> 30 mg, 60 mg, and 180 mg tablets.

#### **JURISDICTION AND VENUE**

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), in that it involves substantial claims arising under the United States Patent Act, 35 U.S.C. § 1 *et. seq.*

6. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy within the Court's jurisdiction to provide a declaratory judgment that the '524 patent is invalid, unenforceable and not infringed.

7. Personal jurisdiction exists over Aventis, because Aventis has its principal place of business within this district, and because Aventis does business within this district.

8. Venue is proper in this Court pursuant to 28 U.S.C. § 1391.

#### **THE PRESENCE OF AN ACTUAL CONTROVERSY**

9. Barr submitted Abbreviated New Drug Application ("ANDA") No. 76-169 for 60 mg fexofenadine hydrochloride capsules, and that ANDA application was approved by the United States Food and Drug Administration ("FDA") on July 13, 2005.

10. Barr submitted Abbreviated New Drug Application ("ANDA") No. 76-191 for 30 mg, 60 mg and 180 mg fexofenadine hydrochloride tablets, and that ANDA application was approved by the United States Food and Drug Administration ("FDA") on August 31, 2005. Barr initiated commercial sales of its 30 mg, 60 mg and 180 mg fexofenadine hydrochloride tablets (Barr's fexofenadine hydrochloride tablets") on or about that date.

11. Barr submitted Abbreviated New Drug Application ("ANDA") No. 76-236 for tablets containing 60 mg fexofenadine hydrochloride and 120 mg pseudoephedrine, and that ANDA application was approved by the United States Food and Drug Administration ("FDA") on April 14, 2005.

12. On August 1, 2001, Aventis, Merrell Pharmaceuticals Inc. and Carderm Capital L.P. filed Civil Action No. 01-CV-3627 (D.N.J.) against Barr alleging that Barr's making, using, selling, offering to sell, or sale of its ANDA No. 76-169 product infringed U.S. Patent Nos. 6,037,353; 6,187,791; 5,738,872; 5,855,912; 5,932,247; 6,113,942; 6,147,216; 6,242,606; 5,663,353; 5,618,940; 5,631,375; 5,644,061; 5,650,516; 5,652,370; 5,654,433; and 5,675,009.

13. On September 7, 2001, Aventis, Merrell Pharmaceuticals Inc. and Carderm Capital L.P. filed Civil Action No. 01-CV-4257 (D.N.J.) against Barr alleging that Barr's making, using, selling, offering to sell, or sale of its ANDA No. 76-191 product infringed U.S. Patent Nos. 6,037,353; 5,738,872; 6,187,791; 5,855,912; 6,113,942; 6,147,216; 6,242,606; 5,663,353; 5,618,940; 5,631,375; 5,644,061; 5,650,516; 5,652,370; 5,654,433; and 5,675,009.

14. On January 28, 2002, Aventis, Merrell Pharmaceuticals Inc. and Carderm Capital L.P. filed Civil Action No. 02-CV-401 (D.N.J.) against Barr alleging that Barr's making, using, selling, offering to sell, or sale of its ANDA No. 76-236 product infringed U.S. Patent Nos. 6,039,974; 6,037,353; 5,738,872; 6,187,791; 5,855,912; 6,113,942; 6,147,216; 6,242,606; 5,663,353; 5,618,940; 5,631,375; 5,644,061; 5,650,516; 5,652,370; 5,654,433; and 5,675,009.

15. By Order dated March 26, 2002, Civil Action Nos. 01-CV-4257 (D.N.J.) and 02-CV-401 (D.N.J.) were consolidated into Civil Action No. 01-CV-3627 (D.N.J.).

16. On March 5, 2004, Aventis and AMR Technology, Inc. filed Civil Action No. 04-CV-1064 (D.N.J.) against Barr, Ranbaxy Laboratories Limited, and Ranbaxy Pharmaceuticals, Inc., alleging infringement of U.S. Patent Nos. 5,581,011 and 5,750,703.

17. On November 14, 2006, Aventis filed an action against Teva Pharmaceuticals, USA, Barr, and Barr Pharmaceuticals, Inc., asserting, inter alia, that Teva USA and Barr have infringed U.S. Patent No. 7,135,571 B2 ("the '571 patent") and that Barr has actively induced Teva USA to infringe the '571 patent. Aventis filed the November 14, 2006 action in the United States District Court for the Eastern District of Texas, and it has been assigned Civil Action No. 2-06CV-469 (E.D. Tx.).

18. The '524 patent, like the '571 patent, claims a particular crystal form of fexofenadine hydrochloride.

19. Aventis has demonstrated that it intends to assert its patents claiming crystal forms of fexofenadine immediately upon issuance.

20. On information and belief, Aventis will assert that the '524 patent is infringed by Barr's 30 mg, 60 mg and 180 mg fexofenadine hydrochloride tablets, the same products that are the subject of Civil Action No. 01-CV-3627 (D.N.J.) and Civil Action No. 04-CV-1064 (D.N.J.).

21. Based on the above, an actual controversy exists between Barr and Aventis with respect to the '524 patent and the sales of Barr's 30 mg, 60 mg and 180 mg fexofenadine hydrochloride tablets.

**COUNT I**  
**DECLARATORY JUDGMENT OF INVALIDITY**

22. The allegations of Paragraphs 1 to 21 are incorporated by reference as if fully set forth herein.

23. The '524 patent is invalid for failure to satisfy the provisions of one or more of sections 101, 102, 103, 112 or 116 of Title 35 of the United States Code.

**COUNT II**  
**DECLARATORY JUDGMENT OF UNENFORCEABILITY**  
**(LACHES)**

24. The allegations of Paragraphs 1 to 23 are incorporated by reference as if fully set forth herein.

25. The '524 patent is unenforceable due to laches, including but not limited to laches during prosecution of the '524 patent before the U.S. Patent & Trademark Office ("PTO").

**COUNT III**  
**DECLARATORY JUDGMENT OF NONINFRINGEMENT**

26. The allegations of Paragraphs 1 to 25 are incorporated by reference as if fully set forth herein.

27. The '524 patent contains a single claim to "Form I anhydrous 4-[4-(4-(hydroxydiphenylmethyl)-1-piperidinyl)-1-hydroxybutyl]- $\alpha,\alpha$ -dimethylbenzeneacetic acid hydrochloride."

28. Barr's fexofenadine hydrochloride tablets have not infringed and do not infringe any valid and properly construed claim of the '524 patent, either literally or under the doctrine of equivalents.

29. Barr's commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of its 30 mg, 60 mg and 180 mg fexofenadine hydrochloride tablets has not infringed and does not infringe any valid and properly construed claim of the '524 patent.

30. Barr has not induced and is not inducing infringement of any valid and properly construed claim of the '524 patent.

**PRAYER FOR RELIEF**

WHEREFORE, Barr respectfully requests the Court enter judgment against Aventis to include:

- A. A declaration that Barr's commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of its 30 mg, 60 mg and 180 mg fexofenadine hydrochloride tablets has not infringed and does not infringe the '524 patent and that Barr has not induced infringement of the '524 patent.
- B. A declaration that the '524 patent is invalid;
- C. A declaration that the '524 patent is unenforceable;
- D. An award of Barr's reasonable costs and attorneys' fees in connection with this action; and
- E. All such other and further relief as the Court may deem just and proper.

Respectfully submitted,

BARR LABORATORIES, INC.

By its attorneys,

  
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November 21, 2006

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