

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BOEHRINGER INGELHEIM PHARMA
GMBH & CO. KG, DR. KARL THOMAE
GMBH, BOEHRINGER INGELHEIM
INTERNATIONAL GMBH, and BOEHRINGER
INGELHEIM PHARMACEUTICALS, INC.,

Plaintiffs,

v.

BARR LABORATORIES, INC. and
BARR PHARMACEUTICALS, INC.,

Defendants.

C. A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

1. Plaintiff Boehringer Ingelheim Pharma GmbH & Co. KG (“BIPKG”) is a limited partnership organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

2. Plaintiff Dr. Karl Thomae GmbH (“Thomae”) is a private limited liability company organized and existing under the laws of Germany, having a principal place of business at Birkendorfer Strasse 65, 88400 Biberach, Germany.

3. Plaintiff Boehringer Ingelheim International GmbH (“BII”) is a private limited liability company organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

4. Plaintiff Boehringer Ingelheim Pharmaceuticals, Inc. (“BIPI”) is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877.

5. BIPKG, Thomae, BII, and BIPI are wholly owned, directly or indirectly, by a common parent company. BIPKG, Thomae, BII, and BIPI are referred to hereinafter collectively as “Boehringer” or “Plaintiffs.”

6. Upon information and belief, Defendant Barr Laboratories, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 223 Quaker Road, Pomona, New York 10970.

7. Upon information and belief, Defendant Barr Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 223 Quaker Road, Pomona, New York 10970.

8. Upon information and belief, Barr Laboratories, Inc. is a wholly owned subsidiary of Barr Pharmaceuticals, Inc., and the two companies have common officers and directors.

9. Upon information and belief, the acts of Barr Laboratories, Inc. complained of herein were done at the direction of, with the authorization of, and with the cooperation, participation, and assistance of and at least in part for the benefit of Barr Pharmaceuticals, Inc.

10. Barr Laboratories, Inc. and Barr Pharmaceuticals, Inc. are referred to hereinafter collectively as “Barr.”

JURISDICTION AND VENUE

11. This action arises under the patent laws of the United States of America, and jurisdiction exists under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391(c) and 1400(b).

12. Barr is subject to jurisdiction in this Court based upon, *inter alia*, its presence in this District.

CLAIM FOR RELIEF

13. Boehringer is the holder of New Drug Application (“NDA”) No. 20-884, by which the United States Food and Drug Administration (“FDA”) first granted approval for 200 mg extended-release dipyridamole / 25 mg acetylsalicylic acid (“aspirin”) capsules. The dipyridamole/aspirin capsules described in Boehringer’s NDA are prescribed to reduce the risk of stroke in patients who have had transient ischemia of the brain or completed ischemic stroke due to thrombosis. Boehringer sells these capsules in the United States under the tradename “AGGRENOX®.”

14. BIPKG and Thomae own United States Patent No. 6,015,577 (“the ’577 patent”), which was duly and legally issued on January 18, 2000, and is titled “Pharmaceutical Compositions Containing Dipyridamole or Mopidamol and Acetylsalicylic Acid or the Physiologically Acceptable Salts Thereof, Processes for Preparing Them and Their Use in Treating Clot Formation.” BII has an exclusive license under the ’577 patent in the United States from BIPKG. BIPI has a license under the ’577 patent from BII.

15. A copy of the ’577 patent is attached as Exhibit A.

16. Upon information and belief, Barr filed with the FDA Abbreviated New Drug Application (“ANDA”) No. 78-804, which included a certification with respect to the ’577 patent under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), seeking approval to manufacture, use, and sell 200 mg extended-release dipyridamole / 25 mg aspirin capsules (“the ANDA product”) prior to the expiration of that patent.

17. On or about May 31, 2007, Barr sent a letter (“Notice Letter”) to BIPKG, Thomae, BIPI, and Boehringer Ingelheim Corporation in which Barr represented that it had filed an ANDA for the ANDA product, including the certification with respect to the ’577 patent, and that it sought approval of its ANDA prior to the expiration of that patent.

18. Because Barr seeks approval of its ANDA to engage in the commercial manufacture, use, or sale of a drug claimed in the ’577 patent before its expiration, Barr has infringed the ’577 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

19. The Notice Letter does not dispute that claims 2, 4, 6, 8, 12-14, and 16-20 of the ’577 patent cover the ANDA product. At least claims 2, 4, 6, 8, 12-14, and 16-20 of the ’577 patent encompass within their scope the ANDA product. The ANDA product would literally infringe at least those claims.

20. Boehringer is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Barr’s ANDA be a date that is not earlier than the expiration date of the ’577 patent, or any later expiration of exclusivity for the ’577 patent to which Boehringer is or becomes entitled.

21. Upon information and belief, Barr was aware of the existence of the ’577 patent and was aware that the filing of its ANDA and certification with respect to the ’577 patent constituted an act of infringement of that patent.

22. Barr’s statement of the factual and legal bases for its opinion regarding the invalidity of the ’577 patent is devoid of any objective good-faith basis in either the facts or the law.

23. This case is an exceptional one, and Boehringer is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

24. Plaintiffs request that:

a. Judgment be entered that Defendants have infringed the '577 patent by submitting the aforesaid ANDA;

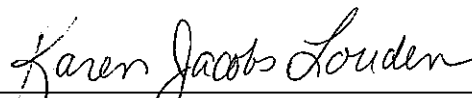
b. Judgment be entered that this case is exceptional, and that Plaintiffs are entitled to their reasonable attorney fees pursuant to 35 U.S.C. § 285;

c. A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining said Defendants, their officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of the drugs or methods of administering drugs claimed in the '577 patent;

d. An order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 78-804 be a date that is not earlier than the expiration date of the '577 patent, or any later expiration of exclusivity for the '577 patent to which Plaintiffs are or become entitled; and

e. For such other and further relief as the Court may deem just and proper under the circumstances.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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