

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI

BOEHRINGER INGELHEIM PHARMA GMBH &)
CO. KG,)
BOEHRINGER INGELHEIM VETMEDICA,)
GMBH, and) **Case No. 4:08-cv-00780-DGK**
BOEHRINGER INGELHEIM VETMEDICA, INC.,)
Plaintiffs,)
)
)
v.)
)
)
NORBROOK LABORATORIES LIMITED, and)
NORBROOK, INC.,)
Defendants,)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Boehringer Ingelheim Pharma GmbH & Co. KG, Boehringer Ingelheim Pharmaceuticals Vetmedica, GmbH, and Boehringer Ingelheim Vetmedica, Inc., by its attorneys, for their Complaint against Norbrook Laboratories Limited and Norbrook Inc. (collectively "Norbrook" or "Defendants"), allege as follows:

NATURE OF ACTION

This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of Defendants' filing of an Abbreviated New Animal Drug Application ("ANADA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell in the United States a generic version of the Plaintiffs' animal drug product Metacam®, prior to the expiration of U.S. Patent No. 6,184,220 ("the '220 patent"). Metacam® is a veterinary pharmaceutical designed to treat inflammation associated with osteoarthritis in animals.

PARTIES

1. Plaintiff Boehringer Ingelheim Pharma GmbH & Co. KG ("BIPH") is a limited partnership organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim am Rhein, Federal Republic of Germany.

2. Plaintiff Boehringer Ingelheim Vetmedica GmbH ("BIVH") is a corporation organized and existing under the laws of Germany, having its principal place of business at Binger Strasse 173, 55216 Ingelheim am Rhein, Federal Republic of Germany.

3. Plaintiff Boehringer Ingelheim Vetmedica, Inc. ("BIVI") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business in this District (St. Joseph Division) at 2621 North Belt Highway, St. Joseph, Missouri 64506. BIVI is a leading supplier of animal health products for livestock producers and veterinarians in this District and across the United States.

4. BIPH, BIVH, and BIVI are referred to hereinafter collectively as "Boehringer" or "Plaintiffs."

5. Upon information and belief, Defendant Norbrook Laboratories Limited is a corporation organized under the laws of Northern Ireland, with its headquarters and principal place of business at Station Works, Newry BT35 GJP, County Down, Northern Ireland.

6. Upon information and belief, Defendant Norbrook Inc. is a subsidiary or division of Norbrook Laboratories Limited, having a place of business located at 3517 Enterprise Drive, Suite D, Kansas City, Missouri 64129.

7. Upon information and belief, Norbrook Inc. is controlled and/or dominated by Norbrook Laboratories Limited, which conducts its U.S. operations, in whole or in part, through Norbrook Inc.

8. Upon information and belief, Norbrook Inc. acts as the agent of Norbrook Laboratories Limited with respect to filings and interactions with the FDA, including in connection with ANADA products, and with respect to the marketing and sale of Norbrook's generic animal drug products in the United States. Upon information and belief, Norbrook Inc. has acted as the agent of Norbrook Laboratories Limited in connection with the filing of the ANADA at issue in this case.

9. Norbrook Laboratories Limited and Norbrook Inc. are referred to hereinafter collectively as “Norbrook.”

JURISDICTION AND VENUE

10. This action arises under the patent laws of the United States of America, 35 U.S.C. § 1 *et seq.*

11. This court has jurisdiction over the subject matter of this dispute pursuant to 28 U.S.C. §§ 1331 and 1338(a).

12. Upon information and belief, personal jurisdiction over Norbrook Laboratories Limited is proper in this District because Norbrook Laboratories Limited regularly transacts business within this District in a substantial and continuous way, including but not limited to, regularly directing the operations and management of Norbrook Inc. within this District, as well as developing, manufacturing, selling and shipping products that are distributed and sold in this District including by Norbrook Inc. Norbrook Inc.’s acts and contacts within this District, as agent of Norbrook Laboratories Limited, are attributable to Norbrook Laboratories Limited for jurisdictional purposes.

13. Upon information and belief, personal jurisdiction over Norbrook Inc. is proper in this District because Norbrook Inc. regularly transacts business within this District in a substantial and continuous way, including but not limited to, having a place of business in this District at 3517 Enterprise Drive, Suite D, Kansas City, Missouri 64129 as well as receiving shipments of animal health products from Norbrook Laboratories Limited and distributing such products within the United States generally, and within this District specifically.

14. Upon information and belief, Norbrook manufactures products for, and markets, distributes and sells those products to, distributors of animal health products based in this District, including, but not limited to, AgriLabs, Durvet, Vedco and Phoenix Pharmaceuticals.

15. Upon information and belief, the Norbrook website regularly and routinely advertises and solicits commercial activity in this District and the state of Missouri, including by permitting Missouri residents to solicit Norbrook product information and offering residents of the state of Missouri opportunities for employment with Norbrook, including within this state.

16. Venue in this judicial district is proper in this Court under 28 U.S.C. §§ 1391(b) and (c) and 28 U.S.C. § 1400(b).

BACKGROUND

17. U.S. Patent No. 6,184,220 (“’220 patent”) entitled “Oral Suspension of Pharmaceutical Substance” was duly and legally issued on February 6, 2001. A true and correct copy of the ‘220 patent is attached as Exhibit A. BIPH is the owner and assignee of the ‘220 patent. BIVH is the exclusive licensee and BIVI is the exclusive sub-licensee of the ‘220 patent.

18. On April 15, 2003, the FDA approved Boehringer’s New Animal Drug Application (“NADA”) No. 141-213 for novel oral suspension formulations containing the active pharmaceutical ingredient meloxicam which are sold under the trademarks and trade names Metacam® for the control of inflammation associated with osteoarthritis in dogs. BIVI is Boehringer’s sponsor of NADA No. 141-23.

19. The ‘220 patent is listed in the FDA’s *Approved Animal Drug Products* (the “Green Book”) for Metacam Oral Suspension.

20. On or about October 6, 2008, Norbrook sent a letter (“Letter No. 1”) which was not addressed to either the patent owner (BIPH) or the holder of Boehringer’s approved NADA No. 141-213 (BIVI), but to “Boehringer Ingelheim Pharmaceuticals, Inc” (“BIPI”).

21. In this letter, Norbrook purported to notify BIPI that Norbrook Laboratories Limited had submitted an application seeking FDA approval for a generic meloxicam oral suspension drug product (“the Product”). Letter No. 1 also indicated that Norbrook’s application

included a "Paragraph IV certification" that the Product would not infringe the claims of the '220 patent.

22. Norbrook's Letter No.1, however, contained certain inconsistencies as to the ingredients of the Product and the type of application which had been filed, including by referring to 21 C.F.R. § 314.95(b) and other statutory provisions for human drugs.

23. On October 24, 2008, Boehringer sent a letter to Norbrook requesting, *inter alia*, clarification of the inconsistencies as well as certain specific documentary and other information necessary to a full assessment and understanding of Norbrook's Product, formulation process, and infringement of the '220 patent. To facilitate exchange of this information, Boehringer offered to enter into a suitable confidentiality agreement with Norbrook.

24. On or about November 5, 2008, Norbrook sent a second letter substantially similar to Letter No.1 which again purported to correct certain of the identified inconsistencies and notify Boehringer that an ANADA application (No. JINAD 011-502) had been submitted for FDA approval which contained a "Paragraph IV certification" ("Letter No. 2"). Norbrook's Letter No. 2 further included a copy of a published patent application which purportedly covered the Product, but did not provide the documentation requested by Boehringer.

25. After receiving Norbrook's Letter No. 2 via facsimile, Boehringer reiterated by email their request for the information specified in their October 24 letter and provided a proposed confidentiality agreement to facilitate the disclosure. Norbrook has not provided access to the requested documentation.

CLAIM FOR RELIEF

26. On information and belief, upon receipt of final approval from the FDA, Norbrook intends to market and sell the Product in the United States, including within this District.

27. Upon information and belief, Norbrook's filing of its ANADA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or

importation into the United States of the Product prior to the expiration of the '220 patent is an act of infringement of that patent under 35 U.S.C. § 271(e)(2).

28. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Norbrook's Product would infringe one or more claims of the '220 patent under 35 U.S.C. § 271.

29. Unless defendant Norbrook is enjoined from infringing the '220 patent, Boehringer will suffer irreparable injury.

WHEREFORE, Plaintiffs request the following relief:

- (a) a judgment that the '220 patent is infringed under 35 U.S.C. § 271(e)(2) by Norbrook's filing of their ANADA;
- (b) a judgment that the commercial manufacture, use, offer to sell, sale or importation of Norbrook's Product will infringe the '220 patent under 35 U.S.C. § 271;
- (c) an order that the effective date of FDA approval of Norbrook's ANADA be not earlier than the expiration date of the '220 patent, inclusive of any extension(s) and additional periods of exclusivity;
- (d) a preliminary and/or permanent injunction prohibiting Norbrook, and all persons acting in concert with Norbrook, from infringing, actively inducing the infringement of, or contributing to the infringement by others of the '220 patent through the commercial manufacture, use, sale, offer for sale, marketing, distribution, or importation into the United States of Norbrook's Product, or any product which infringes one or more claims of the '220 patent, prior to the expiration date of the '220 patent, inclusive of any extension(s) and additional period(s) of exclusivity;
- (e) damages and/or other monetary relief pursuant to 35 U.S.C. § 284 in the event of any commercial manufacture, use, offer for sale, or sale of compositions falling within the scope of one or more claims of the '220 Patent by Norbrook;
- (f) an award of Plaintiffs' interest, costs, expenses, reasonable attorneys' fees and such other relief as the Court deems just and proper pursuant to 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285; and
- (g) such further and other relief as the Court may deem just and proper.

Respectfully submitted,

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