

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

BAYER HEALTHCARE LLC,)
)
 Plaintiff,)
)
 v.)
)
 NORBROOK LABORATORIES)
 LIMITED and NORBROOK, INC. USA,)
)
 Defendants.)

Case No.: 08-CV-2556 KHV/DJW

COMPLAINT

Plaintiff Bayer HealthCare LLC, by its attorneys, for its Complaint, alleges as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the 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 injectible, animal drug product BAYTRIL[®] 100, prior to the expiration of U.S. Patent No. 5,756,506 (“the ‘506 patent”).

PARTIES

2. Plaintiff Bayer HealthCare LLC (“Bayer”) is a limited liability corporation having its Animal Healthcare Division located at 12809 Shawnee Mission Parkway, Shawnee Mission, Kansas 66216. Bayer sells the injectible animal drug product BAYTRIL[®] 100 pursuant to a New Animal Drug Application (“NADA”) held by Bayer which has been approved by the FDA.

3. Upon information and belief, defendant Norbrook Laboratories Limited is a corporation organized under the laws of Northern Ireland, with its headquarters at Station Works, Newry BT35 GJP, Country Down, Northern Ireland.

4. According to its Web site, available at http://www.norbrook.co.uk/company/company.cfm/section/company_info (last checked October 23, 2008), “Norbrook Laboratories Ltd has grown to be one of the world’s leading pharmaceutical companies. With manufacturing facilities on four continents and sales and marketing offices in over 30 countries, the company exports to more than 120 countries worldwide. . . . The Company has a particularly large veterinary division and is the only company in the world licensed by the food and drug administration of the United States to manufacture sterile injections for veterinary use outside the USA and import same for sale in USA territory.”

5. Upon information and belief, defendant Norbrook Inc. USA is a subsidiary or division of Norbrook Laboratories Limited, with a facility located at 9733 Loiret Boulevard, Lenexa, Kansas 66219. Unless otherwise indicated, Norbrook Inc. USA and Norbrook Laboratories Limited are referred to hereinafter collectively as “Norbrook”.

6. According to the Web site of Norbrook Laboratories Limited, available at http://www.norbrook.co.uk/global/global.cfm/section/facilities_usa (last checked October 23, 2008), “Norbrook Inc USA is now a leader in the veterinary pharmaceutical industry with its ultra modern facility based in Kansas City, Kansas. Growing rapidly in market share in the US, it is the world leader in procaine penicillin and oxytetracycline. . . . It has a strong pipeline of products available for the US market. Norbrook can truly claim to be one of the most competitive veterinary pharmaceutical companies in the US giving it a very bright future.”

7. Upon information and belief, Norbrook Inc. USA 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. Norbrook Inc. USA has acted as the agent of

Norbrook Laboratories Limited in connection with the filing of ANADAs, and, upon information and belief, acted as the agent of Norbrook Laboratories Limited in connection with the filing of the ANADA at issue in this case.

8. Upon information and belief, Norbrook Inc. USA is controlled and/or dominated by Norbrook Laboratories Limited.

9. Upon information and belief, Norbrook Laboratories Limited conducts its U.S. operations, in whole or in part, through Norbrook Inc. USA.

JURISDICTION AND VENUE

10. Jurisdiction and venue are proper in this district pursuant to 28 U.S.C. §§ 1331, 1338(a), 1391, 1400(b), and 2201.

11. Upon information and belief, Norbrook Laboratories Limited regularly transacts business within this District in a substantial, continuous and systematic way, including but not limited to, regularly directing the operations and management of Norbrook Inc. USA, as well as shipping products to Norbrook Inc. USA from locations outside the District for distribution by Norbrook Inc. USA within the United States generally, and within this District specifically.

12. Upon information and belief, the acts of Norbrook Laboratories Limited complained of herein were done, in whole or in part, with the cooperation, participation, assistance of, and/or for the benefit of Norbrook Inc. USA.

13. Norbrook Inc. USA's acts and contacts within this District, as agent of Norbrook Laboratories Limited, are attributable to Norbrook Laboratories Limited for jurisdictional purposes.

14. Norbrook Laboratories Limited is subject to personal jurisdiction in this District by virtue of all contacts in the District referenced herein, including, *inter alia*, its placement of Norbrook Inc. USA in this District, its regular conduct of business in this District, its purposeful

availment of the rights and benefits of Kansas law, and its substantial, continuous, and systematic contacts with the State.

15. Norbrook Inc. USA is subject to personal jurisdiction in this District. It regularly transacts business within this District in a substantial, continuous and systematic way, including by having its principal place of business in this District, which, on information and belief, regularly markets, sells, receives and/or sends animal drug products to and from this District and regularly serves as the agent for Norbrook Laboratories Limited in the marketing and sale of generic animal drugs and before the FDA in connection with applications to sell generic animal drug products in the United States, including in this District.

COUNT I

16. Plaintiff Bayer incorporates each of the preceding paragraphs 1-15 as if fully set forth herein.

17. The '506 patent, entitled "Single High Dose Fluoroquinolone Treatment," which is attached hereto as **Exhibit A**, was duly and legally issued on May 26, 1998 to Bayer Corporation, as assignee of Dennis D. Copeland, Kathleen M. Ewert, and Terry S. Wollen, all of Kansas.

18. The '506 patent has subsequently been assigned to Plaintiff Bayer.

19. Plaintiff Bayer owns the '506 patent and will be substantially and irreparably damaged by infringement of the '506 patent.

20. The use of BAYTRIL[®] 100 is covered by one or more claims of the '506 patent, and the '506 patent has been listed in connection with that drug product in *FDA Approved Animal Drug Products*, also known as the "Green Book."

21. By letter addressed to "Bayer USA, Corporate Communications" and received on September 29, 2008 (the "Notice Letter"), defendant Norbrook Laboratories Limited notified

Bayer that Norbrook Laboratories Limited had submitted an ANADA, No. 011-557, seeking approval for a generic animal drug product which contains enrofloxacin to treat cattle with bovine respiratory disease (the “ANADA Product”). The Notice Letter also stated that Norbrook had submitted to the FDA a “Paragraph IV certification” with respect to the ‘506 patent. Upon information and belief, the purpose of the ANADA and Paragraph IV certification was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation into the United States of an animal drug product which contains enrofloxacin to treat cattle with bovine respiratory disease prior to the expiration of the ‘506 patent.

22. The Notice Letter stated that Norbrook made “a Paragraph IV certification” and that ANADA No. 011-557 was submitted under “Section 505(b)(2)” of Title 21 of the FDCA, which provides for submission of an abbreviated new human drug application. Upon information and belief, Norbrook intended to provide notice to Bayer that it had submitted a certification pursuant to Section 512(n)(1)(H)(iv) of the FDCA, 21 U.S.C. § 360b(n)(1)(H)(iv), which is the parallel provision governing abbreviated new animal drug applications. In any event, upon information and belief, Norbrook submitted ANADA No. 011-557 to the FDA with a certification that, in Norbrook’s view, the ‘506 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale and/or importation into the United States of Norbrook’s ANADA Product prior to the expiration of the ‘506 patent.

23. Norbrook has knowledge of the ‘506 patent.

24. 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 Norbrook’s ANADA Product prior to the expiration of the ‘506 patent is an act of infringement of that patent under 35 U.S.C. § 271(e)(2).

25. The use of Norbrook's ANADA Product in a single, high dose to treat cattle with bovine respiratory disease would infringe one or more claims of the '506 patent.

26. Upon information and belief, the use of Norbrook's ANADA Product as described in Norbrook's proposed labeling for that product would infringe one or more claims of the '506 patent.

27. Upon information and belief, the use of Norbrook's ANADA Product as described in Norbrook's proposed labeling will encourage, suggest, teach, and/or induce the product's use in a single, high dose to treat cattle with bovine respiratory disease.

28. Upon information and belief, Norbrook will engage in the commercial manufacture, use, offer for sale, sale and/or importation into the United States of Norbrook's ANADA Product, with its proposed labeling, immediately and imminently upon approval of ANADA No. 011-557.

29. Upon information and belief, Norbrook plans and intends to, and will, actively induce infringement of the '506 patent when its ANADA is approved, and plans and intends to and will, do so immediately and imminently upon approval.

30. Upon information and belief, Norbrook knows that its ANADA Product and its proposed labeling are especially made or adapted for use in infringing the '506 patent, and that Norbrook's ANADA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Norbrook plans and intends to, and will, contribute to infringement of the '506 patent immediately and imminently upon approval of ANADA No. 011-557.

31. The foregoing actions by Norbrook constitute and/or will constitute infringement of the '506 patent under 35 U.S.C. § 271(e)(2), active inducement of infringement of the '506

patent under 35 U.S.C. § 271(b), and contribution to the infringement by others of the '506 patent under 35 U.S.C. § 271(c).

32. Upon information and belief, Norbrook acted without a reasonable basis for believing that it would not be liable for infringement of the '506 patent, actively inducing infringement of the '506 patent, and contributing to the infringement by others of the '506 patent.

33. Unless defendant Norbrook is enjoined from infringing the '506 patent, actively inducing infringement of the '506 patent, and contributing to the infringement by others of the '506 patent, Bayer will suffer irreparable injury. Bayer has no adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Norbrook has infringed the '506 patent, will actively induce infringement of the '506 patent, and will contribute to the infringement by others of the '506 patent.

(b) A judgment ordering that the effective date of any FDA approval for Norbrook to commercially make, use, offer to sell, sell, or import into the United States Norbrook's ANADA Product be not earlier than the expiration date of the '506 patent;

(c) A preliminary and permanent injunction enjoining 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 '506 patent through the making, using, selling, offering for sale, marketing, distributing, or importing into the United States of Norbrook's ANADA Product, or any product the use of which infringes the '506 patent, prior to the expiration date of the '506 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing into the United States of Norbrook's ANADA Product, or any product the use of which infringes the '506 patent, prior to the expiration date of the '506 patent, will actively induce infringement of and will contribute to the infringement by others of the '506 patent;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) Costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

DESIGNATION OF PLACE OF TRIAL

Plaintiff hereby designates Kansas City, Kansas as the place of trial in this case.

Respectfully submitted,

POLSINELLI SHALTON FLANIGAN SUELTHAUS PC

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