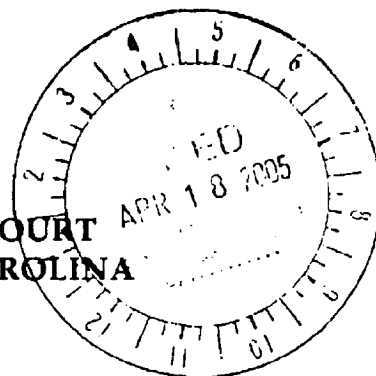


IN THE UNITED STATES DISTRICT COURT
FOR MIDDLE DISTRICT OF NORTH CAROLINA
GREENSBORO DIVISION



BANNER PHARMACAPS INC.)
)
Plaintiff,)
v.)
)
RANBAXY LABORATORIES LTD. and)
RANBAXY LABORATORIES INC.)
)
Defendants.)

Civil Action No. :

1:05CV00346

COMPLAINT

Plaintiff BANNER PHARMACAPS INC. (hereinafter "Banner") for its complaint against Defendant RANBAXY LABORATORIES LTD. (hereinafter "Ranbaxy Ltd.") and Defendant RANBAXY LABORATORIES INC. (hereinafter "Ranbaxy Inc."), alleges as follows:

NATURE OF ACTION

1.

This is an action by Banner against Ranbaxy Ltd. and Ranbaxy Inc. for infringement of United States Patent No. 6,251,426 (the "426 Patent"). This

action relates to a New Drug Application (hereinafter "NDA") that Ranbaxy Ltd. filed with the United States Food and Drug Administration (hereinafter the "FDA") for approval to engage in the commercial manufacture, use, or sale of drug products containing ibuprofen.

PARTIES

2.

Plaintiff Banner is a Delaware corporation having a place of business at 4100 Mendenhall Oaks Parkway, Suite 301, High Point, North Carolina 27265. Banner is engaged in the business of designing, manufacturing, offering for sale, and selling various pharmaceutical products, including soft gelatin capsules and fill compositions containing ibuprofen.

3.

Defendant Ranbaxy Ltd. is an Indian company based in New Delhi, India, and has a place of business at 600 College Road East, Princeton, New Jersey 08540. Upon Banner's information and belief, Ranbaxy Ltd. is engaged in the business of developing, manufacturing, and selling various pharmaceutical capsules, tablets, and suspensions.

4.

Defendant Ranbaxy Inc. is a subsidiary of Ranbaxy Ltd. and has a place of business at 600 College Road East, Princeton, New Jersey 08540. Upon Banner's information and belief, Ranbaxy Inc. is engaged in the business of developing, manufacturing, and selling various pharmaceutical capsules, tablets, and suspensions.

JURISDICTION AND VENUE

5.

This patent infringement action is based on the Patent Laws of the United States, Title 35 of the United States Code, including in particular, §§ 271, 281, 283, 284, and 285. This Court has jurisdiction over the subject matter of this action under Title 28 of the United States Code §§ 1331 and 1338.

6.

Venue is proper in this Court under the provisions of Title 28 of the United States Code §§ 1391 and 1400(b).

FACTUAL BACKGROUND

7.

Before September 2, 1999, Rampurna Prasad Gullapalli (hereinafter the "inventor") conceived of new and unobvious inventions pertaining to soft gelatin capsules containing ibuprofen.

8.

The inventor filed a patent application on September 2, 1999 pertaining to soft gelatin capsules containing ibuprofen. On June 26, 2001, the United States Patent and Trademark Office duly and legally issued the '426 Patent, which expires on September 2, 2019. Banner has attached hereto a copy of the '426 Patent as Exhibit A.

9.

By Assignment, the inventor assigned the entire right, title, and interest in and to the invention, the application, all divisions, substitutes, and continuations thereof, and all patents that resulted therefrom, including the '426 Patent, to Banner. Banner is the owner and assignee of all rights to recover for past, present, and future infringement of the '426 Patent.

10.

Banner holds approved NDA No. 21-472 for capsules containing 200 mg of ibuprofen. Under its approved NDA, Banner sells one or more ibuprofen containing products in the United States. The FDA's official publication of approved drugs (hereinafter the "Orange Book") includes Banner's ibuprofen capsules listed with the '426 Patent. Banner has attached hereto the electronic Orange Book information for NDA No. 21-472 as Exhibit B.

11.

On March 4, 2005, Banner received from Ranbaxy Ltd. a letter (hereinafter the "Notice Letter") in which Ranbaxy Ltd. notified Banner that Ranbaxy Ltd. had submitted NDA No. 21-863 to the FDA proposing drug products in the form of liquid-filled gelatin capsules that contain 200 mg of ibuprofen. Banner has attached hereto Ranbaxy Ltd.'s Notice Letter as Exhibit C.

12.

Ranbaxy Ltd.'s NDA seeks approval from the FDA under Section 505(b)(2) of the Food, Drug and Cosmetic Act (hereinafter the "F.D.C.A."), 21 U.S.C. § 355(b)(2), to engage in the commercial manufacture, use, or sale of drug products containing ibuprofen before expiration of the '426 Patent.

13.

In the Notice Letter, Ranbaxy Ltd. notified Banner that as part of its NDA, Ranbaxy Ltd. had certified under paragraph (iv) of F.D.C.A. § 505(b)(2)(A), 21 U.S.C. § 355(b)(2), that Ranbaxy Ltd.'s manufacture, use, sale, or offer to sell of drug products described in Ranbaxy Ltd.'s NDA would not infringe the '426 Patent.

14.

Upon Banner's information and belief, one or more claims of the '426 Patent would be infringed by the liquid-filled gelatin capsules containing 200 mg of ibuprofen described in Ranbaxy Ltd.'s NDA.

15.

Upon Banner's information and belief, Ranbaxy Inc. has induced, caused, actively encouraged, or directed Ranbaxy Ltd. to file NDA No. No. 21-863 with the FDA.

16.

Under F.D.C.A. § 505(c)(3)(C), 21 U.S.C. § 355(c)(3)(C), Banner has brought this action before the expiration of forty-five days from the date of receipt of Ranbaxy Ltd.'s March 4, 2005 Notice Letter.

COUNT I
PATENT INFRINGEMENT

17.

Banner reasserts, realleges, and incorporates herein Paragraphs 1-16.

18.

Ranbaxy Ltd. has filed NDA No. 21-863 in order to obtain FDA approval to engage in the commercial manufacture, use, or sale of a drug product that would infringe one or more claims of the '426 Patent before the expiration of that Patent. Ranbaxy Ltd.'s act of filing NDA No. 21-863 is an act of infringement of the '426 Patent under 35 U.S.C. § 271(e)(2)(A).

19.

Ranbaxy Ltd.'s commercial manufacture, use, offer for sale, sale, or import of the liquid-filled gelatin capsules described in NDA No. 21-863 will infringe the '426 Patent under 35 U.S.C. § 271(a).

20.

Unless Ranbaxy Ltd. is enjoined from infringing the '426 Patent, Banner will suffer irreparable injury. Banner has no adequate remedy at law.

21.

When Ranbaxy Ltd. filed NDA No. 21-863 seeking FDA approval to commercially manufacture, use, or sell liquid-filled gelatin capsules containing ibuprofen, Ranbaxy Ltd. was aware of the unexpired '426 Patent and that filing of NDA No. 21-863 constituted an act of infringement. Ranbaxy Ltd. acted without a reasonable basis for believing that it would not be liable for infringement of the '426 Patent. Ranbaxy Ltd.'s infringement of '426 Patent was therefore willful and deliberate.

COUNT II

INDUCEMENT OF PATENT INFRINGEMENT

22.

Banner reasserts, realleges, and incorporates herein Paragraphs 1-21.

23.

Upon information and belief, Ranbaxy Inc. has infringed the '426 Patent under 35 U.S.C. § 271(b) by actively inducing Ranbaxy Ltd. to infringe the '426 Patent.

24.

When Ranbaxy Ltd. filed NDA No. 21-863 seeking FDA approval to commercially manufacture, use, or sell liquid-filled gelatin capsules containing ibuprofen, Ranbaxy Inc. was aware of the unexpired '426 Patent and that filing of NDA No. 21-863 constituted an act of infringement. Ranbaxy Inc. acted without a reasonable basis for believing that it would not be liable for infringement of the '426 Patent. Ranbaxy Inc.'s infringement of '426 Patent was therefore willful and deliberate.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Banner prays that the following be entered:

1.

A judgment in its favor providing that the effective date of any FDA approval for Ranbaxy Ltd. to make, use, sell, offer for sale, or import the Ranbaxy Ltd.'s liquid-filled gelatin capsules described in NDA No. 21-863 be no earlier than September 2, 2019, the date on which the '426 Patent expires.

2.

A judgment that Ranbaxy Ltd., its officers, agents, servants, employees, and all others in active concert or participation with Ranbaxy Ltd. be preliminarily and permanently enjoined and restrained from selling, offering to sell, or importing into the United States the Ranbaxy Ltd. liquid-filled gelatin capsules described in NDA No. 21-863 until after the expiration of the '426 Patent.

3.

A judgment in its favor that Ranbaxy Inc. induced infringement of the '426 Patent.

4.

A judgment in its favor that Ranbaxy Ltd.'s infringement of the '426 Patent was willful and deliberate.

5.

A judgment in its favor that Ranbaxy Inc.'s infringement of the '426 Patent was willful and deliberate.

6.

A determination that this is an exceptional case under 35 U.S.C. § 285.

7.

A judgment that Ranbaxy Ltd. and/or Ranbaxy Inc. be required to pay to Banner the cost of this action, interest, and Banner's reasonable attorney fees and disbursements.

8.

A judgment awarding Banner its damages.

9.

A determination that Banner have such other and further legal and equitable relief as this Court deems just and equitable.

This the 18th day of April, 2005.

Respectfully submitted,



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