IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Case No.

BAYER SCHERING PHARMA AG and BAYER HEALTHCARE PHARMACEUTICALS INC.,

Plaintiffs,

v.

SANDOZ, INC.

Defendant.

COMPLAINT FOR PATENT INFRINGEMENT AND JURY DEMAND

Plaintiffs Bayer Schering Pharma AG and Bayer HealthCare Pharmaceuticals Inc., for their Complaint for patent infringement herein against Defendant Sandoz, Inc., allege as follows:

JURISDICTION AND VENUE

1. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

2. Personal jurisdiction over the defendants in Colorado is proper under C.R.S. § 13-1-124 and the United States Constitution because defendant is transacting business in this jurisdiction. Defendant has further submitted to the jurisdiction of the Courts of the State of Colorado by virtue of its incorporation under the laws of this State.

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

PARTIES

4. Plaintiff Bayer Schering Pharma AG ("Bayer Schering"), formerly known as Schering AG, is a corporation organized and existing under the laws of the Federal Republic of Germany, having a principal place of business at Müllerstrasse 178, 13353 Berlin, Germany.

5. Plaintiff Bayer HealthCare Pharmaceuticals Inc. ("Bayer HealthCare"), formerly known as Berlex, Inc., is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045-1000.

6. On information and belief, Defendant Sandoz, Inc. ("Sandoz") is a corporation organized and existing under the laws of the State of Colorado, having a principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540. Sandoz develops, manufacturers and markets generic pharmaceutical products.

7. On information and belief, Sandoz owns and/or operates a manufacturing facility in Broomfield, Colorado, which is within this Judicial District.

8. By virtue of its incorporation under Colorado law, Sandoz is a resident of the State of Colorado.

BACKGROUND

9. Bayer HealthCare is the holder of approved New Drug Application ("NDA") No. 21-676, for YAZ® tablets, which contain as active ingredients micronized drospirenone and micronized 17α -ethinylestradiol. YAZ® tablets have been approved by the United States Food

and Drug Administration ("FDA") for (a) the prevention of pregnancy in women who elect to use an oral contraceptive; (b) the treatment of acne; and (c) premenstrual dysphoric disorder ("PMDD"). YAZ® tablets are sold in the United States by Bayer HealthCare as a 28-day oral contraceptive regimen that contains 24 tablets comprising 3 mg of micronized drospirenone and 0.02 mg of micronized 17α -ethinylestradiol plus 4 placebo tablets.

10. On information and belief, Sandoz submitted to the FDA an Abbreviated New Drug Application ("ANDA") under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of a generic version of Bayer HealthCare's YAZ® tablets. On information and belief, the FDA has assigned this Sandoz ANDA the number 79-221.

11. On information and belief, the composition of the product that is the subject of Sandoz's ANDA contains 3 mg of drospirenone and 0.02 mg of 17α -ethinylestradiol in tablet form for oral contraception in a human female.

12. On information and belief, Sandoz's ANDA seeks approval of a 28-day oral contraceptive regimen that contains 24 tablets comprising 3 mg drospirenone and 0.02 mg 17α – ethinylestradiol plus 4 placebo tablets (hereinafter, "Sandoz's ANDA product").

13. On information and belief, on or about June 19, 2008, Sandoz sent a Notice Letter to Plaintiffs Bayer Schering and Bayer HealthCare, purporting to comply with the provisions of 21 U.S.C. § 355(j)(2)(B) and the FDA regulations relating thereto. Plaintiff Bayer HealthCare received the Notice Letter on or about June 23, 2008. Plaintiff Bayer Schering received the Notice Letter on or about July 2, 2008.

PATENTS-IN-SUIT

14. United States Reissue Patent No. 37,564 ("the '564 reissue patent") is attached to the Complaint as Exhibit 1. Inventors Jürgen Spona, Bernd Düsterberg, and Frank Lüdicke filed their application for this patent on February 15, 2000. The '564 reissue patent was issued February 26, 2002. Bayer Schering is the current owner of the '564 reissue patent.

15. United States Reissue Patent No. 37,838 ("the '838 reissue patent") is attached to the Complaint as Exhibit 2. Inventors Jürgen Spona, Bernd Düsterberg, and Frank Lüdicke filed their application for this patent on February 15, 2000. The '838 reissue patent was issued September 10, 2002. Bayer Schering is the current owner of the '838 reissue patent.

COUNT ONE: CLAIM FOR PATENT INFRINGEMENT OF UNITED STATES REISSUE PATENT NO. 57,564

16. Plaintiffs incorporate each of the preceding paragraphs of this Complaint as if fully set forth here.

17. On information and belief, Sandoz's ANDA product infringes one or more claims of the '564 reissue patent.

18. The '564 reissue patent covers Bayer HealthCare's YAZ® tablets and has been listed for the product in the FDA *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book").

19. On information and belief, Sandoz submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Sandoz's ANDA product before the expiration of the '564 reissue patent.

20. On information and belief, Sandoz made and included in its ANDA a certification under 21 U.S.C. § 355 (j)(2)(A)(vii)(IV) asserting that, in its opinion, the '564 reissue patent is invalid.

21. In its Notice Letter, Sandoz did not allege non-infringement of the claims of the '564 reissue patent.

22. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of its ANDA product before the expiration of the '564 reissue patent, Sandoz has committed an act of infringement under 35 U.S.C. § 271(e)(2).

23. Further, on information and belief, the actual commercial manufacture, use, offer for sale, sale and/or importation of Sandoz's ANDA product will infringe one or more claims of the '564 reissue patent.

24. Plaintiffs Bayer Schering and Bayer HealthCare are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval relating to Sandoz's ANDA shall be a date which is not earlier than June 30, 2014, the current expiration date of the '564 reissue patent, or any later date of exclusivity to which Plaintiffs become entitled. Further, Bayer Schering and Bayer HealthCare are entitled to an award of treble damages for any commercial sale or use of Sandoz's ANDA product, and any act committed by Sandoz with respect to the subject matter claimed in the '564 reissue patent that is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

25. On information and belief, when Sandoz filed its ANDA, it was aware of the '564 reissue patent and was aware that the filing of its ANDA with the request for its approval prior to

the expiration of the '564 reissue patent constituted an act of infringement of the '564 reissue patent.

COUNT TWO: CLAIM FOR PATENT INFRINGEMENT OF UNITED STATES REISSUE PATENT NO. 37,838

26. Plaintiffs incorporate paragraphs 1 - 15 of this Complaint as if fully set forth here.

27. On information and belief, Sandoz's ANDA product infringes one or more claims of the '838 reissue patent.

28. The '838 reissue patent covers Bayer HealthCare's YAZ® tablets and has been listed for the product in the FDA *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book").

29. On information and belief, Sandoz submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Sandoz's ANDA product before the expiration of the '838 reissue patent.

30. On information and belief, Sandoz made and included in its ANDA a certification under 21 U.S.C. § 355 (j)(2)(A)(vii)(IV) asserting that, in its opinion, the '838 reissue patent is invalid.

31. In its notice letter, Sandoz did not allege non-infringement of the '838 reissue patent's claims.

32. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of its ANDA product before the expiration of the '838 reissue patent, Sandoz has committed an act of infringement under 35 U.S.C. § 271(e)(2).

33. Further, on information and belief, the actual commercial manufacture, use, offer for sale, sale and/or importation of Sandoz's ANDA product will also infringe one or more claims of the '838 reissue patent.

34. Plaintiffs Bayer Schering and Bayer HealthCare are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval relating to Sandoz's ANDA shall be a date which is not earlier than June 30, 2014, the current expiration date of the '838 reissue patent, or any later date of exclusivity to which Plaintiffs become entitled. Further, Bayer Schering and Bayer HealthCare are entitled to an award of treble damages for any commercial sale or use of Sandoz's ANDA product, and any act committed by Sandoz with respect to the subject matter claimed in the '838 reissue patent that is not within the limited exclusions of 35 U.S.C. § 271(e)(1)

35. On information and belief, when Sandoz filed its ANDA, it was aware of the '838 reissue patent and was aware that the filing of its ANDA with the request for its approval prior to the expiration of the '838 reissue patent constituted an act of infringement of the '838 reissue patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment that Sandoz has infringed one or more claims of the '564 reissue patent and the '838 reissue patent by filing its ANDA relating to Sandoz's ANDA Product;

B. A permanent injunction restraining and enjoining Sandoz and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into

the United States, of Sandoz's ANDA product;

C. An order that the effective date of any approval of Sandoz's ANDA relating to Sandoz's generic product containing drospirenone and ethinylestradiol be a date which is not earlier than the expiration date of the later of the '564 reissue patent, the '838 reissue patent, or any later date of exclusivity to which Plaintiffs become entitled;

D. Treble damages from Sandoz for any commercial activity constituting infringement of the '564 reissue patent or the '838 reissue patent; and

E. Such other and further relief as the Court may deem just and proper.

JURY DEMAND

Plaintiffs demand a jury trial on all issues so triable.

DATED: August 1, 2008

s/Sundeep K. Addy
Sundeep K. Addy
BARTLIT BECK HERMAN PALENCHAR
& SCOTT LLP
1899 Wynkoop St., 8th Floor
Denver, Colorado 80202
Telephone: (303) 592-3100
Facsimile: (303) 592-3140
E-mail: rob.addy@bartlit-beck.com

Of Counsel:

Peter B. Bensinger, Jr. (*pro hac vice* application to be filed)
Paul J. Skiermont (*pro hac vice* application to be filed)
Adam K. Mortara (*pro hac vice* application to be filed)
BARTLIT BECK HERMAN PALENCHAR
& SCOTT LLP

54 West Hubbard Street
Chicago, Illinois 60610
Telephone: (312) 494-4400
Facsimile: (312) 494-4440
E-mail: peter.bensinger@bartlit-beck.com
E-mail: paul.skiermont@bartlit-beck.com
E-mail: adam.mortara@bartlit-beck.com

Attorneys for Plaintiffs Bayer Schering Pharma AG and Bayer HealthCare Pharmaceuticals Inc.