

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, manufactures 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. 21-098, for Yasmin® tablets, which contain as active ingredients drospirenone and ethinylestradiol. The United States Food and Drug Administration (“FDA”) has approved Yasmin® tablets. Bayer HealthCare sells Yasmin® tablets in the United States as a 28-day oral contraceptive regimen that contains 21 tablets comprising 3 mg of drospirenone and 0.03 mg of ethinylestradiol plus 7 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 Yasmin® tablets. On information and belief, the FDA has assigned this Sandoz ANDA the number 90-114.

11. On information and belief, the composition of the product that is the subject of Sandoz’s ANDA contains 3 mg of drospirenone and 0.03 mg of ethinylestradiol in tablet form for oral contraception in a human female.

12. 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. Plaintiffs received said letter no earlier than March 28, 2008.

PATENT-IN-SUIT

13. The patent-in-suit is United States Patent No. 5,569,652 (“the ‘652 patent”) (attached as Exhibit 1). Inventors Sybille Beier, Walter Elger, Yukishige Nishino, and Rudolf

Wiechert filed their application for this patent on December 7, 1993. The '652 patent issued on October 29, 1996. Bayer Schering is the current owner of the '652 patent.

14. The '652 patent covers certain uses of Bayer HealthCare's Yasmin® tablets and has been listed for the product in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book").

COUNT ONE: CLAIM FOR PATENT INFRINGEMENT OF UNITED STATES PATENT NO. 5,569,652 AGAINST SANDOZ, INC. UNDER 35 U.S.C. §271(E)(2)(A)

15. Plaintiffs incorporate each of the preceding paragraphs of this Complaint as if fully set forth herein.

16. Sandoz's filing of ANDA 90-114 for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer for sale and/or sale, or inducement thereof, of drug products containing drospirenone and ethinylestradiol before the expiration of the '652 patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

17. Sandoz's manufacture, use, importation, offer for sale, and/or sale, or inducement thereof, of its proposed drospirenone and ethinylestradiol drug product will induce infringement of at least one claim of the '652 patent under 35 U.S.C. § 271(e)(2)(A).

18. Upon information and belief, Sandoz is aware, or reasonably should be aware, of the widespread use of Yasmin® (drospirenone and ethinylestradiol) to produce simultaneously a gestagenic, anti-androgenic, and anti-aldosterone effect in premenopausal or menopausal female patients. This use of drospirenone and ethinylestradiol to produce simultaneously these three effects would be readily apparent to customers of Sandoz (*e.g.*, including, without limitation, physicians, pharmacists, pharmacy benefits management companies, health care providers who establish drug formularies for their insurers, and/or patients). Further, by filing its ANDA,

Sandoz has indicated that its ANDA product will be bioequivalent to Plaintiffs' Yasmin® product.

19. Upon information and belief, Sandoz's proposed label for its drospirenone and ethinylestradiol product does not restrict the intended use of its product to the creation of a gestagenic effect in patients. As is well known to Sandoz, a significant proportion of drospirenone and ethinylestradiol prescriptions are written with the intent of producing three pharmacological effects — gestagenic, anti-aldosterone, and anti-androgenic. The beneficial effects of simultaneously and intentionally producing these three effects are well known to Sandoz and customers of Sandoz. On information and belief, Sandoz will be marketing its ANDA product with specific intent, and/or with the desire to actively induce, aid, and abet infringement of the '652 patent. Sandoz knows or reasonably should know that its proposed conduct will induce infringement.

20. Upon information and belief, Sandoz's proposed label provides or will be required by the FDA to provide, information for patients regarding the anti-aldosterone and anti-androgenic properties of drospirenone. By including this information in its proposed label, Sandoz will be marketing its ANDA product with specific intent, and/or with the desire to actively induce, aid, and abet infringement of the '652 patent. Sandoz knows or reasonably should know that its proposed conduct will induce infringement.

21. Drospirenone's pharmacological profile — *i.e.* its three mechanisms of action (gestagen, anti-aldosterone, and anti-mineralocorticoid) — is disclosed in the approved product insert for Yasmin®. The use of drospirenone under conditions where drospirenone will exhibit this pharmacological profile is thus within the scope of the approved product insert.

22. Upon information and belief, Sandoz's generic marketing practices include listing generic products on its website and referring customers (*e.g.*, including, without limitation, physicians, pharmacists, pharmacy benefits management companies, health care providers who establish drug formularies for their insurers, and/or patients) to a corresponding brand name product. Upon information and belief, Sandoz intends to do the same for any approved generic drospirenone and ethinylestradiol product with respect to Bayer HealthCare's Yasmin® tablets.

23. Upon information and belief, Sandoz's generic marketing practices include representing to its customers (*e.g.*, including, without limitation, physicians, pharmacists, pharmacy benefits management companies, health care providers who establish drug formularies for their insurers, and/or patients) that its generic products are bioequivalent to a corresponding brand name product and therefore representing (implicitly or explicitly or both) that Sandoz's generic products are suitable for the same pharmacological uses as the corresponding branded product. Upon information and belief, Sandoz intends to do the same for any approved drospirenone and ethinylestradiol product with respect to Bayer HealthCare's Yasmin® tablets.

24. Upon information and belief, Sandoz has planned and intended to actively induce others to infringe the '652 patent when its ANDA application is approved and plans and intends to do so on approval.

25. Unless Sandoz is enjoined from infringing and inducing the infringement of the '652 patent, Plaintiffs will suffer substantial and irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT TWO: CLAIM FOR PATENT INFRINGEMENT OF UNITED STATES PATENT
NO. 5,569,652 AGAINST SANDOZ, INC. UNDER 35 U.S.C. §271(B)**

26. Plaintiffs incorporate each of the preceding paragraphs of this Complaint as if fully set forth herein.

27. Upon information and belief, approval of ANDA 90-114 is substantially likely to result in the commercial manufacture, use, importation, offer for sale, and/or sale, or inducement thereof, of a drug product which is marketed and sold for use in a method claimed in one or more claims of the '652 patent, immediately or imminently upon approval of the ANDA.

28. Unless Sandoz is enjoined from infringing and inducing the infringement of the '652 patent, Plaintiffs will suffer substantial and irreparable injury. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A declaratory judgment pursuant to 28 U.S.C. § 2201 *et seq.* that making, using, selling, offering to sell and/or importing Defendant's generic drug product containing drospirenone and ethinylestradiol for which Defendant seeks FDA approval will infringe at least one claim of the '652 patent;

B. A declaratory judgment pursuant to 28 U.S.C. § 2201 *et seq.* that inducing the making, using, offering for sale, selling and/or importing of Defendant's generic drug products containing drospirenone and ethinylestradiol, will infringe at least one claim of the '652 patent;

C. A declaratory judgment pursuant to 28 U.S.C. § 2201 *et seq.* and an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval for Defendant to commercially make, use, sell, offer to sell or import its generic drug product

containing drospirenone and ethinylestradiol be no earlier than the date following the expiration date of the '652 patent (as extended, if applicable);

D. A permanent injunction restraining and enjoining Defendant 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 its generic product containing drospirenone and ethinylestradiol;

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

JURY DEMAND

Plaintiffs hereby demand a jury trial on all issues so triable.

Dated: May 12, 2008

s/Sundeep K. Addy
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