

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

BAYER SCHERING PHARMA AG)
 Müllerstrasse 178)
 13353 Berlin, Germany)
)
 BAYER HEALTHCARE)
 PHARMACEUTICALS INC.)
 6 West Belt)
 Wayne, New Jersey 07470)
)
 Plaintiffs,)
)
 v.)
)
 LUPIN LTD.)
 B/4 Laxmi Towers)
 Bandra-Kurla Complex)
 Bandra (A) Mumbai 400 051)
 India)
)
 LUPIN PHARMACEUTICALS, INC.)
 111 South Calvert Street,)
 Baltimore City County)
 Baltimore, Maryland 21202)
)
 Defendants.)

Civil Action No. _____

COMPLAINT

JURY TRIAL DEMANDED

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 Paul J. Skiermont
 Adam K. Mortara
 Sundeep K. Addy
 Matthew R. Ford
 (*pro hac vice* applications to be filed)
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*Attorneys for Plaintiffs Bayer Schering
 Pharma AG and Bayer HealthCare
 Pharmaceuticals Inc.*

Plaintiffs Bayer Schering Pharma AG and Bayer HealthCare Pharmaceuticals Inc. (collectively “Bayer”) bring this Complaint for patent infringement against Defendants Lupin Ltd. and Lupin Pharmaceuticals Inc. (collectively “Lupin”) and allege as follows:

PARTIES

1. 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 in Müllerstrasse 178, 13353 Berlin, Germany.

2. 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 6 West Belt, Wayne, New Jersey 07470.

3. On information and belief, Lupin Ltd. is an Indian corporation having a place of business at B/4 Laxmi Towers, Bandra-Kurla Complex, Bandra (A), Mumbai 400 051, India, and having a registered office at 159 CST Road, Kalina, Santacruz (E), Mumbai 400 098, India. On information and belief, Lupin Ltd. is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products through various operating subsidiaries, including Lupin Pharmaceuticals, Inc.

4. On information and belief, Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the Commonwealth of Virginia, having a place of business at Harborplace Tower, 111 South Calvert Street, Baltimore, Maryland 21202. On information and belief, Lupin Pharmaceuticals, Inc. is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market. Lupin Pharmaceuticals, Inc. is a wholly owned subsidiary and alter ego of Lupin Ltd.

5. On information and belief and consistent with their practice with respect to other generic products, following any FDA approval of an Abbreviated New Drug Application (“ANDA”), Lupin Ltd. and Lupin Pharmaceuticals, Inc. will act in concert to distribute and sell Lupin’s oral-contraceptive

products for ANDA Nos. 20-1661 and 20-1663 throughout the United States, including within Maryland. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals, Inc. know and intend that Lupin's ANDA products for ANDA Nos. 20-1661 and 20-1663 will be distributed and sold in the United States, including within Maryland.

6. On information and belief, and consistent with their practice with respect to other generic products, Lupin Ltd. and Lupin Pharmaceuticals, Inc. acted in concert to prepare and submit ANDA Nos. 20-1661 and 20-1663. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals, Inc. actively participated in the preparation of ANDA Nos. 20-1661 and 20-1663 and both entities submitted these ANDAs to the FDA. On information and belief, Lupin Pharmaceuticals, Inc. acted as the agent of Lupin Ltd. in submitting ANDA Nos. 20-1661 and 20-1663 to the FDA.

JURISDICTION AND VENUE

7. 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).

8. On information and belief, Lupin Ltd. is subject to personal jurisdiction in Maryland because, among other things, Lupin Ltd., itself and through its wholly-owned subsidiary Lupin Pharmaceuticals, Inc., has purposely availed itself of the benefits and protections of Maryland's laws such that it should reasonably anticipate being haled into court here, and because Lupin Ltd. established the principal place of business of its wholly-owned subsidiary Lupin Pharmaceuticals, Inc., in Maryland. On information and belief, Lupin Ltd., itself and through its wholly-owned subsidiary Lupin Pharmaceuticals, Inc., manufactures, markets and sells generic drugs throughout the United States and within the State of Maryland and therefore transacts business within the State of Maryland related to Bayer's claims, and/or has engaged in systematic and continuous business contacts within the State of Maryland. Lupin Ltd. is subject to jurisdiction in Maryland on the basis of its inducement of and/or contribution to Lupin Pharmaceuticals, Inc.'s acts of infringement in Maryland. In addition, Lupin Ltd. is subject to personal jurisdiction in Maryland because, on information and belief, it controls and

dominates Lupin Pharmaceuticals, Inc. and therefore the activities of Lupin Pharmaceuticals, Inc. in this jurisdiction are attributed to Lupin Ltd.

9. On information and belief, this Court has personal jurisdiction over Lupin Pharmaceuticals, Inc. because Lupin Pharmaceuticals, Inc. has its principal place of business in Maryland, is a resident and citizen thereof, and has purposely availed itself of the benefits and protections of Maryland's laws such that it should reasonably anticipate being haled into court here. On information and belief, Lupin Pharmaceuticals, Inc. manufactures, markets and sells generic drugs throughout the United States and within the State of Maryland and therefore transacts business within the State of Maryland related to Bayer's claims, and/or has engaged in systematic and continuous business contacts within the State of Maryland.

10. Venue is proper under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

BACKGROUND

LUPIN'S APPLICATION TO MARKET A GENERIC VERSION OF YAZ®

11. 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 17 α -ethinylestradiol. The United States Food and Drug Administration ("FDA") has approved YAZ® tablets for the prevention of pregnancy in women and for the treatment of moderate acne and the symptoms of premenstrual dysphoric disorder in women who elect to use an oral contraceptive.

12. Bayer HealthCare sells YAZ® tablets in the United States as a 28-day oral contraceptive regimen that contains 24 tablets comprising 3 mg of micronized drospirenone and 0.02 mg of micronized 17 α -ethinylestradiol plus 4 placebo tablets.

13. On information and belief, Lupin submitted to the FDA ANDA No. 20-1661 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's YAZ® tablets.

14. On information and belief, the composition of the product that is the subject of Lupin's

ANDA contains 3 mg of drospirenone and 0.02 mg of ethinylestradiol in tablet form for oral contraception in a human female (hereinafter "Lupin's YAZ® ANDA product").

15. On information and belief, Lupin's ANDA seeks approval of a 28-day oral contraceptive regimen that contains 24 tablets comprising 3 mg of drospirenone and 0.02 mg 17 α -ethinylestradiol plus 4 placebo tablets.

16. On information and belief, on June 2, 2010, Lupin 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.

LUPIN'S APPLICATION TO MARKET A GENERIC VERSION OF YASMIN®

17. Bayer HealthCare is the holder of approved New Drug Application ("NDA") No. 21-098 for Yasmin® tablets, which contain as active ingredients micronized drospirenone and micronized 17 α -ethinylestradiol. The United States Food and Drug Administration ("FDA") has approved Yasmin® tablets.

18. 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.

19. On information and belief, Lupin submitted to the FDA ANDA No. 20-1663 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's Yasmin® tablets.

20. On information and belief, the composition of the product that is the subject of ANDA No. 20-1663 contains 3 mg of drospirenone and 0.03 mg of ethinylestradiol in tablet form for oral contraception in a human female (hereinafter "Lupin's Yasmin® ANDA product").

21. On information and belief, on June 2, 2010, Lupin sent a Notice Letter regarding ANDA No. 20-1663 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.

PATENTS-IN-SUIT

22. The four patents-in-suit are United States Reissue Patent Nos. 37,564, 37,838, 38,253; and United States Patent No. 5,569,652.

23. United States Reissue Patent No. 37,564 (“the ’564 reissue patent”) issued on February 26, 2002. Inventors Jürgen Spona, Bernd Düsterberg, and Frank Lüdicke filed their application for this patent on February 15, 2000. Bayer Schering is the current owner of the ’564 reissue patent. Bayer attaches a true and correct copy of the ’564 reissue patent as Exhibit 1.

24. United States Reissue Patent No. 37,838 (“the ’838 reissue patent”) issued on September 10, 2002. Inventors Jürgen Spona, Bernd Düsterberg, and Frank Lüdicke filed their application for this patent on February 15, 2000. Bayer Schering is the current owner of the ’838 reissue patent. Bayer attaches a true and correct copy of the ’838 reissue patent as Exhibit 2.

25. United States Reissue Patent No. 38,253 (“the ’253 reissue patent”) issued on September 16, 2003. Inventors Jürgen Spona, Bernd Düsterberg, and Frank Lüdicke filed their application for this patent on February 25, 2002. Bayer Schering is the current owner of the ’253 reissue patent. Bayer attaches a true and correct copy of the ’253 reissue patent as Exhibit 3.

26. United States Patent No. 5,569,652 (“the ’652 patent”) issued on October 29, 1996. Inventors Sybille Beier, Walter Elger, Yukishige Nishino and Rudolf Wiechert filed their application for this patent on December 7, 1993. Bayer Schering is the current owner of the ’652 patent. Bayer attaches a true and correct copy of the ’652 patent as Exhibit 4.

**COUNT ONE: CLAIM FOR PATENT INFRINGEMENT OF U.S. REISSUE
PATENT NO. 37,564 BASED ON LUPIN’S YAZ® ANDA**

27. Bayer incorporates paragraphs 1-26 of this Complaint as if fully set forth herein.

28. On information and belief, Lupin’s YAZ® ANDA product infringes one or more claims of the ’564 reissue patent.

29. The ’564 reissue patent covers Bayer HealthCare’s YAZ® tablets, and Bayer has listed

the '564 reissue patent for YAZ® in the FDA *Approved Drug Products and Therapeutic Equivalence Evaluations* ("the Orange Book").

30. On information and belief, Lupin submitted ANDA No. 20-1661 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Lupin's YAZ® ANDA product before the expiration of the '564 reissue patent.

31. On information and belief, Lupin made and included in ANDA No. 20-1661 a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '564 reissue patent is invalid or will not be infringed by the manufacture, use, offer for sale, sale and/or importation of Lupin's YAZ® ANDA product.

32. By filing ANDA No. 20-1661 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 Lupin's YAZ® ANDA product before the expiration of the '564 reissue patent, Lupin has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, on information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Lupin's YAZ® ANDA product will also infringe one or more claims of the '564 reissue patent.

33. 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 ANDA No. 20-1661 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 Bayer becomes entitled. Bayer Schering and Bayer HealthCare are entitled to an award of damages and treble damages for any commercial sale or use of Lupin's YAZ® ANDA product, and any act committed by Lupin 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).

34. On information and belief, when Lupin filed ANDA No. 20-1661, it was aware of the '564 reissue patent and was aware that the filing of ANDA No. 20-1661 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 U.S. REISSUE
PATENT NO. 37,838 BASED ON LUPIN'S YAZ® ANDA**

35. Bayer incorporates paragraphs 1-34 of this Complaint as if fully set forth herein.

36. On information and belief, Lupin's YAZ® ANDA product infringes one or more claims of the '838 reissue patent.

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

38. On information and belief, Lupin submitted ANDA No. 20-1661 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Lupin's YAZ® ANDA product before the expiration of the '838 reissue patent.

39. On information and belief, Lupin made and included in ANDA No. 20-1661 a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '838 reissue patent is invalid or will not be infringed by the manufacture, use, offer for sale, sale and/or importation of Lupin's YAZ® ANDA product.

40. By filing ANDA No. 20-1661 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 Lupin's YAZ® ANDA product before the expiration of the '838 reissue patent, Lupin has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, on information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Lupin's YAZ® ANDA product will also infringe one or more claims of the '838 reissue patent.

41. 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

ANDA No. 20-1661 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 Bayer becomes entitled. Further, Bayer Schering and Bayer HealthCare are entitled to an award of damages and treble damages for any commercial sale or use of Lupin's YAZ® ANDA product, and any act committed by Lupin 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).

42. On information and belief, when Lupin filed ANDA No. 20-1661, it was aware of the '838 reissue patent and was aware that the filing of ANDA No. 20-1661 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.

**COUNT THREE: CLAIM FOR PATENT INFRINGEMENT OF U.S. REISSUE
PATENT NO. 38,253 BASED ON LUPIN'S YAZ® ANDA**

43. Bayer incorporates paragraphs 1-42 of this Complaint as if fully set forth herein.

44. On information and belief, Lupin's YAZ® ANDA product infringes one or more claims of the '253 reissue patent.

45. The '253 reissue patent covers Bayer HealthCare's YAZ® tablets, and Bayer has listed the '253 reissue patent for YAZ® in the FDA *Approved Drug Products and Therapeutic Equivalence Evaluations* ("the Orange Book").

46. On information and belief, Lupin submitted ANDA No. 20-1661 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Lupin's YAZ® ANDA product before the expiration of the '253 reissue patent.

47. On information and belief, Lupin made and included in ANDA No. 20-1661 a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '253 reissue patent is invalid or will not be infringed by the manufacture, use, offer for sale, sale and/or importation of Lupin's YAZ® ANDA product.

48. By filing ANDA No. 20-1661 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 Lupin's YAZ® ANDA product before the expiration of the '253 reissue patent, Lupin has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, on information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Lupin's YAZ® ANDA product will also infringe one or more claims of the '253 reissue patent.

49. 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 ANDA No. 20-1661 shall be a date which is not earlier than June 30, 2014, the current expiration date of the '253 reissue patent, or any later date of exclusivity to which Bayer becomes entitled. Further, Bayer Schering and Bayer HealthCare are entitled to an award of damages and treble damages for any commercial sale or use of Lupin's YAZ® ANDA product, and any act committed by Lupin with respect to the subject matter claimed in the '253 reissue patent that is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

50. On information and belief, when Lupin filed ANDA No. 20-1661, it was aware of the '253 reissue patent and was aware that the filing of its ANDA with the request for its approval prior to the expiration of the '253 reissue patent constituted an act of infringement of the '253 reissue patent.

COUNT FOUR: CLAIM FOR PATENT INFRINGEMENT OF U.S. PATENT NO. 5,569,652 UNDER 35 U.S.C. § 271 (E)(2)(A) BASED ON LUPIN'S YASMIN® ANDA

51. Bayer incorporates paragraphs 1-10, 17-21, and 26 of this Complaint as if fully set forth herein.

52. Lupin's filing of ANDA 20-1663 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 Lupin's Yasmin® ANDA product before the expiration of the '652 patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

53. The '652 patent covers Bayer HealthCare's Yasmin® tablets, and Bayer has listed the '652 patent for Yasmin® in the FDA *Approved Drug Products and Therapeutic Equivalence Evaluations* ("the Orange Book").

54. Lupin's manufacture, use, importation, offer for sale, and/or sale, or inducement thereof, of Lupin's Yasmin® ANDA product will infringe or induce infringement of at least one claim of the '652 patent under 35 U.S.C. § 271 (e)(2)(A).

55. On information and belief, Lupin 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 Lupin (*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 ANDA No. 20-1663, Lupin has indicated that its Yasmin® ANDA product will be bioequivalent to Bayer's Yasmin® product.

56. On information and belief, Lupin's proposed label for its Yasmin® ANDA product does not restrict the intended use of its product to the creation of a gestagenic effect in patients. As is well known to Lupin, 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 Lupin and customers of Lupin. On information and belief, Lupin will be marketing its Yasmin® ANDA product with specific intent, and/or with the desire to actively induce, aid, and abet infringement of the '652 patent. Lupin knows or reasonably should know that its proposed conduct will induce infringement.

57. On information and belief, Lupin's proposed label for its Yasmin® ANDA product provides or will be required by the FDA to provide, information for patients regarding the anti-

aldosterone and antiandrogenic properties of drospirenone. By including this information in its proposed label, Lupin will be marketing its Yasmin® ANDA product with specific intent, and/or with the desire to actively induce, aid, and abet infringement of the '652 patent. Lupin knows or reasonably should know that its proposed conduct will induce infringement.

58. Drospirenone's pharmacological profile -- *i.e.*, its three mechanisms of action (gestagenic, anti-androgenic, 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

59. On information and belief, Lupin'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, Lupin intends to do the same for its Yasmin® ANDA product with respect to Bayer HealthCare's Yasmin® tablets.

60. On information and belief, Lupin'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 Lupin's generic products are suitable for the same pharmacological uses as the corresponding branded product. Upon information and belief, Lupin intends to do the same for its Yasmin® ANDA product with respect to Bayer HealthCare's Yasmin® tablets.

61. On information and belief, Lupin has planned and intended to actively induce others to infringe the '652 patent when ANDA No. 20-1663 is approved and plans and intends to do so on approval.

62. Unless Lupin is enjoined from infringing and inducing the infringement of the '652

patent, Bayer will suffer substantial and irreparable injury. Bayer has no adequate remedy at law.

COUNT FIVE: CLAIM FOR PATENT INFRINGEMENT OF U.S. PATENT NO. 5,569,652 UNDER 35 U.S.C. § 271(B) BASED ON LUPIN'S YASMIN® ANDA

63. Bayer incorporates paragraphs 1-10, 17-21, 26 and 51-62 of this Complaint as if fully set forth herein.

64. On information and belief, approval of Lupin's ANDA 20-1663 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 ANDA 20-1663.

65. Unless Lupin is enjoined from infringing and inducing the infringement of the '652 patent, Bayer will suffer substantial and irreparable injury. Bayer has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE Bayer respectfully requests the following relief:

A. Judgment that Lupin has infringed one or more claims of the '564 reissue patent, the '838 reissue patent, and the '253 reissue patent by filing ANDA No. 20-1661 relating to Lupin's YAZ® ANDA product containing drospirenone and ethinylestradiol;

B. Judgment that Lupin has infringed one or more claims of the '652 patent by filing ANDA No. 20-1663 relating to Lupin's Yasmin® ANDA product containing drospirenone and ethinylestradiol;

C. Judgment pursuant to 28 U.S.C § 2201 et seq. that inducing the making, using, offering for sale, selling and/or importing of Lupin's Yasmin® ANDA product will infringe at least one claim of the '652 patent;

D. A permanent injunction restraining and enjoining Lupin 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 its territories, or importation into the

United States or its territories, of Lupin's YAZ® ANDA product;

E. A permanent injunction restraining and enjoining Lupin 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 its territories, or importation into the United States or its territories, of Lupin's Yasmin® ANDA product;

F. An order that the effective date of any approval of Lupin's ANDA No. 20-1661 relating to Lupin's YAZ® ANDA product containing drospirenone and ethinylestradiol be a date which is not earlier than the expiration date of the last to expire of the '564 reissue patent, the '838 reissue patent, or the '253 reissue patent, or any later date of exclusivity to which Bayer becomes entitled;


G. An order that the effective date of any approval of Lupin's ANDA No. 20-1663 relating to Lupin's Yasmin® ANDA product containing drospirenone and ethinylestradiol be a date which is not earlier than the expiration date of the '652 patent or any later date of exclusivity to which Bayer becomes entitled;

H. Damages and treble damages from Lupin for any commercial activity related to Lupin's YAZ® ANDA constituting infringement of the '564 reissue patent, the '838 reissue patent, or the '253 reissue patent;

I. Damages and treble damages from Lupin for any commercial activity related to Lupin's Yasmin® ANDA constituting infringement of the '652 patent; and

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

DATED this 15th day of July, 2010

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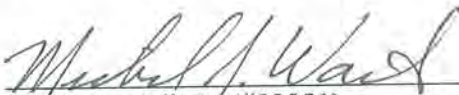
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*Attorneys for Plaintiffs Bayer Schering Pharma AG and Bayer
HealthCare Pharmaceuticals Inc.*

JURY DEMAND

Bayer hereby demands a jury trial on all issues so triable.

DATED this 15th day of July, 2010

By: 
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