IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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BAYER SCHERING PHARMA AG AND BAYER HEALTHCARE PHARMACEUTICALS INC.

Plaintiffs

v.

SUN PHARMACEUTICAL INDUSTRIES LIMITED, SUN PHARMA GLOBAL FZE, SUN PHARMA GLOBAL, & SUN PHARMACEUTICAL INDUSTRIES, INC.

DEFENDANTS.

COMPLAINT

JURY TRIAL

Plaintiffs Bayer Schering Pharma AG and Bayer HealthCare Pharmaceuticals Inc. (collectively "Bayer") bring this Complaint for patent infringement against Defendants Sun Pharmaceutical Industries Ltd., Sun Pharma Global FZE, Sun Pharma Global, & Sun Pharmaceutical Industries, Inc. (collectively "Sun") 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, Sun Pharmaceutical Industries Limited is an Indian corporation having a place of business at Acme Plaza, Andheri-Kurla Road, Andheri (East), Mumbai-400 059, India. On information and belief, Sun Pharmaceutical Industries Limited is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products through various operating subsidiaries, including Sun Pharma Global, Sun Pharma Global FZE, and Sun Pharmaceutical Industries, Inc.

4. On information and belief, Sun Pharma Global is a corporation organized under the laws of the British Virgin Islands having a post-office box at International Trust Building, P.O. Box No. 659, Road Town, Tortola, British Virgin Islands. On information and belief, Sun Pharma Global is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the United States market through various operating subsidiaries, including Sun Pharma Global FZE. Sun Pharma Global is a wholly owned subsidiary and alter ego of Sun Pharmaceutical Industries Limited.

5. On information and belief, Sun Pharma Global FZE is a corporation organized under the laws of the United Arab Emirates having a place of business at United Arab Emirates with a

principal place of business at Executive Suite # 43, Block-Y, SAIF Zone, PO Box 122304, Sharjah, U.A.E. On information and belief, Sun Pharma Global FZE is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products throughout the United States including within the State of New Jersey. Sun Pharma Global FZE is a wholly owned subsidiary and alter ego of Sun Pharma Global.

6. On information and belief, Sun Pharmaceutical Industries, Inc. is a corporation organized under the laws of the State of Michigan with headquarters at 29714 Orion Ct., Farmington Hills, MI 48334 and having its principal place of business at 270 Prospect Plains Road, Cranbury, NJ 08512. On information and belief, Sun Pharmaceutical Industries, Inc. is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products throughout the United States including within the State of New Jersey. Sun Pharmaceutical Industries, Inc. is a wholly owned subsidiary and alter ego of Sun Pharmaceutical Industries Limited.

7. 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"), Sun Pharmaceutical Industries Limited, Sun Pharma Global FZE, Sun Pharma Global, & Sun Pharmaceutical Industries, Inc. will act in concert to distribute and sell Sun's oral-contraceptive products for ANDA No. 20-2318 throughout the United States, including within New Jersey. On information and belief, Sun Pharmaceutical Industries Ltd., Sun Pharma Global FZE, Sun Pharma Global, & Sun Pharmaceutical Industries, Inc. know and intend that Sun's ANDA product for ANDA No. 20-2318 will be distributed and sold in the United States, including within New Jersey.

8. On information and belief, and consistent with their practice with respect to other generic products, Sun Pharmaceutical Industries Ltd., Sun Pharma Global FZE, Sun Pharma Global, & Sun Pharmaceutical Industries, Inc. acted in concert to prepare and submit ANDA No. 20-2318. On information and belief, Sun Pharmaceutical Industries Ltd., Sun Pharma Global FZE, Sun Pharma Global, & Sun Pharmaceutical Industries, Inc. actively participated in the preparation of ANDA No. 20-2318 and these entities caused the submission of this ANDA to the FDA. On information and belief, Sun Pharma Global FZE acted as the agent of Sun Pharmaceutical Industries

Ltd., Sun Pharma Global, & Sun Pharmaceutical Industries, Inc. in submitting ANDA No. 20-2318 to the FDA.

JURISDICTION AND VENUE

9. 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).

10. On information and belief, Sun Pharmaceutical Industries Limited is subject to personal jurisdiction in the State of New Jersey because, among other things, Sun Pharmaceutical Industries Limited, itself and through its wholly-owned and operating subsidiaries Sun Pharma Global FZE, Sun Pharma Global, and Sun Pharmaceutical Industries, Inc., has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Sun Pharmaceutical Industries Limited, itself and through its wholly owned and operating subsidiaries Sun Pharma Global FZE, Sun Pharma Global, and Sun Pharmaceutical Industries, Inc. markets and sells generic drugs throughout the United States and in particular within the State of New Jersey, and therefore Sun Pharmaceutical Industries Limited transacts business within the State of New Jersey such that it has engaged in systematic and continuous business contacts within the State of New Jersey. In addition, Sun Pharmaceutical Industries Limited is subject to personal jurisdiction in New Jersey because, on information and belief, it controls and dominates Sun Pharma Global FZE, Sun Pharma Global, and Sun Pharmaceutical Industries, Inc. and therefore the activities of these companies in this jurisdiction are attributed to Sun Pharmaceutical Industries Limited.

11. On information and belief, Sun Pharmaceutical Industries Limited (itself or through its subsidiaries Sun Pharma Global FZE, Sun Pharma Global, and Sun Pharmaceutical Industries, Inc.) markets its generic drug products to residents of the State of New Jersey through its website.

12. On information and belief, Sun Pharmaceutical Industries Limited (itself or through its subsidiaries Sun Pharma Global FZE, Sun Pharma Global, and Sun Pharmaceutical Industries, Inc.) offers its generic drug products for sale to residents of the State of New Jersey on third-party

websites that New Jersey residents can use to purchase Sun products for shipment to and within the State of New Jersey.

13. On information and belief, residents of the State of New Jersey purchase generic drug products from Sun Pharmaceutical Industries Limited (itself or through its subsidiaries Sun Pharma Global FZE, Sun Pharma Global, and Sun Pharmaceutical Industries, Inc.) in the State of New Jersey.

14. On information and belief, Sun Pharmaceutical Industries Limited (itself or through its subsidiaries Sun Pharma Global FZE, Sun Pharma Global, and Sun Pharmaceutical Industries, Inc.) receives revenue from the sales and marketing of its generic drug products in the State of New Jersey.

15. On information and belief, Sun Pharmaceutical Industries Limited (itself or through its subsidiaries Sun Pharma Global FZE, Sun Pharma Global, and Sun Pharmaceutical Industries, Inc.) uses sales representatives in the State of New Jersey to promote the sales of Sun's generic drugs throughout the State of New Jersey.

16. On information and belief, Sun Pharmaceutical Industries Limited (itself or through its subsidiaries Sun Pharma Global FZE, Sun Pharma Global, and Sun Pharmaceutical Industries, Inc.) has attended trade shows in the State of New Jersey for the purpose of promoting and selling Sun's generic drug products.

17. On information and belief, Sun Pharmaceutical Industries Limited (itself or through its subsidiaries Sun Pharma Global FZE, Sun Pharma Global, and Sun Pharmaceutical Industries, Inc.) has several authorized distributors in the State of New Jersey to distribute Sun's generic drug products throughout the State of New Jersey.

18. On information and belief, Sun Pharmaceutical Industries Limited (itself or through its subsidiaries Sun Pharma Global FZE, Sun Pharma Global, and Sun Pharmaceutical Industries, Inc.) plans to market and sell the product that is the subject of Sun's ANDA No. 20-2318, if approved, in the State of New Jersey as an alternative to Bayer's YAZ® product currently being sold in the State of New Jersey.

19. On information and belief, Sun Pharma Global is subject to personal jurisdiction in the State of New Jersey because, among other things, Sun Pharma Global, itself and through its parent Sun Pharmaceutical Industries Limited, its wholly owned and operating subsidiary Sun Pharma Global FZE or affiliated company Sun Pharmaceutical Industries, Inc. has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Sun Pharma Global, itself and through its parent Sun Pharmaceutical Industries Limited, its wholly owned and operating subsidiary Sun Pharma Global FZE or affiliated company Sun Pharmaceutical Industries, Inc. markets and sells generic drugs throughout the United States and in particular within the State of New Jersey, and therefore Sun Pharma Global transacts business within the State of New Jersey such that it has engaged in systematic and continuous business contacts within the State of New Jersey. In addition, Sun Pharma Global is subject to personal jurisdiction in New Jersey because, on information and belief, it controls and dominates Sun Pharma Global FZE and therefore the activities of this company in this jurisdiction are attributed to Sun Pharma Global.

20. On information and belief, Sun Pharma Global (itself or through its parent Sun Pharmaceutical Industries Limited, its wholly owned subsidiary Sun Pharma Global FZE or affiliated company Sun Pharmaceutical Industries, Inc.) markets its generic drug products to residents of the State of New Jersey through its website.

21. On information and belief, Sun Pharma Global (itself or through its parent Sun Pharmaceutical Industries Limited, its wholly owned subsidiary Sun Pharma Global FZE or affiliated company Sun Pharmaceutical Industries, Inc.) offers its generic drug products for sale to residents of the State of New Jersey on third-party websites that New Jersey residents can use to purchase Sun products for shipment to and within the State of New Jersey.

22. On information and belief, residents of the State of New Jersey purchase generic drug products from Sun Pharma Global (itself or through its parent Sun Pharmaceutical Industries Limited, its wholly owned subsidiary Sun Pharma Global FZE or affiliated company Sun Pharmaceutical Industries, Inc.) in the State of New Jersey.

23. On information and belief, Sun Pharma Global (itself or through its parent Sun Pharmaceutical Industries Limited, its wholly owned subsidiary Sun Pharma Global FZE or affiliated company Sun Pharmaceutical Industries, Inc.) receives revenue from the sales and marketing of its generic drug products in the State of New Jersey.

24. On information and belief, Sun Pharma Global (itself or through its parent Sun Pharmaceutical Industries Limited, its wholly owned subsidiary Sun Pharma Global FZE or affiliated company Sun Pharmaceutical Industries, Inc.) uses sales representatives in the State of New Jersey to promote the sales of Sun's generic drugs throughout the State of New Jersey.

25. On information and belief, Sun Pharma Global (itself or through its parent Sun Pharmaceutical Industries Limited, its wholly owned subsidiary Sun Pharma Global FZE or affiliated company Sun Pharmaceutical Industries, Inc.) has attended trade shows in the State of New Jersey for the purpose of promoting and selling Sun's generic drug products.

26. On information and belief, Sun Pharma Global (itself or through its parent Sun Pharmaceutical Industries Limited, its wholly owned subsidiary Sun Pharma Global FZE or affiliated company Sun Pharmaceutical Industries, Inc.) has several authorized distributors in the State of New Jersey to distribute Sun's generic drug products throughout the State of New Jersey.

27. On information and belief, Sun Pharma Global (itself or through its parent Sun Pharmaceutical Industries Limited, its wholly owned subsidiary Sun Pharma Global FZE or affiliated company Sun Pharmaceutical Industries, Inc.) plans to market and sell the product that is the subject of Sun's ANDA No. 20-2318, if approved, in the State of New Jersey as an alternative to Bayer's YAZ® product currently being sold in the State of New Jersey.

28. On information and belief, Sun Pharma Global FZE is subject to personal jurisdiction in the State of New Jersey because, among other things, Sun Pharma Global FZE (itself or through its parents Sun Pharmaceutical Industries Limited and Sun Pharma Global or its affiliated company Sun Pharmaceutical Industries, Inc.) has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Sun Pharma Global FZE (itself or through its parents Sun Pharmaceutical

Industries Limited and Sun Pharma Global or its affiliated company Sun Pharmaceutical Industries, Inc.) markets and sells generic drugs throughout the United States and in particular within the State of New Jersey, and therefore Sun Pharma Global FZE transacts business within the State of New Jersey such that it has engaged in systematic and continuous business contacts within the State of New Jersey.

29. On information and belief, Sun Pharma Global FZE retained John Dauer as its authorized agent for service of process in New Jersey in connection with ANDA No. 20-2318.

30. On information and belief, Sun Pharma Global FZE (itself or through its parents Sun Pharmaceutical Industries Limited and Sun Pharma Global or its affiliated company Sun Pharmaceutical Industries, Inc.) markets its generic drug products to residents of the State of New Jersey through Sun's website.

31. On information and belief, Sun Pharma Global FZE (itself or through its parents Sun Pharmaceutical Industries Limited and Sun Pharma Global or its affiliated company Sun Pharmaceutical Industries, Inc.) offers its generic drug products for sale to residents of the State of New Jersey on third-party websites that New Jersey residents can use to purchase Sun products for shipment to and within the State of New Jersey.

32. On information and belief, residents of the State of New Jersey purchase generic drug products from Sun Pharma Global FZE (itself or from its parents Sun Pharmaceutical Industries Limited and Sun Pharma Global or its affiliated company Sun Pharmaceutical Industries, Inc.) in the State of New Jersey.

33. On information and belief, Sun Pharma Global FZE (itself or through its parents Sun Pharmaceutical Industries Limited and Sun Pharma Global or its affiliated company Sun Pharmaceutical Industries, Inc.) receives revenue from the sales and marketing of its generic drug products in the State of New Jersey.

34. On information and belief, Sun Pharma Global FZE (itself or through its parents Sun Pharmaceutical Industries Limited and Sun Pharma Global or its affiliated company Sun Pharmaceutical Industries, Inc.) uses sales representatives in the State of New Jersey to promote the

sales of Sun's generic drugs throughout the State of New Jersey.

35. On information and belief, Sun Pharma Global FZE (itself or through its parents Sun Pharmaceutical Industries Limited and Sun Pharma Global or its affiliated company Sun Pharmaceutical Industries, Inc.) has attended trade shows in the State of New Jersey for the purpose of promoting and selling Sun's generic drug products.

36. On information and belief, Sun Pharma Global FZE (itself or through its parents Sun Pharmaceutical Industries Limited and Sun Pharma Global or its affiliated company Sun Pharmaceutical Industries, Inc.) has several authorized distributors in the State of New Jersey to distribute Sun's generic drug products throughout the State of New Jersey.

37. On information and belief, Sun Pharma Global FZE (itself or through its parents Sun Pharmaceutical Industries Limited and Sun Pharma Global or its affiliated company Sun Pharmaceutical Industries, Inc.) plans to market and sell the product that is the subject of Sun's ANDA No. 20-2318, if approved, in the State of New Jersey as an alternative to Bayer's YAZ® product currently being sold in the State of New Jersey.

38. On information and belief, Sun Pharmaceutical Industries, Inc. is subject to personal jurisdiction in the State of New Jersey because, among other things, it has its principal place of business in New Jersey, is a resident and citizen thereof, has listed with the FDA a New Jersey address as the compliance address associated with its labeler code, and has purposely availed itself of the benefits of New Jersey's laws such that it should reasonably anticipate being haled into court here.

39. On information and belief, Sun Pharmaceutical Industries, Inc. (itself or through its parent Sun Pharmaceutical Industries Limited or its affiliated companies Sun Global Pharma or Sun Global Pharma FZE) markets and sells generic drugs throughout the United States and in particular within the State of New Jersey, and therefore Sun Pharmaceutical Industries, Inc. transacts business within the State of New Jersey such that it has engaged in systematic and continuous business contacts within the State of New Jersey.

40. On information and belief, Sun Pharmaceutical Industries, Inc. employee John Dauer

serves as the registered agent for service of process in New Jersey in connection with ANDA No 20-2318.

41. On information and belief, Sun Pharmaceutical Industries, Inc. (itself or through its parent Sun Pharmaceutical Industries Limited or its affiliated companies Sun Global Pharma or Sun Global Pharma FZE) markets its generic drug products to residents of the State of New Jersey through Sun's website.

42. On information and belief, Sun Pharmaceutical Industries, Inc. (itself or through its parent Sun Pharmaceutical Industries Limited or its affiliated companies Sun Global Pharma or Sun Global Pharma FZE) offers its generic drug products for sale to residents of the State of New Jersey on third-party websites that New Jersey residents can use to purchase Sun products for shipment to and within the State of New Jersey.

43. On information and belief, residents of the State of New Jersey purchase generic drug products from Sun Pharmaceutical Industries, Inc. (itself or through its parent Sun Pharmaceutical Industries Limited or its affiliated companies Sun Global Pharma or Sun Global Pharma FZE) in the State of New Jersey.

44. On information and belief, Sun Pharmaceutical Industries, Inc. (itself or through its parent Sun Pharmaceutical Industries Limited or its affiliated companies Sun Global Pharma or Sun Global Pharma FZE) receives revenue from the sales and marketing of its generic drug products in the State of New Jersey.

45. On information and belief, Sun Pharmaceutical Industries, Inc. (itself or through its parent Sun Pharmaceutical Industries Limited or its affiliated companies Sun Global Pharma or Sun Global Pharma FZE) uses sales representatives in the State of New Jersey to promote the sales of Sun's generic drugs throughout the State of New Jersey.

46. On information and belief, Sun Pharmaceutical Industries, Inc. (itself or through its parent Sun Pharmaceutical Industries Limited or its affiliated companies Sun Global Pharma or Sun Global Pharma FZE) has attended trade shows in the State of New Jersey for the purpose of promoting and selling Sun's generic drug products.

47. On information and belief, Sun Pharmaceutical Industries, Inc. (itself or through its parent Sun Pharmaceutical Industries Limited or its affiliated companies Sun Global Pharma or Sun Global Pharma FZE) has several authorized distributors in the State of New Jersey to distribute Sun's generic drug products throughout the State of New Jersey.

48. On information and belief, Sun Pharmaceutical Industries, Inc. (itself or through its parent Sun Pharmaceutical Industries Limited or its affiliated companies Sun Global Pharma or Sun Global Pharma FZE) plans to market and sell the product that is the subject of Sun's ANDA No. 20-2318, if approved, in the State of New Jersey as an alternative to Bayer's YAZ® product currently being sold in the State of New Jersey.

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

BACKGROUND

50. 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. 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.

51. 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 17α-ethinylestradiol plus 4 placebo tablets.

52. On information and belief, Sun submitted to the FDA ANDA No. 20-2318 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.

53. On information and belief, the composition of the product that is the subject of Sun's ANDA contains 3 mg of drospirenone and 0.02 mg of ethinylestradiol in tablet form for oral contraception in a human female (hereinafter "Sun's YAZ® ANDA product").

54. On information and belief, Sun's ANDA seeks approval of a 28-day oral

contraceptive regimen that contains 24 tablets comprising 3 mg of drospirenone and 0.02 mg 17α-ethinylestradiol plus 4 placebo tablets.

55. On information and belief, on November 29, 2010, Sun 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.

PATENTS-IN-SUIT

56. The three patents-in-suit are United States Reissue Patent Nos. 37,564, 37,838, and 38,253.

57. 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.

58. 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.

59. 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.

COUNT ONE: CLAIM FOR PATENT INFRINGEMENT OF U.S. REISSUE PATENT NO. 37,564

60. Bayer incorporates paragraphs 1-59 of this Complaint as if fully set forth herein.

61. On information and belief, Sun's YAZ® ANDA product infringes one or more claims of the '564 reissue patent.

62. 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").

63. On information and belief, Sun submitted ANDA No. 20-2318 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Sun's YAZ® ANDA product before the expiration of the '564 reissue patent.

64. On information and belief, Sun made and included in ANDA No. 20-2318 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 Sun's YAZ® ANDA product.

65. By filing ANDA No. 20-2318 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 Sun's YAZ® ANDA product before the expiration of the '564 reissue patent, Sun 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 Sun's YAZ® ANDA product will also infringe one or more claims of the '564 reissue patent.

66. 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. 20-2318 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 Sun's YAZ® ANDA product, and any act committed by Sun 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).

67. On information and belief, when Sun filed ANDA No. 20-2318, it was aware of the '564 reissue patent and was aware that the filing of ANDA No. 20-2318 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

68. Bayer incorporates paragraphs 1-67 of this Complaint as if fully set forth herein.

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

70. 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").

71. On information and belief, Sun submitted ANDA No. 20-2318 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Sun's YAZ® ANDA product before the expiration of the '838 reissue patent.

72. On information and belief, Sun made and included in ANDA No. 20-2318 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 Sun's YAZ® ANDA product.

73. By filing ANDA No. 20-2318 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 Sun's YAZ® ANDA product before the expiration of the '838 reissue patent, Sun 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 Sun's YAZ® ANDA product will also infringe one or more claims of the '838 reissue patent.

74. 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. 20-2318 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 Sun's YAZ® ANDA product, and any act

committed by Sun 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).

75. On information and belief, when Sun filed ANDA No. 20-2318, it was aware of the '838 reissue patent and was aware that the filing of ANDA No. 20-2318 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

76. Bayer incorporates paragraphs 1-75 of this Complaint as if fully set forth herein.

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

78. 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").

79. On information and belief, Sun submitted ANDA No. 20-2318 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Sun's YAZ® ANDA product before the expiration of the '253 reissue patent.

80. On information and belief, Sun made and included in ANDA No. 20-2318 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 Sun's YAZ® ANDA product.

81. By filing ANDA No. 20-2318 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 Sun's YAZ® ANDA product before the expiration of the '253 reissue patent, Sun 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 Sun's YAZ® ANDA product will also infringe one or more claims of the '253 reissue patent.

82. 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. 20-2318 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 Sun's YAZ® ANDA product, and any act committed by Sun 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).

83. On information and belief, when Sun filed ANDA No. 20-2318, 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.

PRAYER FOR RELIEF

WHEREFORE Bayer respectfully requests the following relief:

A. Judgment that Sun has infringed one or more claims of the '564 reissue patent, the '838 reissue patent, and the '253 reissue patent by filing ANDA No. 20-2318 relating to Sun's YAZ® ANDA product containing drospirenone and ethinylestradiol;

B. A permanent injunction restraining and enjoining Sun 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 Sun's YAZ® ANDA product;

C. An order that the effective date of any approval of Sun's ANDA No. 20-2318 relating to Sun'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;

D. Damages and treble damages from Sun for any commercial activity constituting infringement of the '564 reissue patent, the '838 reissue patent, or the '253 reissue patent; and

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

JURY DEMAND

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

Dated: January 12, 2011

s/ William J. O'Shaughnessy
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