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

18
19 **UNITED STATES DISTRICT COURT**
DISTRICT OF NEVADA

20 BAYER SCHERING PHARMA AG &
21 BAYER HEALTHCARE
22 PHARMACEUTICALS INC.

23 Plaintiffs,

24 v.

25 LUPIN LTD. & LUPIN
26 PHARMACEUTICALS, INC.

27 Defendants.
28

COMPLAINT

JURY TRIAL

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

4 **PARTIES**

5 1. Plaintiff Bayer Schering Pharma AG (“Bayer Schering”), formerly known as
6 Schering AG, is a corporation organized and existing under the laws of the Federal Republic of
7 Germany, having a principal place of business in Müllerstrasse 178, 13353 Berlin, Germany.

8 2. Plaintiff Bayer HealthCare Pharmaceuticals Inc. (“Bayer HealthCare”), formerly
9 known as Berlex, Inc., is a corporation organized and existing under the laws of the State of
10 Delaware, having a principal place of business at 6 West Belt, Wayne, New Jersey 07470.

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

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

23 5. On information and belief and consistent with their practice with respect to other
24 generic products, following any FDA approval of an Abbreviated New Drug Application
25 (“ANDA”), Lupin Ltd. and Lupin Pharmaceuticals, Inc. will act in concert to distribute and sell
26 Lupin’s oral-contraceptive products for ANDA No. 20-1661 throughout the United States,
27 including within Nevada. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals, Inc.
28 know and intend that Lupin’s ANDA product for ANDA No. 20-1661 will be distributed and sold

1 in the United States, including within Nevada.

2 6. On information and belief, and consistent with their practice with respect to other
3 generic products, Lupin Ltd. and Lupin Pharmaceuticals, Inc. acted in concert to prepare and
4 submit ANDA No. 20-1661. On information and belief, Lupin Ltd. and Lupin Pharmaceuticals,
5 Inc. actively participated in the preparation of ANDA No. 20-1661 and both entities submitted
6 these ANDAs to the FDA. On information and belief, Lupin Pharmaceuticals, Inc. acted as the
7 agent of Lupin Ltd. in submitting ANDA No. 20-1661 to the FDA.

8
9 **JURISDICTION AND VENUE**

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

12 8. On information and belief, Lupin Ltd. is subject to personal jurisdiction in the
13 State of Nevada because, among other things, Lupin Ltd., itself and through its wholly-owned
14 subsidiary Lupin Pharmaceuticals, Inc., has purposely availed itself of the benefits and
15 protections of Nevada's laws such that it should reasonably anticipate being haled into court here.
16 On information and belief, Lupin Ltd., itself and through its wholly-owned subsidiary Lupin
17 Pharmaceuticals, Inc. markets and sells branded and generic drugs throughout the United States
18 and in particular within the State of Nevada, and therefore Lupin Ltd. transacts business within
19 the State of Nevada such that it has engaged in systematic and continuous business contacts
20 within the State of Nevada. In addition, Lupin Ltd. is subject to personal jurisdiction in Nevada
21 because, on information and belief, it controls and dominates Lupin Pharmaceuticals, Inc. and
22 therefore the activities of Lupin Pharmaceuticals, Inc. in this jurisdiction are attributed to Lupin
23 Ltd.

24 9. On information and belief, Lupin Ltd. (itself or through its wholly-owned
25 subsidiary Lupin Pharmaceuticals, Inc.) markets its branded and generic drug products to
26 residents of the State of Nevada through its website.

27 10. On information and belief, Lupin Ltd. (itself or through its wholly-owned
28 subsidiary Lupin Pharmaceuticals, Inc.) offers its branded and generic drug products for sale to

1 residents of the State of Nevada on third-party websites that Nevada residents can use to purchase
2 Lupin products for shipment to and within the State of Nevada.

3 11. On information and belief, residents of the State of Nevada purchase branded and
4 generic drug products from Lupin Ltd. (itself or through its wholly-owned subsidiary Lupin
5 Pharmaceuticals, Inc.) in the State of Nevada.

6 12. On information and belief, Lupin Ltd. (itself or through its wholly-owned
7 subsidiary Lupin Pharmaceuticals, Inc.) receives revenue from the sales and marketing of its
8 branded and generic drug products in the State of Nevada.

9 13. On information and belief, Lupin Ltd. (itself or through its wholly-owned
10 subsidiary Lupin Pharmaceuticals, Inc.) uses sales representatives in the State of Nevada to
11 promote the sales of Lupin's branded and generic drugs throughout the State of Nevada.

12 14. On information and belief, Lupin Ltd. (itself or through its wholly-owned
13 subsidiary Lupin Pharmaceuticals, Inc.) has attended trade shows in the State of Nevada for the
14 purpose of promoting and selling Lupin's branded and generic drug products.

15 15. On information and belief, Lupin Ltd. (itself or through its wholly-owned
16 subsidiary Lupin Pharmaceuticals, Inc.) has several authorized distributors in the State of Nevada
17 to distribute Lupin's branded and generic drug products throughout the State of Nevada.

18 16. On information and belief, Lupin Ltd. (itself or through its wholly-owned
19 subsidiary Lupin Pharmaceuticals, Inc.) plans to market and sell the product that is the subject of
20 Lupin's ANDA No. 20-1661, if approved, in the State of Nevada as an alternative to Bayer's
21 YAZ® product currently being sold in the State of Nevada.

22 17. On information and belief, Lupin Pharmaceuticals, Inc. is subject to personal
23 jurisdiction in the State of Nevada because, among other things, it has purposely availed itself of
24 the benefits and protections of Nevada's laws such that it should reasonably anticipate being
25 haled into court here. On information and belief, Lupin Pharmaceuticals, Inc. markets and sells
26 branded and generic drugs throughout the United States and in particular within the State of
27 Nevada, and therefore Lupin Pharmaceuticals, Inc. transacts business within the State of Nevada
28 such that it has engaged in systematic and continuous business contacts within the State of

1 Nevada.

2 18. On information and belief, Lupin Pharmaceuticals, Inc. markets its branded and
3 generic drug product to residents of the State of Nevada through its website.

4 19. On information and belief, Lupin Pharmaceuticals, Inc. offers its branded and
5 generic drug product for sale to residents of the State of Nevada on third-party websites that
6 Nevada residents can use to purchase Lupin products for shipment to and within the State of
7 Nevada.

8 20. On information and belief, residents of the State of Nevada purchase branded and
9 generic drug products from Lupin Pharmaceuticals, Inc. in the State of Nevada.

10 21. On information and belief, Lupin Pharmaceuticals, Inc. receives revenue from the
11 sales and marketing of its branded and generic drug products in the State of Nevada.

12 22. On information and belief, Lupin Pharmaceuticals, Inc. uses sales representatives
13 in the State of Nevada to promote the sales of Lupin's branded and generic drugs throughout the
14 State of Nevada.

15 23. On information and belief, Lupin Pharmaceuticals, Inc. has attended trade shows
16 in the State of Nevada for the purpose of promoting and selling Lupin's branded and generic drug
17 products.

18 24. On information and belief, Lupin Pharmaceuticals, Inc. has several authorized
19 distributors in the State of Nevada to distribute Lupin's branded and generic drug products
20 throughout the State of Nevada.

21 25. On information and belief, Lupin Pharmaceuticals, Inc. plans to market and sell
22 the product that is the subject of ANDA No. 20-1661, if approved, in the State of Nevada as an
23 alternative to Bayer's YAZ® product currently being sold in the State of Nevada.

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

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BACKGROUND

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2 27. Bayer HealthCare is the holder of approved New Drug Application ("NDA") No.
3 21-676 for YAZ® tablets, which contain as active ingredients micronized drospirenone and
4 micronized 17 α -ethinylestradiol. The United States Food and Drug Administration ("FDA") has
5 approved YAZ® tablets for the prevention of pregnancy in women and for the treatment of
6 moderate acne and the symptoms of premenstrual dysphoric disorder in women who elect to use
7 an oral contraceptive.

8 28. Bayer HealthCare sells YAZ® tablets in the United States as a 28-day oral
9 contraceptive regimen that contains 24 tablets comprising 3 mg of micronized drospirenone and
10 0.02 mg of micronized 17 α -ethinylestradiol plus 4 placebo tablets.

11 29. On information and belief, Lupin submitted to the FDA ANDA No. 20-1661 under
12 the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture,
13 use, offer for sale, sale and/or importation of a generic version of Bayer's YAZ® tablets.

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

17 31. On information and belief, Lupin's ANDA seeks approval of a 28-day oral
18 contraceptive regimen that contains 24 tablets comprising 3 mg of drospirenone and 0.02 mg
19 17 α -ethinylestradiol plus 4 placebo tablets.

20 32. On information and belief, on June 2, 2010, Lupin sent a Notice Letter to Plaintiffs
21 Bayer Schering and Bayer HealthCare, purporting to comply with the provisions of 21 U.S.C. §
22 355(j)(2)(B) and the FDA regulations relating thereto.

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24 **PATENTS-IN-SUIT**

25 33. The three patents-in-suit are United States Reissue Patent Nos. 37,564, 37,838, and
26 38,253.

27 34. United States Reissue Patent No. 37,564 ("the '564 reissue patent") issued on
28 February 26, 2002. Inventors Jürgen Spona, Bernd Düsterberg, and Frank Lüdicke filed their

1 application for this patent on February 15, 2000. Bayer Schering is the current owner of the '564
2 reissue patent. Bayer attaches a true and correct copy of the '564 reissue patent as Exhibit 1.

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

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

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

13 37. Bayer incorporates paragraphs 1-36 of this Complaint as if fully set forth herein.

14 38. On information and belief, Lupin's YAZ® ANDA product infringes one or more
15 claims of the '564 reissue patent.

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

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

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

27 42. By filing ANDA No. 20-1661 under 21 U.S.C. § 355(j) for the purpose of
28 obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or

1 importation of Lupin's YAZ® ANDA product before the expiration of the '564 reissue patent,
2 Lupin has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, on information
3 and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Lupin's
4 YAZ® ANDA product will also infringe one or more claims of the '564 reissue patent.

5 43. Plaintiffs Bayer Schering and Bayer HealthCare are entitled to the relief provided
6 by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval
7 relating to ANDA No. 20-1661 shall be a date which is not earlier than June 30, 2014, the current
8 expiration date of the '564 reissue patent, or any later date of exclusivity to which Bayer becomes
9 entitled. Bayer Schering and Bayer HealthCare are entitled to an award of damages and treble
10 damages for any commercial sale or use of Lupin's YAZ® ANDA product, and any act
11 committed by Lupin with respect to the subject matter claimed in the '564 reissue patent that is
12 not within the limited exclusions of 35 U.S.C. § 271(e)(1).

13 44. On information and belief, when Lupin filed ANDA No. 20-1661, it was aware of
14 the '564 reissue patent and was aware that the filing of ANDA No. 20-1661 with the request for
15 its approval prior to the expiration of the '564 reissue patent constituted an act of infringement of
16 the '564 reissue patent.

17 **COUNT TWO: CLAIM FOR PATENT INFRINGEMENT OF U.S. REISSUE**
18 **PATENT NO. 37,838**

19 45. Bayer incorporates paragraphs 1-44 of this Complaint as if fully set forth herein.

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

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

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

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

5 50. By filing ANDA No. 20-1661 under 21 U.S.C. § 355(j) for the purpose of
6 obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or
7 importation of Lupin's YAZ® ANDA product before the expiration of the '838 reissue patent,
8 Lupin has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, on information
9 and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Lupin's
10 YAZ® ANDA product will also infringe one or more claims of the '838 reissue patent.

11 51. Plaintiffs Bayer Schering and Bayer HealthCare are entitled to the relief provided
12 by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval
13 relating to ANDA No. 20-1661 shall be a date which is not earlier than June 30, 2014, the current
14 expiration date of the '838 reissue patent, or any later date of exclusivity to which Bayer becomes
15 entitled. Further, Bayer Schering and Bayer HealthCare are entitled to an award of damages and
16 treble damages for any commercial sale or use of Lupin's YAZ® ANDA product, and any act
17 committed by Lupin with respect to the subject matter claimed in the '838 reissue patent that is
18 not within the limited exclusions of 35 U.S.C. § 271(e)(1).

19 52. On information and belief, when Lupin filed ANDA No. 20-1661, it was aware of
20 the '838 reissue patent and was aware that the filing of ANDA No. 20-1661 with the request for
21 its approval prior to the expiration of the '838 reissue patent constituted an act of infringement of
22 the '838 reissue patent.

23 **COUNT THREE: CLAIM FOR PATENT INFRINGEMENT OF U.S.**
24 **REISSUE PATENT NO. 38,253**

25 53. Bayer incorporates paragraphs 1-52 of this Complaint as if fully set forth herein.

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

28 55. The '253 reissue patent covers Bayer HealthCare's YAZ® tablets, and Bayer has

1 listed the '253 reissue patent for YAZ® in the FDA *Approved Drug Products and Therapeutic*
2 *Equivalence Evaluations* (“the Orange Book”).

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

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

11 58. By filing ANDA No. 20-1661 under 21 U.S.C. § 355(j) for the purpose of
12 obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or
13 importation of Lupin’s YAZ® ANDA product before the expiration of the '253 reissue patent,
14 Lupin has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, on information
15 and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Lupin’s
16 YAZ® ANDA product will also infringe one or more claims of the '253 reissue patent.

17 59. Plaintiffs Bayer Schering and Bayer HealthCare are entitled to the relief provided
18 by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval
19 relating to ANDA No. 20-1661 shall be a date which is not earlier than June 30, 2014, the current
20 expiration date of the '253 reissue patent, or any later date of exclusivity to which Bayer becomes
21 entitled. Further, Bayer Schering and Bayer HealthCare are entitled to an award of damages and
22 treble damages for any commercial sale or use of Lupin’s YAZ® ANDA product, and any act
23 committed by Lupin with respect to the subject matter claimed in the '253 reissue patent that is
24 not within the limited exclusions of 35 U.S.C. § 271(e)(1).

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

1 **PRAYER FOR RELIEF**

2 **WHEREFORE** Bayer respectfully requests the following relief:

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

6 B. A permanent injunction restraining and enjoining Lupin and its officers, agents,
7 attorneys and employees, and those acting in privity or concert with it, from engaging in the
8 commercial manufacture, use, offer to sell, or sale within the United States or its territories, or
9 importation into the United States or its territories, of Lupin's YAZ® ANDA product;

10 C. An order that the effective date of any approval of Lupin's ANDA No. 20-1661
11 relating to Lupin's YAZ® ANDA product containing drospirenone and ethinylestradiol be a date
12 which is not earlier than the expiration date of the last to expire of the '564 reissue patent, the
13 '838 reissue patent, or the '253 reissue patent, or any later date of exclusivity to which Bayer
14 becomes entitled;

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

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

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19 **JURY DEMAND**

20 Bayer hereby demands a jury trial on all issues so triable.
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1 Dated: July 15, 2010

Respectfully submitted,

2
3 /s/

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