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and Bayer HealthCare Pharmaceuticals Inc.*

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

19 Bayer Schering Pharma AG &
20 Bayer HealthCare Pharmaceuticals Inc.,

21 Plaintiffs,

22 v.

23 Mylan Pharmaceuticals Inc.,
24 Mylan Inc., and
Famy Care Ltd.,

25 Defendants.
26

Complaint

Jury Trial Demanded

1 manufacturing and marketing generic pharmaceutical products, including oral contraceptives.

2 8. On information and belief, Mylan Inc. is in the business of, among other things,
3 manufacturing and selling generic copies of branded pharmaceutical products through various
4 operating subsidiaries and partners, including MPI and Famy Care.

5 9. On information and belief, MPI is in the business of, among other things,
6 manufacturing and selling generic copies of branded pharmaceutical products throughout the
7 United States including within the State of Nevada.

8 10. On information and belief, MPI is a wholly-owned subsidiary of Mylan Inc.

9 11. On information and belief, MPI and Mylan Inc. have common officers and
10 directors.

11 12. On information and belief, MPI is an alter ego of Mylan Inc.

12 13. On information and belief, MPI is the U.S. agent for Famy Care with regard to
13 numerous Abbreviated New Drug Application (“ANDAs”) held by Famy Care and on file with the
14 U.S. Food and Drug Administration (“FDA”), including without limitation ANDA No. 20-2594.

15 14. On information and belief, MPI, Mylan Inc., and Famy Care have entered into an
16 agreement whereby MPI will distribute in the United States, including Nevada, at least the product
17 for which approval is sought by ANDA No. 20-2594, if such ANDA is approved by the FDA.

18 15. On information and belief, MPI and Mylan Inc. are the alter egos of Famy Care,
19 including without limitation for the purposes of ANDA No. 20-2594.

20 16. On information and belief and consistent with their stated intentions, following any
21 FDA approval of an ANDA 20-2594, MPI, Mylan Inc., and Famy Care will act in concert to
22 distribute and sell any generic product approved as a result of ANDA 20-2594 throughout the
23 United States, including within Nevada. On information and belief, MPI, Mylan Inc., and Mylan
24 Pharmaceuticals Inc. know and intend that any generic product approved as a result ANDA No.
25 20-2594 will be distributed and sold in the United States, including within Nevada.

26 17. On information and belief, MPI, Mylan Inc., and Famy Care acted in concert to

1 prepare and submit ANDA No. 20-2594.

2 18. On information and belief, MPI, Mylan Inc., and Famy Care actively participated
3 in the preparation of ANDA No. 20-2594, and these entities caused submission of this ANDA to
4 the FDA.

5
6 **JURISDICTION AND VENUE**

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

9 20. On information and belief, Mylan Inc. is subject to personal jurisdiction in the State
10 of Nevada because, among other things, Mylan Inc. (itself and through its wholly-owned operating
11 subsidiary MPI) has purposely availed itself of the benefits and protections of Nevada's laws such
12 that it should reasonably anticipate being haled into court here.

13 21. On information and belief, Mylan Inc. (itself and through its wholly-owned
14 operating subsidiary MPI) markets and sells generic drugs throughout the United States and in
15 particular within the State of Nevada, and therefore Mylan Inc. transacts business within the State
16 of Nevada such that it has engaged in systematic and continuous business contacts within the State
17 of Nevada. In addition, Mylan Inc. is subject to personal jurisdiction in Nevada because, on
18 information and belief, it controls and dominates MPI and therefore the activities of MPI in this
19 jurisdiction are attributed to Mylan Inc.

20 22. On information and belief, Mylan Inc. (itself or through its subsidiary MPI)
21 markets its generic drug products to residents of the State of Nevada through its website.

22 23. On information and belief, Mylan Inc. (itself or through its subsidiary MPI) offers
23 its generic drug products for sale to residents of the State of Nevada on third-party websites that
24 Nevada residents can use to purchase Mylan Inc.'s products for shipment to and within the State
25 of Nevada.

26 24. On information and belief, residents of the State of Nevada purchase generic drug

1 products from Mylan Inc. (itself or through its subsidiary MPI) in the State of Nevada.

2 25. On information and belief, Mylan Inc. (itself or through its subsidiary MPI)
3 receives revenue from the sales and marketing of its generic drug products in the State of Nevada.

4 26. On information and belief, Mylan Inc. (itself or through its subsidiary MPI) uses
5 sales representatives in the State of Nevada to promote the sales of Mylan Inc.'s generic drugs
6 throughout the State of Nevada.

7 27. On information and belief, Mylan Inc. (itself or through its subsidiary MPI) has
8 attended trade shows in the State of Nevada for the purpose of promoting and selling Mylan Inc.'s
9 generic drug products.

10 28. On information and belief, Mylan Inc. (itself or through its subsidiary MPI) has
11 several authorized distributors in the State of Nevada to distribute Mylan Inc.'s generic drug
12 products throughout the State of Nevada.

13 29. On information and belief, Mylan Inc. (itself or through its subsidiary MPI) plans
14 to market and sell the product that is the subject of ANDA No. 20-2594, if approved, in the State
15 of Nevada as an alternative to Bayer's YAZ® product currently being sold in the State of Nevada.

16 30. On information and belief, MPI is subject to personal jurisdiction in the State of
17 Nevada because, among other things, MPI, itself and through its parent Mylan Inc., has purposely
18 availed itself of the benefits and protections of Nevada's laws such that it should reasonably
19 anticipate being haled into court here.

20 31. MPI has purposely availed itself of the benefits and protections of Nevada's laws
21 by registering with the State of Nevada to do business in Nevada and by maintaining an agent for
22 service of process in Nevada. By maintaining an agent for service of process in Nevada, MPI has
23 reasonably anticipated being haled into court here.

24 32. On information and belief, MPI, itself and through its parent Mylan Inc., markets
25 and sells generic drugs throughout the United States and in particular within the State of Nevada,
26 and therefore MPI transacts business within the State of Nevada such that it has engaged in

1 systematic and continuous business contacts within the State of Nevada.

2 33. On information and belief, MPI (itself or through its parent Mylan Inc.) markets its
3 generic drug products to residents of the State of Nevada through its website.

4 34. On information and belief, MPI (itself or through its parent Mylan Inc.) offers its
5 generic drug products for sale to residents of the State of Nevada on third-party websites that
6 Nevada residents can use to purchase MPI's products for shipment to and within the State of
7 Nevada.

8 35. On information and belief, residents of the State of Nevada purchase generic drug
9 products from MPI (itself or through its parent Mylan Inc.) in the State of Nevada.

10 36. On information and belief, MPI (itself or through its parent Mylan Inc.) receives
11 revenue from the sales and marketing of its generic drug products in the State of Nevada.

12 37. On information and belief, MPI (itself or through its parent Mylan Inc.) uses sales
13 representatives in the State of Nevada to promote the sales of MPI's generic drugs throughout the
14 State of Nevada.

15 38. On information and belief, MPI (itself or through its parent Mylan Inc.) has
16 attended trade shows in the State of Nevada for the purpose of promoting and selling MPI's
17 generic drug products.

18 39. On information and belief, MPI (itself or through its parent Mylan, Inc.) has several
19 authorized distributors in the State of Nevada to distribute MPI's generic drug products throughout
20 the State of Nevada.

21 40. On information and belief, MPI (itself or through its parent Mylan, Inc.) plans to
22 market and sell the product that is the subject of ANDA No. 20-2594, if approved, in the State of
23 Nevada as an alternative to Bayer's YAZ® product currently being sold in the State of Nevada.

24 41. On information and belief, Famy Care is subject to personal jurisdiction in the State
25 of Nevada because, among other things, Famy Care, itself and through its agent MPI and its
26 partner Mylan Inc., has purposely availed itself of the benefits and protections of Nevada's laws

1 such that it should reasonably anticipate being haled into court here.

2 42. Famy Care has purposely availed itself of the benefits and protections of Nevada's
3 laws by designating MPI as its U.S. agent for numerous ANDA applications (including ANDA
4 20-3594). MPI has registered with the State of Nevada to do business in Nevada and maintains an
5 agent for service of process in Nevada. By designating an agent that maintains an agent for
6 service of process in Nevada, Famy Care has reasonably anticipated being haled into court here.

7 43. On information and belief, Famy Care, itself and through its agent MPI and its
8 partner Mylan Inc., markets and sells generic drugs throughout the United States and in particular
9 within the State of Nevada, and therefore Famy Care transacts business within the State of Nevada
10 such that it has engaged in systematic and continuous business contacts within the State of
11 Nevada.

12 44. On information and belief, Famy Care (itself or through its agent MPI and its
13 partner Mylan Inc.) markets its generic drug products to residents of the State of Nevada through
14 its website.

15 45. On information and belief, Famy Care (itself or through its agent MPI and its
16 partner Mylan Inc.) offers its generic drug products for sale to residents of the State of Nevada on
17 third-party websites that Nevada residents can use to purchase Famy Care's products for shipment
18 to and within the State of Nevada.

19 46. On information and belief, residents of the State of Nevada purchase generic drug
20 products from Famy Care (itself or through its agent MPI and its partner Mylan Inc.) in the State
21 of Nevada.

22 47. On information and belief, Famy Care (itself or through its agent MPI and its
23 partner Mylan Inc.) receives revenue from the sales and marketing of its generic drug products in
24 the State of Nevada.

25 48. On information and belief, Famy Care (itself or through its agent MPI and its
26 partner Mylan Inc.) uses sales representatives in the State of Nevada to promote the sales of Famy

1 Care's generic drugs throughout the State of Nevada.

2 49. On information and belief, Famy Care (itself or through its agent MPI and its
3 partner Mylan Inc.) has attended trade shows in the State of Nevada for the purpose of promoting
4 and selling Famy Care's generic drug products.

5 50. On information and belief, Famy Care (itself or through its agent MPI and its
6 partner Mylan Inc.) has several authorized distributors in the State of Nevada to distribute Famy
7 Care's generic drug products throughout the State of Nevada.

8 51. On information and belief, Famy Care (itself or through its agent MPI and its
9 partner Mylan Inc.) plans to market and sell the product that is the subject of ANDA No. 20-2594,
10 if approved, in the State of Nevada as an alternative to Bayer's YAZ® product currently being
11 sold in the State of Nevada.

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

13
14 **BACKGROUND**

15 53. Bayer HealthCare is the holder of approved New Drug Application ("NDA") No.
16 21-676 for YAZ® tablets, which contain as active ingredients micronized drospirenone and
17 micronized 17 α -ethinylestradiol. The United States Food and Drug Administration ("FDA") has
18 approved YAZ® tablets for the prevention of pregnancy in women and for the treatment of
19 moderate acne and the symptoms of premenstrual dysphoric disorder in women who elect to use
20 an oral contraceptive.

21 54. Bayer HealthCare sells YAZ® tablets in the United States as a 28-day oral
22 contraceptive regimen that contains 24 tablets comprising 3 mg of micronized drospirenone and
23 0.02 mg of micronized 17 α -ethinylestradiol plus 4 placebo tablets.

24 55. On information and belief, Mylan submitted to the FDA ANDA No. 20-2594
25 ("Mylan's ANDA") under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the
26 commercial manufacture, use, offer for sale, sale and/or importation of a generic version of

1 Bayer's YAZ® tablets.

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

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

8 58. On information and belief, on or about March 7, 2011, Mylan sent a Notice Letter
9 to Plaintiffs Bayer Schering and Bayer HealthCare, purporting to comply with the provisions of
10 21 U.S.C. § 355(j)(2)(B) and the FDA regulations relating thereto.

11

12

PATENT-IN-SUIT

13 59. The patent-in-suit is United States Reissue Patent No. 37,564 ("the '564 reissue
14 patent").

15 60. The '564 reissue patent issued on February 26, 2002. Inventors Jürgen Spona,
16 Bernd Düsterberg, and Frank Lüdicke filed their application for this patent on February 15, 2000.
17 Bayer Schering is the current owner of the '564 reissue patent. Bayer attaches a true and correct
18 copy of the '564 reissue patent as Exhibit 1.

19

COUNT ONE: CLAIM FOR PATENT INFRINGEMENT OF THE '564 REISSUE PATENT

20
21 61. Bayer incorporates paragraphs 1-60 of this Complaint as if fully set forth herein.

22 62. On information and belief, Mylan's YAZ® ANDA product infringes one or more
23 claims of the '564 reissue patent.

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

1 64. On information and belief, Mylan submitted ANDA No. 20-2594 to the FDA for
2 the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale,
3 sale and/or importation of Mylan's YAZ® ANDA product before the expiration of the '564
4 reissue patent.

5 65. On information and belief, Mylan made and included in ANDA No. 20-2594 a
6 certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '564 reissue
7 patent is invalid or will not be infringed by the manufacture, use, offer for sale, sale and/or
8 importation of Mylan's YAZ® ANDA product.

9 66. By filing ANDA No. 20-2594 under 21 U.S.C. § 355(j) for the purpose of
10 obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or
11 importation of Mylan's YAZ® ANDA product before the expiration of the '564 reissue patent,
12 Mylan has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, on information
13 and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Mylan's
14 YAZ® ANDA product will also infringe one or more claims of the '564 reissue patent.

15 67. Plaintiffs Bayer Schering and Bayer HealthCare are entitled to the relief provided
16 by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval
17 relating to ANDA No. 20-2594 shall be a date which is not earlier than June 30, 2014, the current
18 expiration date of the '564 reissue patent, or any later date of exclusivity to which Bayer becomes
19 entitled. Bayer Schering and Bayer HealthCare are entitled to an award of damages and treble
20 damages for any commercial sale or use of Mylan's YAZ® ANDA product, and any act
21 committed by Mylan with respect to the subject matter claimed in the '564 reissue patent that is
22 not within the limited exclusions of 35 U.S.C. § 271(e)(1).

23 68. On information and belief, when Mylan filed ANDA No. 20-2594, it was aware of
24 the '564 reissue patent and was aware that the filing of ANDA No. 20-2594 with the request for its
25 approval prior to the expiration of the '564 reissue patent constituted an act of infringement of the
26 '564 reissue patent.

1 **PRAYER FOR RELIEF**

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

3 A. Judgment that Mylan has infringed one or more claims of the '564 reissue patent by
4 filing ANDA No. 20-2594 relating to Mylan's YAZ® ANDA product containing drospirenone
5 and ethinylestradiol;

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

10 C. An order that the effective date of any approval of Mylan's ANDA No. 20-2594
11 relating to Mylan's YAZ® ANDA product containing drospirenone and ethinylestradiol be a date
12 which is not earlier than June 30, 2014, the expiration date of the '564 reissue patent, or any later
13 date of exclusivity to which Bayer becomes entitled;

14 D. Damages and treble damages from Mylan for any commercial activity constituting
15 infringement of the '564 reissue patent; and

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

17
18 **JURY DEMAND**

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

20
21 Dated: April 18, 2011

22
23 /s/ Michael J. McCue
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