Andrew P. Gordon, (Nevada Bar #3421)
McDonald Carano Wilson LLP
2300 West Sahara Avenue
No.10, Suite 1000
Las Vegas, Nevada 89102
(702) 873-4100 (phone)
(702) 873-9966 (facsimile)
agordon@Mcdonaldcarano.com

Of Counsel:
Peter B. Bensinger, Jr. (*pro hac vice* application to be filed)
Paul J. Skiermont (*pro hac vice* application to be filed)
Adam K. Mortara (*pro hac vice* application to be filed)
Sundeep K. (Rob) Addy (*pro hac vice* application to be filed)
Matthew R. Ford (*pro hac vice* application to be filed)
BARTLIT BECK HERMAN PALENCHAR & SCOTT LLP
54 West Hubbard Street
Chicago, Illinois 60654
(312) 494-4400 (phone)
(312) 494-4440 (facsimile)
peter.bensinger@bartlit-beck.com
paul.skiermont@bartlit-beck.com
adam.mortara@bartlit-beck.com
rob.addy@bartlit-beck.com
matthew.ford@bartlit-beck.com

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

UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

Bayer Schering Pharma AG & Bayer HealthCare Pharmaceuticals Inc., Plaintiffs, v. Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc., Barr Pharmaceuticals LLC, & Barr Laboratories, Inc. Defendants.	Case No. **COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiffs Bayer Schering Pharma AG and Bayer HealthCare Pharmaceuticals Inc. (collectively, "Bayer"), for their Complaint for patent infringement herein against Defendants Teva Pharmaceutical Industries Limited, Teva Pharmaceuticals USA, Inc., Barr Pharmaceuticals, LLC, and Barr Laboratories, Inc. 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 at 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 07470-6945.

3. On information and belief, Defendant Teva Pharmaceutical Industries Limited ("Teva Industries") is an Israeli corporation with its principal place of business at 5 Basel Street, P.O. Box 3190, Petach Tikva 49131, Israel.

4. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. On information and belief, Teva USA is a wholly-owned subsidiary of Defendant Teva Industries.

5. On information and belief, Defendant Barr Pharmaceuticals LLC ("BP LLC") (formerly known as Boron Acquisition LLC) is a Delaware limited liability company having its principal place of business at 223 Summit Avenue, Montvale, New Jersey 07645. Defendant BP LLC develops, manufactures, and markets generic pharmaceutical products through its operating subsidiary Defendant Barr Laboratories, Inc ("Barr Labs"). On information and belief, BP LLC is a wholly-owned subsidiary of Defendant Teva Industries.

6. On information and belief, Defendant Barr Labs is a corporation organized and

McDONALD·CARANO·WILSON LLP
2300 WEST SAHARA AVENUE • SUITE 1000 • LAS VEGAS, NEVADA 89102-4354
PHONE (702) 873-4100 • FAX (702) 873-9966

existing under the laws of the State of Delaware, having a principal place of business at 223 Summit Avenue, Montvale, New Jersey 07645.

7. On information and belief, Defendant Barr Labs is a wholly-owned subsidiary of Defendant BP LLC, and the two have common officers and directors.

8. On information and belief, Defendants Teva Industries, Teva USA, and BP LLC directed, authorized, participated in, assisted, and cooperated with Defendant Barr Labs in all of the acts complained of herein. Hereinafter, all Defendants shall be collectively referred to as "Barr."

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. This Court has personal jurisdiction over Defendants BP LLC, Barr Labs, and Teva USA. On information and belief, BP LLC, Barr Labs, and Teva USA have continuous and systematic general business contacts that approximate physical presence in the forum as a result of pervasive activities conducted within Nevada, including without limitation the sale, offer for sale, importation, and distribution of the generic oral contraceptive Gianvi®. Further, Defendants BP LLC, Barr Labs, and Teva USA have committed and continue to commit acts of patent infringement, directly and/or through agents, intermediaries and/or third parties, by shipping, distributing, importing, offering for sale and/or selling certain infringing products in Nevada. Defendants BP LLC, Barr Labs, and Teva USA have purposefully and voluntarily placed Gianvi® into the stream of commerce with the intent that it will be purchased by consumers in Nevada. On information and belief, Defendants BP LLC, Barr Labs, and Teva USA have purposefully directed their infringing activities toward Nevada and its residents by promoting Gianvi® on their internet web sites with the intent of reaching potential consumers in Nevada and selling Gianvi® to Nevada residents and distributors. Accordingly, personal jurisdiction over Defendants BP LLC,

McDONALD·CARANO·WILSON LLP
2300 WEST SAHARA AVENUE • SUITE 1000 • LAS VEGAS, NEVADA 89102-4354
PHONE (702) 873-4100 • FAX (702) 873-9966

Barr Labs, and Teva USA is appropriate under the Nevada Long-Arm Statute, Nev. Rev. Stat. § 14.065 (2009), the Nevada Constitution, and the United States Constitution.

11. The activities of Defendants BP LLC, Barr Labs, and Teva USA that are the basis for this Complaint, have been and remain, on information and belief, under the control and direction of their parent company, Defendant Teva Industries.

12. Furthermore, on information and belief, Teva Industries engages in continuous and systematic general business contacts that approximate physical presence in the forum by regularly transacting business within Nevada, including but not limited to Teva Industries' direction of the operation and management of Teva USA, BP LLC, and Barr Labs as well as shipping drugs to Teva USA, BP LLC, and Barr Labs from locations outside the United States for distribution within the United States generally and in Nevada specifically.

13. On information and belief, Teva USA, BP LLC, and Barr Labs have acted and will continue to act as agents of Teva Industries with respect to the acts complained of herein.

14. On information and belief, Teva USA, BP LLC and Barr Labs act as the alter egos of Teva Industries in the United States. On information and belief, the unity of interest and ownership between Teva USA, BP LLC, and Barr Labs, on the one hand, and Teva Industries, on the other hand, is such that the separate personalities of the companies no longer exist and failure to disregard their separate identities would result in fraud or injustice.

15. Accordingly, the acts and contacts of Teva USA, BP LLC, and Barr Labs, as an agent of Teva Industries, are attributable to Teva Industries for jurisdictional purposes.

16. Teva Industries is subject to personal jurisdiction in this District by virtue of the acts of its agents and/or alter egos described above as well as its continuous and systematic contacts within Nevada. Accordingly, personal jurisdiction over Teva Industries is appropriate under the Nevada Long-Arm Statute, Nev. Rev. Stat. § 14.065 (2009), the Nevada Constitution, and the United States Constitution.

McDONALD·CARANO·WILSON LLP
2300 WEST SAHARA AVENUE • SUITE 1000 • LAS VEGAS, NEVADA 89102-4354
PHONE (702) 873-4100 • FAX (702) 873-9966

McDONALD·CARANO·WILSON LLP
2300 WEST SAHARA AVENUE • SUITE 1000 • LAS VEGAS, NEVADA 89102-4354
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17. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

a. In particular, the District of Nevada is the appropriate venue for this case because it maximizes judicial efficiency. There are two currently pending related cases in this district regarding the infringement and validity of the patents-in-suit: *Bayer Schering Pharma et al. v. Watson Laboratories*, et al., No. 2:07-cv-01472-KJD-(GWF) and *Bayer Schering Pharma et al. v. Sandoz Inc.*, No. 2:08-cv-00995-KJD-(GWF) (collectively, "the YAZ® Cases").

b. Venue for this case in the District of Nevada in conjunction with the currently pending YAZ® Cases is also appropriate because it will maximize the convenience for all parties.

c. Venue for this case in the District of Nevada in conjunction with the currently pending YAZ® Cases is also appropriate because it will eliminate the risk of inconsistent adjudications.

BACKGROUND

18. 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. YAZ® tablets have been approved by the United States Food and Drug Administration ("FDA") for the prevention of pregnancy in women who elect to use an oral contraceptive and the treatment of acne and premenstrual dysphoric disorder in women who elect to use an oral contraceptive. YAZ® tablets are sold in the United States by Bayer HealthCare 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.

19. On information and belief, Barr submitted to the FDA an Abbreviated New Drug Application ("ANDA") under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in

the commercial manufacture, use, offer for sale, sale, and/or importation of a generic version of Bayer HealthCare's YAZ® tablets.

20. On information and belief, the composition of the product that is the subject of Barr's ANDA contains 3 mg of drospirenone and 0.02 mg of 17α-ethinylestradiol in tablet form for oral contraception in a human female.

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

22. On information and belief, on or about December 28, 2006, Barr 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.

23. On information and belief, on or about March 20, 2009, Barr received FDA approval for its ANDA product.

24. On information and belief, on or about June 1, 2010, Teva Industries announced that it commercially launched Barr's ANDA Product under the name "Gianvi®" (Drospirenone and Ethinyl Estradiol) Tablets, its generic version of Bayer's YAZ® Tablets.

25. On information and belief, Barr has manufactured, tested, imported, used, sold and/or offered to sell Gianvi® within the United States.

26. On information and belief, Gianvi® is currently sold, offered for sale, imported, and/or used within the United States and the District of Nevada.

PATENTS

27. The patents-in-suit are as follows:

28. United States Reissue Patent No. 37,564 ("the '564 reissue patent") (attached as Exhibit 1). Inventors Jürgen Spona, Bernd Düsterberg, and Frank Lüdicke filed their application

McDONALD·CARANO·WILSON LLP
2300 WEST SAHARA AVENUE • SUITE 1000 • LAS VEGAS, NEVADA 89102-4354
PHONE (702) 873-4100 • FAX (702) 873-9966

for this patent on February 15, 2000. The '564 reissue patent was issued February 26, 2002. Bayer Schering is the current owner of the '564 reissue patent.

29. United States Reissue Patent No. 37,838 ("the '838 reissue patent") (attached as Exhibit 2). Inventors Jürgen Spona, Bernd Düsterberg, and Frank Lüdicke filed their application for this patent on February 15, 2000. The '838 reissue patent was issued September 10, 2002. Bayer Schering is the current owner of the '838 reissue patent.

30. United States Reissue Patent No. 37,253 ("the '253 reissue patent") (attached as Exhibit 3). Inventors Jürgen Spona, Bernd Düsterberg, and Frank Lüdicke filed their application for this patent on February 15, 2002. The '253 reissue patent was issued September 16, 2003. Bayer Schering is the current owner of the '253 reissue patent.

COUNT ONE: CLAIM FOR PATENT INFRINGEMENT OF UNITED STATES REISSUE PATENT NO. 37,564

31. Plaintiffs incorporate paragraphs 1-30 of this Complaint as if fully set forth herein.

32. On information and belief, Barr's Gianvi® product directly and indirectly infringes one or more claims of the '564 reissue patent.

33. The '564 reissue patent covers Bayer HealthCare's YAZ® tablets and has been listed for the product in the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book").

34. On information and belief, Barr submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Gianvi® before the expiration of the '564 reissue patent.

35. On information and belief, Barr made and included in its ANDA 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 Gianvi®.

McDONALD·CARANO·WILSON LLP
2300 WEST SAHARA AVENUE • SUITE 1000 • LAS VEGAS, NEVADA 89102-4354
PHONE (702) 873-4100 • FAX (702) 873-9966

36. While Barr alleged noninfringement of several of the '564 reissue patent's claims in its Notice Letter, Barr did not allege noninfringement of all the '564 reissue patent's claims.

37. By filing its ANDA 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 Gianvi® before the expiration of the '564 reissue patent, Barr has committed an act of infringement under 35 U.S.C. § 271(e)(2).

38. 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 Barr's ANDA shall be changed to 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 Plaintiffs become entitled.

39. Barr, on information and belief, has infringed and/or continues to infringe the '564 reissue patent in violation of 35 U.S.C. § 271(a) by making, using, importing, offering to sell, and/or selling Gianvi® in this judicial district and elsewhere in the United States.

40. Barr, on information and belief, is infringing the '564 reissue patent in violation of 35 U.S.C. § 271(b) by actively inducing others to make, use, import, offer to sell, and/or sell Gianvi® in this judicial district and elsewhere in the United States.

41. Barr, on information and belief, is infringing the '564 reissue patent in violation of 35 U.S.C. § 271(c) by contributing to the infringement by others in the making, use, importation, sale, and/or offer for sale of Gianvi® in this judicial district and elsewhere in the United States.

42. Barr's infringement of the '564 reissue patent has been and continues to be willful patent infringement. Barr's ANDA notice letter evidences that it had knowledge of the '564 reissue patent prior to its infringing acts. Barr's objectively reckless acts of making, using, selling and offering to sell Gianvi® deliberately infringed the '564 reissue patent in reckless disregard of Bayer's patent rights.

McDONALD·CARANO·WILSON LLP
2300 WEST SAHARA AVENUE • SUITE 1000 • LAS VEGAS, NEVADA 89102-4354
PHONE (702) 873-4100 • FAX (702) 873-9966

43. Pursuant to 35 U.S.C. § 284, Bayer is entitled to recover from Barr the damages sustained by Bayer as a result of Barr's wrongful acts in an amount subject to proof at trial, including without limitation lost profits and an amount not less than a reasonable royalty together with interest and costs as fixed by this Court.

44. Barr's infringement of the '564 reissue patent will continue to cause Bayer irreparable injury and damage for which there is no adequate remedy at law unless and until Barr is enjoined from infringing the '564 reissue patent.

COUNT TWO: CLAIM FOR PATENT INFRINGEMENT OF UNITED STATES REISSUE PATENT NO. 37,838

45. Plaintiffs incorporate paragraphs 1-30 of this Complaint as if fully set forth herein.

46. On information and belief, Barr's Gianvi® product directly and indirectly infringes one or more claims of the '838 reissue patent.

47. The '838 reissue patent covers Bayer HealthCare's YAZ® tablets and has been listed for the product in the Orange Book.

48. On information and belief, Barr submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Gianvi® before the expiration of the '838 reissue patent.

49. On information and belief, Barr made and included in its ANDA 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 Gianvi®.

50. While Barr alleged noninfringement of several of the '838 reissue patent's claims in its Notice Letter, Barr did not allege noninfringement of all the '838 reissue patent's claims.

51. By filing its ANDA 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 Gianvi®

McDONALD·CARANO·WILSON LLP
2300 WEST SAHARA AVENUE • SUITE 1000 • LAS VEGAS, NEVADA 89102-4354
PHONE (702) 873-4100 • FAX (702) 873-9966

before the expiration of the '838 reissue patent, Barr has committed an act of infringement under 35 U.S.C. § 271(e)(2).

52. 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 Barr's ANDA shall be changed to 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 Plaintiffs become entitled.

53. Barr, on information and belief, has infringed and/or continues to infringe the '838 reissue patent in violation of 35 U.S.C. § 271(a) by making, using, importing, offering to sell, and/or selling Gianvi® in this judicial district and elsewhere in the United States.

54. Barr, on information and belief, is infringing the '838 reissue patent in violation of 35 U.S.C. § 271(b) by actively inducing others to make, use, import, offer to sell, and/or sell Gianvi® in this judicial district and elsewhere in the United States.

55. Barr, on information and belief, is infringing the '838 reissue patent in violation of 35 U.S.C. § 271(c) by contributing to the infringement by others in the making, use, importation, sale, and/or offer for sale of Gianvi® in this judicial district and elsewhere in the United States.

56. Barr's infringement of the '838 reissue patent has been and continues to be willful patent infringement. Barr's ANDA notice letter evidences that it had knowledge of the '838 reissue patent prior to its infringing acts. Barr's objectively reckless acts of making, using, selling and offering to sell Gianvi® deliberately infringed the '838 reissue patent in reckless disregard of Bayer's patent rights.

57. Pursuant to 35 U.S.C. § 284, Bayer is entitled to recover from Barr the damages sustained by Bayer as a result of Barr's wrongful acts in an amount subject to proof at trial, including without limitation lost profits and an amount not less than a reasonable royalty together with interest and costs as fixed by this Court.

McDONALD·CARANO·WILSON LLP
2300 WEST SAHARA AVENUE • SUITE 1000 • LAS VEGAS, NEVADA 89102-4354
PHONE (702) 873-4100 • FAX (702) 873-9966

58. Barr's infringement of the '838 reissue patent will continue to cause Bayer irreparable injury and damage for which there is no adequate remedy at law unless and until Barr is enjoined from infringing the '838 reissue patent.

COUNT THREE: CLAIM FOR PATENT INFRINGEMENT OF UNITED STATES REISSUE PATENT NO. 38,253

59. Plaintiffs incorporate paragraphs 1-30 of this Complaint as if fully set forth herein.

60. On information and belief, Barr's Gianvi® product directly and indirectly infringes one or more claims of the '253 reissue patent.

61. The '253 reissue patent covers Bayer HealthCare's YAZ® tablets and has been listed for the product in the Orange Book.

62. On information and belief, Barr submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Gianvi® before the expiration of the '253 reissue patent.

63. On information and belief, Barr made and included in its ANDA 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 Gianvi®.

64. While Barr alleged noninfringement of several of the '253 reissue patent's claims in its Notice Letter, Barr did not allege noninfringement of all the '253 reissue patent's claims.

65. By filing its ANDA 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 Gianvi® before the expiration of the '253 reissue patent, Barr has committed an act of infringement under 35 U.S.C. § 271(e)(2).

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 Barr's ANDA shall be changed to a date which is not earlier than June 30, 2014, the

McDONALD·CARANO·WILSON LLP
2300 WEST SAHARA AVENUE • SUITE 1000 • LAS VEGAS, NEVADA 89102-4354
PHONE (702) 873-4100 • FAX (702) 873-9966

current expiration date of the '253 reissue patent, or any later date of exclusivity to which Plaintiffs become entitled.

67. Barr, on information and belief, has infringed and/or continues to infringe the '253 reissue patent in violation of 35 U.S.C. § 271(a) by making, using, importing, offering to sell, and/or selling Gianvi® in this judicial district and elsewhere in the United States.

68. Barr, on information and belief, is infringing the '253 reissue patent in violation of 35 U.S.C. § 271(b) by actively inducing others to make, use, import, offer to sell, and/or sell Gianvi® in this judicial district and elsewhere in the United States.

69. Barr, on information and belief, is infringing the '253 reissue patent in violation of 35 U.S.C. § 271(c) by contributing to the infringement by others in the making, use, importation, sale, and/or offer for sale of Gianvi® in this judicial district and elsewhere in the United States.

70. Barr's infringement of the '253 reissue patent has been and continues to be willful patent infringement. Barr's ANDA notice letter evidences that it had knowledge of the '253 reissue patent prior to its infringing acts. Barr's objectively reckless acts of making, using, selling and offering to sell Gianvi® deliberately infringed the '253 reissue patent in reckless disregard of Bayer's patent rights.

71. Pursuant to 35 U.S.C. § 284, Bayer is entitled to recover from Barr the damages sustained by Bayer as a result of Barr's wrongful acts in an amount subject to proof at trial, including without limitation lost profits and an amount not less than a reasonable royalty together with interest and costs as fixed by this Court.

72. Barr's infringement of the '253 reissue patent will continue to cause Bayer irreparable injury and damage for which there is no adequate remedy at law unless and until Barr is enjoined from infringing the '253 reissue patent.

McDONALD·CARANO·WILSON LLP
2300 WEST SAHARA AVENUE • SUITE 1000 • LAS VEGAS, NEVADA 89102-4354
PHONE (702) 873-4100 • FAX (702) 873-9966

McDONALD·CARANO·WILSON LLP
2300 WEST SAHARA AVENUE • SUITE 1000 • LAS VEGAS, NEVADA 89102-4354
PHONE (702) 873-4100 • FAX (702) 873-9966

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment that Barr has infringed one or more claims of the '564 reissue patent, the '838 reissue patent, and the '253 reissue patent by filing its ANDA relating to Gianvi®;

B. Judgment that Barr has directly and/or indirectly infringed one or more claims of the '564 reissue patent, the '838 reissue patent, and the '253 reissue patent by making, using, importing, selling and/or offering to sell Gianvi®;

C. An award to Bayer of damages adequate to compensate Bayer for Barr's acts of infringement together with prejudgment interest;

D. An award to Bayer of enhanced damages, up to and including trebling of Bayer's damages pursuant to 35 U.S.C. § 284, for Barr's willful infringement;

E. An award of Bayer's costs of suit and reasonable attorneys' fees pursuant to 35 U.S.C. § 285 due to the exceptional nature of this case, or as otherwise permitted by law;

F. A permanent injunction restraining and enjoining Barr and its officers, agents, attorneys, employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Gianvi®;

G. An order that the effective date of any approval of Barr's ANDA relating to Gianvi® be changed to a date which is not earlier than the expiration date of the latter of the '564 reissue patent, the '838 reissue patent, and '253 reissue patent, or any later date of exclusivity to which Plaintiffs become entitled; and

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

JURY DEMAND

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

Respectfully Submitted: June 7, 2010

McDONALD CARANO WILSON LLP

/s/ Andrew P. Gordon
Andrew P. Gordon (Nevada Bar # 3421)
2300 West Sahara Avenue, Suite 1000
Las Vegas, Nevada 89102

Of Counsel:
Peter B. Bensinger, Jr.
Paul J. Skiermont
Adam K. Mortara
Sundeep K. (Rob) Addy
Matthew R. Ford
BARTLIT BECK HERMAN PALENCHAR & SCOTT LLP
54 West Hubbard Street
Chicago, Illinois 60654

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

McDONALD·CARANO·WILSON LLP
2300 WEST SAHARA AVENUE • SUITE 1000 • LAS VEGAS, NEVADA 89102-4354
PHONE (702) 873-4100 • FAX (702) 873-9966