

THE PARTIES

2. Plaintiff Pfizer Inc. (“Pfizer”) is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 235 East 42nd Street, New York, New York 10017.

3. Plaintiff UCB Pharma GmbH (“UCB”) is an entity organized and existing under the laws of Germany, having a place of business at Alfred-Nobel-Strasse 10, Monheim, Germany 40789.

4. On information and belief, Amerigen Pharmaceuticals, Inc., is a company organized and existing under the laws of the State of Delaware, having a principal place of business at 9 Polito Ave., Suite 900, Lyndhurst, New Jersey, 07071. On information and belief, Amerigen Pharmaceuticals, Inc. is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States. On further information and belief, Amerigen Pharmaceuticals, Inc. has previously admitted that it is subject to this Court’s jurisdiction and has previously submitted to this Court’s jurisdiction. Amerigen Pharmaceuticals, Inc. has purposefully availed itself of the jurisdiction of this Court by, inter alia, asserting counterclaims in lawsuits filed against it in this District. Amerigen Pharmaceuticals, Inc. is the U.S. agent for Amerigen Pharmaceuticals Ltd.

5. On information and belief, Amerigen Pharmaceuticals Ltd. is a corporation existing under the laws of the Cayman Islands, with a registered office at C/O Codan Trust Company (Cayman) Limited, Cricket Square, Hutchins Drive, P.O. Box 2681, Grand Cayman, KY1-1111 Cayman. On information and belief, Amerigen Pharmaceuticals Ltd. is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States. On further information and belief, Amerigen Pharmaceuticals Ltd. has previously admitted that it is subject to this Court’s

jurisdiction and has previously submitted to this Court's jurisdiction. Amerigen Pharmaceuticals Ltd. has purposefully availed itself of the jurisdiction of this Court by, inter alia, asserting counterclaims in lawsuits filed against it in this District.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over Amerigen by virtue of, inter alia, its presence in Delaware, having conducted business in Delaware and having derived substantial revenue therefrom, having availed itself of the rights and benefits of Delaware law, previously consenting to personal jurisdiction in this Court, availing itself of the jurisdiction of this Court, and having engaged in systematic and continuous contacts with the State of Delaware.

8. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS-IN-SUIT

9. On February 22, 2005, the United States Patent and Trademark Office issued the '650 patent, entitled "Stable Salts of Novel Derivatives of 3,3-Diphenylpropylamines." At the time of its issue, the '650 patent was assigned to Schwarz Pharma AG. UCB, formerly known as Schwarz Pharma AG, currently holds title to the '650 patent, a copy of which is attached to this Complaint as Exhibit A. Pfizer is the exclusive licensee of the '650 patent.

10. On June 10, 2008, the United States Patent and Trademark Office issued the '980 patent, entitled "Derivatives of 3,3-Diphenylpropylamines." At the time of its issue, the '980 patent was assigned to Schwarz Pharma AG. UCB, formerly known as Schwarz

Pharma AG, currently holds title to the '980 patent, a copy of which is attached to this Complaint as Exhibit B. Pfizer is the exclusive licensee of the '980 patent.

11. On December 21, 2010, the United States Patent and Trademark Office issued the '230 patent, entitled "Derivatives of 3,3-Diphenylpropylamines." At the time of its issue, the '230 patent was assigned to UCB, which currently holds title to the '230 patent. A copy of the '230 patent is attached to this Complaint as Exhibit C. Pfizer is the exclusive licensee of the '230 patent.

12. On July 26, 2011, the United States Patent and Trademark Office issued the '772 patent, entitled "Derivatives of 3,3-Diphenylpropylamines." At the time of its issue, the '772 patent was assigned to UCB, which currently holds title to the '772 patent. A copy of the '772 patent is attached to this Complaint as Exhibit D. Pfizer is the exclusive licensee of the '772 patent.

13. On December 25, 2012, the United States Patent and Trademark Office issued the '478 patent, entitled "Derivatives of 3,3-Diphenylpropylamines." At the time of its issue, the '478 patent was assigned to UCB, which currently holds title to the '478 patent. A copy of the '478 patent is attached to this Complaint as Exhibit E. Pfizer is the exclusive licensee of the '478 patent.

TOVIAZ[®]

14. Pfizer holds approved New Drug Application No. 022030 ("the Toviaz[®] NDA") for fesoterodine fumarate extended-release tablets, in 4 and 8 mg dosage strengths, which Pfizer sells under the trade name Toviaz[®].

15. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '650, '980, '230, '772, and '478 patents are listed in the FDA publication, "Approved Drug

Products with Therapeutic Equivalence Evaluations” (the “Orange Book”), with respect to Toviaz®.

AMERIGEN’S ANDA

16. On information and belief, Amerigen has submitted ANDA No. 204504 (“Amerigen’s ANDA”) to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market fesoterodine fumarate extended-release tablets in 4 and 8 mg dosage strengths (“Amerigen’s Product”).

17. On information and belief, Amerigen’s ANDA refers to and relies upon the Toviaz® NDA and contains data that, according to Amerigen, demonstrate the bioequivalence of Amerigen’s Product and Toviaz®.

18. By letter to Pfizer and UCB, dated May 31, 2013, Amerigen stated that Amerigen’s ANDA contained certifications, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the ‘650, ‘980, ‘230, ‘772, and ‘478 patents are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Amerigen’s Product (the “Paragraph IV Certifications”). Amerigen attached a memorandum to its May 31, 2013 letter, in which it alleged factual and legal bases for its Paragraph IV Certifications.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 6,858,650

19. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-18 of this Complaint.

20. Amerigen has infringed the ‘650 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Amerigen’s ANDA, by which Amerigen seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Amerigen’s Product prior to the expiration of the ‘650 patent.

21. Amerigen's sale, offer for sale, use, or commercial manufacture, of Amerigen's Product within the United States, or importation of Amerigen's Product into the United States, during the term of the '650 patent would infringe the '650 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

22. Plaintiffs will be harmed substantially and irreparably if Amerigen is not enjoined from infringing the '650 patent.

23. Plaintiffs have no adequate remedy at law.

24. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 7,384,980

25. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-18 of this Complaint.

26. Amerigen has infringed the '980 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Amerigen's ANDA, by which Amerigen seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Amerigen's Product prior to the expiration of the '980 patent.

27. Amerigen's sale, offer for sale, use, or commercial manufacture, of Amerigen's Product within the United States, or importation of Amerigen's Product into the United States, during the term of the '980 patent would infringe the '980 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

28. Plaintiffs will be harmed substantially and irreparably if Amerigen is not enjoined from infringing the '980 patent.

29. Plaintiffs have no adequate remedy at law.

30. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 7,855,230

31. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-18 of this Complaint.

32. Amerigen has infringed the '230 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Amerigen's ANDA, by which Amerigen seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Amerigen's Product prior to the expiration of the '230 patent.

33. Amerigen's sale, offer for sale, use, or commercial manufacture, of Amerigen's Product within the United States, or importation of Amerigen's Product into the United States, during the term of the '230 patent would infringe the '230 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

34. Plaintiffs will be harmed substantially and irreparably if Amerigen is not enjoined from infringing the '230 patent.

35. Plaintiffs have no adequate remedy at law.

36. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 7,985,772

37. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-18 of this Complaint.

38. Amerigen has infringed the '772 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Amerigen's ANDA, by which Amerigen seeks approval from the

FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Amerigen's Product prior to the expiration of the '772 patent.

39. Amerigen's sale, offer for sale, use, or commercial manufacture, of Amerigen's Product within the United States, or importation of Amerigen's Product into the United States, during the term of the '772 patent would infringe the '772 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

40. Plaintiffs will be harmed substantially and irreparably if Amerigen is not enjoined from infringing the '772 patent.

41. Plaintiffs have no adequate remedy at law.

42. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 8,338,478

43. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-18 of this Complaint.

44. Amerigen has infringed the '478 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Amerigen's ANDA, by which Amerigen seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Amerigen's Product prior to the expiration of the '478 patent.

45. Amerigen's sale, offer for sale, use, or commercial manufacture, of Amerigen's Product within the United States, or importation of Amerigen's Product into the United States, during the term of the '478 patent would infringe the '478 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

46. Plaintiffs will be harmed substantially and irreparably if Amerigen is not enjoined from infringing the '478 patent.

47. Plaintiffs have no adequate remedy at law.

48. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for a judgment in their favor and against Amerigen and respectfully request the following relief:

A. A judgment that Amerigen has infringed the '650 patent;

B. A judgment that Amerigen has infringed the '980 patent;

C. A judgment that Amerigen has infringed the '230 patent;

D. A judgment that Amerigen has infringed the '772 patent;

E. A judgment that Amerigen has infringed the '478 patent;

F. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Amerigen, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from manufacturing, using, offering to sell, or selling Amerigen's Product within the United States, or importing Amerigen's Product into the United States, prior to the expiration of the '650, '980, '230, '772, and '478 patents, including any extensions;

G. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 204504, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), shall not be earlier than the expiration of the '650, '980, '230, '772, and '478 patents, including any extensions;

H. If Amerigen commercially manufactures, uses, offers to sell, or sells Amerigen's Product within the United States, or imports Amerigen's Product into the United

States, prior to the expiration of any of the '650, '980, '230, '772, and '478 patents, including any extensions, a judgment awarding Pfizer monetary relief, together with interest;

- I. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;
- J. Costs and expenses in this action; and
- K. Such other relief as the Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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June 28, 2013