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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

JANSSEN PHARMACEUTICALS, INC. and GRÜNENTHAL GMBH, Plaintiffs, v. ACTAVIS ELIZABETH LLC and ALKEM LABORATORIES LIMITED, Defendants.	Civil Action No. 2:13-cv-04507-CCC-MF

SECOND AMENDED COMPLAINT

In this patent infringement action, Plaintiffs Janssen Pharmaceuticals, Inc. ("Janssen") and Grünenthal GmbH ("Grünenthal"), for their complaint against Defendant Actavis Elizabeth LLC ("Actavis") and Defendant Alkem Laboratories Limited ("Alkem"), allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, in response to the submission of Abbreviated New Drug Applications ("ANDAs") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of NUCYNTA® or NUCYNTA® ER prior to the expiration of U.S. Reissue Patent No. 39,593 E ("the RE593 Patent"), U.S. Patent No. 7,994,364 B2 ("the '364 Patent") and U.S. Patent No. 8,309,060 B2 ("the '060 Patent").

THE PARTIES

2. Plaintiff Grünenthal is a corporation organized and existing under the laws of Germany, having an address at Zieglerstrasse 6, 52078 Aachen, Germany. Grünenthal owns the RE593, '364 and '060 Patents.

3. Plaintiff Janssen is a Pennsylvania corporation, having its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560. As discussed below, Janssen is an exclusive licensee of the RE593, '364 and '060 Patents.

4. Janssen holds FDA-approved New Drug Application ("NDA") No. 022304.

5. Janssen manufactures and markets the drug covered by NDA No. 022304 ("NUCYNTA" or the "NUCYNTA drug product") in the United States. The active ingredient of NUCYNTA is tapentadol hydrochloride. The drug is marketed under the registered trade name NUCYNTA®. Under NDA 022304, NUCYNTA is marketed in 50, 75 and 100 mg tablets.

6. Janssen holds FDA-approved NDA No. 200533.

7. Janssen manufactures and markets the drug covered by NDA No. 200533 ("NUCYNTA ER" or the "NUCYNTA ER drug product") in the United States. The active

ingredient of NUCYNTA ER is tapentadol hydrochloride. The drug is marketed under the registered trade name NUCYNTA® ER. Under NDA No. 200533, NUCYNTA ER is marketed in 50, 100, 150, 200, and 250 mg tablets.

8. NUCYNTA is approved by the FDA for the management of moderate to severe acute pain in adults.

9. NUCYNTA ER is approved by the FDA for the management of moderate to severe chronic pain in adults and neuropathic pain associated with diabetic peripheral neuropathy in adults when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. It is labeled ER because it has extended-release properties.

10. On information and belief, Defendant Actavis is a single member limited liability company organized and existing under the laws of the State of Delaware, having a place of business at 200 Elmora Avenue, Elizabeth, NJ 07207. Actavis Elizabeth is registered to do business in New Jersey under Business I.D. No. 0600272818.

11. On information and belief, Defendant Alkem is an Indian company having its principal place of business at Alkem House, Devashish, Senapati Bapat Marg, Lower Parel (West), Mumbai, India.

THE PATENTS-IN-SUIT

RE593 Patent

12. The RE593 Patent, entitled "1-PHENYL-3-DIMETHYLAMINOPROPANE COMPOUNDS WITH A PHARMACOLOGICAL EFFECTS," was duly and legally issued on April 24, 2007, naming Helmut Buschmann, Elmar Friderichs, and Wolfgang Strassburger as the inventors. A copy of the RE593 Patent is attached hereto as Exhibit 1.

13. The RE593 Patent is a reissue of U.S. Patent No. 6,248,737, issued on June 19, 2001.

14. Plaintiff Grünenthal lawfully owns all right, title and interest in the RE593 Patent, including the right to sue and to recover for past infringement thereof.

15. Plaintiff Janssen is an exclusive licensee of the RE593 Patent, holding an exclusive license to import, market, distribute, promote, offer to sell or sell pharmaceutical formulations containing tapentadol for human use in the field of pain within the United States, with a right to enforce the RE593 Patent.

16. The FDA issues a publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book").

17. In accordance with 21 U.S.C. § 355(b)(1), the RE593 Patent is listed in the Orange Book in connection with NDA No. 022304 as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" NUCYNTA.

18. In accordance with 21 U.S.C. § 355(b)(1), the RE593 Patent is listed in the Orange Book in connection with NDA No. 200533 as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" NUCYNTA ER.

The '364 Patent

19. The '364 Patent, entitled "CRYSTALLINE FORMS OF (-)-(1R,2R)-3-(3-DIMETHYLAMINO-1-ETHYL-2-METHYLPROPYL)-PHENOL HYDROCHLORIDE," was duly and legally issued on August 9, 2011, naming Andreas Fischer, Helmut Buschmann,

Michael Gruss, and Dagmar Lischke as the inventors. A copy of the '364 Patent is attached hereto as Exhibit 2.

20. Plaintiff Grünenthal lawfully owns all right, title and interest in the '364 Patent, including the right to sue and to recover for past infringement thereof.

21. Plaintiff Janssen is an exclusive licensee of the '364 Patent, holding an exclusive license to import, market, distribute, promote, offer to sell or sell pharmaceutical formulations containing tapentadol for human use in the field of pain within the United States, with a right to enforce the '364 Patent.

22. In accordance with 21 U.S.C. § 355(b)(1), the '364 Patent is listed in the Orange Book in connection with NDA No. 022304 as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" NUCYNTA.

23. In accordance with 21 U.S.C. § 355(b)(1), the '364 Patent is listed in the Orange Book in connection with NDA No. 200533 as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" NUCYNTA ER.

The '060 Patent

24. The '060 Patent, entitled "ABUSE-PROOFED DOSAGE FORM," was duly and legally issued on November 13, 2012, naming Johannes Bartholomaus, Heinrich Kugelmann, and Elisabeth Arkenau-Marić as the inventors. A copy of the '060 Patent is attached hereto as Exhibit 3.

25. Plaintiff Grünenthal lawfully owns all right, title and interest in the '060 Patent, including the right to sue and to recover for past infringement thereof.

26. Plaintiff Janssen is an exclusive licensee of the '060 Patent, holding an exclusive license to import, market, distribute, promote, offer to sell or sell pharmaceutical formulations containing tapentadol for human use in the field of pain within the United States, with a right to enforce the '060 Patent.

27. In accordance with 21 U.S.C. § 355(b)(1), the '060 Patent is listed in the Orange Book in connection with NDA No. 200533 as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" NUCYNTA ER.

THE DEFENDANTS' ANDAS

Actavis's ANDA No. 204971

28. On information and belief, Actavis submitted ANDA No. 204971 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking FDA approval to engage in the commercial manufacture, use, importation, offer for sale, and sale of generic 50 mg, 75 mg, and 100 mg tapentadol hydrochloride tablets (the "ANDA No. 204971 Products").

29. On information and belief, Actavis's ANDA No. 204971 contains certification(s) pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification(s)") alleging that the RE593 and '364 Patents are "invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, importation, offer for sale, or sale of the proposed drug products that are the subject of Actavis's ANDA" No. 204971.

30. On information and belief, Actavis is the owner of ANDA No. 204971.

31. On information and belief, if ANDA No. 204971 is approved by the FDA before the expiration of the RE593 and '364 Patents, Actavis will begin manufacturing, using, importing, offering for sale, and/or selling the ANDA No. 204971 Products, despite the patents.

32. On information and belief, if ANDA No. 204971 is approved by the FDA, Actavis will begin marketing the ANDA No. 204971 Products for the management of moderate to severe acute pain in adults, and doctors and patients will use each of the dosage strengths of the ANDA No. 204971 Products for the indication marketed by Actavis.

33. Actavis has correctly represented that the Reference Listed Drug of ANDA No. 204971 is NUCYNTA.

34. Pursuant to FDA regulation 21 C.F.R. § 314.94, in order to secure FDA approval, each of the ANDA No. 204971 Products' dosage strengths must have the same strength as one of the approved dosages for NUCYNTA. In addition, the ANDA No. 204971 Products must be bioequivalent to NUCYNTA.

35. On or about August 1, 2013, Plaintiffs received a letter dated July 30, 2013 (the "July 30, 2013 notice letter"), constituting the notice of ANDA No. 204971, including the Paragraph IV certification(s), required by 21 U.S.C. § 355(j)(2)(B)(i)-(ii). That notice demonstrates an actual and justiciable controversy. The Paragraph IV certification(s) alleged that the claims of the RE593 and '364 Patents are "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, importation, offer for sale, or sale of the proposed drug products that are the subject of Actavis's ANDA" No. 204971.

36. By the filing of the First Amended Complaint, an action was commenced within forty-five days of the date of receipt of the July 30, 2013 notice letter of ANDA No. 204971.

37. On information and belief, Actavis was aware of the RE593 and '364 Patents when ANDA No. 204971 was submitted to the FDA, containing the above-described Paragraph IV certifications concerning these specific patents.

38. Pursuant to 35 U.S.C. § 271(e)(2)(A), the submission of ANDA No. 204971 with Paragraph IV certifications seeking approval to market the ANDA No. 204971 Products is an act of infringement by Actavis of one or more claims of the RE593 and '364 Patents. This infringement entitles Plaintiffs to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 204971 be a date which is not earlier than the expiration date of the last expiring of the RE593 and '364 Patents, including any extensions of that date.

Actavis's ANDA No. 204972

39. On information and belief, Actavis submitted ANDA No. 204972 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking FDA approval to engage in the commercial manufacture, use, importation, offer for sale, and sale of generic 50 mg, 100 mg, 150 mg, 200 mg and 250 mg tapentadol hydrochloride extended release tablets (the "ANDA No. 204972 Products").

40. On information and belief, Actavis's ANDA No. 204972 contains certification(s) pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification(s)") alleging that the RE593, '364 and '060 Patents are "invalid, unenforceable and/or will not be infringed by the

commercial manufacture, use, importation, offer for sale, or sale of the proposed drug products that are the subject of Actavis's ANDA" No. 204972.

41. On information and belief, Actavis is the owner of ANDA No. 204972.

42. On information and belief, if ANDA No. 204972 is approved by the FDA before the expiration of the RE593, '364 and '060 Patents, Actavis will begin manufacturing, using, importing, offering for sale, and/or selling the ANDA No. 204972 Products, despite the patents.

43. On information and belief, if ANDA No. 204972 is approved by the FDA, Actavis will begin marketing the ANDA No. 204972 Products for the management of moderate to severe chronic pain in adults and/or neuropathic pain associated with diabetic peripheral neuropathy in adults, and doctors and patients will use each of the dosage strengths of the ANDA No. 204972 Products for the indications marketed by Actavis.

44. Actavis has correctly represented that the Reference Listed Drug of ANDA No. 204972 is NUCYNTA ER.

45. Pursuant to FDA regulation 21 C.F.R. § 314.94, in order to secure FDA approval, each of the ANDA No. 204972 Products' dosage strengths must have the same strength as one of the approved dosages for NUCYNTA ER. In addition, the ANDA No. 204972 Products must be bioequivalent to NUCYNTA ER.

46. On or about June 13, 2013, Plaintiffs received a letter dated June 12, 2013 (the "June 12, 2013 notice letter"), constituting the notice of ANDA No. 204972, including the Paragraph IV certification(s), required by 21 U.S.C. § 355(j)(2)(B)(i)-(ii). That notice demonstrates an actual and justiciable controversy. The Paragraph IV certification(s) alleged that the claims of the RE593, '364 and '060 Patents are "invalid, unenforceable, and/or will not

be infringed by the commercial manufacture, use, importation, offer for sale, or sale of the proposed drug products that are the subject of Actavis's ANDA" No. 204972.

47. This action was commenced within forty-five days of the date of receipt of the June 12, 2013 notice letter of ANDA No. 204972.

48. On information and belief, Actavis was aware of the RE593, '364 and '060 Patents when ANDA No. 204972 was submitted to the FDA, containing the above-described Paragraph IV certifications concerning these specific patents.

49. Pursuant to 35 U.S.C. § 271(e)(2)(A), the submission of ANDA No. 204972 with Paragraph IV certifications seeking approval to market the ANDA No. 204972 Products is an act of infringement by Actavis of one or more claims of the RE593, '364 and '060 Patents. This infringement entitles Plaintiffs to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 204972 be a date which is not earlier than the expiration date of the last expiring of the RE593, '364 and '060 Patents, including any extensions of that date.

Alkem's ANDA No. 205015

50. On information and belief, Alkem submitted ANDA No. 205015 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking FDA approval to engage in the commercial manufacture, use, importation, offer for sale, and sale of generic 50 mg, 75 mg and 100 mg tapentadol hydrochloride tablets (the "ANDA No. 205015 Products").

51. On information and belief, ANDA No. 205015 contains Paragraph IV certification(s) alleging that the claims of the RE593 and '364 Patents are "invalid,

unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the drug product described by Alkem's ANDA" No. 205015.

52. On information and belief, Alkem is the owner of ANDA No. 205015.

53. On information and belief, if ANDA No. 205015 is approved by the FDA before the expiration of the RE593 and '364 Patents, Alkem will begin manufacturing, using, importing, offering for sale, and/or selling the ANDA No. 205015 Products, despite the patents.

54. On information and belief, if ANDA No. 205015 is approved by the FDA, Alkem will begin marketing the ANDA No. 205015 Products for the management of moderate to severe acute pain in adults, and doctors and patients will use each of the dosage strengths of the ANDA No. 205015 Products for the indication marketed by Alkem.

55. Alkem has correctly represented that the Reference Listed Drug of ANDA No. 205015 is NUCYNTA.

56. Pursuant to FDA regulation 21 C.F.R. § 314.94, in order to secure FDA approval, each of the ANDA No. 205015 Products' dosage strengths must have the same strength as one of the approved dosages for NUCYNTA. In addition, the ANDA No. 205015 Products must be bioequivalent to NUCYNTA.

57. On or about June 20, 2013, Plaintiffs received a letter dated June 19, 2013 (the "June 19, 2013 notice letter"), constituting the notice of ANDA No. 205015, including the Paragraph IV certification(s), required by 21 U.S.C. § 355(j)(2)(B)(i)-(ii). That notice demonstrates an actual and justiciable controversy. The Paragraph IV certification(s) alleged that the claims of the RE593 and '364 Patents are "invalid, unenforceable, and/or will not be

infringed by the commercial manufacture, use, or sale of the drug product described by Alkem's ANDA" No. 205015.

58. This action was commenced within forty-five days of the date of the receipt of the June 19, 2013 notice letter of ANDA No. 205015.

59. On information and belief, Alkem was aware of the RE593 and '364 Patents when ANDA No. 205015 was submitted to the FDA, containing the above-described Paragraph IV certifications concerning these specific patents.

60. Pursuant to 35 U.S.C. § 271(e)(2)(A), the submission of ANDA No. 205015 with Paragraph IV certifications seeking approval to market the ANDA No. 205015 Products is an act of infringement by Alkem of one or more claims of the RE593 and '364 Patents. This infringement entitles Plaintiffs to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 205015 be a date which is not earlier than the expiration date of the last expiring of the RE593 and '364 Patents, including any extensions of that date.

Alkem's ANDA No. 205016

61. On information and belief, Alkem submitted ANDA No. 205016 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking FDA approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of at least generic 100 mg, 200 mg and 250 mg tapentadol hydrochloride extended release tablets.

62. On information and belief, ANDA No. 205016 has been amended to further seek FDA approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of at least generic 50 mg and 150 mg tapentadol hydrochloride extended release tablets.

Hereinafter the 50 mg, 100 mg, 150 mg, 200 mg and 250 mg tapentadol hydrochloride extended release tablets that are the subject of ANDA No. 205016 are referred to the "ANDA No. 205016 Products."

63. On information and belief, ANDA No. 205016 contains Paragraph IV certification(s) that the RE593 and '364 Patents are "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the drug product described by Alkem's ANDA" No. 205016.

64. On information and belief, Alkem is the owner of ANDA No. 205016.

65. On information and belief, if ANDA No. 205016 is approved by the FDA before the expiration of the RE593 and '364 Patents, Alkem will begin manufacturing, using, importing, offering for sale, and/or selling the ANDA No. 205016 Products, despite the patents.

66. On information and belief, if ANDA No. 205016 is approved by the FDA, Alkem will begin marketing the ANDA No. 205016 Products for the management of moderate to severe chronic pain in adults and/or neuropathic pain associated with diabetic peripheral neuropathy in adults, and doctors and patients will use each of the dosage strengths of the ANDA No. 205016 Products for the indications marketed by Alkem.

67. Alkem has correctly represented that the Reference Listed Drug of ANDA No. 205016 is NUCYNTA ER.

68. Pursuant to FDA regulation 21 C.F.R. § 314.94, in order to secure FDA approval each of the ANDA No. 205016 Products' dosage strengths must have the same strength as one of the approved dosages for NUCYNTA ER. In addition, the ANDA No. 205016 Products must be bioequivalent to NUCYNTA ER.

69. On or about July 1, 2013, Plaintiffs received a letter dated June 28, 2013 (the "June 28, 2013 notice letter"), constituting the notice of ANDA No. 205016, including the Paragraph IV certification(s), required by 21 U.S.C. § 355(j)(2)(B)(i)-(ii). On or about July 8, 2014, Janssen received a letter dated July 7, 2014 (the "July 7, 2014" notice letter) and on or about July 9, 2014, Grünenthal received the July 7, 2014 notice letter, constituting the notice of Alkem's amendment of ANDA No. 205016, including the Paragraph IV certification, required by 21 U.S.C. § 355(j)(2)(B)(i)-(ii). Those notices demonstrate an actual and justiciable controversy. The Paragraph IV certification(s) alleged that the claims of the RE593 and '364 Patents are "invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the drug product described by Alkem's ANDA" No. 205016.

70. This action was commenced within forty-five days of the date of the receipt of the June 28, 2013 notice letter of ANDA No. 205016. This Second Amended Complaint was filed within forty-five days of the date of the receipt of the July 7, 2014 notice letter of Alkem's further amendment of ANDA No. 205016.

71. On information and belief, Alkem was aware of the RE593 and '364 Patents when ANDA No. 205016 was submitted to the FDA, containing the above-described Paragraph IV certifications concerning these specific patents.

72. Pursuant to 35 U.S.C. § 271(e)(2)(A), the submission of ANDA No. 205016 with Paragraph IV certifications seeking approval to market the ANDA No. 205016 Products by Alkem is an act of infringement of one or more claims of the RE593 and '364 Patents. This infringement entitles Plaintiffs to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 205016 be a date

which is not earlier than the expiration date of the last expiring of the RE593 and '364 Patents, including any extensions of that date.

SUBJECT MATTER JURISDICTION

73. This action for patent infringement arises under 35 U.S.C. § 1 *et seq*. generally and 35 U.S.C. § 271(e)(2) specifically.

74. This Court has subject matter jurisdiction over this dispute pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

PERSONAL JURISDICTION OVER ACTAVIS

75. This Court has personal jurisdiction over Actavis by virtue of the fact that, *inter alia*, Actavis has committed, or aided, abetted, contributed to and/or participated in the commission of, a tortious act of patent infringement, and intends a future course of conduct that includes acts of patent infringement in New Jersey by Actavis. These acts have led and will lead to foreseeable harm and injury to a New Jersey resident corporation, Plaintiff Janssen, in New Jersey. In particular, on information and belief, Actavis is actively preparing to make the proposed generic copies of NUCYNTA that are the subject of ANDA No. 204971 and the proposed generic copies of NUCYNTA ER that are the subject of ANDA No. 204972, and to use, sell and offer for sale such generic copies in this State and this judicial district. This Court has personal jurisdiction over Actavis for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

76. Personal jurisdiction over Actavis is proper because, on information and belief, it resides in the State of New Jersey and has purposely availed itself of the privilege of doing business in this state.

PERSONAL JURISDICTION OVER ALKEM

77. This Court has personal jurisdiction over Alkem by virtue of the fact that, *inter alia*, Alkem has committed, or aided, abetted, contributed to and/or participated in the commission of, a tortious act of patent infringement, and intends a future course of conduct that includes acts of patent infringement in New Jersey by Alkem. These acts have led and will lead to foreseeable harm and injury to a New Jersey resident corporation, Plaintiff Janssen, in New Jersey. In particular, on information and belief, Alkem is actively preparing to make the proposed generic copies of NUCYNTA that are the subject of ANDA No. 205015 and the proposed generic copies of NUCYNTA ER that are the subject of ANDA No. 205016, and to use, sell and offer for sale such generic copies in this State and this judicial district. This Court has personal jurisdiction over Alkem for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

78. Personal jurisdiction over Alkem is proper because counsel for Alkem has stated that Alkem will not object to jurisdiction in this judicial district for the limited scope of the matters involving ANDA No. 205015 and ANDA No. 205016.

VENUE

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

JOINDER

80. The joinder of the claims asserted herein is proper under Fed. R. Civ. P. 18 and 20. The same active ingredient is present in each proposed ANDA product that is the subject of this case, and Plaintiffs allege that submission of each ANDA infringed at least the RE593 and '364 Patents. The claims for infringement of the RE593 and '364 Patents therefore arise out of

the same transaction, occurrence, or series of transactions or occurrences, and questions of law or fact common to all plaintiffs will arise in the action.

COUNT I: INFRINGEMENT OF THE RE593 PATENT BY ACTAVIS'S SUBMISSION OF ANDA NO. 204971

81. Plaintiffs incorporate and reallege paragraphs 1-5, 8, 10, 12-17, 28-38, 73-76, and 79-80 above.

82. The submission of ANDA No. 204971 with a Paragraph IV certification regarding the RE593 Patent was an act of infringement by Actavis of one or more claims of the RE593 Patent under 35 U.S.C. § 271(e)(2)(A).

83. On information and belief, the ANDA No. 204971 Products are covered by one or more claims of the RE593 Patent.

84. On information and belief, Actavis's commercial importation, manufacture, use, sale, and/or offer for sale of the ANDA No. 204971 Products before the expiration of the RE593 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the RE593 Patent.

85. On information and belief, the use of Actavis's ANDA No. 204971 Products in accordance with and as directed by Actavis's proposed labeling will infringe one or more claims of the RE593 Patent.

86. On information and belief, by seeking approval to distribute the ANDA No. 204971 Products with their proposed labeling, Actavis intends to cause others, specifically, for example, medical professionals and patients, to perform acts that Actavis knows will infringe one or more claims of the RE593 Patent.

87. On information and belief, unless enjoined by this Court, Actavis plans and intends to, and will, actively induce infringement of one or more claims of the RE593 Patent immediately following approval of ANDA No. 204971.

88. On information and belief, unless enjoined by this Court, Actavis plans and intends to, and will, contribute to the infringement of one or more claims of the RE593 Patent immediately following approval of ANDA No. 204971.

89. On information and belief, Actavis knows that its ANDA No. 204971 Products and their proposed labeling are especially made or adapted for use in infringing one or more claims of the RE593 Patent, and that Actavis's ANDA No. 204971 Products and their proposed labeling are not suitable for any substantial noninfringing use.

90. On information and belief, Actavis has been aware of the existence of the RE593 Patent since before the submission of ANDA No. 204971.

91. On information and belief, Actavis has no reasonable basis for believing that its ANDA No. 204971 Products will not infringe one or more valid claims of the RE593 Patent, and no reasonable basis for believing that the infringed claims are invalid.

92. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

93. On information and belief, unless enjoined by this Court, Actavis plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the ANDA No. 204971 Products with their proposed labeling immediately following approval of ANDA No. 204971.

94. The acts of infringement by Actavis set forth above will cause Plaintiffs Janssen and Grünenthal irreparable harm for which they have no adequate remedy at law, and those acts will continue unless enjoined by this Court.

95. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Actavis's ANDA No. 204971 to be a date which is not any earlier than the expiration date of the RE593 Patent, including any extensions of that date.

COUNT II: INFRINGEMENT OF THE '364 PATENT BY ACTAVIS'S SUBMISSION OF ANDA NO. 204971

96. Plaintiffs incorporate and reallege 1-5, 8, 10, 19-22, 28-38, 73-76, and 79-80 above.

97. The submission of ANDA No. 204971 with a Paragraph IV certification regarding the '364 Patent was an act of infringement by Actavis of one or more claims of the '364 Patent under 35 U.S.C. § 271(e)(2)(A).

98. On information and belief, the ANDA No. 204971 Products are covered by one or more claims of the '364 Patent.

99. On information and belief, Actavis's commercial importation, manufacture, use, sale, and/or offer for sale of the ANDA No. 204971 Products before the expiration of the '364 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '364 Patent.

100. On information and belief, the use of Actavis's ANDA No. 204971 Products in accordance with and as directed by Actavis's proposed labeling will infringe one or more claims of the '364 Patent.

101. On information and belief, by seeking approval to distribute the ANDA No. 204971 Products with their proposed labeling, Actavis intends to cause others, specifically, for example, medical professionals and patients, to perform acts that Actavis knows will infringe one or more claims of the '364 Patent.

102. On information and belief, unless enjoined by this Court, Actavis plans and intends to, and will, actively induce infringement of one or more claims of the '364 Patent immediately following approval of ANDA No. 204971.

103. On information and belief, unless enjoined by this Court, Actavis plans and intends to, and will, contribute to the infringement of one or more claims of the '364 Patent immediately following approval of ANDA No. 204971.

104. On information and belief, Actavis knows that its ANDA No. 204971 Products and their proposed labeling are especially made or adapted for use in infringing one or more claims of the '364 Patent, and that Actavis's ANDA No. 204971 Products and their proposed labeling are not suitable for any substantial noninfringing use.

105. On information and belief, Actavis has been aware of the existence of the '364 Patent since before the submission of ANDA No. 204971.

106. On information and belief, Actavis has no reasonable basis for believing that its ANDA No. 204971 Products will not infringe one or more valid claims of the '364 Patent and no reasonable basis for believing that the infringed claims are invalid.

107. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

108. On information and belief, unless enjoined by this Court, Actavis plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or

importation of the ANDA No. 204971 Products with their proposed labeling immediately following approval of ANDA No. 204971.

109. The acts of infringement by Actavis set forth above will cause Plaintiffs Janssen and Grünenthal irreparable harm for which they have no adequate remedy at law, and those acts will continue unless enjoined by this Court.

110. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Actavis's ANDA No. 204971 to be a date which is not any earlier than the expiration date of the '364 Patent, including any extensions of that date.

COUNT III: INFRINGEMENT OF THE RE593 PATENT BY ACTAVIS'S SUBMISSION OF ANDA NO. 204972

111. Plaintiffs incorporate and reallege paragraphs 1-3, 6-7, 9-10, 12-16, 18, 39-49, 73-76, and 79-80 above.

112. The submission of ANDA No. 204972 with a Paragraph IV certification regarding the RE593 Patent was an act of infringement by Actavis of one or more claims of the RE593 Patent under 35 U.S.C. § 271(e)(2)(A).

113. On information and belief, the ANDA No. 204972 Products are covered by one or more claims of the RE593 Patent.

114. On information and belief, Actavis's commercial importation, manufacture, use, sale, and/or offer for sale of the ANDA No. 204972 Products before the expiration of the RE593 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the RE593 Patent.

115. On information and belief, the use of Actavis's ANDA No. 204972 Products in accordance with and as directed by Actavis's proposed labeling will infringe one or more claims of the RE593 Patent.

116. On information and belief, by seeking approval to distribute the ANDA No. 204972 Products with their proposed labeling, Actavis intends to cause others, specifically, for example, medical professionals and patients, to perform acts that Actavis knows will infringe one or more claims of the RE593 Patent.

117. On information and belief, unless enjoined by this Court, Actavis plans and intends to, and will, actively induce infringement of one or more claims of the RE593 Patent immediately following approval of ANDA No. 204972.

118. On information and belief, unless enjoined by this Court, Actavis plans and intends to, and will, contribute to the infringement of one or more claims of the RE593 Patent immediately following approval of ANDA No. 204972.

119. On information and belief, Actavis knows that its ANDA No. 204972 Products and their proposed labeling are especially made or adapted for use in infringing one or more claims of the RE593 Patent, and that Actavis's ANDA No. 204972 Products and their proposed labeling are not suitable for any substantial noninfringing use.

120. On information and belief, Actavis has been aware of the existence of the RE593 Patent since before the submission of ANDA No. 204972.

121. On information and belief, Actavis has no reasonable basis for believing that its ANDA No. 204972 Products will not infringe one or more valid claims of the RE593 Patent, and no reasonable basis for believing that the infringed claims are invalid.

122. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

123. On information and belief, unless enjoined by this Court, Actavis plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the ANDA No. 204972 Products with their proposed labeling immediately following approval of ANDA No. 204972.

124. The acts of infringement by Actavis set forth above will cause Plaintiffs Janssen and Grünenthal irreparable harm for which they have no adequate remedy at law, and those acts will continue unless enjoined by this Court.

125. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Actavis's ANDA No. 204972 to be a date which is not any earlier than the expiration date of the RE593 Patent, including any extensions of that date.

COUNT IV: INFRINGEMENT OF THE '364 PATENT BY ACTAVIS'S SUBMISSION OF ANDA NO. 204972

126. Plaintiffs incorporate and reallege paragraphs 1-3, 6-7, 9-10, 19-21, 23, 39-49, 73-76, and 79-80 above.

127. The submission of ANDA No. 204972 with a Paragraph IV certification regarding the '364 Patent was an act of infringement by Actavis of one or more claims of the '364 Patent under 35 U.S.C. § 271(e)(2)(A).

128. On information and belief, the ANDA No. 204972 Products are covered by one or more claims of the '364 Patent.

129. On information and belief, Actavis's commercial importation, manufacture, use, sale, and/or offer for sale of the ANDA No. 204972 Products before the expiration of the '364

Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '364 Patent.

130. On information and belief, the use of Actavis's ANDA No. 204972 Products in accordance with and as directed by Actavis's proposed labeling will infringe one or more claims of the '364 Patent.

131. On information and belief, by seeking approval to distribute the ANDA No. 204972 Products with their proposed labeling, Actavis intends to cause others, specifically, for example, medical professionals and patients, to perform acts that Actavis knows will infringe one or more claims of the '364 Patent.

132. On information and belief, unless enjoined by this Court, Actavis plans and intends to, and will, actively induce infringement of one or more claims of the '364 Patent immediately following approval of ANDA No. 204972.

133. On information and belief, unless enjoined by this Court, Actavis plans and intends to, and will, contribute to the infringement of one or more claims of the '364 Patent immediately following approval of ANDA No. 204972.

134. On information and belief, Actavis knows that its ANDA No. 204972 Products and their proposed labeling are especially made or adapted for use in infringing one or more claims of the '364 Patent, and that Actavis's ANDA No. 204972 Products and their proposed labeling are not suitable for any substantial noninfringing use.

135. On information and belief, Actavis has been aware of the existence of the '364 Patent since before the submission of ANDA No. 204972.

136. On information and belief, Actavis has no reasonable basis for believing that its ANDA No. 204972 Products will not infringe one or more valid claims of the '364 Patent and no reasonable basis for believing that the infringed claims are invalid.

137. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

138. On information and belief, unless enjoined by this Court, Actavis plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the ANDA No. 204972 Products with their proposed labeling immediately following approval of ANDA No. 204972.

139. The acts of infringement by Actavis set forth above will cause Plaintiffs Janssen and Grünenthal irreparable harm for which they have no adequate remedy at law, and those acts will continue unless enjoined by this Court.

140. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Actavis's ANDA No. 204972 to be a date which is not any earlier than the expiration date of the '364 Patent, including any extensions of that date.

COUNT V: INFRINGEMENT OF THE '060 PATENT BY ACTAVIS'S SUBMISSION OF ANDA NO. 204972

141. Plaintiffs incorporate and reallege paragraphs 1-3, 6-7, 9-10, 24-27, 39-49, 73-76, and 79-80 above.

142. The submission of ANDA No. 204972 with a Paragraph IV certification regarding the '060 Patent was an act of infringement by Actavis of one or more claims of the '060 Patent under 35 U.S.C. § 271(e)(2)(A).

143. On information and belief, the ANDA No. 204972 Products are covered by one or more claims of the '060 Patent.

144. On information and belief, Actavis's commercial importation, manufacture, use, sale, and/or offer for sale of the ANDA No. 204972 Products before the expiration of the '060 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '060 Patent.

145. On information and belief, the use of Actavis's ANDA No. 204972 Products in accordance with and as directed by Actavis's proposed labeling will infringe one or more claims of the '060 Patent.

146. On information and belief, by seeking approval to distribute the ANDA No. 204972 Products with their proposed labeling, Actavis intends to cause others, specifically, for example, medical professionals and patients, to perform acts that Actavis knows will infringe one or more claims of the '060 Patent.

147. On information and belief, unless enjoined by this Court, Actavis plans and intends to, and will, actively induce infringement of one or more claims of the '060 Patent immediately following approval of ANDA No. 204972.

148. On information and belief, unless enjoined by this Court, Actavis plans and intends to, and will, contribute to the infringement of one or more claims of the '060 Patent immediately following approval of ANDA No. 204972.

149. On information and belief, Actavis knows that its ANDA No. 204972 Products and their proposed labeling are especially made or adapted for use in infringing one or more

claims of the '060 Patent, and that Actavis's ANDA No. 204972 Products and their proposed labeling are not suitable for any substantial noninfringing use.

150. On information and belief, Actavis has been aware of the existence of the '060 Patent since before the submission of ANDA No. 204972.

151. On information and belief, Actavis has no reasonable basis for believing that its ANDA No. 204972 Products will not infringe one or more valid claims of the '060 Patent and no reasonable basis for believing that the infringed claims are invalid.

152. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

153. On information and belief, unless enjoined by this Court, Actavis plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the ANDA No. 204972 Products with their proposed labeling immediately following approval of ANDA No. 204972.

154. The acts of infringement by Actavis set forth above will cause Plaintiffs Janssen and Grünenthal irreparable harm for which they have no adequate remedy at law, and those acts will continue unless enjoined by this Court.

155. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Actavis's ANDA No. 204972 to be a date which is not any earlier than the expiration date of the '060 Patent, including any extensions of that date.

COUNT VI: INFRINGEMENT OF THE RE593 PATENT BY ALKEM'S SUBMISSION OF ANDA NO. 205015

156. Plaintiffs incorporate and reallege paragraphs 1-5, 8, 11-17, 50-60, 73-74, and 77-80 above.

157. The submission of ANDA No. 205015 with a Paragraph IV certification regarding the RE593 Patent was an act of infringement by Alkem of one or more claims of the RE593 Patent under 35 U.S.C. § 271(e)(2)(A).

158. On information and belief, the ANDA No. 205015 Products are covered by one or more claims of the RE593 Patent.

159. On information and belief, Alkem's commercial importation, manufacture, use, sale, and/or offer for sale of the ANDA No. 205015 Products before the expiration of the RE593 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the RE593 Patent.

160. On information and belief, the use of Alkem's ANDA No. 205015 Products in accordance with and as directed by Alkem's proposed labeling will infringe one or more claims of the RE593 Patent.

161. On information and belief, by seeking approval to distribute the ANDA No. 205015 Products with their proposed labeling, Alkem intends to cause others, specifically, for example, medical professionals and patients, to perform acts that Alkem knows will infringe one or more claims of the RE593 Patent.

162. On information and belief, unless enjoined by this Court, Alkem plans and intends to, and will, actively induce infringement of one or more claims of the RE593 Patent immediately following approval of ANDA No. 205015.

163. On information and belief, unless enjoined by this Court, Alkem plans and intends to, and will, contribute to the infringement of one or more claims of the RE593 Patent immediately following approval of ANDA No. 205015.

164. On information and belief, Alkem knows that its ANDA No. 205015 Products and their proposed labeling are especially made or adapted for use in infringing one or more claims of the RE593 Patent, and that Alkem's ANDA No. 205015 Products and their proposed labeling are not suitable for any substantial noninfringing use.

165. On information and belief, Alkem has been aware of the existence of the RE593 Patent since before the submission of ANDA No. 205015.

166. On information and belief, Alkem has no reasonable basis for believing that its ANDA No. 205015 Products will not infringe one or more valid claims of the RE593 Patent and no reasonable basis for believing that the infringed claims are invalid.

167. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

168. On information and belief, unless enjoined by this Court, Alkem plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the ANDA No. 205015 Products with their proposed labeling immediately following approval of ANDA No. 205015.

169. The acts of infringement by Alkem set forth above will cause Plaintiffs Janssen and Grünenthal irreparable harm for which they have no adequate remedy at law, and those acts will continue unless enjoined by this Court.

170. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Alkem's ANDA No. 205015 to be a date which is not any earlier than the expiration date of the RE593 Patent, including any extensions of that date.

COUNT VII: INFRINGEMENT OF THE '364 PATENT BY ALKEM'S SUBMISSION OF ANDA NO. 205015

171. Plaintiffs incorporate and reallege paragraphs 1-5, 8, 11, 19-22, 50-60, 73-74, and 77-80 above.

172. The submission of ANDA No. 205015 with a Paragraph IV certification regarding the '364 Patent was an act of infringement by Alkem of one or more claims of the '364 Patent under 35 U.S.C. § 271 (e)(2)(A).

173. On information and belief, the ANDA No. 205015 Products are covered by one or more claims of the '364 Patent.

174. On information and belief, Alkem's commercial importation, manufacture, use, sale, and/or offer for sale of the ANDA No. 205015 Products before the expiration of the '364 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '364 Patent.

175. On information and belief, the use of Alkem's ANDA No. 205015 Products in accordance with and as directed by Alkem's proposed labeling will infringe one or more claims of the '364 Patent.

176. On information and belief, by seeking approval to distribute the ANDA No. 205015 Products with their proposed labeling, Alkem intends to cause others, specifically, for example, medical professionals and patients, to perform acts that Alkem knows will infringe one or more claims of the '364 Patent.

177. On information and belief, unless enjoined by this Court, Alkem plans and intends to, and will, actively induce infringement of one or more claims of the '364 Patent immediately following approval of ANDA No. 205015.

178. On information and belief, unless enjoined by this Court, Alkem plans and intends to, and will, contribute to the infringement of one or more claims of the '364 Patent immediately following approval of ANDA No. 205015.

179. On information and belief, Alkem knows that its ANDA No. 205015 Products and their proposed labeling are especially made or adapted for use in infringing one or more claims of the '364 Patent, and that Alkem's ANDA No. 205015 Products and their proposed labeling are not suitable for any substantial noninfringing use.

180. On information and belief, Alkem has been aware of the existence of the '364 Patent since before the submission of ANDA No. 205015.

181. On information and belief, Alkem has no reasonable basis for believing that its ANDA No. 205015 Products will not infringe one or more valid claims of the '364 Patent and no reasonable basis for believing that the infringed claims are invalid.

182. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

183. On information and belief, unless enjoined by this Court, Alkem plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the ANDA No. 205015 Products with their proposed labeling immediately following approval of ANDA No. 205015.

184. The acts of infringement by Alkem set forth above will cause Plaintiffs Janssen and Grünenthal irreparable harm for which they have no adequate remedy at law, and those acts will continue unless enjoined by this Court.

185. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Alkem's

ANDA No. 205015 to be a date which is not any earlier than the expiration date of the '364 Patent, including any extensions of that date.

COUNT VIII: INFRINGEMENT OF THE RE593 PATENT BY ALKEM'S SUBMISSION OF ANDA NO. 205016

186. Plaintiffs incorporate and reallege paragraphs 1-3, 6-7, 9, 11-16, 18, 61-74, and 77-80 above.

187. The submission of ANDA No. 205016 with a Paragraph IV certification regarding the RE593 Patent was an act of infringement by Alkem of one or more claims of the RE593 Patent under 35 U.S.C. § 271(e)(2)(A).

188. On information and belief, the ANDA No. 205016 Products are covered by one or more claims of the RE593 Patent.

189. On information and belief, Alkem's commercial importation, manufacture, use, sale, and/or offer for sale of the ANDA No. 205016 Products before the expiration of the RE593 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the RE593 Patent.

190. On information and belief, the use of Alkem's ANDA No. 205016 Products in accordance with and as directed by Alkem's proposed labeling will infringe one or more claims of the RE593 Patent.

191. On information and belief, by seeking approval to distribute the ANDA No. 205016 Products with their proposed labeling, Alkem intends to cause others, specifically, for example, medical professionals and patients, to perform acts that Alkem knows will infringe one or more claims of the RE593 Patent.

192. On information and belief, unless enjoined by this Court, Alkem plans and intends to, and will, actively induce infringement of one or more claims of the RE593 Patent immediately following approval of ANDA No. 205016.

193. On information and belief, unless enjoined by this Court, Alkem plans and intends to, and will, contribute to the infringement of one or more claims of the RE593 Patent immediately following approval of ANDA No. 205016.

194. On information and belief, Alkem knows that its ANDA No. 205016 Products and their proposed labeling are especially made or adapted for use in infringing one or more claims of the RE593 Patent, and that Alkem's ANDA No. 205016 Products and their proposed labeling are not suitable for any substantial noninfringing use.

195. On information and belief, Alkem has been aware of the existence of the RE593 Patent since before the submission of ANDA No. 205016.

196. On information and belief, Alkem has no reasonable basis for believing that its ANDA No. 205016 Products will not infringe one or more valid claims of the RE593 Patent and no reasonable basis for believing that the infringed claims are invalid.

197. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

198. On information and belief, unless enjoined by this Court, Alkem plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the ANDA No. 205016 Products with their proposed labeling immediately following approval of ANDA No. 205016.

199. The acts of infringement by Alkem set forth above will cause Plaintiffs Janssen and Grünenthal irreparable harm for which they have no adequate remedy at law, and those acts will continue unless enjoined by this Court.

200. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Alkem's ANDA No. 205016 to be a date which is not any earlier than the expiration date of the RE593 Patent, including any extensions of that date.

COUNT IX: INFRINGEMENT OF THE '364 PATENT BY ALKEM'S SUBMISSION OF ANDA NO. 205016

201. Plaintiffs incorporate and reallege paragraphs 1-3, 6-7, 9, 11, 19-21, 23, 61-74, and 77-80 above.

202. The submission of ANDA No. 205016 with a Paragraph IV certification regarding the '364 Patent was an act of infringement by Alkem of one or more claims of the '364 Patent under 35 U.S.C. § 271 (e)(2)(A).

203. On information and belief, the ANDA No. 205016 Products are covered by one or more claims of the '364 Patent.

204. On information and belief, Alkem's commercial importation, manufacture, use, sale, and/or offer for sale of the ANDA No. 205016 Products before the expiration of the '364 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '364 Patent.

205. On information and belief, the use of Alkem's ANDA No. 205016 Products in accordance with and as directed by Alkem's proposed labeling will infringe one or more claims of the '364 Patent.

206. On information and belief, by seeking approval to distribute the ANDA No. 205016 Products with their proposed labeling, Alkem intends to cause others, specifically, for example, medical professionals and patients, to perform acts that Alkem knows will infringe one or more claims of the '364 Patent.

207. On information and belief, unless enjoined by this Court, Alkem plans and intends to, and will, actively induce infringement of one or more claims of the '364 Patent immediately following approval of ANDA No. 205016.

208. On information and belief, unless enjoined by this Court, Alkem plans and intends to, and will, contribute to the infringement of one or more claims of the '364 Patent immediately following approval of ANDA No. 205016.

209. On information and belief, Alkem knows that its ANDA No. 205016 Products and their proposed labeling are especially made or adapted for use in infringing one or more claims of the '364 Patent, and that Alkem's ANDA No. 205016 Products and their proposed labeling are not suitable for any substantial noninfringing use.

210. On information and belief, Alkem has been aware of the existence of the '364 Patent since before the submission of ANDA No. 205016.

211. On information and belief, Alkem has no reasonable basis for believing that its ANDA No. 205016 Products will not infringe one or more valid claims of the '364 Patent and no reasonable basis for believing that the infringed claims are invalid.

212. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

213. On information and belief, unless enjoined by this Court, Alkem plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation

of the ANDA No. 205016 Products with their proposed labeling immediately following approval of ANDA No. 205016.

214. The acts of infringement by Alkem set forth above will cause Plaintiffs Janssen and Grünenthal irreparable harm for which they have no adequate remedy at law, and those acts will continue unless enjoined by this Court.

215. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Alkem's ANDA No. 205016 to be a date which is not any earlier than the expiration date of the '364 Patent, including any extensions of that date.

RELIEF SOUGHT

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment in favor of Plaintiffs and against Defendants;

B. Judgment that the RE593, '364 and '060 Patents have not been proven invalid and unenforceable;

C. Judgment that Actavis has infringed, literally or by the doctrine of equivalents, the RE593 and '364 Patents by the submission of ANDA No. 204971, and that the commercial importation, sale, offer for sale, use, and/or manufacture of the ANDA No. 204971 Products, in the United States, would infringe, induce infringement of, and/or contribute to the infringement of the RE593 and '364 Patents;

D. Judgment that Actavis has infringed, literally or by the doctrine of equivalents, the RE593, '364 and '060 Patents by the submission of ANDA No. 204972, and that

the commercial importation, sale, offer for sale, use, and/or manufacture of the ANDA No. 204972 Products, in the United States, would infringe, induce infringement of, and/or contribute to the infringement of the RE593, '364 and '060 Patents;

E. Judgment that Alkem has infringed, literally or by the doctrine of equivalents, the RE593 and '364 Patents by the submission of ANDA No. 205015, and that the commercial importation, sale, offer for sale, use, and/or manufacture of the ANDA No. 205015 Products, in the United States, would infringe, induce infringement of, and/or contribute to the infringement of the RE593 and '364 Patents;

F. Judgment that Alkem has infringed, literally or by the doctrine of equivalents, the RE593 and '364 Patents by the submission of ANDA No. 205016, and that the commercial importation, sale, offer for sale, use, and/or manufacture of the ANDA No. 205016 Products, in the United States, would infringe, induce infringement of, and/or contribute to the infringement of the RE593 and '364 Patents;

G. Judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of approval of ANDA No. 204971 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), shall be a date not earlier than the date of expiration of the latest of the RE593 and '364 Patents plus any additional periods of exclusivity;

H. Judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of approval of ANDA No. 204972 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21

U.S.C. § 355(j)), shall be a date not earlier than the date of expiration of the latest of the RE593, '364 and '060 Patents plus any additional periods of exclusivity;

I. Judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of approval of ANDA No. 205015 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), shall be a date not earlier than the date of expiration of the latest of the RE593 and '364 Patents plus any additional periods of exclusivity;

J. Judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of approval of ANDA No. 205016 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), shall be a date not earlier than the date of expiration of the latest of the RE593 and '364 Patents plus any additional periods of exclusivity;

K. A preliminary and permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., enjoining Actavis, and its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any ANDA No. 204971 Product, and any product that is similar to or only colorably different from those products, before the date of expiration of the latest of the RE593 and '364 Patents and any additional periods of exclusivity;

L. A preliminary and permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., enjoining Actavis, and its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any ANDA No. 204972 Product, and any product that is similar to or only colorably different from those products, before the date of expiration of the latest of the RE593, '364 and '060 Patents and any additional periods of exclusivity;

M. A preliminary and permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., enjoining Alkem and its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any ANDA No. 205015 Product, and any product that is similar to or only colorably different from those products, before the date of expiration of the latest of the RE593 and '364 Patents and any additional periods of exclusivity;

N. A preliminary and permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., enjoining Alkem, and its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related

business entities and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any ANDA No. 205016 Product, and any product that is similar to or only colorably different from those products, before the date of expiration of the latest of the RE593 and '364 Patents and any additional periods of exclusivity;

O. A declaration that this is an exceptional case and an award to Plaintiffs Janssen and Grünenthal of their reasonable attorneys' fees and expenses, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

P. Damages or other monetary relief, including prejudgment interest, if Actavis engages in the commercial manufacture, use, offering to sell, sale, marketing, distribution, or importation of ANDA No. 204971 Products, or any other products that infringe the RE593 and/or '364 Patents, or the inducement of or contribution to the foregoing, prior to the expiration of the RE593 and/or '364 Patents;

Q. Damages or other monetary relief, including prejudgment interest, if Actavis engages in the commercial manufacture, use, offering to sell, sale, marketing, distribution, or importation of ANDA No. 204972 Products, or any other products that infringe the RE593, '364 and/or '060 Patents, or the inducement of or contribution to the foregoing, prior to the expiration of the RE593, '364 and/or '060 Patents;

R. Damages or other monetary relief, including prejudgment interest, if Alkem engages in the commercial manufacture, use, offering to sell, sale, marketing, distribution, or importation of ANDA No. 205015 Products, or any other products that infringe the RE593 and/or '364 Patents, or the inducement of or contribution to the foregoing, prior to the expiration of the RE593 and/or '364 Patents;

S. Damages or other monetary relief, including prejudgment interest, if Alkem engages in the commercial manufacture, use, offering to sell, sale, marketing, distribution, or importation of ANDA No. 205016 Products, or any other products that infringe the RE593 and/or '364 Patents, or the inducement of or contribution to the foregoing, prior to the expiration of the RE593 and/or '364 Patents;

T. An award of pre judgment and post judgment interest on each and every award;

U. An award of Plaintiffs' taxable costs in bringing and prosecuting this action; and

V. Such other and further relief to Plaintiffs Janssen and Grünenthal as this Court may deem just and proper.

Dated: August 20, 2014

Respectfully submitted,

Donald A. Robinson

s/Donald A. Robinson

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