IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS INTERNATIONAL GMBH, TAKEDA PHARMACEUTICALS USA, INC., TAKEDA PHARMACEUTICALS AMERICA, INC., and OREXIGEN THERAPEUTICS, INC., Plaintiffs, v. ACTAVIS LABORATORIES FL, INC., Defendant.	C. A. No.: 15-451-RGA

DEFENDANT'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendant Actavis Laboratories FL, Inc. ("Actavis"), through its attorneys, hereby submits this Answer, Affirmative Defenses, and Counterclaims to the Complaint filed by Plaintiffs Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals International Gmbh, Takeda Pharmaceuticals USA, Inc., Takeda Pharmaceuticals America, Inc., and Orexigen Therapeutics, Inc. (collectively, "Plaintiffs") as follows. Pursuant to a Stipulation and Proposed Order filed on July 24, 2015 (D.I. 10), the parties have agreed to the dismissal of defendants Andrx Corporation, Actavis Pharma, Inc., and Actavis, Inc. from the above-captioned litigation. As a result, the following answers are made solely on behalf of Actavis and no statement made herein shall be construed as an admission of Andrx Corporation, Actavis Pharma, Inc., and/or Actavis, Inc. Each of the paragraphs below corresponds to the same-numbered paragraphs in the Complaint. Actavis denies all allegations in the Complaint, whether express or implied, that are not specifically admitted below. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications, or

speculations that arguably follow from the admitted facts. Actavis denies that Plaintiffs are entitled to the relief requested or any other relief. Actavis responds to the Complaint as follows:

NATURE OF THE ACTION

1. Actavis admits that the Complaint purports to state an action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, and in particular under 35 U.S.C. § 271(e). Actavis admits that the Complaint purports to state that the action relates to Abbreviated New Drug Application ("ANDA") No. 208043 filed by Actavis with the United States Food and Drug Administration ("FDA") for approval to market generic versions of Plaintiffs' CONTRAVE® product prior to the expiration of various patents owned or exclusively licensed by Plaintiffs that cover CONTRAVE®. Actavis denies the remaining allegations of paragraph 1.

THE PARTIES

2. Actavis lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 2, and, therefore, denies the same.

3. Actavis lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 3, and, therefore, denies the same.

4. Actavis lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 4, and, therefore, denies the same.

5. Actavis lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 5, and, therefore, denies the same.

6. Actavis lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 6, and, therefore, denies the same.

7. Actavis admits that Actavis is a company organized and existing under the laws of Florida and with a place of business at 2945 W. Corporate Lakes Blvd., Weston Florida. Actavis admits that it is a wholly-owned subsidiary of Andrx.

8. Actavis does not contest personal jurisdiction over Actavis for purposes of this action only, and therefore, Actavis denies the allegations of paragraph 8.

9. Actavis does not contest personal jurisdiction over Actavis for purposes of this action only, and therefore, Actavis denies the allegations of paragraph 9.

10. As the parties have agreed to the dismissal of Andrx Corporation, a response as to Andrx Corporation is unnecessary. Therefore, Actavis denies the allegations of paragraph 10.

11. As the parties have agreed to the dismissal of Actavis Pharma, Inc., a response as to Actavis Pharma, Inc. is unnecessary. Therefore, Actavis denies the allegations of paragraph 11.

12. As the parties have agreed to the dismissal of Actavis Pharma, Inc., a response as to Actavis Pharma, Inc. is unnecessary. Therefore, Actavis denies the allegations of paragraph 12.

13. As the parties have agreed to the dismissal of Actavis, Inc., a response as to Actavis, Inc. is unnecessary. Therefore, Actavis denies the allegations of paragraph 13.

14. As the parties have agreed to the dismissal of Actavis, Inc., a response as to Actavis, Inc. is unnecessary. Therefore, Actavis denies the allegations of paragraph 14.

JURISDICTION AND VENUE

15. Actavis admits that the Complaint purports to state an action for patent infringement of the patents-in-suit arising under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, but denies that Plaintiffs' claims have merit.

16. Actavis does not contest that the Court has subject matter jurisdiction over Plaintiffs' claims against Actavis under 35 U.S.C. §271(e)(2). Actavis specifically denies that there is subject matter jurisdiction for any claim against Andrx Corporation, Actavis Pharma, Inc., or Actavis, Inc. The remaining allegations of paragraph 16 are legal conclusions to which no response is required.

17. Actavis does not contest venue for purposes of this action only.

18. Actavis does not contest personal jurisdiction over Actavis for purposes of this action only, and therefore, Actavis denies the remaining allegations of paragraph 18.

19. As the parties have agreed to the dismissal of Andrx Corporation, Actavis Pharma, Inc., and Actavis, Inc., a response as to Andrx Corporation, Actavis Pharma, Inc., and Actavis, Inc. is unnecessary. Actavis does not contest personal jurisdiction over Actavis for purposes of this action only, and therefore, Actavis denies the remaining allegations of paragraph 19.

20. As the parties have agreed to the dismissal of Andrx Corporation, Actavis Pharma, Inc., and Actavis, Inc., a response as to Andrx Corporation, Actavis Pharma, Inc., and Actavis, Inc. is unnecessary. Actavis does not contest personal jurisdiction over Actavis for purposes of this action only, and therefore, Actavis denies the remaining allegations of paragraph 20.

21. As the parties have agreed to the dismissal of Andrx Corporation, Actavis Pharma, Inc., and Actavis, Inc., a response as to Andrx Corporation, Actavis Pharma, Inc., and Actavis, Inc. is unnecessary. Actavis does not contest personal jurisdiction over Actavis for purposes of this action only, and therefore, Actavis denies the remaining allegations of paragraph 21.

22. Actavis does not contest personal jurisdiction over Actavis, for purposes of this action only, and therefore, Actavis denies the allegations of paragraph 22.

23. As the parties have agreed to the dismissal of Actavis Pharma, Inc., a response as to Actavis Pharma, Inc. is unnecessary. Therefore, Actavis denies the allegations of paragraph 23.

24. As the parties have agreed to the dismissal of Andrx Corporation, a response as to Andrx Corporation is unnecessary. Therefore, Actavis denies the allegations of paragraph 24.

25. As the parties have agreed to the dismissal of Actavis, Inc., a response as to Actavis, Inc. is unnecessary. Therefore, Actavis denies the allegations of paragraph 25.

RELEVANT FACTS

THE BRAND NAME PRODUCT

26. Actavis admits that Takeda Pharmaceuticals USA, Inc. is identified in the electronic version of the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") as the holder of NDA No. 200063 for CONTRAVE®. Actavis admits that according to the records of the FDA, NDA No. 200063 was approved on September 10, 2014. Actavis lacks knowledge or information sufficient to form a

belief as to the truth of the remaining allegations of paragraph 26, and, therefore, denies the same.

27. Actavis admits that the CONTRAVE® label states that "CONTRAVE is a combination of naltrexone, an opioid antagonist, and bupropion, an aminoketone antidepressant, indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of: 30 kg/m2 or greater (obese) or 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia)." Actavis lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 27, and, therefore, denies the same.

THE PATENTS-IN-SUIT

28. Actavis admits that the '111 patent is titled "Compositions for Affecting Weight Loss" and lists an issue date of December 8, 1998. Actavis admits that a copy was attached to the complaint as exhibit A. Actavis lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 28, and, therefore, denies the same.

29. Actavis admits that the '626 patent is titled "Compositions for Affecting Weight Loss" and lists an issue date of December 9, 2008. Actavis admits that a copy was attached to the complaint as exhibit B. Actavis lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 29, and, therefore, denies the same.

30. Actavis admits that the '786 patent is titled "Layered Pharmaceutical Formulations" and lists an issue date of January 3, 2012. Actavis admits that a copy was

attached to the complaint as exhibit C. Actavis lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 30, and, therefore, denies the same.

31. Actavis admits that the '788 patent is titled "Layered Pharmaceutical Formulations" and lists an issue date of November 27, 2012. Actavis admits that a copy was attached to the complaint as exhibit D. Actavis lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 31, and, therefore, denies the same.

32. Actavis admits that the '085 patent is titled "Methods for Administering Weight Loss Medications" and lists an issue date of May 13, 2014. Actavis admits that a copy was attached to the complaint as exhibit E. Actavis lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 32, and, therefore, denies the same.

33. Actavis admits that the '889 patent is titled "Composition and Methods for Increasing Insulin Sensitivity" and lists an issue date of August 26, 2014. Actavis admits that a copy was attached to the complaint as exhibit F. Actavis lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 33, and, therefore, denies the same.

34. Actavis admits that the '195 patent is titled "Sustained Release Formulation of Naltrexone" and lists an issue date of December 23, 2014. Actavis admits that a copy was attached to the complaint as exhibit G. Actavis lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 34, and, therefore, denies the same.

35. Actavis lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 35, and, therefore, denies the same.

36. Actavis admits that the patents-in-suit are listed in the Orange Book for CONTRAVE®. Actavis lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 36, and, therefore, denies the same.

ACTAVIS'S ANDA

37. As the parties have agreed to the dismissal of Actavis Pharma, Inc., a response as to Andrx Corporation, Actavis Pharma, Inc., and Actavis, Inc. is unnecessary. Actavis admits that Actavis submitted ANDA No. 208043 to the FDA including a certification with respect to the patents-in-suit under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355), seeking approval to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the ANDA Product prior to expiration of the patents-in-suit. Actavis denies the remaining allegations of paragraph 37.

38. Actavis admits that ANDA No. 208043 includes a certification that the claims of the patents-in-suit are invalid, unenforceable, or would not be infringed by the commercial manufacture, use or sale of the Actavis ANDA Product. Actavis denies the remaining allegations of paragraph 38.

39. Actavis admits that Actavis sent Takeda Pharmaceuticals U.S.A., Inc. and Orexigen Therapeutics, Inc. a letter on April 20, 2015 that provided notification of Actavis's ANDA and its accompanying § 505(j)(2)(A)(vii)(IV) certifications. Actavis lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 39, and, therefore, denies the same.

40. Actavis admits that Actavis sent Takeda Pharmaceuticals U.S.A., Inc. and Orexigen Therapeutics, Inc. a letter on April 20, 2015 containing a Paragraph IV certification of the type described in 21 U.S.C. § 355(j)(2)(A) with respect to the patents-in-suit. Actavis admits that 21 U.S.C. § 355(j)(2)(A)(vii)(IV) states the following:

> (A) An abbreviated application for a new drug shall contain—
> (vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section—
> (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

Actavis admits that 21 C.F.R. § 314.95(c)(6) states the following:

> (c) Contents of a notice. In the notice, the applicant shall cite section 505(j)(2)(B)(ii) of the act and shall include, but not be limited to, the following information:
> (6) A detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed. The applicant shall include in the detailed statement:
> (i) For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed.
> (ii) For each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation.

Actavis lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 40, and, therefore, denies the same.

41. Actavis admits that, at the time the Notice Letter was served, Actavis was aware of the statutory provisions and regulations referred to in paragraph 40 above. Actavis denies the remaining allegations of paragraph 41.

42. Actavis admits that the Notice Letter complies with the statutory and regulatory requirements referred to in paragraph 40, above. Actavis denies the remaining allegations of paragraph 42.

43. Actavis admits that Actavis sent Takeda Pharmaceuticals U.S.A., Inc. and Orexigen Therapeutics, Inc. a letter on April 20, 2015, with written notification of ANDA No. 208043 which included an offer of confidential access ("OCA"). Actavis admits that Takeda Pharmaceuticals U.S.A., Inc. and Orexigen Therapeutics, Inc. did not agree to the terms of the OCA. Actavis denies the remaining allegations of paragraph 43.

44. Actavis admits that as of the date of Plaintiffs' complaint, Actavis had not provided any portions of Actavis's ANDA or other information regarding the ANDA Product beyond the information contained in the Notice Letter. Actavis denies the remaining allegations of paragraph 44.

45. Actavis lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 45, and, therefore, denies the same.

46. The contents of Actavis' Notice Letter speaks for itself. The Notice Letter states that Actavis will not infringe any valid and enforceable claim of the '111 patent and reserves the right to assert additional defenses in the event of litigation. Actavis denies the remaining allegations of paragraph 46.

47. The contents of Actavis' Notice Letter speaks for itself. The Notice Letter states that Actavis will not infringe any valid and enforceable claim of the '626 patent and reserves the right to assert additional defenses in the event of litigation. Actavis denies the allegations of paragraph 47.

48. The contents of Actavis' Notice Letter speaks for itself. The Notice Letter states that Actavis will not infringe any valid and enforceable claim of the '085 patent and reserves the right to assert additional defenses in the event of litigation. Actavis denies the allegations of paragraph 48.

49. Actavis denies the allegations of paragraph 49.

50. Actavis admits that it will have the right to commercially market its product upon FDA approval. Actavis denies the remaining allegations of paragraph 50.

ACTAVIS'S INFRINGEMENT OF THE PATENTS-IN-SUIT

COUNT 1: '111 PATENT

51. Actavis incorporates its answers to paragraphs 1 through 50 as if fully set forth herein.

52. Actavis denies the allegations of paragraph 52.

53. Actavis denies the allegations of paragraph 53.

54. Actavis denies the allegations of paragraph 54.

55. Actavis denies the allegations of paragraph 55.

56. Actavis denies the allegations of paragraph 56.

57. Actavis denies the allegations of paragraph 57.

58. Actavis denies the allegations of paragraph 58.

COUNT 2: '626 PATENT

59. Actavis incorporates its answers to paragraphs 1 through 58 as if fully set forth herein.

60. Actavis denies the allegations of paragraph 60.

61. Actavis denies the allegations of paragraph 61.

62. Actavis denies the allegations of paragraph 62.

63. Actavis denies the allegations of paragraph 63.

64. Actavis denies the allegations of paragraph 64.

65. Actavis denies the allegations of paragraph 65.

66. Actavis denies the allegations of paragraph 66.

COUNT 3: '786 PATENT

67. Actavis incorporates its answers to paragraphs 1 through 66 as if fully set forth herein.

68. Actavis denies the allegations of paragraph 68.

69. Actavis denies the allegations of paragraph 69.

70. Actavis denies the allegations of paragraph 70.

71. Actavis denies the allegations of paragraph 71.

72. Actavis denies the allegations of paragraph 72.

73. Actavis denies the allegations of paragraph 73.

74. Actavis denies the allegations of paragraph 74.

COUNT 4: '788 PATENT

75. Actavis incorporates its answers to paragraphs 1 through 74 as if fully set forth herein.

76. Actavis denies the allegations of paragraph 76.

77. Actavis denies the allegations of paragraph 77.

78. Actavis denies the allegations of paragraph 78.

79. Actavis denies the allegations of paragraph 79.

80. Actavis denies the allegations of paragraph 80.

81. Actavis denies the allegations of paragraph 81.

82. Actavis denies the allegations of paragraph 82.

COUNT 5: '085 PATENT

83. Actavis incorporates its answers to paragraphs 1 through 82 as if fully set forth herein.

84. Actavis denies the allegations of paragraph 84.

85. Actavis denies the allegations of paragraph 85.

86. Actavis denies the allegations of paragraph 86.

87. Actavis denies the allegations of paragraph 87.

88. Actavis denies the allegations of paragraph 88.

89. Actavis denies the allegations of paragraph 89.

90. Actavis denies the allegations of paragraph 90.

COUNT 6: '889 PATENT

91. Actavis incorporates its answers to paragraphs 1 through 90 as if fully set forth herein.

92. Actavis denies the allegations of paragraph 92.

93. Actavis denies the allegations of paragraph 93.

94. Actavis denies the allegations of paragraph 94.

95. Actavis denies the allegations of paragraph 95.

96. Actavis denies the allegations of paragraph 96.

97. Actavis denies the allegations of paragraph 97.

98. Actavis denies the allegations of paragraph 98.

COUNT 7: '195 PATENT

99. Actavis incorporates its answers to paragraphs 1 through 98 as if fully set forth herein.

100. Actavis denies the allegations of paragraph 100.

101. Actavis denies the allegations of paragraph 101.

102. Actavis denies the allegations of paragraph 102.

103. Actavis denies the allegations of paragraph 103.

104. Actavis denies the allegations of paragraph 104.

105. Actavis denies the allegations of paragraph 105.

106. Actavis denies the allegations of paragraph 106.

PRAYER FOR RELIEF

Actavis denies that Plaintiffs are entitled to any of the relief requested in their Prayer for Relief and requests that this Court dismiss Plaintiffs' claims with prejudice.

ACTAVIS'S AFFIRMATIVE DEFENSES

Actavis asserts the following defenses without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not otherwise expressly admitted.

107. The manufacture, use, offer for sale, sale, or importation of the ANDA Product will not infringe, literally, directly, indirectly, contributorily, by way of inducement and/or under the doctrine of equivalents, any valid and enforceable claim of the '111 patent.

108. The manufacture, use, offer for sale, sale, or importation of the ANDA Product will not infringe, literally, directly, indirectly, contributorily, by way of inducement and/or under the doctrine of equivalents, any valid and enforceable claim of the '626 patent.

109. The manufacture, use, offer for sale, sale, or importation of the ANDA Product will not infringe, literally, directly, indirectly, contributorily, by way of inducement and/or under the doctrine of equivalents, any valid and enforceable claim of the '786 patent.

110. The manufacture, use, offer for sale, sale, or importation of the ANDA Product will not infringe, literally, directly, indirectly, contributorily, by way of inducement and/or under the doctrine of equivalents, any valid and enforceable claim of the '788 patent.

111. The manufacture, use, offer for sale, sale, or importation of the ANDA Product will not infringe, literally, directly, indirectly, contributorily, by way of inducement and/or under the doctrine of equivalents, any valid and enforceable claim of the '085 patent.

112. The manufacture, use, offer for sale, sale, or importation of the ANDA Product will not infringe, literally, directly, indirectly, contributorily, by way of inducement and/or under the doctrine of equivalents, any valid and enforceable claim of the '889 patent.

113. The manufacture, use, offer for sale, sale, or importation of the ANDA Product will not infringe, literally, directly, indirectly, contributorily, by way of inducement and/or under the doctrine of equivalents, any valid and enforceable claim of the '195 patent.

114. One or more claims of the '111 patent are invalid and/or unenforceable under 35 U.S.C. §§101 *et seq.* including inter alia, §§ 103 and/or 112, or under other judicially-created bases of invalidation.

115. One or more claims of the '626 patent are invalid and/or unenforceable under 35 U.S.C. §§101 *et seq.* including inter alia, §§ 103 and/or 112, or under other judicially-created bases of invalidation.

116. One or more claims of the '786 patent are invalid and/or unenforceable under 35 U.S.C. §§101 *et seq.* including inter alia, §§ 103 and/or 112, or under other judicially-created bases of invalidation.

117. One or more claims of the '788 patent are invalid and/or unenforceable under 35 U.S.C. §§101 *et seq.* including inter alia, §§ 103 and/or 112, or under other judicially-created bases of invalidation.

118. One or more claims of the '085 patent are invalid and/or unenforceable under 35 U.S.C. §§101 *et seq.* including inter alia, §§ 103 and/or 112, or under other judicially-created bases of invalidation.

119. One or more claims of the '889 patent are invalid and/or unenforceable under 35 U.S.C. §§101 *et seq.* including inter alia, §§ 103 and/or 112, or under other judicially-created bases of invalidation.

120. One or more claims of the '195 patent are invalid and/or unenforceable under 35 U.S.C. §§101 *et seq.* including inter alia, §§ 103 and/or 112, or under other judicially-created bases of invalidation.

121. Plaintiffs are barred by 35 U.S.C. § 288 from recovering any costs associated with this suit.

122. Each purported claim for relief in the Complaint is barred for failure to state a claim on which relief can be granted.

123. Plaintiffs' Complaint lacks subject matter jurisdiction over any and all claims asserted under 35 U.S.C. §§271(a), (b), and/or (c).

124. Plaintiffs' fail to state a proper claim for an exceptional case and/or willful infringement.

Actavis reserves the right to plead additional affirmative defenses or counterclaims that may be revealed through the course of discovery.

COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Actavis Laboratories FL, Inc. ("Actavis") through its attorneys, brings the following Counterclaims against Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals International GmbH, Takeda Pharmaceuticals USA, Inc., Takeda Pharmaceuticals America, Inc., and Orexigen Therapeutics, Inc. (collectively "Plaintiffs/Counterclaim Defendants"):

1. Actavis repeats and incorporates by reference each of the foregoing paragraphs of Defendant's Answer and Affirmative Defenses to the Complaint.

2. These are Actavis's counterclaims for declaratory judgment of non-infringement and invalidity of one or more claims of United States Patent Nos. 7,375,111; 7,462,626; 8,088,786; 8,318,788; 8,722,085; 8,815,889 and 8,916,195 (collectively, "the patents-in-suit") under 35 U.S.C. §271(e)(5), 28 U.S.C. §§2201 and 2202, and 21 U.S.C. §355(b)(2).

PARTIES

3. Actavis is a company organized and existing under the laws of Florida and with a place of business at 2945 W. Corporate Lakes Blvd., Weston FL Florida.

4. On information and belief, Takeda Pharmaceutical Company Limited is a Japanese corporation having a principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645, Japan.

5. On information and belief, Takeda Pharmaceuticals International GmbH is a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited in Switzerland, having

a principal place of business at Thurgauerstrasse 130, 8152 Glattpark-Opfikon, Zurich, Switzerland.

6. On information and belief, Takeda Pharmaceuticals USA, Inc. is a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited in the United States, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

7. On information and belief, Takeda Pharmaceuticals America, Inc. is a wholly-owned subsidiary of Takeda Pharmaceuticals USA, Inc., having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

8. On information and belief, Orexigen is a corporation organized and existing under the laws of the State of Delaware, having its primary place of business at 3344 North Torrey Pines Court, Suite 200, La Jolla, California 92037.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§1331, 1338(a), 2201, 2202; and/or 21 U.S.C. §355(j), based on an actual controversy between the parties arising under the Patent Laws of the United States, 35 U.S.C. §1, *et seq.*

10. Personal jurisdiction over Plaintiffs/Counterclaim Defendants is proper because, *inter alia*, Plaintiffs/Counterclaim Defendants have consented to the personal jurisdiction of the Court by commencing their action for patent infringement in this Judicial District, as set forth in their Complaint.

11. Venue is proper in this judicial district under 28 U.S.C. §§1391 and 1400 based at least on the filing by Plaintiffs of this lawsuit in this venue.

12. There is an actual justiciable controversy between the parties concerning

non-infringement and invalidity of the patents-in-suit.

FACTUAL BACKGROUND

13. On information and belief, United States Patent No. 7,375,111 ("the '111 patent") is titled "Composition for Affecting Weight Loss," and it was issued by the U.S. Patent and Trademark Office on May 20, 2008. On information and belief, Plaintiff/Counterclaim Defendant, Orexigen Therapeutics, Inc. is the owner of the '111 patent.

14. On information and belief, United States Patent No. 7,462,626 ("the '626 patent") is titled "Compositions for Affecting Weight Loss," and it was issued by the U.S. Patent and Trademark Office on December 9, 2008. On information and belief, Plaintiff/Counterclaim Defendant, Orexigen Therapeutics, Inc. is the owner of the '626 patent.

15. On information and belief, United States Patent No. 8,088,786 ("the '786 patent") is titled "Layered Pharmaceutical Formulations," and it was issued by the U.S. Patent and Trademark Office on January 3, 2012. On information and belief, Plaintiff/Counterclaim Defendant, Orexigen Therapeutics, Inc. is the owner of the '786 patent.

16. On information and belief, United States Patent No. 8,318,788 ("the '788 patent") is titled "Layered Pharmaceutical Formulations," and it was issued by the U.S. Patent and Trademark Office on November 27, 2012. On information and belief, Plaintiff/Counterclaim Defendant, Orexigen Therapeutics, Inc. is the owner of the '788 patent.

17. On information and belief, United States Patent No. 8,722,085 ("the '085 patent") is titled "Methods for Administering Weight Loss Medications," and it was issued by the U.S. Patent and Trademark Office on May 13, 2014. Upon information and belief, Plaintiff/Counterclaim Defendant, Orexigen Therapeutics, Inc. is the owner of the '085 patent.

18. On information and belief, United States Patent No. 8,815,889 ("the '889 patent") is titled "Compositions and Methods for Increasing Insulin Sensitivity," and it was issued by the U.S. Patent and Trademark Office on August 26, 2014. On information and belief, Plaintiff/Counterclaim Defendant, Orexigen Therapeutics, Inc. is the owner of the '889 patent.

19. On information and belief, United States Patent No. 8,916,195 ("the '195 patent") is titled "Sustained Release Formulation of Naltrexone," and it was issued by the U.S. Patent and Trademark Office on December 23, 2014. On information and belief, Plaintiff/Counterclaim Defendant, Orexigen Therapeutics, Inc. is the owner of the '195 patent.

20. On information and belief and according to Plaintiffs/Counterclaim Defendants' Complaint, Takeda Pharmaceutical Company Limited is an exclusive licensee to the patents-in-suit. On information and belief and according to Plaintiffs/Counterclaim Defendants' complaint, Takeda Pharmaceuticals International GmbH is a sublicensee of Takeda Pharmaceutical Company Limited to the patents-in-suit. On information and belief and according to Plaintiffs/Counterclaim Defendants' complaint, Takeda Pharmaceuticals USA, Inc. is a sublicensee of Takeda Pharmaceuticals International GmbH to the patents-in-suit. On information and belief and according to Plaintiffs/Counterclaim Defendants' complaint, Takeda Pharmaceuticals America, Inc. is a sublicensee of Takeda Pharmaceuticals USA, Inc to the patents-in-suit.

21. On information and belief and according to Plaintiffs/Counterclaim Defendants' Complaint, Takeda Pharmaceuticals USA, Inc. holds approved New Drug Application ("NDA") No. 200063, under which the United States Food and Drug Administration ("FDA") granted approval on September 10, 2014 for Extended-Release Tablets containing 8 mg of Naltrexone Hydrochloride and 90 mg of Bupropion Hydrochloride. On information and belief

and according to Plaintiffs/Counterclaim Defendants' complaint, Takeda Pharmaceuticals USA, Inc. markets and sells these tablets in the United States, including in this district, under the brand name CONTRAVE®.

22. On information and belief, Plaintiffs/Counterclaim Defendants caused the FDA to publish the patents-in-suit in the FDA publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), in connection with ANDA No. 200063 as covering CONTRAVE® and/or its use.

23. Actavis filed New Drug Application No. 208043 ("ANDA No. 208043") with FDA seeking approval to market its proposed Naltrexone Hydrochloride and Bupropin Hydrochloride Extended-Release Tablets (the "ANDA Product").

24. ANDA No. 208043 contained a "paragraph IV certifications" under 21 U.S.C. § 355(J)(2)(A)(vii)(IV) that the patents-in-suit patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of the ANDA Product.

25. In accordance with the requirements of 21 U.S.C. §355(j)(2)(B), Actavis sent Takeda Pharmaceuticals U.S.A., Inc. and Orexigen Therapeutics, Inc. a Notice Letter dated April 20, 2015, stating that ANDA No. 208043 included a Paragraph IV certification, alleging that the patents-in-suit are invalid, unenforceable, and will not be infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product.

26. In response to ANDA No. 208043 and Actavis's Paragraph IV certification against the patents-in-suit, Plaintiffs/Counterclaim Defendants filed this infringement action under 35 U.S.C. §271(e)(2), asserting the patents-in-suit against Defendants. There has been and is now an actual and justiciable controversy between Plaintiffs/Counterclaim Defendants and Actavis as to whether the product disclosed in ANDA No. 208043 infringes any

claim of the patents-in-suit, and whether any valid and enforceable claim of the patents-in suit exists.

EXCEPTIONAL CASE

27. This case is an exceptional one, and Actavis is entitled to an award of its reasonable attorneys' fees and costs under 35 U.S.C. §285.

COUNT I

(Declaratory Judgment of Invalidity of the '111 Patent)

28. Actavis repeats and incorporates by reference each of the foregoing paragraphs of Defendant's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

29. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. §100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§2201 and 2202. An actual, substantial and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between the parties concerning the invalidity of the claims of the '111 patent.

30. The claims of the '111 patent are invalid for failure to comply with the requirements of patentability as specified in 35 U.S.C. §§100 *et seq.*, including, without limitation, 35 U.S.C. §§ 103 and/or 112, and/or other judicially-created bases for invalidation.

31. The '111 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

32. The alleged invention of the '111 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '111 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '498 patent and would have had a reasonable expectation of success in doing so.

33. The subject matter claimed in the '111 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

34. The '111 patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby. Actavis is therefore entitled to a declaration that the claims of the '111 patent are invalid.

COUNT II

(Declaratory Judgment of Invalidity of the '626 Patent)

35. Actavis repeats and incorporates by reference each of the foregoing paragraphs of Defendant's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

36. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. §100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§2201 and 2202. An actual,

substantial and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between the parties concerning the invalidity of the claims of the '626 patent.

37. The claims of the '626 patent are invalid for failure to comply with the requirements of patentability as specified in 35 U.S.C. §§100 *et seq.*, including, without limitation, 35 U.S.C. §§ 103 and/or 112, and/or other judicially-created bases for invalidation.

38. The '626 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

39. The alleged invention of the '626 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '626 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '498 patent and would have had a reasonable expectation of success in doing so.

40. The subject matter claimed in the '626 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

41. The '626 patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms

as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

42. Actavis is therefore entitled to a declaration that the claims of the '626 patent are invalid.

COUNT III

(Declaratory Judgment of Invalidity of the '085 Patent)

43. Actavis repeats and incorporates by reference each of the foregoing paragraphs of Defendant's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

44. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. §100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§2201 and 2202. An actual, substantial and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between the parties concerning the invalidity of the claims of the '085 patent.

45. The claims of the '085 patent are invalid for failure to comply with the requirements of patentability as specified in 35 U.S.C. §§100 *et seq.*, including, without limitation, 35 U.S.C. §§ 103 and/or 112, and/or other judicially-created bases for invalidation.

46. The '085 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

47. The alleged invention of the '085 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged

improvement over the prior art set forth in the '085 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '498 patent and would have had a reasonable expectation of success in doing so.

48. The subject matter claimed in the '085 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

49. The '085 patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

50. Actavis is therefore entitled to a declaration that the claims of the '085 patent are invalid.

COUNT IV

(Declaratory Judgment of Invalidity of the '889 Patent)

51. Actavis repeats and incorporates by reference each of the foregoing paragraphs of Defendant's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

52. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. §100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§2201 and 2202. An actual, substantial and continuing justiciable controversy having adverse legal interest of sufficient

immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between the parties concerning the invalidity of the claims of the '889 patent.

53. The claims of the '889 patent are invalid for failure to comply with the requirements of patentability as specified in 35 U.S.C. §§100 *et seq.*, including, without limitation, 35 U.S.C. §§ 103 and/or 112, and/or other judicially-created bases for invalidation.

54. The '889 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

55. The alleged invention of the '889 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '889 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '498 patent and would have had a reasonable expectation of success in doing so.

56. The subject matter claimed in the '889 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

57. The '889 patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms

as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

58. Actavis is therefore entitled to a declaration that the claims of the '889 patent are invalid.

COUNT V

(Declaratory Judgment of Invalidity of the '195 Patent)

59. Actavis repeats and incorporates by reference each of the foregoing paragraphs of Defendant's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

60. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. §100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§2201 and 2202. An actual, substantial and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between the parties concerning the invalidity of the claims of the '195 patent.

61. The claims of the '195 patent are invalid for failure to comply with the requirements of patentability as specified in 35 U.S.C. §§100 *et seq.*, including, without limitation, 35 U.S.C. §§ 103 and/or 112, and/or other judicially-created bases for invalidation.

62. The '195 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

63. The alleged invention of the '195 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged

improvement over the prior art set forth in the '195 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '498 patent and would have had a reasonable expectation of success in doing so.

64. The subject matter claimed in the '195 patent fails to comply with 35 U.S.C. §§ 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

65. The '195 patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

66. Actavis is therefore entitled to a declaration that the claims of the '195 patent are invalid.

COUNT VI

(Declaratory Judgment of Non-infringement of the '111 Patent)

67. Actavis repeats and incorporates by reference each of the foregoing paragraphs of Defendant's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

68. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. §100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§2201 and 2202. An actual, substantial and continuing justiciable controversy having adverse legal interest of sufficient

immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between the parties concerning the infringement of the claims of the '111 patent.

69. Actavis has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '111 patent either literally or under the doctrine of equivalents and are not liable for such infringement.

70. Actavis is entitled to a judicial declaration that they have not infringed, contributed to the infringement of, or induced the infringement of the '111 patent either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of the Watson Products that are the subject of the Actavis ANDA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the '111 patent.

COUNT VII

(Declaratory Judgment of Non-infringement of the '626 Patent)

71. Actavis repeats and incorporates by reference each of the foregoing paragraphs of Defendant's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

72. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. §100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§2201 and 2202. An actual, substantial and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between the parties concerning the infringement of the claims of the '626 patent.

73. Actavis has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '626 patent either literally or under the doctrine of equivalents and are not liable for such infringement.

74. Actavis is entitled to a judicial declaration that they have not infringed, contributed to the infringement of, or induced the infringement of the '626 patent either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of the Watson Products that are the subject of the Actavis ANDA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the '626 patent.

COUNT VIII

(Declaratory Judgment of Non-infringement of the '786 Patent)

75. Actavis repeats and incorporates by reference each of the foregoing paragraphs of Defendant's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

76. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. §100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§2201 and 2202. An actual, substantial and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between the parties concerning the infringement of the claims of the '786 patent.

77. Actavis has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '786 patent either literally or under the doctrine of equivalents and are not liable for such infringement.

78. Actavis is entitled to a judicial declaration that they have not infringed, contributed to the infringement of, or induced the infringement of the '786 patent either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of the Watson Products that are the subject of the Actavis ANDA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the '786 patent.

COUNT IX

(Declaratory Judgment of Non-infringement of the '788 Patent)

79. Actavis repeats and incorporates by reference each of the foregoing paragraphs of Defendant's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

80. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. §100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§2201 and 2202. An actual, substantial and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between the parties concerning the infringement of the claims of the '788 patent.

81. Actavis has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '788 patent either literally or under the doctrine of equivalents and are not liable for such infringement.

82. Actavis is entitled to a judicial declaration that they have not infringed, contributed to the infringement of, or induced the infringement of the '788 patent either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of the Watson Products that are the subject of the Actavis ANDA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the '788 patent.

COUNT X

(Declaratory Judgment of Non-infringement of the '085 Patent)

83. Actavis repeats and incorporates by reference each of the foregoing paragraphs of Defendant's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

84. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. §100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§2201 and 2202. An actual, substantial and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between the parties concerning the infringement of the claims of the '085 patent.

85. Actavis has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '085 patent either literally or under the doctrine of equivalents and are not liable for such infringement.

86. Actavis is entitled to a judicial declaration that they have not infringed, contributed to the infringement of, or induced the infringement of the '085 patent either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of the Watson Products that are the subject of the Actavis ANDA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the '085 patent.

COUNT XI

(Declaratory Judgment of Non-infringement of the '889 Patent)

87. Actavis repeats and incorporates by reference each of the foregoing paragraphs of Defendant's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

88. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. §100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§2201 and 2202. An actual, substantial and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between the parties concerning the infringement of the claims of the '889 patent.

89. Actavis has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '889 patent either literally or under the doctrine of equivalents and are not liable for such infringement.

90. Actavis is entitled to a judicial declaration that they have not infringed, contributed to the infringement of, or induced the infringement of the '889 patent either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of the Watson Products that are the subject of the Actavis ANDA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the '889 patent.

COUNT XII

(Declaratory Judgment of Non-infringement of the '195 Patent)

91. Actavis repeats and incorporates by reference each of the foregoing paragraphs of Defendant's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

92. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. §100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§2201 and 2202. An actual, substantial and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between the parties concerning the infringement of the claims of the '195 patent.

93. Actavis has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '195 patent either literally or under the doctrine of equivalents and are not liable for such infringement.

94. Actavis is entitled to a judicial declaration that they have not infringed, contributed to the infringement of, or induced the infringement of the '195 patent either literally

or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of the Watson Products that are the subject of the Actavis ANDA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the '195 patent.

DEFENDANT'S PRAYER FOR RELIEF

WHEREFORE, Actavis prays that the Court enter judgment in its favor and against Plaintiffs/Counterclaim Defendants and issue an order:

1. Dismissing Plaintiffs/Counterclaim Defendants' Complaint with prejudice and denying each request for relief made by Plaintiffs/Counterclaim Defendants;

2. Declaring all claims of the patents-in-suit invalid;

3. Declaring that the filing of ANDA No. 208043 has not infringed and does not infringe any valid and enforceable claim, if any, of the patents-in-suit;

4. Declaring that Actavis has not infringed, literally, directly, indirectly, contributorily, by way of inducement and/or under the doctrine of equivalents, any valid and enforceable claim, if any, of the patents-in-suit;

5. Declaring that the manufacture, use, offer for sale, sale, and/or importation into the United States of the ANDA Product does not, and would not, if marketed, literally, directly, indirectly, contributorily, by way of inducement and/or under the doctrine of equivalents, infringe any valid and enforceable claim, if any, of the patents-in-suit;

6. Enjoining Plaintiffs/Counterclaim Defendants and their agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice hereof from threatening or initiating infringement litigation against Actavis or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors,

or customers, or charging them either orally or in writing with infringement of the patents-in-suit;

7. Denying Plaintiffs/Counterclaim Defendants' request for injunctive relief;

8. Finding this case to be exceptional under 35 U.S.C. §285 and awarding Actavis its costs and reasonable attorneys' fees; and

9. Awarding any other such relief as is just and proper.

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