IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ICEUTICA PTY LTD and IROKO PHARMACEUTICALS, LLC, Plaintiffs, v. NOVITIUM PHARMA LLC, Defendant.	C.A. No. 18-599-VAC-CJB

DEFENDANT NOVITIUM PHARMA LLC'S ANSWER, DEFENSES, AND COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT

Defendant Novitium Pharma LLC ("Novitium") hereby responds to Plaintiffs iCeutica Pty Ltd and Iroko Pharmaceuticals, LLC's (collectively, "Plaintiffs") Complaint as follows:

NATURE OF ACTION

1. The Complaint alleges infringement of United States Patent Nos. 9,526,734 ("the '734 patent"), 9,649,318 ("the '318 patent") and 9,808,468 ("the '468 patent") (collectively, "the Patents-In-Suit") in relation to Plaintiff's VIVLODEX brand Meloxicam capsules 5 mg and 10 mg that are approved by the U.S. Food and Drug Agency ("FDA") for the management of osteoarthritis pain. Except as otherwise admitted, the allegations are denied.

THE PARTIES

2. Novitium lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 2, and therefore denies them.

3. Novitium lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 3, and therefore denies them.

4. Novitium admits that Novitium is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 70 Lake Drive, East Windsor, NJ 08520.

5. Novitium admits that (i) Novitium develops and manufactures generic pharmaceutical products for sale throughout the United States, including throughout the state of Delaware; (ii) Novitium submitted ANDA No. 211398 ("Novitium's ANDA") seeking FDA approval to market Meloxicam Capsules, 5 mg and 10 mg ("Novitium's ANDA Products") throughout the United States, including throughout the State of Delaware; and (iii) Novitium distributes generic pharmaceutical products for sale throughout the United States, including throughout the state of Delaware. Novitium denies any remaining allegations contained in Paragraph 5.

6. Novitium admits that Novitium sells and distributes generic pharmaceutical products, including those manufactured by Novitium, in the United States, including throughout the State of Delaware. The remaining allegations in Paragraph 6 state legal conclusions to which no response is required. To the extent a response is required, Novitium denies the allegations.

JURISDICTION AND VENUE

7. The allegations in Paragraph 7 state legal conclusions to which no response is required. To the extent a response is required, Novitium does not dispute subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338, 2201, and 2202 for the purposes of this action only.

8. Novitium denies that it has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs. The remaining allegations in Paragraph 8 state legal conclusions to which no response is required. To the extent a response is required, Novitium

does not dispute personal jurisdiction for the purposes of this action only. Novitium denies any remaining allegations contained in Paragraph 8.

9. The allegations in Paragraph 9 state legal conclusions to which no response is required. To the extent a response is required, Novitium does not dispute personal jurisdiction for the purposes of this action only. Novitium denies any of the remaining allegations contained in Paragraph 9.

10. Novitium admits that Novitium distributes drug products for sale throughout the United States, including throughout the State of Delaware. The remaining allegations in Paragraph 10 state legal conclusions to which no response is required. To the extent a response is required, Novitium does not dispute personal jurisdiction for the purposes of this action only. Novitium denies any of the remaining allegations contained in Paragraph 10.

11. Novitium admits that it submitted Novitium's ANDA seeking FDA approval to market Novitium's ANDA Products throughout the United States, including throughout the State of Delaware. The remaining allegations in Paragraph 11 state legal conclusions to which no response is required. To the extent a response is required, Novitium does not dispute personal jurisdiction for the purposes of this action only. Novitium denies any of the remaining allegations contained in Paragraph 11.

12. The allegations in Paragraph 12 state legal conclusions to which no response is required. To the extent a response is required, Novitium does not dispute personal jurisdiction for the purposes of this action only.

13. The allegations in Paragraph 13 state legal conclusions to which no response is required. To the extent a response is required, Novitium does not dispute venue for the purposes of this action only.

FACTUAL BACKGROUND

14. Novitium admits that Exhibit A of the Complaint purports to be a version of the '734 patent; that it is entitled "Formulation of Meloxicam"; that it apparently issued on December 27, 2016; and that on its face H. William Bosch is listed as an inventor. Novitium denies any remaining allegations contained in Paragraph 14.

15. Novitium admits that Exhibit B of the Complaint purports to be a version of the '318 patent; that it is entitled "Formulation of Meloxicam"; that it apparently issued on May 16, 2017; and that on its face H. William Bosch is listed as an inventor. Novitium denies any remaining allegations contained in Paragraph 15.

16. Novitium admits that Exhibit C of the Complaint purports to be a version of the '468 patent; that it is entitled "Formulation of Meloxicam"; that it apparently issued on November 7, 2017; and that on its face H. William Bosch is listed as an inventor. Novitium denies any remaining allegations contained in Paragraph 16.

17. Novitium admits that Exhibits A, B, and C of the Complaint, which respectively purport to be versions of the '734, '318, and '468 patents, each list iCeutica Pty Ltd. as assignee on their face. Novitium lacks sufficient information to form a belief as to the truth of any remaining allegations in Paragraph 17, and therefore denies them.

18. Novitium lacks sufficient information to form a belief as to the truth of any allegations in Paragraph 18, and therefore denies them.

19. Novitium lacks sufficient information to form a belief as to the truth of any allegations in Paragraph 19, and therefore denies them.

20. On information and belief, Novitium admits that Iroko is listed on the FDA website as the holder of NDA No. 207233 for Meloxicam capsules 5 mg and 10 mg. On information and belief, Novitium admits that the product that is the subject of NDA No. 207233

is sold under the name VIVLODEX. Novitium lacks sufficient information to form a belief as to the truth of any remaining allegations contained in Paragraph 20, and therefore denies them.

21. Novitium admits that the '734, '318, and '468 patents are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book") for VIVLODEX. Novitium lacks sufficient information to form a belief as to the truth of any remaining allegations contained in Paragraph 21, and therefore denies them.

22. Novitium lacks sufficient information to form a belief as to the truth of any allegations contained in Paragraph 22, and therefore denies them.

23. Denied.

24. Novitium admits that a letter ("Novitium's Paragraph IV Letter") dated March 9, 2018 and signed by David H. Silverstein was sent to Plaintiffs on behalf of Novitium, and that Novitium's Paragraph IV Letter was delivered to Plaintiffs on or about March 12, 2018. Novitium lacks sufficient information to form a belief as to the truth of any remaining allegations contained in Paragraph 24, and therefore denies them.

25. Novitium admits that Novitium's Paragraph IV Letter stated that Novitium had submitted, and FDA had received, Novitium's ANDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), seeking approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of Novitium's ANDA Products prior to expiration of the '734, '318, and '468 patents. Novitium admits that its ANDA is application 211398. Novitium denies any remaining allegations contained in Paragraph 25.

26. Novitium admits Novitium's Paragraph IV Letter stated that Novitium's ANDA indicates that Novitium intends to market Novitium's ANDA Products before the expiration of the '734, '318, and '468 patents, and contains certifications pursuant to 21 U.S.C.

§ 355(j)(2)(A)(vii)(IV) that, in Novitium's opinion, the patents are invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of the product for which the application is submitted. Novitium denies any remaining allegations contained in Paragraph 26.

27. Admitted.

28. Admitted.

29. Novitium admits that it is seeking FDA approval to market Novitium's ANDA Products in the United States. Novitium denies any remaining allegations contained in Paragraph 29.

30. Novitium admits that it is seeking FDA approval to market Novitium's ANDA Products in the United States. Novitium lacks sufficient information to form a belief as to the truth of any remaining allegations in Paragraph 30, and therefore denies them.

31. Novitium admits that it is seeking FDA approval to market Novitium's ANDA Products in the United States. Novitium lacks sufficient information to form a belief as to the truth of any remaining allegations in Paragraph 31, and therefore denies them.

32. Novitium admits that it has provided Plaintiffs with an Offer of Confidential Access to Novitium's ANDA, but denies that the terms of the proposed offer "would not allow Plaintiffs to meaningfully process the information contained in the ANDA." Novitium admits receipt of Plaintiffs' letters dated March 16, March 22, and April 2, 2018. Novitium admits that Plaintiffs filed the Complaint prior to Novitium's response to their April 2, 2018 letter. Novitium denies any remaining allegations contained in Paragraph 32.

33. Novitium lacks sufficient information to form a belief as to the truth of the allegations of Paragraph 33, and therefore denies them.

34. Novitium lacks sufficient information to form a belief as to the truth of the allegations of Paragraph 34, and therefore denies them.

COUNT I

Infringement of the '734 Patent Under 35 U.S.C. § 271(e)(2) by Novitium's Proposed Generic Meloxicam capsules 5 mg and 10 mg

35. Novitium repeats and incorporates its responses to Paragraphs 1-34 as if fully set forth herein.

36. Novitium admits that Novitium's ANDA was submitted to FDA under Section 505(j) of the FDCA to obtain approval to market Novitium's ANDA Products in the United States. Novitium denies any remaining allegations contained in Paragraph 36.

37. Paragraph 37 states legal conclusions to which no response is required. To the extent a response is required, denied.

38. Denied.

39. Denied.

40. Denied.

COUNT II

Declaratory Judgment of Infringement of the '734 Patent Under 35 U.S.C. § 271(a) by Novitium's Proposed Generic Meloxicam capsule 5 mg and 10 mg

41. Novitium repeats and incorporates its responses to each of the preceding Paragraphs as if fully set forth herein.

42. Paragraph 42 states legal conclusions to which no response is required. To the extent a response is required, denied.

43. Paragraph 43 states legal conclusions to which no response is required. To the extent a response is required, denied.

44. Novitium admits that it is seeking FDA approval to market Novitium's ANDA Products. Novitium lacks sufficient information to form a belief as to the truth of any remaining allegations in Paragraph 44, and therefore denies them.

45. Novitium admits that it is seeking FDA approval to market Novitium's ANDA Products, and that it submitted ANDA No. 211398 with a Paragraph IV certification as to the '734 patent. Novitium denies any remaining allegations contained in Paragraph 45.

46. Denied.

47. Denied.

48. Denied.

49. Denied.

COUNT III

Declaratory Judgment of Infringement of the '734 Patent Under 35 U.S.C. § 271(b) by Novitium's Proposed Generic Meloxicam capsules 5 mg and 10 mg

50. Novitium repeats and incorporates its responses to each of the preceding Paragraphs as if fully set forth herein.

51. Paragraph 51 states legal conclusions to which no response is required. To the extent a response is required, denied.

52. Paragraph 52 states legal conclusions to which no response is required. To the extent a response is required, denied.

53. Novitium admits that it is seeking FDA approval to market Novitium's ANDA Products. Novitium lacks sufficient information to form a belief as to the truth of any remaining allegations in Paragraph 53, and therefore denies them.

54. Novitium admits that it is seeking FDA approval to market Novitium's ANDA Products, and that it submitted ANDA No. 211398 with a Paragraph IV certification as to the

'734 patent. Novitium denies any remaining allegations contained in Paragraph 54.

55. Denied.

56. Denied.

57. Denied.

58. Denied.

59. Denied.

60. Denied.

61. Denied.

62. Denied.

COUNT IV

Infringement of the '318 Patent Under 35 U.S.C. § 271(e)(2) by Novitium's Proposed Generic Meloxicam capsules 5 mg and 10 mg

63. Novitium repeats and incorporates its responses to each of the preceding Paragraphs as if fully set forth herein.

64. Novitium admits that Novitium's ANDA was submitted to FDA under Section 505(j) of the FDCA to obtain approval to market Novitium's ANDA Products in the United States. Novitium denies any remaining allegations contained in Paragraph 64.

65. Denied.

66. Denied.

67. Denied.

68. Denied.

COUNT V

Declaratory Judgment of Infringement of the '318 Patent Under 35 U.S.C. § 271(a) by Novitium's Proposed Generic Meloxicam capsule 5 mg and 10 mg

69. Novitium repeats and incorporates its responses to each of the preceding Paragraphs as if fully set forth herein.

70. Paragraph 70 states legal conclusions to which no response is required. To the extent a response is required, denied.

71. Paragraph 71 states legal conclusions to which no response is required. To the extent a response is required, denied.

72. Novitium admits that it is seeking FDA approval to market Novitium's ANDA Products. Novitium lacks sufficient information to form a belief as to the truth of any remaining allegations in Paragraph 72, and therefore denies them.

73. Novitium admits that it is seeking FDA approval to market Novitium's ANDA Products, and that it submitted ANDA No. 211398 with a Paragraph IV certification as to the '318 patent. Novitium denies any remaining allegations contained in Paragraph 73.

74. Denied.

75. Denied.

76. Denied.

77. Denied.

COUNT VI

Declaratory Judgment of Infringement of the '318 Patent Under 35 U.S.C. § 271(b) by Novitium's Proposed Generic Meloxicam capsule 5 mg and 10 mg

78. Novitium repeats and incorporates its responses to each of the preceding Paragraphs as if fully set forth herein.

79. Paragraph 79 states legal conclusions to which no response is required. To the extent a response is required, denied.

80. Paragraph 80 states legal conclusions to which no response is required. To the

extent a response is required, denied.

81. Novitium admits that it is seeking FDA approval to market Novitium's ANDA Products. Novitium lacks sufficient information to form a belief as to the truth of any remaining allegations in Paragraph 81, and therefore denies them.

82. Novitium admits that it is seeking FDA approval to market Novitium's ANDA Products, and that it submitted ANDA No. 211398 with a Paragraph IV certification as to the '318 patent. Novitium denies any remaining allegations contained in Paragraph 82.

83. Denied.

84. Denied.

85. Denied.

86. Denied.

87. Denied.

88. Denied.

89. Denied.

90. Denied.

COUNT VII

Infringement of the '468 Patent Under 35 U.S.C. § 271(e)(2) by Novitium's Proposed Generic Meloxicam capsules 5 mg and 10 mg

91. Novitium repeats and incorporates its responses to each of the preceding Paragraphs as if fully set forth herein.

92. Novitium admits that Novitium's ANDA was submitted to FDA under Section 505(j) of the FDCA to obtain approval to market Novitium's ANDA Products in the United States. Novitium denies any remaining allegations contained in Paragraph 92.

93. Denied.

94. Denied.

95. Denied.

96. Denied.

97. Denied.

98. Denied.

99. Denied.

100. Denied.

101. Denied.

102. Denied.

103. Denied.

104. Denied.

COUNT VIII

Declaratory Judgment of Infringement of the '468 Patent Under 35 U.S.C. § 271(b) by Novitium's Proposed Generic Meloxicam capsule 5 mg and 10 mg

105. Novitium repeats and incorporates its responses to each of the preceding Paragraphs as if fully set forth herein.

106. Paragraph 106 states legal conclusions to which no response is required. To the extent a response is required, denied.

107. Paragraph 107 states legal conclusions to which no response is required. To the extent a response is required, denied.

108. Novitium admits that it is seeking FDA approval to market Novitium's ANDA Products. Novitium lacks sufficient information to form a belief as to the truth of any remaining allegations in Paragraph 108, and therefore denies them.

109. Denied.

110. Denied.

111. Denied.

112. Denied.

113. Denied.

114. Denied.

115. Denied.

116. Denied.

117. Denied.

118. Denied.

119. Denied.

120. Denied.

JURY TRIAL DEMAND

Novitium denies that Plaintiffs are entitled to a trial by jury.

RELIEF SOUGHT

Novitium denies that Plaintiffs are entitled to any of the relief requested in Paragraphs (A) through (I) of the Relief Sought section of the Complaint.

DEFENSES

Without any admissions as to the burdens of proof, or as to any of the allegations in the Complaint, Novitium states the following:

FIRST DEFENSE
(Non-Infringement of the '734 Patent)

121. The submission of Novitium's ANDA to FDA and the importation, manufacture, use, offer for sale, or sale of Novitium's ANDA Products will not directly, indirectly,

contributorily and/or by inducement infringe, either literally or under the doctrine of equivalents, any valid claim of the '734 patent under any section of 35 U.S.C. § 271.

SECOND DEFENSE
(Non-Infringement of the '318 Patent)

122. The submission of Novitium's ANDA to FDA and the importation, manufacture, use, offer for sale, or sale of Novitium's ANDA Products will not directly, indirectly, contributorily and/or by inducement infringe, either literally or under the doctrine of equivalents, any valid claim of the '318 patent under any section of 35 U.S.C. § 271.

THIRD DEFENSE
(Non-Infringement of the '468 Patent)

123. The submission of ANDA No. 211398 to FDA and the importation, manufacture, use, offer for sale, or sale of Novitium's ANDA Products will not directly, indirectly, contributorily and/or by inducement infringe, either literally or under the doctrine of equivalents, any valid claim of the '468 patent under any section of 35 U.S.C. § 271.

FOURTH DEFENSE
(No Relief Available)

124. Plaintiffs have not suffered any damages.

125. Plaintiffs are not suffering an irreparable injury.

126. Plaintiffs are barred from obtaining relief pursuant to one or more provisions of 35 U.S.C. § 1, *et seq*. and 21 U.S.C. § 355.

FIFTH DEFENSE
(Failure to State a Claim)

127. The Complaint, in whole or in part, fails to state a claim upon which relief can be granted.

SIXTH DEFENSE

128. Plaintiffs fail to state a proper claim for an exceptional case.

RESERVATION OF RIGHTS

129. Novitium reserves the right to assert such other defenses and damages that may appear as discovery proceeds in this case.

* * *

NOVITIUM'S COUNTERCLAIMS

Novitium Pharma LLC ("Novitium" or "Counterclaim Plaintiff"), for its counterclaims against iCeutica Pty Ltd ("iCeutica") and Iroko Pharmaceuticals, LLC ("Iroko") (together, "Counterclaim Defendants"), alleges as follows:

THE PARTIES

1. Novitium Pharma LLC is a corporation organized and existing under the laws of Delaware, having a principal place of business at 70 Lake Drive, East Windsor, NJ 08520.

2. On information and belief, based on Counterclaim Defendants' allegations, iCeutica Pty Ltd is a corporation organized and existing under the laws of Delaware, having a principal place of business at Unit 2, 32 Mumford Place, Balcatta Western Australia 6021.

3. On information and belief, including based on Counterclaim Defendants' allegations, Iroko Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at One Kew Place, 150 Rouse Boulevard, Philadelphia, PA, 19112.

NATURE OF THE ACTION

4. These counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 and under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*

5. Novitium seeks a declaration that Novitium has not infringed, is not infringing, and will not infringe, or contribute to or induce infringement of any valid and enforceable claim of United States Patent Nos. 9,526,734 ("the '734 patent"); 9,649,318 ("the '318 patent"); and 9,808,468 ("the '468 patent") (collectively, "the Patents-In-Suit"), literally or under the doctrine of equivalents.

6. As a consequence of Counterclaim Defendants' Complaint against Novitium, and based on Novitium's denials in its Answer, there exists an actual, continuing, and substantial case or controversy between Counterclaim Defendants and Novitium having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the alleged infringement of the Patents-In-Suit.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. Counterclaim Defendants have submitted to this Court's personal jurisdiction by suing Novitium in this District. On information and belief, Counterclaim Defendants sell pharmaceutical products in this District, including the Vivlodex product that Counterclaim Defendants contend is covered by at least one claim of the Patents-In-Suit, and conducts substantial business in, and has regular and systemic contacts with this District.

9. This Court is the proper venue under 28 U.S.C. §§ 1391, 1400(b).

BACKGROUND

10. The face of the '734 patent, titled "Formulation of Meloxicam," indicates that it issued on December 27, 2016.

11. On information and belief, based on Counterclaim Defendants' allegations, iCeutica Pty Ltd is the owner of the '734 patent.

12. The face of the ’318 patent, titled “Formulation of Meloxicam,” indicates that it issued on May 16, 2017.

13. On information and belief, based on Counterclaim Defendants’ allegations, iCeutica Pty Ltd is the owner of the ’318 patent.

14. The face of the ’468 patent, titled “Formulation of Meloxicam,” indicates that it issued on November 7, 2017.

15. On information and belief, based on Counterclaim Defendants’ allegations, iCeutica Pty Ltd is the owner of the ’468 patent.

16. On information and belief, based on Counterclaim Defendants’ allegations and based on the electronic version of FDA’s publication *Approved Drug Products with Therapeutic Equivalence Evaluation* (commonly known as the “Orange Book”), Iroko is the holder of New Drug Application (“NDA”) No. 207233 for Meloxicam capsules, 5 mg and 10 mg, sold in the United States as Vivlodex.

17. Novitium submitted ANDA No. 211398 to FDA seeking approval to market Meloxicam capsules, 5 mg and 10 mg (“Novitium’s ANDA Products”) before the purported expiration of the Patents-In-Suit.

18. The Patents-In-Suit are listed in the Orange Book for Vivlodex.

19. Novitium has certified under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the claims of the Patents-In-Suit will not be infringed by Novitium’s ANDA Products.

20. On March 9, 2018, Novitium sent a letter (“Novitium’s Paragraph IV Letter”) to Counterclaim Defendants stating that ANDA No. 211398 contained certifications under 21 U.S.C. § 355(j)(2)(B)(iv) regarding the Patents-In-Suit.

21. On April 20, 2018, Counterclaim Defendants filed their Complaint in this Court alleging that Novitium's act of submitting ANDA No. 211398 ("Novitium's ANDA") infringes the Patents-In-Suit.

22. Novitium denies that it infringes or will infringe any valid and enforceable claim of the Patents-In-Suit.

23. Novitium denies that Novitium's ANDA Products infringe or will infringe any valid and enforceable claim of the Patents-In-Suit.

24. As a result of the actions of Counterclaim Defendants in listing the Patents-In-Suit in the Orange Book, and bringing suit against Novitium for infringement of the Patents-In-Suit, Novitium is and will be prevented from selling Novitium's ANDA Products, and is thus being injured.

25. Unless enjoined, Counterclaim Defendants will continue to assert that Novitium infringes the claims of the Patents-In-Suit. Novitium believes that this will continue to interfere with Novitium's business with respect to Novitium's ANDA Products.

26. Novitium will be irreparably harmed if Counterclaim Defendants are not enjoined from asserting the Patents-In-Suit against Novitium.

FIRST CLAIM FOR RELIEF
(Declaratory Judgment of Non-Infringement of the '734 Patent)

27. Novitium realleges Paragraphs 1-26 as if fully set forth herein.

28. Novitium does not infringe any valid and enforceable claim of the '734 patent, whether directly, indirectly (i.e., contributorily or by inducement), literally, or under the doctrine of equivalents.

29. The sale, offer for sale, manufacture, importation, and/or use of Novitium's ANDA Products will not constitute infringement of any valid and enforceable claim of the '734

patent, whether directly, indirectly (i.e., contributorily or by inducement), literally, or under the doctrine of equivalents.

30. Novitium's ANDA Products will not infringe any claim of the '734 patent at least because Novitium's ANDA Products do not meet all limitations of any valid and enforceable claim of the '734 patent.

31. Novitium is entitled to a judgment that the sale, offer for sale, manufacture, importation, and/or use of Novitium's ANDA Products do not (and, if marketed, would not) infringe any valid and enforceable claim of the '734 patent.

SECOND CLAIM FOR RELIEF
(Declaratory Judgment of Non-Infringement of the '318 Patent)

32. Novitium realleges Paragraphs 1-31 as if fully set forth herein.

33. Novitium does not infringe any valid and enforceable claim of the '318 patent, whether directly, indirectly (i.e., contributorily or by inducement), literally, or under the doctrine of equivalents.

34. The sale, offer for sale, manufacture, importation, and/or use of Novitium's ANDA Products will not constitute infringement of any valid and enforceable claim of the '318 patent, whether directly, indirectly (i.e., contributorily or by inducement), literally, or under the doctrine of equivalents.

35. Novitium's ANDA Products will not infringe any claim of the '318 patent at least because Novitium's ANDA Products do not meet all limitations of any valid and enforceable claim of the '318 patent.

36. Novitium is entitled to a judgment that the sale, offer for sale, manufacture, importation, and/or use of Novitium's ANDA Products do not (and, if marketed, would not) infringe any valid and enforceable claim of the '318 patent.

THIRD CLAIM FOR RELIEF
(Declaratory Judgment of Non-Infringement of the '468 Patent)

37. Novitium realleges Paragraphs 1-36 as if fully set forth herein.

38. Novitium does not infringe any valid and enforceable claim of the '468 patent, whether directly, indirectly (i.e., contributorily or by inducement), literally, or under the doctrine of equivalents.

39. The sale, offer for sale, manufacture, importation, and/or use of Novitium's ANDA Products will not constitute infringement of any valid and enforceable claim of the '468 patent, whether directly, indirectly (i.e., contributorily or by inducement), literally, or under the doctrine of equivalents.

40. Novitium's ANDA Products will not infringe any claim of the '468 patent at least because Novitium's ANDA Products do not meet all limitations of any valid and enforceable claim of the '468 patent.

41. Novitium is entitled to a judgment that the sale, offer for sale, manufacture, importation, and/or use of Novitium's ANDA Products do not (and, if marketed, would not) infringe any valid and enforceable claim of the '468 patent.

DEMAND FOR JUDGMENT

WHEREFORE, Novitium respectfully prays that this Court enter judgment in its favor and grant the following relief:

A. Declare that by filing ANDA No. 211398, Novitium has not infringed, is not infringing, and will not infringe, or contribute to or induce infringement of any valid and enforceable claim of the Patents-In-Suit, literally or under the doctrine of equivalents, and that Novitium has a lawful right to obtain FDA approval of Novitium's ANDA Products;

B. Declare that Novitium will not infringe, or contribute to or induce infringement of any valid and enforceable claim of the Patents-In-Suit, literally or under the doctrine of equivalents, by the importation, manufacture, use, offer for sale, or sale of Novitium's ANDA Products;

C. Enjoin Counterclaim Defendants, their officers, employees, agents, representatives, attorneys, and others acting on their behalf, from threatening or initiating infringement litigation against Novitium or its customers, dealers or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Novitium, or charging them either verbally or in writing with infringement of the Patents-In-Suit with respect to the Novitium's ANDA Products;

D. Ordering that Counterclaim Defendants' Complaint be dismissed with prejudice and judgment entered in favor of Novitium;

E. Declare that this is an exceptional case, and that Novitium be awarded its attorney fees and costs pursuant to 35 U.S.C. § 285;

F. Declare that Counterclaim Defendants are entitled to no damages, interest, costs, or other relief (including injunctive relief) from or against Novitium for infringement of the Patents-In-Suit;

G. Award costs and expenses to Novitium; and

H. Award Novitium such further relief as this Court may deem necessary, just, and proper.

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Dated: May 14, 2018

/s/ Steven J. Fineman

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