IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ICEUTICA PTY LTD and IROKO PHARMACEUTICALS, LLC, Plaintiffs, v. NOVITIUM PHARMA LLC Defendants.	C.A. No. _____ **JURY TRIAL DEMANDED**

COMPLAINT

For their Complaint against Defendant Novitium Pharma LLC, Plaintiffs iCeutica Pty Ltd ("iCeutica") and Iroko Pharmaceuticals, LLC ("Iroko") (collectively, "Plaintiffs"), by their attorneys, allege as follow:

NATURE OF ACTION

1. This is an action for 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") under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, including §§ 271(e)(2) and 271(a)-(c), and for a declaratory judgment of infringement of the '734, '318, and '468 patents under 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. § 271. Plaintiffs institute this action to enforce their patent rights covering VIVLODEX® brand Meloxicam capsules 5 mg and 10 mg that are approved in the United States by the U.S. Food and Drug Agency ("FDA") for the management of osteoarthritis pain.

THE PARTIES

2. Plaintiff iCeutica Pty Ltd is a company organized and existing under the laws of Australia with a principal place of business at Unit 2, 32 Mumford Place, Balcatta Western Australia 6021.

3. Plaintiff Iroko Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of Delaware, with a principal place of business at One Kew Place, 150 Rouse Boulevard, Philadelphia, PA, 19112.

4. Upon information and belief, Defendant Novitium Pharma LLC ("Novitium") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business located at 70 Lake Drive, East Windsor, NJ 08520.

5. Upon information and belief, Novitium is in the business of, *inter alia*: (i) the development and manufacture of generic pharmaceutical products for sale throughout the world, including throughout the United States and, more specifically, throughout the State of Delaware; (ii) the preparation, submission, and filing of Abbreviated New Drug Applications ("ANDAs") seeking FDA approval to market generic drugs throughout the United States, including throughout the State of Delaware; and (iii) the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of Delaware.

6. Upon information and belief, Novitium engages in the sale and distribution of generic versions of branded pharmaceutical products, including those manufactured by Novitium, in the United States, including in this judicial district and the State of Delaware, through its own systematic, continuous, constant and pervasive actions and through those of their agents.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, et seq., including §§ 271(e)(2), 271(a), 271(b), 271(c), and 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

8. This Court has personal jurisdiction over Novitium as it is incorporated in Delaware. As a domestic corporation, Novitium is registered to do business with the Delaware Department of State Division of Corporations. This Court also has personal jurisdiction over Novitium by virtue of, *inter alia*, the fact that Novitium 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, including Iroko Pharmaceuticals LLC, a Delaware company that conducts business in Delaware and derives substantial revenue therefrom, and because Novitium has engaged in purposeful systematic and continuous contacts with the State of Delaware. This Court has personal jurisdiction over Novitium for the additional reasons set forth below and for other reasons that will be presented to the Court if jurisdiction is challenged.

9. This Court has personal jurisdiction over Novitium because, upon information and belief, Novitium regularly does business in Delaware and has engaged in a persistent course of conduct within Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware, and/or by directly selling pharmaceutical products in Delaware.

10. This Court has personal jurisdiction over Novitium by virtue of*, inter alia*, the fact that Novitium distributes drug products for sale throughout the United States, including in this judicial district.

11. This Court has personal jurisdiction over Novitium because, on information and belief, Novitium has engaged in conduct that reliably predicts Delaware activities by Novitium. On information and belief, Novitium, by submitting ANDA No. 211398, has taken the

significant step of applying to the FDA for approval to engage in future activities—including wrongful marketing of its generic drugs—that will be purposefully directed at Delaware.

12. This Court has personal jurisdiction over Novitium by virtue of, *inter alia*, the fact that it has availed itself of the rights and benefits of Delaware law, and has engaged in systematic, continuous, constant and pervasive contacts with the State.

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

FACTUAL BACKGROUND

14. The ’734 patent, entitled “Formulation of Meloxicam,” issued on December 27, 2016 and names H. William Bosch as the inventor. A true and accurate copy of the ’734 patent is attached hereto as Exhibit A.

15. The ’318 patent, entitled “Formulation of Meloxicam,” issued on May 16, 2017 and names H. William Bosch as the inventor. A true and accurate copy of the ’318 patent is attached hereto as Exhibit B.

16. The ’468 patent, entitled “Formulation of Meloxicam,” issued on November 7, 2017 and names H. William Bosch as the inventor. A true and accurate copy of the ’468 patent is attached hereto as Exhibit C.

17. iCeutica, as assignee, owns the entire right, title and interest in the ’734, ’318, and ’468 patents.

18. Iroko is the exclusive licensee to the ’734, ’318, and ’468 patents in the United States.

19. Collectively, Plaintiffs are in possession of all rights, title and interest in and to the ’734, ’318, and ’468 patents, including all rights to sue and recover for infringement thereof.

20. Iroko is the holder of an approved New Drug Application ("NDA") No. 20-7233 for Meloxicam capsules 5 mg and 10 mg, sold under the VIVLODEX® registered trademark.

21. In conjunction with that NDA, Iroko has listed with the FDA the '734, '318, and '468 patents. The FDA has published the '734, '318, and '468 patents in the Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as the "Orange Book").

22. VIVLODEX ® is covered by at least one claim of the '734, '318, and '468 patents.

23. On information and belief, Novitium became aware of the '734, '318, and '468 patents no later than when each patent was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of VIVLODEX®.

24. On or about March 12, 2018, Plaintiffs received a letter, dated March 9, 2018, signed on behalf of Novitium by David H. Silverstein ("Novitium's Paragraph IV Letter").

25. Novitium's Paragraph IV Letter stated that Novitium had submitted, and the FDA had received, an Abbreviated New Drug Application ("ANDA") under section 505(j)(2)(B)(ii) 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 Meloxicam capsules 5 mg and 10 mg, a generic version of the VIVLODEX® product, prior to expiration of the '734, '318, and '468 patents. The ANDA number for Novitium's application is 211398.

26. Novitium's Paragraph IV Letter stated that the '734, '318, and '468 patents are invalid and/or would not be infringed by the commercial manufacture, importation, use, sale, or offer for sale of Novitium's proposed generic Meloxicam capsules 5 mg and 10 mg.

27. Attached to Novitium's Paragraph IV Letter was a statement of the factual and legal bases for Novitium's opinion that the '734, '318, and '468 patents will not be infringed by the manufacture, use, or sale of its proposed generic Meloxicam capsules 5 mg and 10 mg.

28. In Novitium's Paragraph IV Letter, Novitium did not identify any factual or legal basis as to why the '734, '318, and '468 patents are invalid or unenforceable.

29. In filing its ANDA No. 211398, Novitium has requested the FDA's approval to market a generic version of the VIVLODEX® product throughout the United States, including in this judicial district.

30. On information and belief, following FDA approval of ANDA No. 211398, Novitium will manufacture, sell, offer to sell, and/or import the approved generic version of the VIVLODEX® product throughout the United States, including in this judicial district.

31. On information and belief, following FDA approval of ANDA No. 211398, Novitium will sell and/or offer to sell the approved generic version of the VIVLODEX® product manufactured by Novitium throughout the United States, including in this judicial district.

32. After receiving Novitium's Paragraph IV Letter, and prior to the filing of this Complaint, Plaintiffs attempted to procure a copy of ANDA No. 211398 from Novitium. Because the terms of the proposed offer would not allow Plaintiffs to meaningfully process the information contained in the ANDA Plaintiffs could not agree to the terms of the original offer. On March 16 and 22, 2018 and, most recently, April 2, 2018, counsel for Plaintiffs sent Novitium's counsel letters in an attempt to negotiate Plaintiffs' access to ANDA 211398. As of the filing of the Complaint, Novitium's counsel has not responded to Plaintiffs' April 2, 2018 letter. As of the filing of the Complaint, the parties could not reach acceptable terms for accessing the ANDA.

33. Plaintiffs are not aware of any other means for obtaining information regarding Novitium's proposed generic Meloxicam capsules 5 mg and 10 mg. In the absence of such information, Plaintiffs resorted to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm its allegations of infringement and to present the Court evidence that Novitium's proposed Meloxicam capsules 5 mg and 10 mg fall within the scope of one or more claims of the '734, '318, and/or '468 patents.

34. Plaintiffs allege the causes herein based on the representations contained in Novitium's Paragraph IV Letter and the other facts alleged herein.

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. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

36. Novitium submitted ANDA No. 211398 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its proposed generic Meloxicam capsules 5 mg and 10 mg throughout the United States. By submitting this application, Novitium has committed an act of infringement of the '734 patent under 35 U.S.C. § 271(e)(2)(A).

37. The commercial manufacture, importation, use, sale, or offer for sale of Novitium's proposed generic Meloxicam capsules 5 mg and 10 mg will constitute an act of direct infringement of the '734 patent.

38. The commercial manufacture, importation, use, sale, or offer for sale of Novitium's proposed generic Meloxicam capsules 5 mg and 10 mg in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

39. Unless and until Novitium is enjoined from infringing the ’734 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

40. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court stating that the effective date of approval for Novitium’s ANDA be a date that is not earlier than the expiration date of the ’734 patent.

COUNT II

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

41. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

42. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

43. There is an actual case or controversy such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

44. On information and belief, Novitium will engage in the commercial manufacture, use, offer for sale, sale and/or importation of its proposed generic Meloxicam capsules 5 mg and 10 mg immediately and imminently upon approval of ANDA No. 211398.

45. Novitium’s actions, including but not limited to, the development of its proposed generic Meloxicam capsules 5 mg and 10 mg, and the filing of an ANDA with a Paragraph IV certification, reliably predict that Novitium has made and will continue to make, substantial preparation in the United States, including the District of Delaware, to manufacture, sell, offer to sell, and/or import Novitium’s proposed generic Meloxicam capsules 5 mg and 10 mg.

46. The commercial manufacture, importation, use, sale, or offer for sale of Novitium's proposed generic Meloxicam capsules 5 mg and 10 mg will constitute an act of direct infringement of the '734 patent.

47. The commercial manufacture, importation, use, sale, or offer for sale of Novitium's proposed generic Meloxicam capsules 5 mg and 10 mg in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

48. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of Novitium's proposed generic Meloxicam capsules 5 mg and 10 mg before patent expiration by Novitium will constitute direct infringement of the '734 patent.

49. Unless and until Novitium is enjoined from infringing the '734 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

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. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

51. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

52. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

53. On information and belief, Novitium will engage in the commercial manufacture, use, offer for sale, sale and/or importation of its proposed generic Meloxicam capsules 5 mg and 10 mg immediately and imminently upon approval of ANDA No. 211398.

54. Novitium's actions, including but not limited to, the development of its proposed generic Meloxicam capsules 5 mg and 10 mg, and the filing of an ANDA with a Paragraph IV certification, reliably predict that Novitium has made and will continue to make, substantial preparation in the United States, including the District of Delaware, to manufacture, sell, offer to sell, and/or import Novitium's proposed generic Meloxicam capsules 5 mg and 10 mg.

55. On information and belief, Novitium will include within the packaging of its proposed generic Meloxicam capsules 5 mg and 10 mg, or will otherwise make available to prospective patients upon FDA approval, a label and/or instructions for use that instruct patients to use the capsule claimed in the '734 patent.

56. On information and belief, a patient's use of Novitium's proposed generic Meloxicam capsules 5 mg and 10 mg according to the instructions included in the label and/or instructions for use of those products will constitute an act of direct infringement of one or more of the claims in the '734 patent.

57. On information and belief, Novitium became aware of the '734 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of VIVLODEX®.

58. On information and belief, upon awareness of the '734 patent, Novitium either actually knew of the potential for infringement of one or more claims of the '734 patent, or was willfully blind as to the potential for that infringement at least because the label and/or instructions for use instruct patients to use the capsule claimed in the '734 patent.

59. The commercial manufacture, importation, use, sale, or offer for sale of Novitium's proposed generic Meloxicam capsules 5 mg and 10 mg will constitute an act of active inducement of infringement of the '734 patent.

60. The commercial manufacture, importation, use, sale, or offer for sale of Novitium's proposed generic Meloxicam capsules 5 mg and 10 mg in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

61. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of Novitium's proposed generic Meloxicam capsules 5 mg and 10 mg before patent expiration by Novitium will constitute active inducement of infringement of the '734 patent.

62. Unless and until Novitium is enjoined from infringing the '734 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

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. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

64. Novitium submitted ANDA No. 211398 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its proposed generic Meloxicam capsules 5 mg and 10 mg throughout the United States. By submitting this application, Novitium has committed an act of infringement of the '318 patent under 35 U.S.C. § 271(e)(2)(A).

65. The commercial manufacture, importation, use, sale, or offer for sale of Novitium's proposed generic Meloxicam capsules 5 mg and 10 mg will constitute an act of direct infringement of the '318 patent.

66. The commercial manufacture, importation, use, sale, or offer for sale of Novitium's proposed generic Meloxicam capsules 5 mg and 10 mg in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

67. Unless and until Novitium is enjoined from infringing the ’318 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

68. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court stating that the effective date of approval for Novitium’s ANDA be a date that is not earlier than the expiration date of the ’318 patent.

COUNT V

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

69. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

70. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

71. There is an actual case or controversy such that the Court may entertain Plaintiffs’ request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

72. On information and belief, Novitium will engage in the commercial manufacture, use, offer for sale, sale and/or importation of its proposed generic Meloxicam capsules 5 mg and 10 mg immediately and imminently upon approval of ANDA No. 211398.

73. Novitium’s actions, including but not limited to, the development of its proposed generic Meloxicam capsules 5 mg and 10 mg, and the filing of an ANDA with a Paragraph IV certification, reliably predict that Novitium has made and will continue to make, substantial preparation in the United States, including the District of Delaware, to manufacture, sell, offer to sell, and/or import Novitium’s proposed generic Meloxicam capsules 5 mg and 10 mg.

74. The commercial manufacture, importation, use, sale, or offer for sale of Novitium's proposed generic Meloxicam capsules 5 mg and 10 mg will constitute an act of direct infringement of the '318 patent.

75. The commercial manufacture, importation, use, sale, or offer for sale of Novitium's proposed generic Meloxicam capsules 5 mg and 10 mg in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

76. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of Novitium's proposed generic Meloxicam capsules 5 mg and 10 mg before patent expiration by Novitium will constitute direct infringement of the '318 patent.

77. Unless and until Novitium is enjoined from infringing the '318 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

COUNT VI

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

78. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

79. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

80. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

81. On information and belief, Novitium will engage in the commercial manufacture, use, offer for sale, sale and/or importation of its proposed generic Meloxicam capsules 5 mg and 10 mg immediately and imminently upon approval of ANDA No. 211398.

82. Novitium's actions, including but not limited to, the development of its proposed generic Meloxicam capsules 5 mg and 10 mg, and the filing of an ANDA with a Paragraph IV certification, reliably predict that Novitium has made and will continue to make, substantial preparation in the United States, including the District of Delaware, to manufacture, sell, offer to sell, and/or import Novitium's proposed generic Meloxicam capsules 5 mg and 10 mg.

83. On information and belief, Novitium will include within the packaging of its proposed generic Meloxicam capsules 5 mg and 10 mg, or will otherwise make available to prospective patients upon FDA approval, a label and/or instructions for use that instruct patients to use the capsule claimed in the '318 patent.

84. On information and belief, a patient's use of Novitium's proposed generic Meloxicam capsules 5 mg and 10 mg according to the instructions included in the label and/or instructions for use of those products will constitute an act of direct infringement of one or more of the claims in the '318 patent.

85. On information and belief, Novitium became aware of the '318 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of VIVLODEX®.

86. On information and belief, upon awareness of the '318 patent, Novitium either actually knew of the potential for infringement of one or more claims of the '318 patent, or was willfully blind as to the potential for that infringement at least because the label and/or instructions for use instruct patients to use the capsule claimed in the '318 patent.

87. The commercial manufacture, importation, use, sale, or offer for sale of Novitium's proposed generic Meloxicam capsules 5 mg and 10 mg will constitute an act of active inducement of infringement of the '318 patent.

88. The commercial manufacture, importation, use, sale, or offer for sale of Novitium's proposed generic Meloxicam capsules 5 mg and 10 mg in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

89. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of Novitium's proposed generic Meloxicam capsules 5 mg and 10 mg before patent expiration by Novitium will constitute active inducement of infringement of the '318 patent.

90. Unless and until Novitium is enjoined from infringing the '318 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

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. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

92. Novitium submitted ANDA No. 211398 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its proposed generic Meloxicam capsules 5 mg and 10 mg throughout the United States. By submitting this application, Novitium has committed an act of infringement of the '468 patent under 35 U.S.C. § 271(e)(2)(A).

93. On information and belief, Novitium will include within the packaging of its generic Meloxicam capsules 5 mg and 10 mg, or will otherwise make available to prospective patients upon FDA approval, a label and/or instructions for use that instruct patients to perform one or more of the methods claimed in the '468 patent.

94. On information and belief, a patient's use of Novitium's proposed generic Meloxicam capsules 5 mg and 10 mg according to the instructions included in the label and/or

instructions for use of those products will constitute an act of direct infringement of one or more of the methods claimed in the ’468 patent.

95. Novitium’s proposed generic Meloxicam capsules 5 mg and 10 mg are a material part of one or more of the methods claimed in the ’468 patent.

96. Novitium’s proposed generic Meloxicam capsules 5 mg and 10 mg have no substantial uses that do not constitute infringement of one or more of the methods claimed in the ’468 patent.

97. On information and belief, Novitium became aware of the ’468 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using the approved formulation of VIVLODEX®.

98. On information and belief, upon awareness of the ’468 patent, Novitium either actually knew of the potential for infringement of one or more claims of the ’468 patent, or was willfully blind as to the potential for that infringement at least because the label and/or instructions for use instruct patients to perform one or more methods claimed in the ’468 patent.

99. Any commercial manufacture, distribution, marketing, offer for sale, sale, and/or importation of Novitium’s proposed generic Meloxicam capsules 5 mg and 10 mg before patent expiration will constitute an act of contributory infringement and/or active inducement of infringement of the ’468 patent.

100. On information and belief, Novitium knew or should have known that its commercial manufacture, distribution, marketing, offer for sale, sale, and/or importation of its proposed generic Meloxicam capsules 5 mg and 10 mg will actively induce the actual infringement of the ’468 patent.

101. On information and belief, Novitium knew or should have known that its

proposed generic Meloxicam capsules 5 mg and 10 mg will be especially made or especially adapted for use in an infringement of the '468 patent, and not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, distribution, marketing, offer for sale, sale, and/or importation of its proposed generic Meloxicam capsules 5 mg and 10 mg will actively contribute to the actual infringement of the '468 patent.

102. The commercial manufacture, distribution, marketing, use, offer for sale, sale, and/or importation of Novitium's proposed generic Meloxicam capsules 5 mg and 10 mg in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

103. Unless and until Novitium is enjoined from infringing the '468 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

104. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court stating that the effective date of approval for Novitium's ANDA be a date that is not earlier than the expiration date of the '468 patent.

COUNT VIII

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

105. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

106. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

107. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

108. On information and belief, Novitium will engage in the commercial manufacture, distribution, use, offer for sale, sale and/or importation of its proposed generic Meloxicam capsules 5 mg and 10 mg immediately and imminently upon approval of ANDA No. 211398.

109. Novitium's actions, including but not limited to, the development of its proposed generic Meloxicam capsules 5 mg and 10 mg, filing of an ANDA with Paragraph IV certifications, and, on information and belief, the manufacture of exhibit batches of its proposed generic Meloxicam capsules 5 mg and 10 mg, indicate a refusal to change the course of its actions in the face of acts by Plaintiffs.

110. On information and belief, Novitium has made and will continue to make, substantial preparation in the United States, including the District of Delaware, to manufacture, distribute, sell, offer to sell, and/or import Novitium's proposed generic Meloxicam capsules 5 mg and 10 mg.

111. On information and belief, Novitium will include within the packaging of its generic Meloxicam capsules 5 mg and 10 mg, or will otherwise make available to prospective patients upon FDA approval, a label and/or instructions for use that instruct patients to perform one or more of the methods claimed in the '468 patent.

112. On information and belief, a patient's use of Novitium's proposed generic Meloxicam capsules 5 mg and 10 mg according to the instructions included in the label and/or instructions for use of those products will constitute an act of direct infringement of one or more of the methods claimed in the '468 patent.

113. Novitium's proposed generic Meloxicam capsules 5 mg and 10 mg are a material part of one or more of the methods claimed in the '468 patent.

114. Novitium's proposed generic Meloxicam capsules 5 mg and 10 mg have no substantial uses that do not constitute infringement of one or more of the methods claimed in the '468 patent.

115. On information and belief, Novitium became aware of the '468 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering methods of using the approved formulation of VIVLODEX®.

116. On information and belief, upon awareness of the '468 patent, Novitium either actually knew of the potential for infringement of one or more claims of the '468 patent, or was willfully blind as to the potential for that infringement at least because the label and/or instructions for use instruct patients to perform one or more methods claimed in the '468 patent.

117. Any commercial manufacture, distribution, marketing, offer for sale, sale, and/or importation of Novitium's proposed generic Meloxicam capsules 5 mg and 10 mg before patent expiration will constitute an act of contributory infringement and/or active inducement of infringement of the '468 patent.

118. Any commercial manufacture, distribution, marketing, offer for sale, sale, and/or importation of Novitium's proposed generic Meloxicam capsules 5 mg and 10 mg in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

119. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, distribution, marketing, offer for sale, sale, and/or importation of Novitium's proposed generic Meloxicam capsules 5 mg and 10 mg before patent expiration by Novitium will constitute contributory infringement and/or active inducement of infringement of the '468 patent.

120. Unless and until Novitium is enjoined from infringing the '468 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs hereby request a trial by jury of all issues so triable.

RELIEF SOUGHT

WHEREFORE, Plaintiffs request:

A) A judgment that Novitium has infringed the ’734, ’318, and ’468 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 211398 under section 505(j) of the FDCA, and that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Novitium’s proposed generic Meloxicam capsules 5 mg and 10 mg will constitute an act of infringement of the ’734, ’318, and ’468 patents;

B) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Novitium’s ANDA No. 211398 shall be a date which is not earlier than the expiration date of the ’734 patent, the ’318 patent, or the ’468 patent, as extended by any applicable period of exclusivity;

C) An injunction pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Novitium, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the ’734, ’318, and ’468 patents;

D) A judgment declaring that if Novitium engages in the commercial manufacture, use, offer to sell, sale, or importation of Novitium’s generic product disclosed in its ANDA No. 211398 prior to the expiration of the ’734 patent, the ’318 patent, or the ’468 patent, as extended

by any applicable period of exclusivity, a preliminary injunction and/or permanent injunction will be entered enjoining such conduct pursuant to 35 U.S.C. § 283;

E) A judgment declaring that if Novitium engages in the commercial manufacture, use, offer to sell, sale, or importation of Novitium's generic product disclosed in its ANDA No. 211398 prior to the expiration of the '734 patent, the '318 patent, or the '468 patent, as extended by any applicable period of exclusivity, Plaintiffs are entitled to damages or other monetary relief resulting from such infringement under 35 U.S.C. § 271(e)(4)(C);

F) A judgment issued pursuant to 28 U.S.C. § 2201 declaring that if Novitium, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Novitium's proposed generic Meloxicam capsules 5 mg and 10 mg prior to the expiration of the '734, '318, and '468 patents, it will constitute an act of infringement of the '734, '318, and '468 patents;

G) A judgment that this is an exceptional case under 35 U.S.C. § 285, and that Plaintiffs be awarded reasonable attorneys' fees and costs;

H) An accounting for infringing sales not presented at trial and an award by the Court of additional damages for any such infringing sales; and

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

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