IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTELLAS PHARMA INC., ASTELLAS US LLC, ASTELLAS PHARMA US, INC., MEDIVATION LLC, MEDIVATION PROSTATE THERAPEUTICS LLC, and THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, Plaintiffs, v. EUGIA PHARMA SPECIALITIES LTD., AUROBINDO PHARMA USA, INC., and AUROBINDO PHARMA LTD., Defendants.	)	C.A. No. 18-757-GMS

DEFENDANTS' ANSWER AND
AUROBINDO PHARMA USA, INC.'S COUNTERCLAIMS

Defendants Aurobindo Pharma Limited, Aurobindo Pharma USA, Inc. and Eugia Pharma Specialities Limited (collectively "Aurobindo"), for their answer to the Complaint by their undersigned attorneys allege as follows:

THE PARTIES

1. Deny knowledge or information sufficient to form a belief as to the allegations of paragraph 1 of the Complaint.

2. Deny knowledge or information sufficient to form a belief as to the allegations of paragraph 2 of the Complaint.

3. Deny knowledge or information sufficient to form a belief as to the allegations of paragraph 3 of the Complaint.

4. Deny knowledge or information sufficient to form a belief as to the allegations of paragraph 4 of the Complaint.

5. Deny knowledge or information sufficient to form a belief as to the allegations of paragraph 5 of the Complaint.

6. Deny knowledge or information sufficient to form a belief as to the allegations of paragraph 6 of the Complaint.

7. Admit.

8. Admit that Eugia Pharma Specialities Limited is a pharmaceutical company in the business of manufacturing, importing and selling generic pharmaceutical products, and except as so expressly admitted, deny the allegations of paragraph 8 of the Complaint.

9. Admit.

10. Admit that Aurobindo Pharma USA, Inc. is a pharmaceutical company in the business of manufacturing, importing and selling generic pharmaceutical products, and except as so expressly admitted, deny the allegations of paragraph 10 of the Complaint.

11. Admit.

12. Admit that Aurobindo Pharma Limited is a pharmaceutical company in the business of developing generic drug products, and except as so expressly admitted, deny the allegations of paragraph 12 of the Complaint.

13. Admit that Curepro Parenterals Limited owns 67.82% of Eugia Pharma Specialties Limited, Curepro Parenterals Limited is a wholly owned subsidiary of Aurobindo Pharma Limited, and except as so expressly admitted, deny the allegations of paragraph 13 of the Complaint.

14. Admit Aurobindo Pharma USA, Inc. is a wholly owned subsidiary of Aurobindo Pharma Ltd., and the United States agent for Eugia Pharma Specialities Ltd with respect to ANDA No. 211465, and except as so expressly admitted, deny the allegations of paragraph 14 of the Complaint.

15. Deny the allegations of paragraph 15 of the Complaint.

16. Deny the allegations of paragraph 16 of the Complaint.

17. Admit that Aurobindo USA, Inc. and Eugia Pharma Specialties Limited submitted ANDA No. 211465 with the FDA and plan to commercially manufacture and sell the ANDA product proposed in ANDA No. 211465 ("proposed ANDA product") at some time after approval by the FDA, and except as so expressly admitted, deny the allegations of paragraph 17 of the Complaint.

NATURE OF THE ACTION

18. Admit that the Complaint purports to bring an action for infringement under the patent laws of the United States, 35 U.S.C. § 100, et seq., and that Aurobindo USA, Inc. and Eugia Pharma Specialties Limited submitted ANDA No. 211465 with the FDA, and except as so expressly admitted, deny the allegations of paragraph 18 of the Complaint.

JURISDICTION AND VENUE

19. Admit that subject matter jurisdiction is appropriate only for claims under 35 U.S.C. § 271(e)(2)(A), and except as so expressly admitted, deny the allegations of paragraph 19 of the Complaint.

20. For the limited purposes of this action only, Aurobindo Pharma USA, Inc. and

Eugia Pharma Specialties Limited consent to personal jurisdiction of this Court, and except as so expressly admitted, deny the allegations of paragraph 20 of the Complaint.

21. For the limited purposes of this action only, Aurobindo Pharma USA, Inc. and Eugia Pharma Specialties Limited consent to personal jurisdiction of this Court and, except as so expressly admitted, deny the allegations of paragraph 21 of the Complaint.

22. Admit that Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, and, for the limited purposes of this action only, Aurobindo Pharma USA Inc. consents to personal jurisdiction of this Court.

23. Admit that Aurobindo Pharma USA, Inc. has been sued in this Court, consented to personal jurisdiction for the limited purposes of those lawsuits, and asserted counterclaims, and, for the limited purposes of this action only, Aurobindo Pharma USA Inc. consents to personal jurisdiction of this Court, and except as so expressly admitted, deny the allegations of paragraph 23 of the Complaint.

24. Admit that Aurobindo Pharma Limited has been sued in this Court, consented to personal jurisdiction for the limited purposes of those lawsuits, and asserted counterclaims, and except as so expressly admitted, deny the allegations of paragraph 24 of the Complaint.

25. For the limited purposes of this action only, Eugia Pharma Specialities Limited consents to personal jurisdiction of this Court, and except as so expressly admitted, deny the allegations of paragraph 25 of the Complaint.

26. For the limited purposes of this action only, Aurobindo Pharma USA, Inc. and Eugia Pharma Specialties Limited do not contest venue in this Judicial District.

THE XTANDI® NDA

27. Deny knowledge or information sufficient to form a belief as to the allegations of paragraph 27 of the Complaint.

28. Deny knowledge or information sufficient to form a belief as to the allegations of paragraph 28 of the Complaint.

29. Deny knowledge or information sufficient to form a belief as to the allegations of paragraph 29 of the Complaint.

30. Deny knowledge or information sufficient to form a belief as to the allegations of paragraph 30 of the Complaint.

31. Deny knowledge or information sufficient to form a belief as to the allegations of paragraph 31 of the Complaint.

32. Admit that Plaintiffs purport to describe the chemical names and depict the chemical structure of enzalutamide, and except as so expressly admitted, deny the allegations of paragraph 32 of the Complaint.

THE PATENTS-IN-SUIT

33. Admit that the '517 patent was issued on May 4, 2010, deny knowledge and information sufficient to form a belief as to the ownership of the '517 patent, admit that a copy of the '517 patent is attached to the Complaint as Exhibit A, and except as so expressly admitted, deny the allegations of paragraph 33 of the Complaint.

34. Admit that the '274 patent was issued on May 22, 2012, deny knowledge and information sufficient to form a belief as to the ownership of the '274 patent, admit that a copy

of the '274 patent is attached to the Complaint as Exhibit B, and except as so expressly admitted, deny the allegations of paragraph 34 of the Complaint.

35. Admit that the '941 patent was issued on September 8, 2015, deny knowledge and information sufficient to form a belief as to the ownership of the '941 patent, admit that a copy of the '941 patent is attached to the Complaint as Exhibit C, and except as so expressly admitted, deny the allegations of paragraph 35 of the Complaint.

36. Admit that the '517, '274, and '941 patents have been listed in the Orange book in connection with Xtandi®, and except as so expressly admitted, deny the allegations of paragraph 36 of the Complaint.

37. Deny knowledge or information sufficient to form a belief as to the allegations of paragraph 37 of the Complaint.

38. Deny knowledge or information sufficient to form a belief as to the allegations of paragraph 38 of the Complaint.

39. Deny knowledge or information sufficient to form a belief as to the allegations of paragraph 39 of the Complaint.

CLAIMS FOR RELIEF-PATENT INFRINGEMENT

40. Refer to the letter dated April 11, 2018 for the contents thereof, and except as so expressly admitted, deny the allegations of paragraph 40 of the Complaint.

41. Admit that Aurobindo Pharma USA, Inc. and Eugia Pharma Specialities Limited submitted ANDA No. 211465 to the FDA, and plan to commercially manufacture and sell the proposed ANDA product, at some time after approval by the FDA, and except as so expressly admitted, deny the allegations of paragraph 41 of the Complaint.

42. Admit that the proposed ANDA product is for the indication of treatment of metastatic castration-resistant prostate cancer.

43. Refer to the letter dated April 11, 2018 for the contents thereof, and except as so expressly admitted, deny the allegations of paragraph 43 of the Complaint.

44. Refer to the letter dated April 11, 2018 for the contents thereof and except as so expressly admitted, deny the allegations of paragraph 44 of the Complaint.

45. Deny the allegations of paragraph 45 of the Complaint.

46. Refer to the letter dated April 11, 2018 for the contents thereof and except as so expressly admitted, deny the allegations of paragraph 46 of the Complaint.

47. Deny the allegations of paragraph 47 of the Complaint.

48. Refer to the letter dated April 11, 2018 for the contents thereof and except as so expressly admitted, deny the allegations of paragraph 48 of the Complaint.

49. Deny the allegations of paragraph 49 of the Complaint.

50. Admit.

51. Admit.

COUNT I

(INFRINGEMENT OF THE '517 PATENT)

52. Aurobindo realleges the answers to paragraphs 1--51 of the Complaint as if fully set forth herein.

53. Admit that the submission of ANDA No. 211465 constitutes a technical act of infringement for the purpose only of giving the court jurisdiction to litigate the issues of patent

infringement, validity, and enforceability, and except as so expressly admitted, deny the allegations of paragraph 53 of the Complaint.

54. Refer to the '517 patent for the contents thereof, admit that enzalutamide is recited in certain '517 patent claims, and except as so expressly admitted, deny the allegations of paragraph 54 of the Complaint.

55. Admit that the proposed ANDA product contains enzalutamide, and except as so expressly admitted, deny the allegations of paragraph 55 of the Complaint.

56. Deny the allegations of paragraph 56 of the Complaint.

57. Admit that the proposed ANDA product contains enzalutamide, and except as so expressly admitted, deny the allegations of paragraph 57 of the Complaint.

58. Admit that Aurobindo had knowledge of the '517 patent and its listing in the Orange Book, refer to the letter dated April 11, 2018 for the contents thereof, and except as so expressly admitted, deny the allegations of paragraph 58 of the Complaint.

59. Deny the allegations of paragraph 59 of the Complaint.

60. Deny the allegations of paragraph 60 of the Complaint.

61. Deny the allegations of paragraph 61 of the Complaint.

COUNT II

(INFRINGEMENT OF THE '274 PATENT)

62. Aurobindo realleges the answers to paragraphs 1--61 of the Complaint as if fully set forth herein.

63. Admit that the submission of ANDA No. 211465 constitutes a technical act of

infringement for the purpose only of giving the court jurisdiction to litigate the issues of patent infringement, validity, and enforceability, and except as so expressly admitted, deny the allegations of paragraph 63 of the Complaint.

64. Refer to the '274 patent for the contents thereof, admit that methods of treating prostate cancer are recited in certain '274 patent claims, and except as so expressly admitted, deny the allegations of paragraph 64 of the Complaint.

65. Deny the allegations of paragraph 65 of the Complaint.

66. Deny the allegations of paragraph 66 of the Complaint.

67. Admit that the proposed ANDA product contains enzalutamide, and except as so expressly admitted, deny the allegations of paragraph 67 of the Complaint.

68. Admit that the proposed ANDA product has a label that copies certain sections in the Xtandi® label, and the proposed ANDA product label includes "the treatment of patients with metastatic castration-resistant prostate cancer" in the "indications and usage" section, and except as so expressly admitted, deny the allegations of paragraph 68 of the Complaint.

69. Deny the allegations of paragraph 69 of the Complaint.

70. Deny the allegations of paragraph 70 of the Complaint.

71. Deny the allegations of paragraph 71 of the Complaint.

72. Deny the allegations of paragraph 72 of the Complaint.

73. Deny the allegations of paragraph 73 of the Complaint.

74. Admit that Aurobindo had knowledge of the '274 patent and its listing in the Orange Book, refer to the letter dated April 11, 2018 for the contents thereof, and except as so

expressly admitted, deny the allegations of paragraph 74 of the Complaint.

75. Deny the allegations of paragraph 75 of the Complaint.

76. Deny the allegations of paragraph 76 of the Complaint.

COUNT III

(INFRINGEMENT OF THE '941 PATENT)

77. Aurobindo realleges the answers to paragraphs 1--76 of the Complaint as if fully set forth herein.

78. Admit that the submission of ANDA No. 211465 constitutes a technical act of infringement for the purpose only of giving the court jurisdiction to litigate the issues of patent infringement, validity, and enforceability, and except as so expressly admitted, deny the allegations of paragraph 78 of the Complaint.

79. Refer to the '941 patent for the contents thereof, admit that methods of treating prostate cancer are recited in certain '941 patent claims, and except as so expressly admitted, deny the allegations of paragraph 79 of the Complaint.

80. Deny the allegations of paragraph 80 of the Complaint.

81. Deny the allegations of paragraph 81 of the Complaint.

82. Admit that the proposed ANDA product contains enzalutamide, and except as so expressly admitted, deny the allegations of paragraph 82 of the Complaint.

83. Admit that the proposed ANDA product has a label that copies certain sections in the Xtandi® label, and the proposed ANDA product label includes "the treatment of patients with metastatic castration-resistant prostate cancer" in the "indications and usage" section, and

except as so expressly admitted, deny the allegations of paragraph 83 of the Complaint.

84. Deny the allegations of paragraph 84 of the Complaint.

85. Deny the allegations of paragraph 85 of the Complaint.

86. Deny the allegations of paragraph 86 of the Complaint.

87. Deny the allegations of paragraph 87 of the Complaint.

88. Deny the allegations of paragraph 88 of the Complaint.

89. Admit that Aurobindo had knowledge of the '941 patent and its listing in the Orange Book, refer to the letter dated April 11, 2018 for the contents thereof, and except as so expressly admitted, deny the allegations of paragraph 89 of the Complaint.

90. Deny the allegations of paragraph 90 of the Complaint.

91. Deny the allegations of paragraph 91 of the Complaint.

PLAINTIFFS' PRAYER FOR RELIEF

92. Deny that Plaintiffs are entitled to any relief requested by its Prayer for Relief.

FIRST DEFENSE
(INVALIDITY OF THE '517 PATENT)

93. The claims of United States Patent No. 7,709,517 ("the '517 patent") are invalid and/or unenforceable for failure to comply with one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, 102, 103, or 112, or under other judicially-created bases for invalidation.

SECOND DEFENSE
(INVALIDITY OF THE '274 PATENT)

94. The claims of United States Patent No. 8,183,274 ("the '274 patent") are invalid and/or unenforceable for failure to comply with one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, 102, 103, or 112, or under other judicially-created bases for invalidation.

THIRD DEFENSE
(INVALIDITY OF THE '941 PATENT)

95. The claims of United States Patent No. 9,126,941 ("the '941 patent") are invalid and/or unenforceable for failure to comply with one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, 102, 103, or 112, or under other judicially-created bases for invalidation.

FOURTH DEFENSE
(NONINFRINGEMENT OF THE '517 PATENT)

96. The manufacture, use, sale, offer for sale, or importation of the products that are the subject of Aurobindo's ANDA No. 211465 does not infringe, and will not, if marketed, infringe directly or indirectly, either literally or under the doctrine of equivalents, any valid and/or enforceable claim of the '517 patent.

FIFTH DEFENSE
(NONINFRINGEMENT OF THE '274 PATENT)

97. The manufacture, use, sale, offer for sale, or importation of the products that are the subject of Aurobindo's ANDA No. 211465 does not infringe, and will not, if marketed, infringe directly or indirectly, either literally or under the doctrine of equivalents, any valid and/or enforceable claim of the '274 patent.

SIXTH DEFENSE
(NONINFRINGEMENT OF THE '941 PATENT)

98. The manufacture, use, sale, offer for sale, or importation of the products that are the subject of Aurobindo's ANDA No. 211465 does not infringe, and will not, if marketed, infringe directly or indirectly, either literally or under the doctrine of equivalents, any valid and/or enforceable claim of the '941 patent.

SEVENTH DEFENSE

99. Plaintiffs' Complaint fails to state a claim upon which relief can be granted.

EIGHTH DEFENSE

100. Plaintiffs' Complaint fails to state a proper claim for willful infringement or for this being an exceptional case justifying an award of attorney's fees.

NINTH DEFENSE

101. Astellas US LLC lacks standing to bring suit for infringement of the '517, '274 and/or '941 patents.

TENTH DEFENSE

102. Plaintiffs are not entitled to any of the relief sought in the Complaint.

ELEVENTH DEFENSE

103. The Court lacks personal jurisdiction over Aurobindo Pharma Ltd.

TWELTH DEFENSE

104. Aurobindo reserves the right to assert any additional defenses that are made

known to it in the course of discovery.

AUROBINDO PHARMA USA, INC.'S COUNTERCALIMS

Defendant/Counterclaim-Plaintiff Aurobindo Pharma USA, Inc. ("Aurobindo USA") asserts the following Counterclaims against Plaintiffs Astellas Pharma Inc., Astellas US LLC, and Astellas Pharma US, Inc. (collectively, "Astellas"), Medivation LLC and Medivation Prostate Therapeutics LLC (collectively, "Medivation"), and The Regents of the University of California ("The Regents") (collectively, "Plaintiffs"):

THE PARTIES

105. Aurobindo Pharma USA, Inc. is a company organized and existing under the laws of the State of Delaware, having a principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520.

106. Plaintiff Astellas Pharma Inc. purports to be a corporation organized and existing under the laws of Japan having its principal place of business at 2-5-1, Nihonbashi-Honcho, Chuo-Ku, Tokyo 103-8411, Japan.

107. Plaintiff Astellas US LLC purports to be a limited liability company organized and existing under the laws of the State of Delaware having its principal place of business at 1 Astellas Way, Northbrook, Illinois 60062, United States.

108. Plaintiff Astellas Pharma US, Inc. purports to be a corporation organized and existing under the laws of the State of Delaware having its principal place of business at 1 Astellas Way, Northbrook, Illinois 60062, United States.

109. Plaintiff Medivation LLC purports to be a limited liability company organized

and existing under the laws of the State of Delaware having its principal place of business at 525 Market St., 36th Floor, San Francisco, California 94105, United States.

110. Plaintiff Medivation Prostate Therapeutics LLC purports to be a limited liability company organized and existing under the laws of the State of Delaware having its principal place of business at 525 Market St., 36th Floor, San Francisco, California 94105, United States.

111. Plaintiff The Regents of the University of California purports to be a public corporation organized and existing under the laws of the State of California operating under Article 9, Section 9 of the California Constitution, having its corporate offices located at 1111 Franklin Street, Oakland, California 94607-5200, United States.

JURISDICTION AND VENUE

112. Aurobindo USA denies infringement and asserts that each of the patents asserted in this action are invalid, and an actual and present controversy exits between Aurobindo USA and Plaintiffs.

113. This Court has jurisdiction of these counterclaims pursuant to 28 U.S.C. §§ 2201 and 1338.

114. Venue is proper in this district.

FIRST COUNTERCLAIM

115. The allegations of paragraphs 1--114 are reincorporated herein as if fully set forth.

116. The claims of the ‘517 patent that recite enzalutamide or compositions containing enzalutamide are invalid as obvious under 35 U.S.C. § 103, because enzalutamide is included in or rendered obvious by the phenylimidazolidine structures disclosed in the prior art as androgen

receptor inhibitors that were believed to be effective for the treatment of prostate cancer. *See, e.g.*, U. S. Patent Nos. 5,411,981; 5,985,868; 5,627,201; 5,434,176; 6,087,509; 5,750,553; and RE35,956.

117. The claims of the '517 patent are further rendered obvious by the combination of any of the above prior art references teaching the use of phenylimidazolidine compounds as androgen receptor inhibitors with Bohl, et. al., *J. Med. Chem*., 2004, 47 (15), pp. 3765-3776 ("Bohl"). Bohl teaches the structure activity relationships of androgen receptor inhibitors, and most commonly used prior art androgen receptor inhibitor bicalutamide. These teachings combined render enzalutamide obvious.

118. The claims of the '517 patent are invalid under 35 U.S.C. § 103.

SECOND COUNTERCLAIM

119. The allegations of paragraphs 1--118 are reincorporated herein as if fully set forth.

120. The claims of the '274 patent reciting methods of treatment by administering the compounds including enzalutamide described in the '517 patent are invalid as obvious under 35 U.S.C. § 103, because enzalutamide is included in or rendered obvious by the phenylimidazolidine structures disclosed in the prior art as androgen receptor inhibitors that were believed to be effective in treating prostate cancer. *See, e.g.*, U. S. Patent Nos. 5,411,981; RE 35,968; 5,750,553; 6,087,509; and Bohl.

121. Claim 6 of the '274 patent reciting a method of claim 1 "wherein the prostate cancer is hormone refractory prostate cancer" is obvious. The prior art teaches the possible conversion of antagonists to agonists and suggest the use of that information in anti-androgen design. *See, e.g.*, Rahman, "Reducing the Agonist Activity of Antiandrogens by Dominant-

negative Androgen Receptor Coregulator ARA70 in Prostate Cancer Cells." *J. Biological Chem*., 278 (22) (May 30, 2003) pp. 19619-19626, and WO 2005/060661. It would have been obvious to test enzalutamide in hormone resistant prostate cancer cell assay to confirm that the compound would be useful for the treatment of the recited prostate cancer. Claim 6 of the '274 patent is obvious.

122. Claims 2-5 and 15-24 of the '274 patent reciting certain doses are invalid as obvious under 35 U.S.C. § 103 in view of the prior art references including *e.g*., U. S. Patent No. 6,087,509. Other prior art references, *e.g*., Harmonised Tripartite Guideline, Dose-Response Information to Support Drug Registration (March 10, 1994) published by the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use ("ICH") discloses that, for example, "assessment of dose response should be an integral component of drug development," and "conducting dose-response studies at an early stage of clinical development may reduce the number of failed Phase 3 trials, speeding the drug development process and conserving development resources." The Guideline discloses that the knowledge of the relationships among dose, drug concentration in blood, and clinical response is important for safe and effective use of drugs in individual patients. These disclosures render the '274 patent claims 2-5 and 15 -24 obvious.

123. Claims 7-10 the '274 patent reciting administration by injection or orally are obvious in view of prior art references, *e.g*., U. S. Patent No. 5,411,981.

124. Claims 33 and claim 37 of the '274 patent reciting a method of treating breast cancer and a method of treating ovarian cancer respectively are obvious in view of the prior art reference, *e.g*., U.S. Patent No. 6,087,509.

125. The claims of the '274 patent are invalid under 35 U.S.C. § 103.

THIRD COUNTERCLAIM

126. The allegations of paragraphs 1--125 are reincorporated herein as if fully set forth.

127. The claims of the '941 patent reciting methods of treatment by administering the compounds including enzalutamide are invalid as obvious under 35 U.S.C. § 103, because enzalutamide is included in or rendered obvious by the phenylimidazolidine structures disclosed in the prior art as androgen receptor inhibitors that were believed to be effective in treating prostate cancer. *See, e.g.*, U.S. Patent Nos. 5,411,981; RE 35,968; 5,750,553; 6,087,509; and Bohl.

128. The claims of the '941 patent are invalid under 35 U.S.C. § 103.

FOURTH COUNTERCLAIM

129. The allegations of paragraphs 1--128 are reincorporated herein as if fully set forth.

130. Claims 13, 14, 16, 17, 26, and 27 of the '941 patent are invalid under 35 U.S.C. §112, because the claims are indefinite in that they include a limitation requiring a result that would be unknown until after, perhaps long after, enzalutamide is administered to a patient. In order to determine infringement, prediction of the result recited in the claims, *e.g.*, whether the administration of enzalutamide "prevents the prostate cancer from progressing to hormone refractory prostate cancer" in a patient is required. These claims are therefore invalid because there is no reasonable certainty regarding the scope of the alleged inventions.

FIFTH COUNTERCLAIM

131. The allegations of paragraphs 1--130 are reincorporated herein as if fully set forth.

132. Aurobindo USA is a pharmaceutical company that does not treat patients or

administer pharmaceuticals.

133. Aurobindo USA will not directly infringe nor induce infringement nor contribute to infringement of any of the method of treatment claims of the '274 and '941 patents.

SIXTH COUNTERCLAIM

134. The allegations of paragraphs 1--133 are reincorporated herein as if fully set forth.

135. Plaintiffs had knowledge that the patents in suit were invalid and not infringed when they commenced this action.

136. This is an exceptional case.

WHEREFORE, Defendant Aurobindo Pharma USA, Inc. respectfully request the Court to grant the following relief:

1. Dismiss the Complaint with prejudice;

2. Declare each of the claims of the patents in suit invalid;

3. Declare that no valid claim of the patents in suit is infringed by Aurobindo Pharma USA, Inc.;

4. Award to Aurobindo Pharma USA, Inc. its costs and attorneys' fees;

5. Such other and further relief as is just and proper.

Respectfully submitted,

GREENBERG TRAURIG, LLP

/s/ Benjamin J. Schladweiler

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Dated: June 8, 2018

CERTIFICATE OF SERVICE

I, Benjamin J. Schladweiler, hereby certify that on June 8, 2018, I caused the foregoing ***Defendants' Answer and Aurobindo Pharma USA, Inc.'s Counterclaims*** to be served via electronic mail upon the following counsel of record:

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