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Attorneys for Defendant Ascent Pharmaceuticals, Inc.

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

ASTELLAS PHARMA INC., ASTELLAS US LLC; ASTELLAS PHARMA US, INC.; MEDIVATION LLC; MEDIVATION PROSTATE THERAPEUTICS LLC; THE REGENTS OF THE UNIVERSITY OF CALIFORNIA,	:	Document Filed Electronically
	:	C.A. No. 3:25-cv-00035-MAS-RLS
	:	Michael A. Shipp, U.S.D.J.
	:	Rukhsanah L. Singh, U.S.M.J.
	:	
Plaintiffs,	:	
v.	:	
ASCENT PHARMACEUTICALS, INC.,	:	
	:	
Defendant.	:	x

DEFENDANT ASCENT'S ANSWER TO COMPLAINT

Defendant Ascent Pharmaceuticals, Inc. ("Ascent") hereby provides the following Answer to the numbered paragraphs set forth in the Complaint of Plaintiffs Astellas Pharma, Inc., Astellas US LLC, Astellas Pharma US, Inc., Medivation LLC, Medivation

Prostate Therapeutics LLC, and The Regents of the University of California, (collectively “Astellas” or “Plaintiffs”).

Ascent denies each and every allegation of the Complaint that is not specifically admitted below.

RESPONSE TO THE PARTIES

1. Ascent lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in this Paragraph of the Complaint and therefore denies them.

2. Ascent lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in this Paragraph of the Complaint and therefore denies them.

3. Ascent lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in this Paragraph of the Complaint and therefore denies them.

4. Ascent lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in this Paragraph of the Complaint and therefore denies them.

5. Ascent lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in this Paragraph of the Complaint and therefore denies them.

6. Ascent lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in this Paragraph of the Complaint and therefore denies them.

7. Admitted.

8. Denied.

NATURE OF THE ACTION

9. Ascent admits that this action purports to be an action for patent infringement and that Ascent filed an ANDA seeking FDA approval to market a generic enzalutamide product prior to expiration of one or more of the patents-in-suit. Ascent denies any infringement and denies the remaining allegations contained in this Paragraph of the Complaint.

JURISDICTION AND VENUE

10. Admitted.

11. Denied. Nevertheless, Ascent does not contest personal jurisdiction for the purpose of this action only.

12. Denied. Nevertheless, Ascent does not contest personal jurisdiction for the purpose of this action only.

13. Denied. Nevertheless, Ascent does not contest personal jurisdiction for the purpose of this action only.

14. Denied. Nevertheless, Ascent does not contest personal jurisdiction for the purpose of this action only.

15. Denied. Nevertheless, Ascent does not contest personal jurisdiction for the purpose of this action only.

16. Denied. Nevertheless, Ascent does not contest venue for the purpose of this action only.

17. Denied. Nevertheless, Ascent does not contest venue for the purpose of this action only.

18. Denied. Nevertheless, Ascent does not contest venue for the purpose of this action only.

RESPONSE TO “THE XTANDI® CAPSULE NDA”

19. Ascent lacks information sufficient to form a belief as to the allegations in this Paragraph of the Complaint and therefore denies them.

20. Ascent lacks information sufficient to form a belief as to the allegations in this Paragraph of the Complaint and therefore denies them.

21. Ascent lacks information sufficient to form a belief as to the allegations in this Paragraph of the Complaint and therefore denies them.

RESPONSE TO “THE PATENTS-IN-SUIT”

22. Ascent admits that a copy of the '517 Patent was attached as Exhibit A to the Complaint and denies the remaining allegations in this Paragraph of the Complaint.

23. Ascent admits that a copy of the '274 Patent was attached as Exhibit B to the Complaint and denies the remaining allegations in this Paragraph of the Complaint.

24. Ascent admits that the FDA's Orange Book lists the '517 and '274 Patents in connection Xtandi 40 mg capsules. The remaining allegations in this Paragraph of the

Complaint are legal conclusions to which no answer is required. Ascent lacks information sufficient to form a belief as to the remaining allegations in this Paragraph of the Complaint and therefore denies them.

25. Ascent lacks information sufficient to form a belief as to the allegations in this Paragraph of the Complaint and therefore denies them.

26. Ascent lacks information sufficient to form a belief as to the allegations in this Paragraph of the Complaint and therefore denies them.

27. Ascent lacks information sufficient to form a belief as to the allegations in this Paragraph of the Complaint and therefore denies them.

28. Ascent lacks information sufficient to form a belief as to the allegations in this Paragraph of the Complaint and therefore denies them.

29. Ascent lacks information sufficient to form a belief as to the allegations in this Paragraph of the Complaint and therefore denies them.

30. Ascent lacks information sufficient to form a belief as to the allegations in this Paragraph of the Complaint and therefore denies them.

31. Ascent lacks information sufficient to form a belief as to the allegations in this Paragraph of the Complaint and therefore denies them.

32. Ascent admits that a copy of the '628 Patent was attached as Exhibit C to the Complaint and denies the remaining allegations in this Paragraph of the Complaint.

33. Ascent lacks information sufficient to form a belief as to the allegations in this Paragraph of the Complaint and therefore denies them.

RESPONSE TO “CLAIMS FOR RELIEF—PATENT INFRINGEMENT”

34. Ascent admits that it sent a Notice Letter to Plaintiffs, as required by law, regarding ANDA No. 220025, regarding generic enzalutamide capsules. Ascent asserts that the Notice Letter and ANDA speak for themselves. Ascent lacks information sufficient to form a belief as to the remaining allegations in this Paragraph of the Complaint and therefore denies them.

35. Ascent admits that it submitted ANDA No. 220025 regarding generic enzalutamide capsules to the FDA consistent with law. Ascent asserts that the ANDA speaks for itself and denies any remaining allegations in this Paragraph of the Complaint.

36. Ascent asserts that its ANDA No. 220025 speaks for itself and denies any remaining allegations in this Paragraph of the Complaint.

37. Ascent admits that its Notice Letter gave Plaintiffs notice of its Paragraph IV certification regarding one or more Orange Book-listed patents, including a factual and legal basis for that certification, as required by law. Ascent denies any remaining allegation in this Paragraph of the Complaint.

38. Ascent avers that its Notice Letter gave Plaintiffs notice of its Paragraph IV certification regarding one or more Orange Book-listed patents, including a factual and legal basis for that certification, as required by law. Ascent denies any remaining allegation in this Paragraph of the Complaint.

39. Denied.

40. Ascent avers that its Notice Letter gave Plaintiffs notice of its Paragraph IV certification regarding one or more Orange Book-listed patents, including a factual and

legal basis for that certification, as required by law. Ascent denies any remaining allegation in this Paragraph of the Complaint.

41. Denied.

42. Admitted.

43. Ascent lacks information sufficient to form a belief as to the allegations in this Paragraph of the Complaint and therefore denies them.

RESPONSE TO “COUNT I—INFRINGEMENT OF THE ’517 PATENT”

44. Ascent incorporates and realleges by this reference, as if fully set forth herein, Paragraphs 1-43 of this Answer.

45. Denied.

46. Ascent lacks information sufficient to form a belief as to the allegations in this Paragraph of the Complaint and therefore denies them.

47. Denied.

48. Denied.

49. Denied.

50. Ascent admits that it was aware of the existence of the ’517 Patent and its listing in the Orange Book by the time of its Notice Letter.

51. Denied.

52. Denied.

53. Denied.

54. Denied.

RESPONSE TO “COUNT II—INFRINGEMENT OF THE ’274 PATENT”

55. Ascent incorporates and realleges by this reference, as if fully set forth herein, Paragraphs 1-54 of this Answer.

56. Denied.

57. Ascent lacks information sufficient to form a belief as to the allegations in this Paragraph of the Complaint and therefore denies them.

58. Ascent avers that the allegations in this Paragraph of the Complaint are directed to future events, which cannot be admitted or denied. To the extent a further response is required, the allegations in this Paragraph are denied.

59. Denied.

60. Denied.

61. Denied.

62. Denied.

63. Denied

64. Denied,

65. Denied.

66. Denied.

67. Ascent admits that it was aware of the existence of the ’274 Patent and its listing in the Orange Book as of the date of its Notice Letter.

68. Denied.

69. Denied.

70. Denied.

RESPONSE TO “COUNT III—INFRINGEMENT OF THE ’628 PATENT”

71. Ascent incorporates and realleges by this reference, as if fully set forth herein, Paragraphs 1-70 of this Answer.

72. Denied.

73. Ascent lacks information sufficient to form a belief as to the allegations in this Paragraph of the Complaint and therefore denies them.

74. Denied.

75. Denied.

76. Ascent lacks information sufficient to form a belief as to the allegations in this Paragraph of the Complaint and therefore denies them.

77. Denied.

78. Denied.

79. Denied.

80. Denied.

81. Denied.

82. Denied.

83. Denied.

84. Denied.

RESPONSE TO “COUNT IV—DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’628 PATENT”

85. Ascent incorporates and realleges by this reference, as if fully set forth herein, Paragraphs 1-84 of this Answer.

86. Denied.

87. Ascent lacks information sufficient to form a belief as to the allegations in this Paragraph of the Complaint and therefore denies them.

88. Denied.

89. Denied.

90. Denied.

91. Denied.

92. Denied.

93. Denied.

94. Denied.

95. Denied.

96. Denied.

FIRST AFFIRMATIVE DEFENSE

Ascent has not, and will not, infringe directly, by contribution or by inducement, literally or under the doctrine of equivalents, any valid and enforceable claim of the patents-in-suit.

SECOND AFFIRMATIVE DEFENSE

One or more claims of the patents-in-suit are invalid and/or unenforceable for failure to comply with one or more statutory or judicial requirements, including but not limited to the conditions for patentability set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112.

THIRD AFFIRMATIVE DEFENSE

One or more counts of the Complaint is subject to dismissal for failure to state a claim.

FOURTH AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to injunctive relief, at least because any alleged injury to Plaintiffs is not immediate or irreparable, because Plaintiffs have an adequate remedy at law, and because public policy concerns weigh against any injunctive relief.

FIFTH AFFIRMATIVE DEFENSE

Ascent reserves all defenses available under the Federal Rules of Civil Procedure and the U.S. Patent laws, and any additional defenses that discovery may reveal, including that Plaintiffs have failed to aver any factors supporting the conclusion that this is an exceptional case or that an award of attorney's fees under 35 U.S.C. § 285 is warranted.

PRAYER FOR RELIEF

WHEREFORE, Defendant Ascent Pharmaceuticals, Inc. respectfully prays for judgment as follows:

- A. Dismissing the Complaint with prejudice;
- B. Denying Plaintiffs the relief requested in the Complaint and any relief whatsoever;
- C. Awarding Ascent its reasonable attorney's fees under 35 U.S.C. § 285;
- D. Awarding Ascent its costs; and

E. Awarding Ascent such other and further relief as the Court deems just and equitable.

Dated: March 24, 2025

Respectfully submitted,

By: s/ Gregory S. Gewirtz

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