

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VELOXIS PHARMACEUTICALS, INC.,)
)
Plaintiff,)
)
v.) C.A. No. 25-458-MN
)
GLENMARK PHARMACEUTICALS INC.,)
USA,)
)
Defendant.)

GLENMARK'S ANSWER,
AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendant Glenmark Pharmaceuticals Inc., USA (“Glenmark”), by and through the undersigned attorneys, answer the Complaint of Plaintiff Veloxis Pharmaceuticals, Inc. (“Veloxis” or “Plaintiff”), as follows. This pleading is based upon Glenmark’s knowledge as to its own activities, and upon information and belief as to the activities of others. Pursuant to Fed. R. Civ. P. 8(b)(3), Glenmark denies all allegations in Plaintiff’s Complaint except those specifically admitted below.

NATURE OF THE ACTION

1. Glenmark admits that the Complaint purports to bring an action for infringement of U.S. Patent Nos. 8,685,998 (“the ’998 patent”); 9,549,918 (“the ’918 patent”); 10,166,190 (“the ’190 patent”); 10,864,199 (“the ’199 patent”); 11,110,081 (“the ’081 patent”); 11,123,331 (“the ’331 patent”); 11,419,823 (“the ’823 patent”); and 12,083,103 (“the ’103 patent”) (collectively, the “Patents-in-Suit”), and that the action purports to arise under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.* Glenmark further admits that this action purportedly relates to Glenmark’s ANDA No. 217905 (“Glenmark’s ANDA”), which was filed to obtain approval from

the United States Food and Drug Administration (“FDA”) to market and sell 0.75 mg, 1 mg, and 4 mg extended release tablets of tacrolimus (“Glenmark’s ANDA Products”). Glenmark otherwise denies the remaining allegations of paragraph 1.

2. Glenmark admits that according to the records of the U.S. Patent and Trademark Office (“USPTO”), Veloxis is the assignee of the Patents-in-Suit. Glenmark further admits that according to the records of the FDA, Veloxis is the holder of NDA No. 206406 for ENVARSUS XR®. Glenmark also admits that Glenmark’s ANDA seeks approval of 0.75 mg, 1 mg, and 4 mg extended release tablets of tacrolimus. The remaining allegations in this paragraph contain legal conclusions to which no answer is required, and therefore Glenmark denies the same.

THE PARTIES

3. On information and belief, Glenmark admits that Veloxis is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 2000 Regency Parkway, Suite 500, Cary, NC 27518.

4. Glenmark admits that Glenmark Pharmaceuticals Inc., USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 750 Corporate Drive, Mahwah, New Jersey 07430.

JURISDICTION AND VENUE

5. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark does not contest subject matter jurisdiction over Plaintiff’s infringement claims against Glenmark under 35 U.S.C. § 271(e)(2)(A) for purposes of this action only. Glenmark otherwise denies the remaining allegations of paragraph 5.

6. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark does not contest personal jurisdiction for purposes of this

action only and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Veloxis. Glenmark further admits that Glenmark Pharmaceuticals Inc., USA is a corporation organized and existing under the laws of the State of Delaware. Glenmark otherwise denies the allegations of paragraph 6.

7. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark does not contest personal jurisdiction for purposes of this action only and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Veloxis. Glenmark otherwise denies the allegations of paragraph 7.

8. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark does not contest personal jurisdiction for purposes of this action only and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Veloxis. Glenmark otherwise denies the allegations of paragraph 8.

9. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark does not contest that venue is proper in this judicial district for the purposes of this action only and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Veloxis. Glenmark otherwise denies the allegations of paragraph 9.

PATENTS-IN-SUIT

10. Glenmark admits that a purported copy of the '998 patent is attached to Plaintiff's Complaint as Exhibit A, and that on its face, the '998 patent is titled "Tacrolimus for Improved Treatment of Transplant Patients" and bears an issuance date of April 1, 2014. Glenmark further admits that, according to USPTO records, Veloxis is the assignee of the '998 patent. Glenmark denies that the '998 patent was legally or properly issued. Glenmark otherwise denies the remaining allegations of paragraph 10.

11. Glenmark admits that a purported copy of the '918 patent is attached to Plaintiff's Complaint as Exhibit B, and that on its face, the '918 patent is titled "Stabilized Tacrolimus Composition" and bears an issuance date of January 24, 2017. Glenmark further admits that, according to USPTO records, Veloxis is the assignee of the '918 patent. Glenmark denies that the '918 patent was legally or properly issued. Glenmark otherwise denies the remaining allegations of paragraph 11.

12. Glenmark admits that a purported copy of the '190 patent is attached to Plaintiff's Complaint as Exhibit C, and that on its face, the '190 patent is titled "Stabilized Tacrolimus Composition" and bears an issuance date of January 1, 2019. Glenmark further admits that, according to USPTO records, Veloxis is the assignee of the '190 patent. Glenmark denies that the '190 patent was legally or properly issued. Glenmark otherwise denies the remaining allegations of paragraph 12.

13. Glenmark admits that a purported copy of the '199 patent is attached to Plaintiff's Complaint as Exhibit D, and that on its face, the '199 patent is titled "Tacrolimus for Improved Treatment of Transplant Patients" and bears an issuance date of December 15, 2020. Glenmark further admits that, according to USPTO records, Veloxis is the assignee of the '199 patent. Glenmark denies that the '199 patent was legally or properly issued. Glenmark otherwise denies the remaining allegations of paragraph 13.

14. Glenmark admits that a purported copy of the '081 patent is attached to Plaintiff's Complaint as Exhibit E, and that on its face, the '081 patent is titled "Tacrolimus for Improved Treatment of Transplant Patients" and bears an issuance date of September 7, 2021. Glenmark further admits that, according to USPTO records, Veloxis is the assignee of the '081 patent.

Glenmark denies that the '081 patent was legally or properly issued. Glenmark otherwise denies the remaining allegations of paragraph 14.

15. Glenmark admits that a purported copy of the '331 patent is attached to Plaintiff's Complaint as Exhibit F, and that on its face, the '331 patent is titled "Tacrolimus for Improved Treatment of Transplant Patients" and bears an issuance date of September 21, 2021. Glenmark further admits that, according to USPTO records, Veloxis is the assignee of the '331 patent. Glenmark denies that the '331 patent was legally or properly issued. Glenmark otherwise denies the remaining allegations of paragraph 15.

16. Glenmark admits that a purported copy of the '823 patent is attached to Plaintiff's Complaint as Exhibit G, and that on its face, the '823 patent is titled "Stabilized Tacrolimus Composition" and bears an issuance date of August 23, 2022. Glenmark further admits that, according to USPTO records, Veloxis is the assignee of the '823 patent. Glenmark denies that the '823 patent was legally or properly issued. Glenmark otherwise denies the remaining allegations of paragraph 16.

17. Glenmark admits that a purported copy of the '103 patent is attached to Plaintiff's Complaint as Exhibit H, and that on its face, the '103 patent is titled "Tacrolimus for Improved Treatment of Transplant Patients" and bears an issuance date of September 10, 2024. Glenmark further admits that, according to USPTO records, Veloxis is the assignee of the '103 patent. Glenmark denies that the '103 patent was legally or properly issued. Glenmark otherwise denies the remaining allegations of paragraph 17.

VELOXIS' ENVARSUS XR®

18. Glenmark admits that according to the records of the FDA, Veloxis is the holder of NDA No. 206406 for ENVARSUS XR®, which is the tradename for tacrolimus extended-release

tablets. Glenmark is without sufficient knowledge and information to form a belief as to the remaining allegations of paragraph 18 and therefore denies the same.

19. Glenmark admits that a purported copy of the prescribing information for ENVARSUS XR® is attached to Plaintiff's Complaint as Exhibit I, and that, on its face, the ENVARSUS XR® prescribing information revised in December 2018 states Envarsus XR® is indicated for the prophylaxis of organ rejection in de novo kidney transplant patients in combination with other immunosuppressants and the prophylaxis of organ rejection in kidney transplant patients converted from tacrolimus immediate-release formulations in combination with other immunosuppressants. Glenmark otherwise denies the remaining allegations of paragraph 19.

20. Glenmark admits that the '998, '918, '190, '199, '081, '331, '823, and '103 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") in connection with ENVARSUS XR®. Glenmark otherwise denies the remaining allegations of paragraph 20.

ACTS GIVING RISE TO THIS ACTION

21. Glenmark admits that it sent Veloxis a letter dated March 3, 2025 ("the Notice Letter"), pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, notifying Veloxis that Glenmark had submitted ANDA No. 217905 to the FDA. Glenmark further admits that Veloxis received the Notice Letter on March 4, 2025. Glenmark otherwise denies the remaining allegations of paragraph 21.

22. Glenmark admits that the Notice Letter notifies Veloxis that Glenmark is seeking FDA approval to engage in the manufacture, use, or sale Glenmark's ANDA Products in the United States prior to expiration of the '998 patent, the '918 patent, the '190 patent, the '199 patent, the '331 patent, and the '823 patent. Glenmark otherwise denies the remaining allegations of paragraph 22.

23. Paragraph 23 contains legal conclusions to which no answer is required. To the extent a response is required, Glenmark admits that Glenmark's ANDA Products are expected to contain tacrolimus as the active ingredient, and that Glenmark's ANDA seeks FDA approval for 0.75 mg, 1 mg, and 4 mg extended release tablets of tacrolimus. Glenmark otherwise denies the remaining allegations in paragraph 23.

24. Glenmark admits that the Notice Letter notifies Veloxis that Glenmark's ANDA No. 217905 includes a Paragraph IV Certification that the '998 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Glenmark's ANDA Products in the United States. Glenmark otherwise denies the remaining allegations of paragraph 24.

25. Glenmark admits that the Notice Letter notifies Veloxis that Glenmark's ANDA No. 217905 includes a Paragraph IV Certification that the '918 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Glenmark's ANDA Products in the United States. Glenmark otherwise denies the remaining allegations of paragraph 25.

26. Glenmark admits that the Notice Letter notifies Veloxis that Glenmark's ANDA No. 217905 includes a Paragraph IV Certification that the '190 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Glenmark's ANDA Products in the United States. Glenmark otherwise denies the remaining allegations of paragraph 26.

27. Glenmark admits that the Notice Letter notifies Veloxis that Glenmark's ANDA No. 217905 includes a Paragraph IV Certification that the '199 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Glenmark's ANDA Products in or into the United States. Glenmark otherwise denies the remaining allegations of paragraph 27.

28. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 28.

29. Glenmark admits that the Notice Letter notifies Veloxis that Glenmark's ANDA No. 217905 includes a Paragraph IV Certification that the '331 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Glenmark's ANDA Products in the United States. Glenmark otherwise denies the remaining allegations of paragraph 29.

30. Glenmark admits that the Notice Letter notifies Veloxis that Glenmark's ANDA No. 217905 includes a Paragraph IV Certification that the '823 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Glenmark's ANDA Products in the United States. Glenmark otherwise denies the remaining allegations of paragraph 30.

31. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 31.

COUNT I
INFRINGEMENT OF THE '998 PATENT

32. Glenmark restates its answers to paragraphs 1–31 as if fully set forth herein.

33. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 33.

34. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 34.

35. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 35.

36. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 36.

37. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 37.

38. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 38.

39. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 39.

40. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 40.

41. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark admits that it was aware of the '998 patent at the time of filing ANDA No. 217905. Glenmark otherwise denies the remaining allegations of paragraph 41.

42. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 42.

COUNT II
INFRINGEMENT OF THE '918 PATENT

43. Glenmark restates its answers to paragraphs 1–42 as if fully set forth herein.

44. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 44.

45. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 45.

46. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 46.

47. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 47.

48. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 48.

49. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 49.

50. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 50.

51. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 51.

52. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark admits that it was aware of the '918 patent at the time of filing ANDA No. 217905. Glenmark otherwise denies the remaining allegations of paragraph 52.

53. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 53.

COUNT III
INFRINGEMENT OF THE '190 PATENT

54. Glenmark restates its answers to paragraphs 1–53 as if fully set forth herein.

55. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 55.

56. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 56.

57. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 57.

58. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 58.

59. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 59.

60. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 60.

61. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 61.

62. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 62.

63. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark admits that it was aware of the '190 patent at the time of filing ANDA No. 217905. Glenmark otherwise denies the remaining allegations of paragraph 63.

64. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 64.

COUNT IV
INFRINGEMENT OF THE '199 PATENT

65. Glenmark restates its answers to paragraphs 1–64 as if fully set forth herein.

66. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 66.

67. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 67.

68. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 68.

69. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 69.

70. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 70.

71. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 71.

72. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 72.

73. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark admits that it was aware of the '199 patent at the time of filing ANDA No. 217905. Glenmark otherwise denies the remaining allegations of paragraph 73.

74. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark the allegations of paragraph 74.

COUNT V
INFRINGEMENT OF THE '081 PATENT

75. Glenmark restates its answers to paragraphs 1–74 as if fully set forth herein.

76. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 76.

77. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 77.

78. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 78.

79. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 79.

80. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 80.

81. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 81.

82. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 82.

83. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark admits that it was aware of the '081 patent at the time of filing ANDA No. 217905. Glenmark otherwise denies the remaining allegations of paragraph 83.

84. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 84.

COUNT VI
INFRINGEMENT OF THE '331 PATENT

85. Glenmark restates its answers to paragraphs 1–84 as if fully set forth herein.

86. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 86.

87. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 87.

88. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 88.

89. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 89.

90. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 90.

91. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 91.

92. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 92.

93. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark admits that it was aware of the '331 patent at the time of filing ANDA No. 217905. Glenmark otherwise denies the remaining allegations of paragraph 93.

94. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 94.

COUNT VII
INFRINGEMENT OF THE '823 PATENT

95. Glenmark restates its answers to paragraphs 1–94 as if fully set forth herein.

96. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 96.

97. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 97.

98. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 98.

99. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 99.

100. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 100.

101. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 101.

102. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 102.

103. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 103.

104. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark admits that it was aware of the '823 patent at the time of filing ANDA No. 217905. Glenmark otherwise denies the remaining allegations of paragraph 104.

105. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 105.

COUNT VIII
INFRINGEMENT OF THE '103 PATENT

106. Glenmark restates its answers to paragraphs 1–105 as if fully set forth herein.

107. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 107.

108. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 108.

109. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 109.

110. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 110.

111. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 111.

112. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 112.

113. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 113.

114. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark admits that it was aware of the '103 patent at the time of filing ANDA No. 217905. Glenmark otherwise denies the remaining allegations of paragraph 114.

115. This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Glenmark denies the allegations of paragraph 115.

RESPONSE TO PRAYER FOR RELIEF

The remainder of Plaintiff's Complaint recites a prayer for relief to which no response is required. To the extent any response is required, Glenmark denies that Plaintiff is entitled to any remedy or relief. Further, Glenmark prays that the Plaintiff's Complaint be dismissed in its entirety, that Plaintiff takes nothing by way of the allegations complained of in the Complaint, and that Glenmark be awarded its costs, including reasonable attorneys' fees incurred in defense of this action, and for all other appropriate relief.

GLENMARK'S AFFIRMATIVE DEFENSES

Glenmark asserts the following defenses without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not otherwise admitted. Glenmark does not assume the burden of proof on any such defenses, except as required by applicable law with respect to the particular defense asserted. Glenmark reserves the right to assert other defenses and/or to otherwise supplement this Answer upon discovery of facts or evidence rendering such action appropriate.

FIRST DEFENSE

The claims of the '998, '918, '190, '199, '081, '331, '823, and '103 patents are invalid for failure to comply with the statutory provisions of Title 35 of the United States Code, including, without limitation, sections 101, 102, 103 and/or 112, or other judicially created bases for invalidity.

SECOND DEFENSE

The filing of Glenmark's ANDA has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the Patents-in-Suit.

THIRD DEFENSE

The manufacture, use, sale, offer for sale, or importation of Glenmark's ANDA Products has not, does not, and would not infringe, directly or indirectly, any valid and enforceable claim of the Patents-in-Suit, either literally or under the doctrine of equivalents.

FOURTH DEFENSE

Plaintiff's Complaint fails to state a claim upon which relief may be granted.

FIFTH DEFENSE

Glenmark's actions in defending this case do not give rise to an exception case under 35 U.S.C. § 285.

SIXTH DEFENSE

Glenmark has not willfully infringed any claim of the Patents-in-Suit.

SEVENTH DEFENSE

Plaintiff is estopped from asserting infringement by the doctrine of prosecution history estoppel, judicial estoppel, and/or other equitable doctrines.

EIGHTH DEFENSE

Any additional defenses that discovery may reveal.

COUNTERCLAIMS

Defendant and Counterclaim-Plaintiff Glenmark Pharmaceuticals Inc., USA (“Glenmark”), by way of counterclaim against Plaintiff-Counterclaim Defendant Veloxis Pharmaceuticals, Inc. (“Veloxis”), states as follows:

THE PARTIES

1. Glenmark Pharmaceuticals Inc., USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 750 Corporate Drive, Mahwah, New Jersey 07430.

2. On information and belief, Veloxis is a company organized and existing under the laws of the State of Delaware, having a principal place of business at 2000 Regency Parkway, Suite 500, Cary, NC 27518.

NATURE OF THE ACTION

3. Glenmark seeks declaratory judgment under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, that United States Patent Nos. 8,685,998 (“the ’998 patent”); 9,549,918 (“the ’918 patent”); 10,166,190 (“the ’190 patent”); 10,864,199 (“the ’199 patent”); 11,110,081 (“the ’081 patent”); 11,123,331 (“the ’331 patent”); 11,419,823 (“the ’823 patent”); 12,083,103 (“the ’103 patent”); and 8,664,239 (“the ’239 patent”) (collectively, the “Patents-in-Suit”) are invalid and/or not infringed.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331, 1337, 1338, 1367, 2201, and 2202.

5. This Court has personal jurisdiction over Veloxis because, among other reasons, Veloxis commenced and continue to maintain this action against Glenmark in this judicial district.

6. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(a) and 1400(b) for purposes of this case, and by Veloxis’s choice of forum.

FACTUAL BACKGROUND

A. The Patents-in-Suit & Glenmark's ANDA.

7. On information and belief, Veloxis is the assignee of the Patents-in-Suit.
8. On information and belief, Veloxis is the holder of NDA No. 206406.
9. On information and belief, NDA No. 206406 purportedly covers Veloxis's ENVARSUS XR® product.
10. On information and belief, Veloxis caused the '998, '918, '190, '199, '081, '331, '823, '103, and '239 patents to be listed in the publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly called the "Orange Book," in connection with NDA No. 206406.
11. By listing the '998, '918, '190, '199, '081, '331, '823, '103, and '239 patents in the Orange Book, Veloxis created a reasonable apprehension that it would file a patent infringement suit against applicants seeking regulatory approval for a generic version of ENVARSUS XR®.
12. Glenmark submitted ANDA No. 217905 to the FDA pursuant to 21 U.S.C. §§ 355(j)(1) and 2(A) to obtain approval to engage in the commercial manufacture, use, and sale of extended-release tacrolimus tablets ("Glenmark's ANDA Products") within the United States.
13. Glenmark's ANDA No. 217905 includes "Paragraph IV" certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '998, '918, '190, '199, '331, '823, and '239 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Glenmark's ANDA Products.
14. Glenmark's ANDA No. 217905 contains a "Section viii" statement under 21 U.S.C. § 355 (j)(2)(A)(viii) that the '081 and '103 patents do not claim a use for which Glenmark is presenting seeking approval.

15. By letter dated March 3, 2025, Glenmark sent Veloxis written notice of Glenmark's Paragraph IV Certifications ("Glenmark's Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95. Glenmark's Notice Letter asserted that the claims of the '998, '918, '190, '199, '331, '823, and '239 patents are invalid, unenforceable, and/or will not be infringed by Glenmark's ANDA or the products or activities described therein.

16. Glenmark's Notice Letter contained a Detailed Statement setting forth the factual and legal basis the Paragraph IV Certifications included in Glenmark's ANDA pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

17. On April 14, 2025, Veloxis filed its Complaint against Glenmark alleging infringement of the '998, '918, '190, '199, '331, '823, '081, and '103 patents. There has been and now is an actual and justiciable controversy between the parties as to whether Glenmark's ANDA Products infringe, induce infringement, or contribute to the infringement of any valid and enforceable claim of the Patents-in-Suit.

**FIRST COUNTERCLAIM:
DECLARATION OF NON-INFRINGEMENT OF THE '998 PATENT**

18. Glenmark restates and incorporates the allegations in the foregoing paragraphs as if fully set forth herein.

19. There is an actual, substantial, continuing, and justiciable controversy between Glenmark and Veloxis regarding, *inter alia*, the issue of whether the filing of Glenmark's ANDA and/or the manufacture, use, or sale in the United States of Glenmark's ANDA Products infringe, have infringed, and/or will infringe any valid or enforceable claim of the '998 patent.

20. Glenmark has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '998 patent and is not liable for any alleged infringement.

21. Glenmark incorporates by reference Glenmark's Notice Letter, which contains exemplary and nonlimiting explanations for why the '998 patent is not infringed by Glenmark's ANDA or the Glenmark ANDA Products or activities described therein.

22. Glenmark is entitled to a declaration that the manufacture, use, or sale of Glenmark's ANDA Products would not infringe any valid or enforceable claims of the '998 patent.

**SECOND COUNTERCLAIM:
DECLARATION OF INVALIDITY OF THE '998 PATENT**

23. Glenmark restates and incorporates the allegations in the foregoing paragraphs as if fully set forth herein.

24. One or more claims of the '998 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

25. The '998 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

26. The alleged invention of the '998 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '998 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '998 patent and would have had a reasonable expectation of success in doing so.

27. The subject matter claimed in the '998 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which

the claimed subject matter pertains.

28. There is an actual, substantial, continuing, and justiciable controversy between Glenmark and Veloxis regarding, *inter alia*, whether the filing of Glenmark's ANDA and/or the manufacture, use, or sale in the United States of Glenmark's ANDA Products infringe, have infringed, and/or will infringe any valid or enforceable claim of the '998 patent.

29. Glenmark incorporates by reference Glenmark's Notice Letter, which contains exemplary and nonlimiting explanations for why the '998 patent is not infringed by Glenmark's ANDA or the Glenmark ANDA Products or activities described therein.

30. Glenmark is entitled to a declaration that all claims of the '998 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

**THIRD COUNTERCLAIM:
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '918 PATENT**

31. Glenmark restates and incorporates the allegations in the foregoing paragraphs as if fully set forth herein.

32. There is an actual, substantial, continuing, and justiciable controversy between Glenmark and Veloxis regarding, *inter alia*, the issue of whether the filing of Glenmark's ANDA and/or the manufacture, use, or sale in the United States of Glenmark's ANDA Products infringe, have infringed, and/or will infringe any valid and enforceable claim of the '918 patent.

33. Glenmark has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '918 patent and is not liable for any alleged infringement.

34. Glenmark incorporates by reference Glenmark's Notice Letter, which contains exemplary and nonlimiting explanations for why the '918 patent is not infringed by Glenmark's ANDA or the Glenmark ANDA Products or activities described therein.

35. Glenmark is entitled to a judicial declaration that the manufacture, use, or sale of Glenmark's ANDA Products would not infringe any valid or enforceable claims of the '918 patent.

**FOURTH COUNTERCLAIM:
DECLARATION OF INVALIDITY OF THE '918 PATENT**

36. Glenmark restates and incorporates the allegations in the foregoing paragraphs as if fully set forth herein.

37. One or more claims of the '918 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

38. The '918 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

39. The alleged invention of the '918 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '918 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '918 patent and would have had a reasonable expectation of success in doing so.

40. The subject matter claimed in the '918 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which

the claimed subject matter pertains.

41. There is an actual, substantial, continuing, and justiciable controversy between Glenmark and Veloxis regarding, *inter alia*, whether the filing of Glenmark's ANDA and/or the manufacture, use, or sale in the United States of Glenmark's ANDA Products infringe, have infringed, and/or will infringe any valid or enforceable claim of the '918 patent.

42. Glenmark incorporates by reference Glenmark's Notice Letter, which contains exemplary and nonlimiting explanations for why the '918 patent is not infringed by Glenmark's ANDA or the Glenmark ANDA Products or activities described therein.

43. Glenmark is entitled to a declaration that all claims of the '918 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

**FIFTH COUNTERCLAIM:
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '190 PATENT**

44. Glenmark restates and incorporates the allegations in the foregoing paragraphs as if fully set forth herein.

45. There is an actual, substantial, continuing, and justiciable controversy between Glenmark and Veloxis regarding, *inter alia*, the issue of whether the filing of Glenmark's ANDA and/or the manufacture, use, or sale in the United States of Glenmark's ANDA Products infringe, have infringed, and/or will infringe any valid and enforceable claim of the '190 patent.

46. Glenmark has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '190 patent and is not liable for any alleged infringement.

47. Glenmark incorporates by reference Glenmark's Notice Letter, which contains exemplary and nonlimiting explanations for why the '190 patent is not infringed by Glenmark's ANDA or the Glenmark ANDA Products or activities described therein.

48. Glenmark is entitled to a judicial declaration that the manufacture, use, or sale of Glenmark's ANDA Products would not infringe any valid or enforceable claims of the '190 patent.

**SIXTH COUNTERCLAIM:
DECLARATION OF INVALIDITY OF THE '190 PATENT**

49. Glenmark restates and incorporates the allegations in the foregoing paragraphs as if fully set forth herein.

50. One or more claims of the '190 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

51. The '190 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

52. The alleged invention of the '190 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '190 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '190 patent and would have had a reasonable expectation of success in doing so.

53. The subject matter claimed in the '190 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which

the claimed subject matter pertains.

54. There is an actual, substantial, continuing, and justiciable controversy between Glenmark and Veloxis regarding, *inter alia*, whether the filing of Glenmark's ANDA and/or the manufacture, use, or sale in the United States of Glenmark's ANDA Products infringe, have infringed, and/or will infringe any valid or enforceable claim of the '190 patent.

55. Glenmark incorporates by reference Glenmark's Notice Letter, which contains exemplary and nonlimiting explanations for why the '190 patent is not infringed by Glenmark's ANDA or the Glenmark ANDA Products or activities described therein.

56. Glenmark is entitled to a declaration that all claims of the '190 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

**SEVENTH COUNTERCLAIM:
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '199 PATENT**

57. Glenmark restates and incorporates the allegations in the foregoing paragraphs as if fully set forth herein.

58. There is an actual, substantial, continuing, and justiciable controversy between Glenmark and Veloxis regarding, *inter alia*, the issue of whether the filing of Glenmark's ANDA and/or the manufacture, use, or sale in the United States of Glenmark's ANDA Products infringe, have infringed, and/or will infringe any valid and enforceable claim of the '199 patent.

59. Glenmark has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '199 patent and is not liable for any alleged infringement.

60. Glenmark incorporates by reference Glenmark's Notice Letter, which contains exemplary and nonlimiting explanations for why the '199 patent is not infringed by Glenmark's ANDA or the Glenmark ANDA Products or activities described therein.

61. Glenmark is entitled to a judicial declaration that the manufacture, use, or sale of Glenmark's ANDA Products would not infringe any valid or enforceable claims of the '199 patent.

**EIGHTH COUNTERCLAIM:
DECLARATION OF INVALIDITY OF THE '199 PATENT**

62. Glenmark restates and incorporates the allegations in the foregoing paragraphs as if fully set forth herein.

63. One or more claims of the '199 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

64. The '199 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

65. The alleged invention of the '199 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '199 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '199 patent and would have had a reasonable expectation of success in doing so.

66. The subject matter claimed in the '199 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which

the claimed subject matter pertains.

67. There is an actual, substantial, continuing, and justiciable controversy between Glenmark and Veloxis regarding, *inter alia*, whether the filing of Glenmark's ANDA and/or the manufacture, use, or sale in the United States of Glenmark's ANDA Products infringe, have infringed, and/or will infringe any valid or enforceable claim of the '199 patent.

68. Glenmark incorporates by reference Glenmark's Notice Letter, which contains exemplary and nonlimiting explanations for why the '199 patent is not infringed by Glenmark's ANDA or the Glenmark ANDA Products or activities described therein.

69. Glenmark is entitled to a declaration that all claims of the '199 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

**NINTH COUNTERCLAIM:
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '081 PATENT**

70. Glenmark restates and incorporates the allegations in the foregoing paragraphs as if fully set forth herein.

71. There is an actual, substantial, continuing, and justiciable controversy between Glenmark and Veloxis regarding, *inter alia*, the issue of whether the filing of Glenmark's ANDA and/or the manufacture, use, or sale in the United States of Glenmark's ANDA Products infringe, have infringed, and/or will infringe any valid and enforceable claim of the '081 patent.

72. The following use code is listed in the FDA's Orange Book in connection with the '081 patent: U-2678, which recites "Prophylaxis of Organ Rejection in De Novo Transplant Patient."

73. Glenmark's Section viii statement to the '081 patent provides that Glenmark is not presently seeking approval for prophylaxis of organ rejection in de novo transplant patients.

74. In accordance with 21 U.S.C. § 355(j)(2)(A)(viii) and 21 C.F.R. § 314.94(a)(12)(iii), information concerning the prophylaxis of organ rejection in de novo transplant patients has been omitted from the proposed label for Glenmark's ANDA Products.

75. Insofar as the claims of the '081 patent recite a use covered by U-2678, i.e., prophylaxis of organ rejection in de novo transplant patients, such claims do not cover the indication for which Glenmark is presently seeking FDA approval. The only indication on Glenmark's proposed ANDA product label will be for the prophylaxis of organ rejection in kidney transplant patients converted from tacrolimus immediate-release formulations in combination with other immunosuppressants.

76. Glenmark has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '081 patent and is not liable for any alleged infringement.

77. Glenmark is entitled to a judicial declaration that the manufacture, use, or sale of Glenmark's ANDA Products would not infringe any valid or enforceable claims of the '081 patent.

**TENTH COUNTERCLAIM:
DECLARATION OF INVALIDITY OF THE '081 PATENT**

78. Glenmark restates and incorporates the allegations in the foregoing paragraphs as if fully set forth herein.

79. One or more claims of the '081 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

80. The '081 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

81. The alleged invention of the '081 patent does no more than combine familiar

elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '081 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '081 patent and would have had a reasonable expectation of success in doing so.

82. The subject matter claimed in the '081 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

83. There is an actual, substantial, continuing, and justiciable controversy between Glenmark and Veloxis regarding, *inter alia*, whether the filing of Glenmark's ANDA and/or the manufacture, use, or sale in the United States of Glenmark's ANDA Products infringe, have infringed, and/or will infringe any valid or enforceable claim of the '081 patent.

84. Glenmark is entitled to a declaration that all claims of the '081 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

**ELEVENTH COUNTERCLAIM:
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '331 PATENT**

85. Glenmark restates and incorporates the allegations in the foregoing paragraphs as if fully set forth herein.

86. There is an actual, substantial, continuing, and justiciable controversy between Glenmark and Veloxis regarding, *inter alia*, the issue of whether the filing of Glenmark's ANDA

and/or the manufacture, use, or sale in the United States of Glenmark's ANDA Products infringe, have infringed, and/or will infringe any valid and enforceable claim of the '331 patent.

87. Glenmark has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '331 patent and is not liable for any alleged infringement.

88. Glenmark incorporates by reference Glenmark's Notice Letter, which contains exemplary and nonlimiting explanations for why the '331 patent is not infringed by Glenmark's ANDA or the Glenmark ANDA Products or activities described therein.

89. Glenmark is entitled to a judicial declaration that the manufacture, use, or sale of Glenmark's ANDA Products would not infringe any valid or enforceable claims of the '331 patent.

**TWELFTH COUNTERCLAIM:
DECLARATION OF INVALIDITY OF THE '331 PATENT**

90. Glenmark restates and incorporates the allegations in the foregoing paragraphs as if fully set forth herein.

91. One or more claims of the '331 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

92. The '331 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

93. The alleged invention of the '331 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '331 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '331 patent and would

have had a reasonable expectation of success in doing so.

94. The subject matter claimed in the '331 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

95. There is an actual, substantial, continuing, and justiciable controversy between Glenmark and Veloxis regarding, *inter alia*, whether the filing of Glenmark's ANDA and/or the manufacture, use, or sale in the United States of Glenmark's ANDA Products infringe, have infringed, and/or will infringe any valid or enforceable claim of the '331 patent.

96. Glenmark incorporates by reference Glenmark's Notice Letter, which contains exemplary and nonlimiting explanations for why the '331 patent is not infringed by Glenmark's ANDA or the Glenmark ANDA Products or activities described therein.

97. Glenmark is entitled to a declaration that all claims of the '331 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

**THIRTEENTH COUNTERCLAIM:
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '823 PATENT**

98. Glenmark restates and incorporates the allegations in the foregoing paragraphs as if fully set forth herein.

99. There is an actual, substantial, continuing, and justiciable controversy between Glenmark and Veloxis regarding, *inter alia*, the issue of whether the filing of Glenmark's ANDA and/or the manufacture, use, or sale in the United States of Glenmark's ANDA Products infringe, have infringed, and/or will infringe any valid and enforceable claim of the '823 patent.

100. Glenmark has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '823 patent and is not liable for any alleged infringement.

101. Glenmark incorporates by reference Glenmark's Notice Letter, which contains exemplary and nonlimiting explanations for why the '823 patent is not infringed by Glenmark's ANDA or the Glenmark ANDA Products or activities described therein.

102. Glenmark is entitled to a judicial declaration that the manufacture, use, or sale of Glenmark's ANDA Products would not infringe any valid or enforceable claims of the '823 patent.

**FOURTEENTH COUNTERCLAIM:
DECLARATION OF INVALIDITY OF THE '823 PATENT**

103. Glenmark restates and incorporates the allegations in the foregoing paragraphs as if fully set forth herein.

104. One or more claims of the '823 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

105. The '823 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

106. The alleged invention of the '823 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '823 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '823 patent and would have had a reasonable expectation of success in doing so.

107. The subject matter claimed in the '823 patent fails to comply with 35 U.S.C. § 103

in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

108. There is an actual, substantial, continuing, and justiciable controversy between Glenmark and Veloxis regarding, *inter alia*, whether the filing of Glenmark's ANDA and/or the manufacture, use, or sale in the United States of Glenmark's ANDA Products infringe, have infringed, and/or will infringe any valid or enforceable claim of the '823 patent.

109. Glenmark incorporates by reference Glenmark's Notice Letter, which contains exemplary and nonlimiting explanations for why the '823 patent is not infringed by Glenmark's ANDA or the Glenmark ANDA Products or activities described therein.

110. Glenmark is entitled to a declaration that all claims of the '823 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

**FIFTEENTH COUNTERCLAIM:
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '103 PATENT**

111. Glenmark restates and incorporates the allegations in the foregoing paragraphs as if fully set forth herein.

112. There is an actual, substantial, continuing, and justiciable controversy between Glenmark and Veloxis regarding, *inter alia*, the issue of whether the filing of Glenmark's ANDA and/or the manufacture, use, or sale in the United States of Glenmark's ANDA Products infringe, have infringed, and/or will infringe any valid and enforceable claim of the '103 patent.

113. The following use code is listed in the FDA's Orange Book in connection with the '103 patent: U-2678, which recites "Prophylaxis of Organ Rejection in De Novo Transplant Patient."

114. Glenmark's Section viii statement to the '103 patent provides that Glenmark is not presently seeking approval for prophylaxis of organ rejection in de novo transplant patients.

115. In accordance with 21 U.S.C. § 355(j)(2)(A)(viii) and 21 C.F.R. § 314.94(a)(12)(iii), information concerning the prophylaxis of organ rejection in de novo transplant patients has been omitted from the proposed label for Glenmark's ANDA Products.

116. Insofar as the claims of the '103 patent recite a use covered by U-2678, i.e., prophylaxis of organ rejection in de novo transplant patients, such claims do not cover the indication for which Glenmark is presently seeking FDA approval. The only indication on Glenmark's proposed ANDA product label will be for the prophylaxis of organ rejection in kidney transplant patients converted from tacrolimus immediate-release formulations in combination with other immunosuppressants.

117. Glenmark has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '103 patent and is not liable for any alleged infringement.

118. Glenmark is entitled to a judicial declaration that the manufacture, use, or sale of Glenmark's ANDA Products would not infringe any valid or enforceable claims of the '103 patent.

**SIXTEENTH COUNTERCLAIM:
DECLARATION OF INVALIDITY OF THE '103 PATENT**

119. Glenmark restates and incorporates the allegations in the foregoing paragraphs as if fully set forth herein.

120. One or more claims of the '103 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

121. The '103 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

122. The alleged invention of the '103 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '103 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '103 patent and would have had a reasonable expectation of success in doing so.

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

124. There is an actual, substantial, continuing, and justiciable controversy between Glenmark and Veloxis regarding, *inter alia*, whether the filing of Glenmark's ANDA and/or the manufacture, use, or sale in the United States of Glenmark's ANDA Products infringe, have infringed, and/or will infringe any valid or enforceable claim of the '103 patent.

125. Glenmark incorporates by reference Glenmark's Notice Letter, which contains exemplary and nonlimiting explanations for why the '103 patent is not infringed by Glenmark's ANDA or the Glenmark ANDA Products or activities described therein.

126. Glenmark is entitled to a declaration that all claims of the '103 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

**SEVENTEENTH COUNTERCLAIM:
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '239 PATENT**

127. Glenmark restates and incorporates the allegations in the foregoing paragraphs as if fully set forth herein.

128. There is an actual, substantial, continuing, and justiciable controversy between Glenmark and Veloxis regarding, *inter alia*, the issue of whether the filing of Glenmark's ANDA and/or the manufacture, use, or sale in the United States of Glenmark's ANDA Products infringe, have infringed, and/or will infringe any valid and enforceable claim of the '239 patent.

129. Glenmark has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '239 patent and is not liable for any alleged infringement.

130. Glenmark incorporates by reference Glenmark's Notice Letter, which contains exemplary and nonlimiting explanations for why the '239 patent is not infringed by Glenmark's ANDA or the Glenmark ANDA Products or activities described therein.

131. Glenmark is entitled to a judicial declaration that the manufacture, use, or sale of Glenmark's ANDA Products would not infringe any valid or enforceable claims of the '239 patent.

**EIGHTEENTH COUNTERCLAIM:
DECLARATION OF INVALIDITY OF THE '239 PATENT**

132. Glenmark restates and incorporates the allegations in the foregoing paragraphs as if fully set forth herein.

133. One or more claims of the '239 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

134. The '239 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

135. The alleged invention of the '239 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '239 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '239 patent and would have had a reasonable expectation of success in doing so.

136. The subject matter claimed in the '239 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

137. There is an actual, substantial, continuing, and justiciable controversy between Glenmark and Veloxis regarding, *inter alia*, whether the filing of Glenmark's ANDA and/or the manufacture, use, or sale in the United States of Glenmark's ANDA Products infringe, have infringed, and/or will infringe any valid or enforceable claim of the '239 patent.

138. Glenmark incorporates by reference Glenmark's Notice Letter, which contains exemplary and nonlimiting explanations for why the '239 patent is not infringed by Glenmark's ANDA or the Glenmark ANDA Products or activities described therein.

139. Glenmark is entitled to a declaration that all claims of the '239 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity and unenforceability.

REQUEST FOR RELIEF

WHEREFORE, Counterclaim-Plaintiff Glenmark respectfully requests that this Court enter a Judgment and Order in its favor and against Counterclaim Defendant Veloxis as follows:

- (a) Declaring that the filing of Glenmark's ANDA has not infringed and does not infringe any valid and enforceable claim of the '998, '918, '190, '199, '081, '331, '823, '103, and '239 patents;
- (b) Declaring that the manufacture, use, offer to sell, sale, and/or importation in the United States of Glenmark's ANDA Products does not and will not infringe any valid and enforceable claim of the '998, '918, '190, '199, '081, '331, '823, '103, and '239 patents;
- (c) Declaring that the claims of the '998, '918, '190, '199, '081, '331, '823, '103, and '239 patents are invalid and/or unenforceable;
- (d) Awarding Glenmark its costs and expenses in this action;
- (e) Declaring this an exceptional case in favor of Glenmark pursuant to 35 U.S.C. § 285, and awarding Glenmark its reasonable attorneys' fees; and
- (f) Awarding Glenmark any further and additional relief as the Court deems just and proper.

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