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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

GENENTECH, INC., Plaintiff, vs. TANVEX BIOPHARMA USA, INC., TANVEX BIOPHARMA, INC., TANVEX BIOLOGICS, INC., and TANVEX BIOLOGICS CORPORATION, Defendants.	Case No. 3:22-CV-0809-RBM-JLB **DEFENDANTS' ANSWER, AFFIRMATIVE DEFENSES** **DEMAND FOR JURY TRIAL**
TANVEX BIOPHARMA USA, INC., Counter-Claimant, vs. GENENTECH, INC., Counterclaim-Defendant.	**AND** **TANVEX BIOPHARMA USA, INC.'S COUNTERCLAIMS** **DEMAND FOR JURY TRIAL**

DEFENDANTS' ANSWER, AFFIRMATIVE DEFENSES, AND TANVEX BIOPHARMA USA, INC'S COUNTERCLAIMS

Defendants Tanvex BioPharma USA, Inc., Tanvex BioPharma, Inc., Tanvex Biologics, Inc., and Tanvex Biologics Corporation ("Tanvex"), as their Answer to the numbered paragraphs in the Complaint for Patent Infringement ("Complaint") of Plaintiff Genentech, Inc. ("Genentech" or "Plaintiff"), respond and allege as follows, based upon Tanvex's knowledge of its own activities, and upon information and belief as to the activities of others.

ANSWER

NATURE OF THE ACTION

1. Tanvex admits that the Complaint purports to allege an action for patent infringement of United States Patent Nos. 10,662,237 ("the '237 patent"), 10,808,037 ("the '037 patent"), and 8,574,869 ("the '869 patent") (collectively, "Asserted Patents") arising under the patent laws of the United States, Title 35, United States Code, including 35 U.S.C. § 271(e)(2)(C), which was enacted in 2010 as part of the Biologics Price Competition and Innovation Act of 2009 ("the BPCIA"), Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010) (amending, inter alia, 35 U.S.C. § 271 and 42 U.S.C. § 262), but Tanvex denies that the Complaint states such a cause of action and/or that Tanvex has committed or will commit any infringing acts giving rise to such a cause of action. To the extent this paragraph contains any further allegations of fact to which a response is required, denied.

2. Tanvex admits that Tanvex BioPharma USA, Inc. is seeking the U.S. Food and Drug Administration's ("FDA") approval of TX05, which is trastuzumab injection, powder, lyophilized for solution. Tanvex BioPharma USA, Inc.'s BLA No. 761266 for TX05 identifies Herceptin® as the biological reference product. To the extent this paragraph contains any further allegations of fact to which a response is required, denied.

3. Tanvex admits that Genentech and Tanvex BioPharma USA, Inc. exchanged information under the BPCIA and agreed pursuant to 42 U.S.C. § 262(*l*)(4)(A) to three patents to litigate with respect to Tanvex BioPharma USA, Inc.'s BLA submission for TX05. To the extent this paragraph contains any further allegations of fact to which a response is required, denied.

PARTIES

4. Tanvex lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 4 and thus denies the same.

5. Tanvex admits that Tanvex BioPharma USA, Inc. is a California corporation with a place of business at 10394 Pacific Center Court, San Diego, California 92121. Tanvex admits that Tanvex BioPharma USA, Inc. filed a BLA for TX05, which is trastuzumab injection, powder, lyophilized for solution and that Tanvex BioPharma USA, Inc.'s BLA No. 761266 for TX05 identifies Herceptin® as the biological reference product. Tanvex denies any remaining allegations in paragraph 5.

6. Tanvex admits that Tanvex BioPharma, Inc. is a Cayman Islands corporation, with a place of business in Taipei City 106, Taiwan at 13F.-1, No. 376, Sec. 4, Ren'ai Rd., D'an Dist., Taipei City 106, Taiwan. Tanvex denies any remaining allegations in paragraph 6.

7. Tanvex admits that Tanvex Biologics, Inc. is a California corporation with a place of business at 2030 Main Street, #600, Irvine, California 92614. Tanvex denies any remaining allegations in paragraph 7.

8. Tanvex admits that Tanvex Biologics Corporation is a Taiwan corporation with a place of business in New Taipei City 221, Taiwan at 33F, No. 99, Sec. 1, Xintai 5th Road, Xizhi District, New Taipei City 221, Taiwan. Tanvex denies any remaining allegations in paragraph 8.

JURISDICTION AND VENUE

9. This paragraph contains legal conclusions to which no answer is required. Tanvex admits that this action purports to arise under the BPCIA, 42 U.S.C. § 262(*l*), the Patent Laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202. For purposes of this action, Tanvex BioPharma USA, Inc. does not contest that this Court has subject matter jurisdiction. Tanvex denies any remaining allegations in paragraph 9.

10. This paragraph contains legal conclusions to which no answer is required. For purposes of this action only, Tanvex does not contest venue in this judicial district. Tanvex denies any remaining allegations in paragraph 10.

11. For the purposes of this action only, Tanvex does not contest personal jurisdiction in this judicial district. Tanvex denies any remaining allegations in paragraph 11.

A. Tanvex BioPharma USA, Inc.

12. This paragraph contains legal conclusions to which no answer is required. Tanvex admits that Tanvex BioPharma USA, Inc. is a corporation organized and existing under the laws of the State of California, with places of business at 10394 Pacific Center Court, San Diego, California 92121 and 2030 Main Street, #600, Irvine, California 92614. Tanvex admits that Tanvex BioPharma USA, Inc. develops biopharmaceutical products. For the purposes of this action only, Tanvex BioPharma USA, Inc. does not contest venue in this judicial district. To the extent this paragraph contains any further allegations of fact to which a response is required, denied.

13. For purposes of this action only, Tanvex BioPharma USA, Inc. does not contest personal jurisdiction in this judicial district. Tanvex denies any remaining allegations in paragraph 13.

14. Admitted

15. Tanvex admits that Tanvex BioPharma USA, Inc. is seeking FDA approval for TX05. Tanvex denies any remaining allegations in paragraph 15.

16. To the extent that Genentech purports to characterize a document, the document speaks for itself and no response is required. To the extent this paragraph contains any further allegations of fact to which a response is required, denied.

17. This paragraph contains legal conclusions to which no answer is required. Defendants admit that Tanvex BioPharma USA, Inc. is a wholly owned subsidiary of Tanvex BioPharma, Inc. To the extent this paragraph contains any further allegations of fact to which a response is required, denied.

B. Tanvex BioPharma, Inc.

18. This paragraph contains legal conclusions to which no answer is required. To the extent that Genentech purports to characterize a document, the document speaks for itself and no response is required. For purposes of this action only, Tanvex BioPharma, Inc. does not contest personal jurisdiction in this judicial district. To the extent this paragraph contains any further allegations of fact to which a response is required, denied.

19. For purposes of this action only, Tanvex BioPharma, Inc. does not contest personal jurisdiction in this judicial district. To the extent this paragraph contains any further allegations of fact to which a response is required, denied.

20. To the extent that Genentech purports to characterize a document, the document speaks for itself and no response is required. To the extent this paragraph contains any further allegations of fact to which a response is required, denied.

21. To the extent that Genentech purports to characterize a document, the document speaks for itself and no response is required. To the extent this paragraph contains any further allegations of fact to which a response is required, denied.

22. To the extent that Genentech purports to characterize a document, the document speaks for itself and no response is required. To the extent this paragraph contains any further allegations of fact to which a response is required, denied.

23. To the extent that Genentech purports to characterize a document, the document speaks for itself and no response is required. To the extent this paragraph contains any further allegations of fact to which a response is required, denied.

24. Admitted.

25. To the extent that Genentech purports to characterize a document, the document speaks for itself and no response is required. To the extent this paragraph contains any further allegations of fact to which a response is required, denied.

26. To the extent that Genentech purports to characterize a document, the document speaks for itself and no response is required. To the extent this paragraph contains any further allegations of fact to which a response is required, denied.

27. Denied.

28. Denied.

29. This paragraph contains legal conclusions to which no answer is required. For purposes of this action only, Tanvex BioPharma, Inc. does not contest personal jurisdiction in this judicial district. To the extent this paragraph contains any further allegations of fact to which a response is required, denied.

30. This paragraph contains legal conclusions to which no answer is required. Tanvex admits that Tanvex BioPharma, Inc. is a Cayman Islands corporation, with a registered office in Taiwan. For purposes of this action only, Tanvex BioPharma, Inc. does not contest venue in this judicial district. To the extent this paragraph contains any further allegations of fact to which a response is required, denied.

C. Tanvex Biologics, Inc.

31. This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Tanvex admits that Tanvex Biologics, Inc. is a California corporation with a place of business at 2030 Main Street, #600, Irvine, California 92614. For purposes of this action only, Tanvex Biologics, Inc. does not contest venue in this judicial district. To the extent this

paragraph contains any further allegations of fact to which a response is required, denied.

32. This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Tanvex admits that Tanvex Biologics, Inc. is a California corporation with a place of business at 2030 Main Street, #600, Irvine, California 92614. For purposes of this action only, Tanvex Biologics, Inc. does not contest personal jurisdiction in this judicial district. To the extent this paragraph contains any further allegations of fact to which a response is required, denied.

33. To the extent that Genentech purports to characterize a document, the document speaks for itself and no response is required. To the extent this paragraph contains any further allegations of fact to which a response is required, denied.

34. Tanvex admits that Tanvex BioPharma USA, Inc. is seeking approval from the FDA for TX05. To the extent this paragraph contains any further allegations of fact to which a response is required, denied.

D. Tanvex Biologics Corporation

35. This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Tanvex admits that Tanvex Biologics Corporation is a Taiwan corporation. For purposes of this action only, Tanvex Biologics Corporation does not contest venue in this judicial district. To the extent this paragraph contains any further allegations of fact to which a response is required, denied.

36. This paragraph contains legal conclusions to which no answer is required. For purposes of this action only, Tanvex does not contest personal jurisdiction in this judicial district. To the extent this paragraph contains any further allegations of fact to which a response is required, denied.

37. This paragraph contains legal conclusions to which no answer is required. For purposes of this action only, Tanvex BioPharma, Inc. does not

contest personal jurisdiction in this judicial district. To the extent this paragraph contains any further allegations of fact to which a response is required, denied.

38. To the extent that Genentech purports to characterize a document, the document speaks for itself and no response is required. To the extent this paragraph contains any further allegations of fact to which a response is required, denied.

39. This paragraph contains legal conclusions to which no answer is required. For purposes of this action only, Tanvex Biologics Corporation does not contest personal jurisdiction in this judicial district. To the extent this paragraph contains any further allegations of fact to which a response is required, denied.

40. Denied.

FACTUAL ALLEGATIONS

A. Genentech & Herceptin®

41. Tanvex is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 41, and therefore denies those allegations.

42. Tanvex admits that FDA approved Herceptin® in 1998 and that Herceptin® contains a genetically engineered antibody known as trastuzumab, which works by attaching to receptors to inhibit the growth of human tumor cells that overexpress the receptors. Tanvex is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 42, which concern Genentech's clinical testing and sales of Herceptin®, and therefore denies those allegations.

43. Denied.

B. Tanvex BioPharma USA, Inc.'s BLA, Manufacture, Importation, and Sale of TX05

44. Tanvex admits that Tanvex BioPharma USA, Inc. submitted BLA No. 761266 with the FDA seeking approval to market its TX05 product in the United States. Tanvex admits that Tanvex BioPharma, Inc. announced on October 4, 2021

that the FDA had accepted the BLA for review. Tanvex denies any remaining allegations in paragraph 44.

45. Tanvex admits that Tanvex BioPharma, Inc. announced on October 4, 2021 that the FDA had accepted Tanvex BioPharma USA, Inc.'s BLA for TX05 for review and that the BLA identifies Herceptin® as the biological reference product. To the extent that Genentech purports to characterize a document, the document speaks for itself and no response is required. To the extent this paragraph contains any further allegations of fact to which a response is required, denied.

46. Denied.

47. Denied.

48. To the extent that Genentech purports to characterize a document, the document speaks for itself and no response is required. To the extent a response is required, Tanvex admits that paragraph 48 contains quotes from Tanvex BioPharma, Inc.'s website, but omits context. Tanvex denies any remaining allegations in paragraph 48.

49. To the extent that Genentech purports to characterize a document, the document speaks for itself and no response is required. To the extent a response is required, Tanvex admits that Exhibit 8 purports to be a page from Tanvex BioPharma, Inc.'s website. Tanvex denies any remaining allegations in paragraph 49.

50. Denied.

51. Tanvex admits that Tanvex BioPharma USA, Inc. submitted a BLA to FDA through which it is seeking approval from the FDA for TX05. Tanvex denies any remaining allegations in paragraph 51.

52. Denied.

C. The Parties' Exchanges Under the BPCIA

53. Tanvex admits that on October 4, 2021, Tanvex BioPharma, Inc. announced that the FDA had accepted Tanvex BioPharma USA, Inc.'s BLA for

TX05 for review. The BLA was assigned No. 761266. Tanvex denies any remaining allegations in paragraph 53.

54. Tanvex admits that on October 27, 2021, Tanvex BioPharma USA, Inc. provided Genentech with a copy of its BLA. Tanvex denies any remaining allegations in paragraph 54.

55. To the extent that Genentech purports to characterize a document, the document speaks for itself and no response is required. To the extent a response is required, Tanvex admits that via a letter dated November 12, 2021, Genentech purportedly identified deficiencies in Tanvex BioPharma USA, Inc.'s production of manufacturing information and requested additional information concerning the manufacturing of TX05. Tanvex denies any remaining allegations in paragraph 55.

56. Denied.

57. To the extent that Genentech purports to characterize a document, the document speaks for itself and no response is required. To the extent a response is required, Tanvex admits that Genentech provided a list of seven patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) on December 24, 2021. Tanvex denies any remaining allegations in paragraph 57.

58. To the extent that Genentech purports to characterize a document, the document speaks for itself and no response is required. To the extent a response is required, Tanvex admits that Tanvex BioPharma USA, Inc. timely provided its detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) on February 22, 2022 ("3B Statement"). Tanvex denies any remaining allegations in paragraph 58.

59. To the extent that Genentech purports to characterize a document, the document speaks for itself and no response is required. To the extent a response is required, Tanvex admits that, on April 21, 2022, Genentech responded to Tanvex BioPharma USA, Inc.'s 3B Statement pursuant to 42 U.S.C. § 262(*l*)(3)(C) ("3C Statement"). Tanvex denies the allegations made in Genentech's response and any remaining allegations in paragraph 59.

60. To the extent that Genentech purports to characterize a document, the document speaks for itself and no response is required. To the extent a response is required, Tanvex admits that, on April 21, 2022, Genentech provided a 3C Statement along with a cover letter. The cover letter stated, "We propose agreeing that the three patents addressed in Genentech's 3C Statement be included in the infringement action under § 262(1)(6) – *i.e.*, U.S. Patent Nos. 8,574,869, 10,662,237, and 10,808,037." Tanvex denies any remaining allegations in paragraph 60.

61. Tanvex admits that on May 3, 2022, Tanvex BioPharma USA, Inc. sent correspondence in which it agreed to Genentech's proposal that the three patents addressed in Genentech's 3C Statement "be include[d] in the infringement action . . . ." Tanvex denies any remaining allegations in paragraph 61.

62. This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Tanvex admits that Genentech filed the present litigation on June 2, 2022, which is within 30 days of May 3, 2022. Tanvex denies any remaining allegations in paragraph 62.

D. Genentech's Patents-in-Suit

63. Denied.

64. Tanvex admits that Exhibit 1 purports to be a copy of U.S. Patent No. 10,662,237 ("the '237 patent"), titled "Method to Improve Virus Filtration Capacity." Tanvex admits that the '237 patent lists on its face an issue date of May 26, 2020 and purports to relate to methods of viral filtration. To the extent that Genentech purports to characterize a document, the document speaks for itself and no response is required. Tanvex lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 64 and thus denies the same.

65. Tanvex admits that Exhibit 2 purports to be a copy of U.S. Patent No. 10,808,037 ("the '037 patent"), titled "Prevention of Disulfide Bond Reduction

During Recombinant Production of Polypeptides." Tanvex admits that the '037 patent lists on its face an issue date of October 20, 2020 and purports to relate generally to methods for producing an antibody. To the extent that Genentech purports to characterize a document, the document speaks for itself and no response is required. Tanvex lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 65 and thus denies the same.

66. Tanvex admits that Exhibit 3 purports to be a copy of U.S. Patent No. 8,574,869 ("the '869 patent"), titled "Prevention of Disulfide Bond Reduction During Recombinant Production of Polypeptides." Tanvex admits that the '869 patent lists on its face an issue date of November 5, 2013 and purports to relate generally to a method for the prevention of the reduction of a disulfide bond in an antibody expressed in a recombinant host cell. To the extent that Genentech purports to characterize a document, the document speaks for itself and no response is required. Tanvex lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 66 and thus denies the same.

GENENTECH'S FIRST CLAIM FOR RELIEF

(ALLEGED INFRINGEMENT OF THE '237 PATENT)

67. Tanvex repeats and realleges the responses in the foregoing paragraphs of this Answer, as set forth above, and incorporates them by reference as if fully set forth herein.

68. Tanvex admits that Genentech included the '237 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and provided a 3C Statement with respect to the '237 patent. To the extent that Genentech purports to characterize those documents, the documents speak for themselves and no response is required. To the extent a response is required, Tanvex denies the allegations of patent infringement made in Genentech's 3C Statement concerning the '237 patent. Tanvex is without knowledge or information sufficient to form a belief as to the

truth of the allegations regarding Genentech's beliefs in paragraph 68, and therefore denies them. Tanvex denies any remaining allegations in paragraph 68.

69. Tanvex admits that Tanvex BioPharma USA, Inc. submitted a BLA to FDA through which it is seeking approval from FDA for TX05. Tanvex denies any remaining allegations in paragraph 69.

70. Denied.

71. Tanvex admits that paragraph 71 contains the text of claim 1 of the '237 patent. Tanvex denies any remaining allegations in paragraph 71.

72. Denied.

73. Denied.

74. Tanvex admits that on or about December 24, 2021, Genentech sent a letter listing the '237 patent. Tanvex denies any remaining allegations in paragraph 74.

75. Denied.

76. Denied.

GENENTECH'S SECOND CLAIM FOR RELIEF

(ALLEGED INFRINGEMENT OF THE '037 PATENT)

77. Tanvex repeats and realleges the responses in the foregoing paragraphs of this Answer, as set forth above, and incorporates them by reference as if fully set forth herein.

78. Tanvex admits that Genentech included the '037 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and provided a 3C Statement with respect to the '037 patent. To the extent that Genentech purports to characterize those documents, the documents speak for themselves and no response is required. To the extent a response is required, Tanvex denies the allegations of patent infringement made in Genentech's 3C Statement concerning the '037 patent. Tanvex is without knowledge or information sufficient to form a belief as to the

truth of the allegations regarding Genentech's beliefs in paragraph 78, and therefore denies them. Tanvex denies any remaining allegations in paragraph 78.

79. Tanvex admits that Tanvex BioPharma USA, Inc. submitted a BLA to FDA through which it is seeking approval from FDA for TX05. Tanvex denies any remaining allegations in paragraph 79.

80. Denied.

81. Tanvex admits that paragraph 81 contains the text of claim 1 of the '037 patent. Tanvex denies any remaining allegations in paragraph 81.

82. Denied.

83. Denied.

84. Tanvex admits that on or about December 24, 2021, it received a letter from Genentech listing the '037 patent. Tanvex denies any remaining allegations in paragraph 84.

85. Denied.

86. Denied.

GENENTECH'S THIRD CLAIM FOR RELIEF

(ALLEGED INFRINGEMENT OF THE '869 PATENT)

87. Tanvex repeats and realleges the responses in the foregoing paragraphs of this Answer, as set forth above, and incorporates them by reference as if fully set forth herein.

88. Tanvex admits that Genentech included the '869 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and provided a 3C Statement with respect to the '869 patent. To the extent that Genentech purports to characterize those documents, the documents speak for themselves and no response is required. To the extent a response is required, Tanvex denies the allegations of patent infringement made in Genentech's 3C Statement concerning the '869 patent. Tanvex is without knowledge or information sufficient to form a belief as to the

truth of the allegations regarding Genentech's beliefs in paragraph 88, and therefore denies them. Tanvex denies any remaining allegations of paragraph 88.

89. Tanvex admits that Tanvex BioPharma USA, Inc. submitted a BLA to FDA through which it is seeking approval from the FDA for TX05. Tanvex denies any remaining allegations in paragraph 89.

90. Denied.

91. Tanvex admits that paragraph 91 contains the text of claim 1 of the '869 patent. Tanvex denies any remaining allegations in paragraph 91.

92. Denied.

93. Denied.

94. Tanvex admits that on or about December 24, 2021, it received a letter from Genentech listing the '869 patent. Tanvex denies any remaining allegations in paragraph 94.

95. Denied.

96. Denied.

* * *

Tanvex denies any remaining allegations not expressly admitted or responded to herein. Tanvex further denies that Genentech is entitled to any relief whatsoever, including the relief sought in paragraphs 1-6 of the Prayer for Relief. Tanvex respectfully requests that the Court:

(a) deny all relief requested by Genentech;

(b) enter judgment in favor of Tanvex;

(c) award Tanvex its reasonable attorneys' fees and costs of defending this action pursuant to 35 U.S.C. § 285; and

(d) award Tanvex such further relief as the Court deems just and appropriate.

AFFIRMATIVE DEFENSES

97. Without prejudice to the denials set forth in the Answer, without admitting any averments in the Complaint not otherwise admitted, and without assuming any burden other than that imposed by operation of law or admitting that it bears the burden of proof with respect to any of the following, Tanvex states the following defenses to the allegations of the Complaint.

FIRST AFFIRMATIVE DEFENSE

NONINFRINGEMENT OF U.S. PATENT NO. 10,662,237

98. Tanvex has not infringed and does not infringe, under any theory of infringement, including directly, indirectly, contributorily, or by inducement, and either literally or under the doctrine of equivalents, any valid and enforceable claim of the '237 patent.

SECOND AFFIRMATIVE DEFENSE

INVALIDITY OF U.S. PATENT NO. 10,662,237

99. Each claim of the '237 patent is invalid for failure to satisfy one or more requirements for patentability set forth in the patent laws of the United States, Title 35, United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting.

THIRD AFFIRMATIVE DEFENSE

NONINFRINGEMENT OF U.S. PATENT NO. 10,808,037

100. Tanvex has not infringed and does not infringe, under any theory of infringement, including directly, indirectly, contributorily, or by inducement, and either literally or under the doctrine of equivalents, any valid and enforceable claim of the '037 patent.

FOURTH AFFIRMATIVE DEFENSE

INVALIDITY OF U.S. PATENT NO. 10,080,037

101. Each claim of the '037 patent is invalid for failure to satisfy one or more requirements for patentability set forth in the patent laws of the United States,

Title 35, United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting.

FIFTH AFFIRMATIVE DEFENSE

NONINFRINGEMENT OF U.S. PATENT NO. 8,574,869

102. Tanvex has not infringed and does not infringe, under any theory of infringement, including directly, indirectly, contributorily, or by inducement, and either literally or under the doctrine of equivalents, any valid and enforceable claim of the '869 patent.

SIXTH AFFIRMATIVE DEFENSE

INVALIDITY OF U.S. PATENT NO. 8,574,869

103. Each claim of the '869 patent is invalid for failure to satisfy one or more requirements for patentability set forth in the patent laws of the United States, Title 35, United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting.

SEVENTH AFFIRMATIVE DEFENSE

FAILURE TO STATE A CLAIM

104. Genentech has failed to state a claim upon which relief can be granted.

EIGHTH AFFIRMATIVE DEFENSE

PROSECUTION HISTORY ESTOPPEL

105. Genentech's infringement claims are barred as a result of prosecution history estoppel, prosecution disclaimer, and/or due to statements or amendments made during prosecution of the applications that issued as the Asserted Patents, or related patents and applications, or during any other proceedings in the U.S. Patent and Trademark Office or in any court.

NINTH AFFIRMATIVE DEFENSE

NO DAMAGES

106. Plaintiff's claim for damages is statutorily limited by the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 271(e)(3), (4), 286, 287, and/or 288.

TENTH AFFIRMATIVE DEFENSE

NO WILLFUL INFRINGEMENT

107. Genentech cannot prove willful infringement and is not entitled to any increased damages under 35 U.S.C. § 284 in this action related to an application submitted to FDA pursuant to 21 U.S.C. § 262.

ELEVENTH AFFIRMATIVE DEFENSE

NO EXCEPTIONAL CASE

108. Genentech cannot prove that this is an exceptional case justifying an award of any attorney fees or costs against Tanvex pursuant to 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285.

TWELFTH AFFIRMATIVE DEFENSE

35 U.S.C. § 271(e)(1) SAFE HARBOR

109. The manufacture, use, and importation of TX05 related to the development and submission of information to FDA related to BLA No. 761266 is exempt from liability under the safe harbor provision of 35 U.S.C. § 271(e)(1).

THIRTEENTH AFFIRMATIVE DEFENSE

OTHER AFFIRMATIVE DEFENSES

110. Tanvex reserves the right to assert any additional defenses or counterclaims that discovery may reveal, including all affirmative defenses under Rule 8(c) of the Federal Rules of Civil Procedure, the patent laws of the United States, and any other defenses at law or in equity.

COUNTERCLAIMS

Tanvex BioPharma USA, Inc. brings counterclaims against Genentech, Inc.

("Genentech") under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, to obtain a declaratory judgment that each and every claim of the '237, '037, and '869 patents is invalid and/or not infringed.

THE PARTIES

1. Counterclaim-Plaintiff Tanvex BioPharma USA, Inc. is a California corporation with a place of business at 10421 Pacific Center Court, Suite 100, San Diego, California 92121.

2. Counterclaim-Defendant Genentech Inc. purports to be a company organized and existing under the laws of Delaware, with its corporate headquarters at 1 DNA Way, South San Francisco, California 94080.

JURISDICTION AND VENUE

3. The Court has subject matter jurisdiction over these Counterclaims under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the patent laws of the United States 35 U.S.C. § 101 *et seq*., including 28 U.S.C. §§ 1331 and 1338(a).

4. This Court has personal jurisdiction over Genentech because Genentech commenced this action and continues to maintain it against Tanvex BioPharma USA, Inc. in this judicial district, thus availing itself of the rights and privileges and subjecting itself to jurisdiction in this forum.

5. The Court has personal jurisdiction over Genentech for the additional reason that Genentech also regularly conducts business in this judicial district.

6. Venue is proper in this judicial district pursuant to, without limitation, 28 U.S.C. § 1400(b) and 28 U.S.C. §§ 1391(b) and (c), because this suit was filed in this district by Genentech.

PATENTS AT ISSUE

7. U.S. Patent No. 10,662,237 ("the '237 patent") lists on its face an issue date of May 26, 2020, and is entitled "Method to Improve Virus Filtration

Capacity." Upon information and belief, Genentech purports to be the owner of all title, right, and interest in and to the '237 patent.

8. U.S. Patent No. 10,808,037 ("the '037 patent") lists on its face an issue date of October 20, 2020, and is entitled "Prevention of Disulfide Bond Reduction During Recombinant Production of Polypeptides." Upon information and belief, Genentech purports to be the owner of all title, right, and interest in and to the '037 patent.

9. U.S. Patent No. 8,574,869 ("the '869 patent") lists on its face an issue date of November 5, 2013, and is entitled "Prevention of Disulfide Bond Reduction During Recombinant Production of Polypeptides." Upon information and belief, Genentech purports to be the owner of all title, right, and interest in and to the '869 patent.

10. Hereinafter, the '237 patent, '037 patent, and '869 patent, shall be collectively referred to as the "Asserted Patents."

NATURE OF THE ACTION

11. Tanvex BioPharma USA, Inc. asserts counterclaims under the Federal Declaratory Judgment Act, seeking declaratory judgments under the patent laws of the United States, United States Code Title 35, that each claim of the Asserted Patents is invalid and/or not infringed.

THE PARTIES' BPCIA INFORMATION EXCHANGES

12. The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") sets forth a process whereby the reference product sponsor and the biosimilar applicant exchange information in advance of a specific and statutorily prescribed action for patent infringement.

13. On or about July 21, 2021, Tanvex BioPharma USA, Inc. submitted to FDA its Biologics License Application ("BLA") No. 761266 for its trastuzumab product known as TX05. BLA No. 761266 lists Genentech's Herceptin® as the biological reference product.

14. Pursuant to the BPCIA information exchange process, on October 20, 2021, Tanvex BioPharma USA, Inc. notified Genentech that it had been notified by FDA on September 30, 2021 that its BLA for TX05 had been accepted for review.

15. On October 27, 2021, Tanvex BioPharma USA, Inc. timely sent to Genentech its disclosure under 42 U.S.C. § 262(*l*)(2)(A).

16. Tanvex BioPharma USA, Inc.'s October 27, 2021 disclosure included a complete copy of BLA No. 761266.

17. Tanvex BioPharma USA, Inc.'s § 262(*l*)(2)(A) disclosure contained, among other things, extensive information regarding the manufacturing processes used to make TX05. The copy of BLA No. 761266 contains extensive technical details describing the manufacture of TX05. Tanvex BioPharma USA, Inc.'s production contained sufficiently detailed information regarding its biosimilar product and manufacturing processes, in compliance with 42 U.S.C. § 262(*l*)(2)(A)-(B), which enabled Genentech to undertake its obligations under 42 U.S.C. § 262(*l*)(3)(A).

18. Despite the fact that Tanvex BioPharma USA, Inc.'s October 27, 2021 disclosure fully met the requirements of 42 U.S.C. § 262(*l*)(2)(A), Tanvex BioPharma USA, Inc. nonetheless produced thousands of pages of additional documents on December 15, 2022.

19. On December 24, 2021, Genentech provided Tanvex BioPharma USA, Inc. with its list of patents purporting to comply with 42 U.S.C. § 262(*l*)(3)(A) that "it believe[d] reasonably could be asserted against Tanvex's proposed TX05 product" ("(3)(A) List"). Genentech's (3)(A) List included the Asserted Patents.

20. On February 22, 2022, Tanvex BioPharma USA, Inc. responded to Genentech's (3)(A) List by timely providing Genentech a statement under 42 U.S.C. § 262(*l*)(3)(B)(ii) ("3B Statement") that describes on a claim-by-claim basis the factual and legal bases for Tanvex BioPharma USA, Inc.'s opinion that all of

the patents on Genentech's (3)(A) List, including the Asserted Patents, are not infringed, invalid, and/or unenforceable.

21. On April 21, 2022, and subject to its objections, Genentech provided its response pursuant to 42 U.S.C. § 262(*l*)(3)(C) ("3C Statement"). With Genentech's 3C Statement, Genentech proposed that Tanvex BioPharma USA, Inc. agree that all three of the Asserted Patents be included in a first-phase infringement action under § 262(*l*)(6).

22. Although Tanvex BioPharma USA, Inc. believed – and continues to believe – that the Asserted Patents are not infringed and/or are invalid or unenforceable, on May 3, 2022, Tanvex BioPharma USA, Inc. sent correspondence to Genentech stating that it agreed to Genentech's inclusion of the Asserted Patents in an infringement action.

23. On June 2, 2022, Genentech filed suit against Tanvex BioPharma USA, Inc. alleging that Tanvex BioPharma USA, Inc.'s manufacture, importation, sale, offer for sale, use, and promotion of the use of TX05 will infringe, directly and/or indirectly, one or more claims of each of the Asserted Patents.

COUNTERCLAIM I

Declaratory Judgment of Non-Infringement of U.S. Patent No. 10,662,237

24. Tanvex BioPharma USA, Inc. incorporates by reference and realleges each of the allegations set forth in the foregoing paragraphs of these Counterclaims.

25. By virtue of Genentech's June 2, 2022 complaint for patent infringement, there is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the submission of BLA No. 761266 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of TX05 prior to the expiration of the '237 patent will infringe any valid and enforceable claim of the '237 patent.

26. Tanvex BioPharma USA, Inc. has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the ’237 patent either literally or under the doctrine of equivalents and is not liable for such infringement, for at least the reasons set forth in Tanvex BioPharma USA, Inc.’s 3B Statement.

27. Under 35 U.S.C. § 271(e)(1), Tanvex BioPharma USA, Inc. has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the ’237 patent because particular activities related to TX05, such as the manufacture and testing of TX05 related to the submission of BLA No. 761266, were and will be solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs.

28. The commercial manufacture, use, sale, offer for sale, and importation of TX05 prior to the expiration of the ’237 patent will not infringe the ’237 patent directly or indirectly, literally or under the doctrine of equivalents, for at least the reasons set forth in Tanvex BioPharma USA, Inc.’s 3B Statement.

29. Tanvex BioPharma USA, Inc. is entitled to judgment that the manufacture, use, sale, offer for sale, and importation of TX05 that is the subject of BLA No. 761266 has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the ’237 patent.

COUNTERCLAIM II

Declaratory Judgment of Invalidity of U.S. Patent No. 10,662,237

30. Tanvex BioPharma USA, Inc. incorporates by reference and realleges each of the allegations set forth in the foregoing paragraphs of these Counterclaims.

31. By virtue of Genentech’s June 2, 2022 complaint for patent infringement, there is an actual, substantial, continuing, and justiciable controversy between the parties regarding he invalidity of the ’237 patent.

32. The claims of the ’237 patent are invalid for failure to satisfy the requirements of patentability under 35 U.S.C. § 101 et seq., including but not limited to 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting.

33. One non-limiting example of how one or more claims of the ’237 patent is invalid includes that the claims are invalid for failure to meet the definiteness requirement of 35 U.S.C. § 112, ¶ 2 because they fail to inform the person of ordinary skill in the art about the scope of the invention with reasonable certainty based on at least the claim term reciting “having or suspected of having a parvovirus contaminant.”

34. Another non-limiting example of how one or more claims of the ’237 patent is invalid includes that the claims are invalid due to anticipation and/or obviousness under 35 U.S.C. §§ 102 and/or 103 in view of prior art disclosing processes for methods of for the production and purification of recombinant proteins, including, but not limited to: Amit Mehta, et al., *Purifying Therapeutic Monoclonal Antibodies*, 104(5), Chem. Eng’g. Prog. (CEP) Sl4-S20 (2008); Kenji Furuya, et al., *Implementation of a 20-nm Pore-Size Filter in the Plasma Derived Factor VIII Manufacturing Process*, 91 Vox Sanguinis, 119-25 (2006); Barbra Tipton, et al., *Retrovirus and Parvovirus Clearance from an Affinity Column Product Using Adsorptive Depth Filtration*, 15(9) BioPharm 43-50 (2002); H. Abe, et al., *Removal of Parvovirus Bl9 from Hemoglobin Solution by Nanofiltration*, 28(5) Artificial Cells, Blood Subs. and Biotech. 375-83 (2000); and/or U.S. Patent Publication No. 2007/0014724. The alleged invention of the ’237 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 ’237 patent is no 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 '237 patent and would have had a reasonable expectation of success in doing so.

35. Tanvex BioPharma USA, Inc. is entitled to a judgment that the claims of the '237 patent are invalid under one or more of 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting.

COUNTERCLAIM III

Declaratory Judgment of Non-Infringement of U.S. Patent No. 10,808,037

36. Tanvex BioPharma USA, Inc. incorporates by reference and realleges each of the allegations set forth in the foregoing paragraphs of these Counterclaims.

37. By virtue of Genentech's June 2, 2022 complaint for patent infringement, there is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the submission of BLA No. 761266 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of TX05 prior to the expiration of the '037 patent will infringe any valid and enforceable claim of the '037 patent.

38. Tanvex BioPharma USA, Inc. has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '037 patent either literally or under the doctrine of equivalents and is not liable for such infringement, for at least the reasons set forth in Tanvex BioPharma USA, Inc.'s 3B Statement.

39. Under 35 U.S.C. § 271(e)(1), Tanvex BioPharma USA, Inc. has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the '037 patent because particular activities related to TX05, such as the manufacture and testing of TX05 related to the submission of BLA No. 761266, were and will be solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs.

40. The commercial manufacture, use, sale, offer for sale, and importation of TX05 prior to the expiration of the ’037 patent will not infringe the ’037 patent directly or indirectly, literally or under the doctrine of equivalents, for at least the reasons set forth in Tanvex BioPharma USA, Inc.’s 3B Statement.

41. Tanvex BioPharma USA, Inc. is entitled to judgment that the manufacture, use, sale, offer for sale, and importation of TX05 that is the subject of BLA No. 761266 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the ’037 patent.

COUNTERCLAIM IV

Declaratory Judgment of Invalidity of U.S. Patent No. 10,808,037

42. Tanvex BioPharma USA, Inc. incorporates by reference and realleges each of the allegations set forth in the foregoing paragraphs of these Counterclaims.

43. By virtue of Genentech’s June 2, 2022 complaint for patent infringement, there is an actual, substantial, continuing, and justiciable controversy between the parties regarding he invalidity of the ’037 patent.

44. The claims of the ’037 patent are invalid for failure to satisfy the requirements of patentability under 35 U.S.C. § 101 et seq., including but not limited to 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double patenting.

45. One non-limiting example of how one or more claims of the ’037 patent is invalid includes that the claims are invalid for failure to meet the written description requirement of 35 U.S.C. § 112, ¶ 1 based on at least the claim term reciting “following a production phase of the cell culture, sparging the pre-harvest cell culture fluid” as the patent is silent concerning any air sparging of a pre-harvest cell culture fluid, let alone a post-fermentation, pre-harvest solution.

46. Another non-limiting example of how one or more claims of the ’037 patent is invalid includes that the claims are invalid due to anticipation and/or obviousness under 35 U.S.C. §§ 102 and/or 103 in view of prior art disclosing

processes for methods of preventing the reduction of disulfide bonds via air sparging, including, but not limited to: U.S. Patent Publication No. 2004/0029229; S.H. de Kock, et al. *Oxygen and Carbon Dioxide Kinetic Challenges for Thermophilic Mineral Bioleaching Processes*, 32(2) Biochem. Soc. Trans. 273-75 (2004); and Jason Christiansen, et al., *Catalytic and Biophysical Properties of a Nitrogenase Apo-MoFe Protein Produced by a nifB-Deletion Mutant of Azotobacter vinelandii*, 37 Biochem. 12611-23 (1998); Alvin W. Nienow, *Reactor Engineering in Large Scale Animal Cell Culture*, 50 Cytotech. 9-33 (2006); and John R. Birch & Andrew J. Racher, *Antibody Production*, 58 Adv. Drug Del. Rev's. 671-85 (2006). The alleged invention of the '037 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 '037 patent is no 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 '037 patent and would have had a reasonable expectation of success in doing so.

47. Tanvex BioPharma USA, Inc. is entitled to a judgment that the claims of the '037 patent are invalid under one or more of 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting.

COUNTERCLAIM V

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,574,869

48. Tanvex BioPharma USA, Inc. incorporates by reference and realleges each of the allegations set forth in the foregoing paragraphs of these Counterclaims.

49. By virtue of Genentech's June 2, 2022 complaint for patent infringement, there is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the submission of BLA No. 261266 and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of

TX05 prior to the expiration of the ’869 patent will infringe any valid and enforceable claim of the ’869 patent.

50. Tanvex BioPharma USA, Inc. has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the ’869 patent either literally or under the doctrine of equivalents, for at least the reasons set forth in Tanvex BioPharma USA, Inc.’s 3B Statement and is not liable for such infringement.

51. Under 35 U.S.C. § 271(e)(1), Tanvex BioPharma USA, Inc. has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the ’869 patent because particular activities related to TX05, such as the manufacture and testing of TX05 related to the submission of BLA No. 761266, were and will be solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs.

52. The commercial manufacture, use, sale, offer for sale, and importation of TX05 prior to the expiration of the ’869 patent will not infringe the ’869 patent directly or indirectly, literally or under the doctrine of equivalents, for at least the reasons set forth in Tanvex BioPharma USA, Inc.’s 3B Statement.

53. Tanvex BioPharma USA, Inc. is entitled to a judgment that the manufacture, use, sale, offer for sale, and importation of TX05 that is the subject of BLA No. 761266 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the ’869 patent.

COUNTERCLAIM VI

Declaratory Judgment of Invalidity of U.S. Patent No. 8,574,869

54. Tanvex BioPharma USA, Inc. incorporates by reference and realleges each of the allegations set forth in the foregoing paragraphs of these Counterclaims.

55. By virtue of Genentech's June 2, 2022 complaint for patent infringement, there is an actual, substantial, continuing, and justiciable controversy between the parties regarding he invalidity of the '869 patent.

56. The claims of the '869 patent are invalid for failure to satisfy the requirements of patentability under 35 U.S.C. § 101 et seq., including but not limited to 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or the doctrine of obviousness-type double patenting.

57. One non-limiting example of how one or more claims of the '869 patent is invalid includes that the claims are invalid for failure to meet the written description requirement of 35 U.S.C. § 112, ¶ 1 based on at least the claim term "following fermentation, sparging the preharvest or harvested culture fluid" as the patent is silent concerning any air sparging of a pre-harvest cell culture fluid, let alone a post-fermentation, pre-harvest solution.

58. Another non-limiting example of how one or more claims of the '869 patent is invalid includes that the claims are invalid due to anticipation and/or obviousness under 35 U.S.C. §§ 102 and/or 103 in view of prior art disclosing processes for methods of preventing the reduction of disulfide bonds via air sparging, including, but not limited to: U.S. Patent Publication No. 2004/0029229; S.H. de Kock, et al. *Oxygen and Carbon Dioxide Kinetic Challenges for Thermophilic Mineral Bioleaching Processes*, 32(2) Biochem. Soc. Trans. 273-75 (2004); Jason Christiansen, et al., *Catalytic and Biophysical Properties of a Nitrogenase Apo-MoFe Protein Produced by a nifB-Deletion Mutant of Azotobacter vinelandii*, 37 Biochem. 12611-23 (1998); Alvin W. Nienow, *Reactor Engineering in Large Scale Animal Cell Culture*, 50 Cytotech. 9-33 (2006); and John R. Birch & Andrew J. Racher, *Antibody Production*, 58 Adv. Drug Del. Rev's. 671-85 (2006). The alleged invention of the '869 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 '869 patent is no 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 '869 patent and would have had a reasonable expectation of success in doing so.

59. Tanvex BioPharma USA, Inc. is entitled to a judgment that the claims of the '869 patent are invalid under one or more of 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type double patenting.

PRAYER FOR RELIEF

WHEREFORE, Tanvex BioPharma USA, Inc. respectfully requests that the Court enter judgment as follows:

a That the Complaint be dismissed with prejudice, and that all relief requested by Genentech therein be denied;

b That Tanvex BioPharma USA, Inc. does not infringe, directly or indirectly, and has not infringed, directly or indirectly, any valid and enforceable claim of the '237, '037, and '869 patents;

c That each claim of the '237, '037, and '869 patents is invalid;

d That this is an exceptional case pursuant to 35 U.S.C. § 285, and therefore that Tanvex BioPharma USA, Inc. is entitled to an award of attorneys' fees, costs, and expenses in this action; and

e That Tanvex BioPharma USA, Inc. be awarded such other and further relief that the Court may deem just and proper.

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DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Tanvex demands a trial by jury of all issues so triable.

Dated: September 1, 2022

CROWELL & MORING LLP

By: */s/ Joanna M. Fulle*

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