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15	Biologics, Inc., and Tanvex Biologics C	orporation	
16	UNITED STATES DISTRICT COURT		
17	SOUTHERN DISTR	ICT OF CALIFORNIA	
18	GENENTECH, INC.,	Case No. 3:22-CV-0809-RBM-JLB	
19	Plaintiff, vs.	DEFENDANTS' ANSWER, AFFIRMATIVE DEFENSES	
20		DEMAND FOR JURY TRIAL	
21	TANVEX BIOPHARMA USA, INC., TANVEX BIOPHARMA, INC., TANVEX BIOLOGICS, INC., and TANVEX BIOLOGICS		
22	TANVEX BIOLOGICS		
23	Defendants.	AND	
24	TANVEX BIOPHARMA USA, INC.,		
25 26	Counter-Claimant, vs.	TANVEX BIOPHARMA USA, INC.'S COUNTERCLAIMS	
26 27	GENENTECH, INC.,	INC.'S COUNTERCLAIMS DEMAND FOR JURY TRIAL	
27 28	Counterclaim-Defendant.	νεινιατυγυκί i kial	
20 D		DEFENDANTS' ANSWER, AFFIRMATIVE DEFENS	

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### 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**

Tanvex admits that the Complaint purports to allege an action for 1. 11 patent infringement of United States Patent Nos. 10,662,237 ("the '237 patent"), 12 10,808,037 ("the '037 patent"), and 8,574,869 ("the '869 patent") (collectively, 13 "Asserted Patents") arising under the patent laws of the United States, Title 35, 14 United States Code, including 35 U.S.C. § 271(e)(2)(C), which was enacted in 2010 15 as part of the Biologics Price Competition and Innovation Act of 2009 ("the 16 BPCIA"), Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010) 17 (amending, inter alia, 35 U.S.C. § 271 and 42 U.S.C. § 262), but Tanvex denies that 18 the Complaint states such a cause of action and/or that Tanvex has committed or 19 will commit any infringing acts giving rise to such a cause of action. To the extent 20 this paragraph contains any further allegations of fact to which a response is 21 required, denied. 22

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.

CROWELL & MORING LLP Attorneys At Law

1	3. Tanvex admits that Genentech and Tanvex BioPharma USA, Inc.
2	exchanged information under the BPCIA and agreed pursuant to 42 U.S.C.
3	§ 262( <i>l</i> )(4)(A) to three patents to litigate with respect to Tanvex BioPharma USA,
4	Inc.'s BLA submission for TX05. To the extent this paragraph contains any further
5	allegations of fact to which a response is required, denied.
6	PARTIES
7	4. Tanvex lacks knowledge or information sufficient to form a belief as
8	to the truth of the allegations in paragraph 4 and thus denies the same.
9	5. Tanvex admits that Tanvex BioPharma USA, Inc. is a California
10	corporation with a place of business at 10394 Pacific Center Court, San Diego,
11	California 92121. Tanvex admits that Tanvex BioPharma USA, Inc. filed a BLA
12	for TX05, which is trastuzumab injection, powder, lyophilized for solution and that
13	Tanvex BioPharma USA, Inc.'s BLA No. 761266 for TX05 identifies Herceptin®
14	as the biological reference product. Tanvex denies any remaining allegations in
15	paragraph 5.
16	6. Tanvex admits that Tanvex BioPharma, Inc. is a Cayman Islands
17	corporation, with a place of business in Taipei City 106, Taiwan at 13F1, No. 376,
18	Sec. 4, Ren'ai Rd., D'an Dist., Taipei City 106, Taiwan. Tanvex denies any
19	remaining allegations in paragraph 6.
20	7. Tanvex admits that Tanvex Biologics, Inc. is a California corporation
21	with a place of business at 2030 Main Street, #600, Irvine, California 92614.
22	Tanvex denies any remaining allegations in paragraph 7.
23	8. Tanvex admits that Tanvex Biologics Corporation is a Taiwan
24	corporation with a place of business in New Taipei City 221, Taiwan at 33F, No.
25	99, Sec. 1, Xintai 5th Road, Xizhi District, New Taipei City 221, Taiwan. Tanvex
26	denies any remaining allegations in paragraph 8.
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JURISDICTION AND VENUE 1 9. This paragraph contains legal conclusions to which no answer is 2 required. Tanvex admits that this action purports to arise under the BPCIA, 42 3 4 U.S.C. § 262(1), 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 5 6 action, Tanvex BioPharma USA, Inc. does not contest that this Court has subject matter jurisdiction. Tanvex denies any remaining allegations in paragraph 9. 7 10. This paragraph contains legal conclusions to which no answer is 8 9 required. For purposes of this action only, Tanvex does not contest venue in this judicial district. Tanvex denies any remaining allegations in paragraph 10. 10 For the purposes of this action only, Tanvex does not contest personal 11 11. jurisdiction in this judicial district. Tanvex denies any remaining allegations in 12 13 paragraph 11. **Tanvex BioPharma USA, Inc.** 14 A. 12. This paragraph contains legal conclusions to which no answer is 15 required. Tanvex admits that Tanvex BioPharma USA, Inc. is a corporation 16 organized and existing under the laws of the State of California, with places of 17 business at 10394 Pacific Center Court, San Diego, California 92121 and 2030 18 19 Main Street, #600, Irvine, California 92614. Tanvex admits that Tanvex 20 BioPharma USA, Inc. develops biopharmaceutical products. For the purposes of this action only, Tanvex BioPharma USA, Inc. does not contest venue in this 21 judicial district. To the extent this paragraph contains any further allegations of fact 22 23 to which a response is required, denied. For purposes of this action only, Tanvex BioPharma USA, Inc. does 13. 24 not contest personal jurisdiction in this judicial district. Tanvex denies any 25 remaining allegations in paragraph 13. 26

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27 28 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.

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### Tanvex BioPharma, Inc.

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

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

20 20. To the extent that Genentech purports to characterize a document, the 21 document speaks for itself and no response is required. To the extent this paragraph 22 contains any further allegations of fact to which a response is required, denied.

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

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

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1 23. To the extent that Genentech purports to characterize a document, the 2 document speaks for itself and no response is required. To the extent this paragraph 3 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.

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

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27. Denied.

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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.

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# 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

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1 paragraph contains any further allegations of fact to which a response is required, denied. 2

32. This paragraph contains legal conclusions to which no answer is 3 required. To the extent a response is required, Tanvex admits that Tanvex 4 Biologics, Inc. is a California corporation with a place of business at 2030 Main 5 6 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 7 extent this paragraph contains any further allegations of fact to which a response is 8 9 required, denied.

To the extent that Genentech purports to characterize a document, the 10 33. 11 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. 12

34. Tanvex admits that Tanvex BioPharma USA, Inc. is seeking approval 13 from the FDA for TX05. To the extent this paragraph contains any further 14 allegations of fact to which a response is required, denied. 15

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#### D. **Tanvex Biologics Corporation**

35. This paragraph contains legal conclusions to which no answer is 17 required. To the extent a response is required, Tanvex admits that Tanvex 18 19 Biologics Corporation is a Taiwan corporation. For purposes of this action only, 20 Tanvex Biologics Corporation does not contest venue in this judicial district. To 21 the extent this paragraph contains any further allegations of fact to which a response is required, denied. 22

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36. This paragraph contains legal conclusions to which no answer is required. For purposes of this action only, Tanvex does not contest personal 24 jurisdiction in this judicial district. To the extent this paragraph contains any 25 further allegations of fact to which a response is required, denied. 26

37. This paragraph contains legal conclusions to which no answer is 27 required. For purposes of this action only, Tanvex BioPharma, Inc. does not 28

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contest personal jurisdiction in this judicial district. To the extent this paragraph 1 contains any further allegations of fact to which a response is required, denied. 2

38. To the extent that Genentech purports to characterize a document, the 3 document speaks for itself and no response is required. To the extent this paragraph 4 contains any further allegations of fact to which a response is required, denied. 5

6 39. This paragraph contains legal conclusions to which no answer is required. For purposes of this action only, Tanvex Biologics Corporation does not 7 contest personal jurisdiction in this judicial district. To the extent this paragraph 8 9 contains any further allegations of fact to which a response is required, denied. Denied. 40. 10

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A.

# Genentech & Herceptin®

41. Tanvex is without knowledge or information sufficient to form a belief 13 as to the truth of the allegations in paragraph 41, and therefore denies those 14 allegations. 15

**FACTUAL ALLEGATIONS** 

42. Tanvex admits that FDA approved Herceptin® in 1998 and that 16 Herceptin® contains a genetically engineered antibody known as trastuzumab, 17 which works by attaching to receptors to inhibit the growth of human tumor cells 18 19 that overexpress the receptors. Tanvex is without knowledge or information 20 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<sup>®</sup>, and 21 therefore denies those allegations. 22

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- Denied.
- Tanvex BioPharma USA, Inc.'s BLA, Manufacture, Importation, В. and Sale of TX05

44. Tanvex admits that Tanvex BioPharma USA, Inc. submitted BLA No. 26 27 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 28

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.

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47. Denied.

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.

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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

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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.

6 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 7 required, Tanvex admits that via a letter dated November 12, 2021, Genentech 8 9 purportedly identified deficiencies in Tanvex BioPharma USA, Inc.'s production of manufacturing information and requested additional information concerning the 10 manufacturing of TX05. Tanvex denies any remaining allegations in paragraph 55. 11 56. Denied. 12

13 57. To the extent that Genentech purports to characterize a document, the 14 document speaks for itself and no response is required. To the extent a response is 15 required, Tanvex admits that Genentech provided a list of seven patents pursuant to 16 42 U.S.C. § 262(l)(3)(A) on December 24, 2021. Tanvex denies any remaining 17 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.

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1	60. To the extent that Genentech purports to characterize a document, the	
2	document speaks for itself and no response is required. To the extent a response is	
3	required, Tanvex admits that, on April 21, 2022, Genentech provided a 3C	
4	Statement along with a cover letter. The cover letter stated, "We propose agreeing	
5	that the three patents addressed in Genentech's 3C Statement be included in the	
6	infringement action under § $262(1)(6) - i.e.$ , U.S. Patent Nos. 8,574,869,	
7	10,662,237, and 10,808,037." Tanvex denies any remaining allegations in	
8	paragraph 60.	
9	61. Tanvex admits that on May 3, 2022, Tanvex BioPharma USA, Inc.	
10	sent correspondence in which it agreed to Genentech's proposal that the three	
11	patents addressed in Genentech's 3C Statement "be include[d] in the infringement	
12	action" Tanvex denies any remaining allegations in paragraph 61.	
13	62. This paragraph contains legal conclusions to which no answer is	
14	required. To the extent a response is required, Tanvex admits that Genentech filed	
15	the present litigation on June 2, 2022, which is within 30 days of May 3, 2022.	
16	Tanvex denies any remaining allegations in paragraph 62.	
17	D. Genentech's Patents-in-Suit	
18	63. Denied.	
19	64. Tanvex admits that Exhibit 1 purports to be a copy of U.S. Patent No.	
20	10,662,237 ("the '237 patent"), titled "Method to Improve Virus Filtration	
21	Capacity." Tanvex admits that the '237 patent lists on its face an issue date of May	
22	26, 2020 and purports to relate to methods of viral filtration. To the extent that	
23	Genentech purports to characterize a document, the document speaks for itself and	
24	no response is required. Tanvex lacks knowledge or information sufficient to form	
25	a belief as to the truth of the remaining allegations in paragraph 64 and thus denies	
26	the same.	
27	65. Tanvex admits that Exhibit 2 purports to be a copy of U.S. Patent No.	
28	10,808,037 ("the '037 patent"), titled "Prevention of Disulfide Bond Reduction	

During Recombinant Production of Polypeptides." Tanvex admits that the '037 1 patent lists on its face an issue date of October 20, 2020 and purports to relate 2 generally to methods for producing an antibody. To the extent that Genentech 3 purports to characterize a document, the document speaks for itself and no response 4 is required. Tanvex lacks knowledge or information sufficient to form a belief as to 5 6 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. 7 8,574,869 ("the '869 patent"), titled "Prevention of Disulfide Bond Reduction 8 9 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 10 generally to a method for the prevention of the reduction of a disulfide bond in an 11 antibody expressed in a recombinant host cell. To the extent that Genentech 12 purports to characterize a document, the document speaks for itself and no response 13 is required. Tanvex lacks knowledge or information sufficient to form a belief as to 14 the truth of the remaining allegations in paragraph 66 and thus denies the same. 15

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#### **GENENTECH'S FIRST CLAIM FOR RELIEF**

#### (ALLEGED INFRINGEMENT OF THE '237 PATENT)

Tanvex repeats and realleges the responses in the foregoing paragraphs 67. 18 19 of this Answer, as set forth above, and incorporates them by reference as if fully set 20 forth herein.

68. Tanvex admits that Genentech included the '237 patent in its 21 disclosure of patents pursuant to 42 U.S.C. § 262(l)(3)(A) and provided a 3C 22 23 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 24 is required. To the extent a response is required, Tanvex denies the allegations of 25 patent infringement made in Genentech's 3C Statement concerning the '237 patent. 26 Tanvex is without knowledge or information sufficient to form a belief as to the 27

1	truth of the allegations regarding Genentech's beliefs in paragraph 68, and therefore	
2	denies them. Tax	nvex denies any remaining allegations in paragraph 68.
3	69. Tan	vex admits that Tanvex BioPharma USA, Inc. submitted a BLA to
4	FDA through wh	hich it is seeking approval from FDA for TX05. Tanvex denies any
5	remaining allegations in paragraph 69.	
6	70. Den	ied.
7	71. Tan	vex admits that paragraph 71 contains the text of claim 1 of the
8	'237 patent. Tan	vex denies any remaining allegations in paragraph 71.
9	72. Den	ied.
10	73. Den	ied.
11	74. Tan	vex admits that on or about December 24, 2021, Genentech sent a
12	letter listing the	237 patent. Tanvex denies any remaining allegations in paragraph
13	74.	
14	75. Den	ied.
15	76. Den	ied.
15 16		ied. ENENTECH'S SECOND CLAIM FOR RELIEF
	GI	
16	<u>G</u> (ALLI	ENENTECH'S SECOND CLAIM FOR RELIEF
16 17	<u>GI</u> (ALLI 77. Tan	<u>ENENTECH'S SECOND CLAIM FOR RELIEF</u> EGED INFRINGEMENT OF THE '037 PATENT)
16 17 18	<u>GI</u> (ALLI 77. Tan	ENENTECH'S SECOND CLAIM FOR RELIEF EGED INFRINGEMENT OF THE '037 PATENT) vex repeats and realleges the responses in the foregoing paragraphs
16 17 18 19	<u>GI</u> (ALLH 77. Tan of this Answer, a forth herein.	ENENTECH'S SECOND CLAIM FOR RELIEF EGED INFRINGEMENT OF THE '037 PATENT) vex repeats and realleges the responses in the foregoing paragraphs
16 17 18 19 20	GI (ALLH 77. Tan of this Answer, a forth herein. 78. Tan	ENENTECH'S SECOND CLAIM FOR RELIEF EGED INFRINGEMENT OF THE '037 PATENT) vex repeats and realleges the responses in the foregoing paragraphs as set forth above, and incorporates them by reference as if fully set
16 17 18 19 20 21	<u>GI</u> (ALLH 77. Tan of this Answer, a forth herein. 78. Tan disclosure of pate	ENENTECH'S SECOND CLAIM FOR RELIEF EGED INFRINGEMENT OF THE '037 PATENT) vex repeats and realleges the responses in the foregoing paragraphs as set forth above, and incorporates them by reference as if fully set vex admits that Genentech included the '037 patent in its
<ol> <li>16</li> <li>17</li> <li>18</li> <li>19</li> <li>20</li> <li>21</li> <li>22</li> </ol>	GI (ALLI 77. Tan of this Answer, a forth herein. 78. Tan disclosure of pate Statement with re	<b>ENENTECH'S SECOND CLAIM FOR RELIEF</b> <b>EGED INFRINGEMENT OF THE '037 PATENT)</b> vex repeats and realleges the responses in the foregoing paragraphs as set forth above, and incorporates them by reference as if fully set vex admits that Genentech included the '037 patent in its ents pursuant to 42 U.S.C. § $262(l)(3)(A)$ and provided a 3C
<ol> <li>16</li> <li>17</li> <li>18</li> <li>19</li> <li>20</li> <li>21</li> <li>22</li> <li>23</li> </ol>	GI (ALLI 77. Tan of this Answer, a forth herein. 78. Tan disclosure of pat Statement with re characterize thos	<b>ENENTECH'S SECOND CLAIM FOR RELIEF</b> <b>EGED INFRINGEMENT OF THE '037 PATENT)</b> vex repeats and realleges the responses in the foregoing paragraphs as set forth above, and incorporates them by reference as if fully set vex admits that Genentech included the '037 patent in its ents pursuant to 42 U.S.C. § $262(l)(3)(A)$ and provided a 3C espect to the '037 patent. To the extent that Genentech purports to
<ol> <li>16</li> <li>17</li> <li>18</li> <li>19</li> <li>20</li> <li>21</li> <li>22</li> <li>23</li> <li>24</li> </ol>	GI (ALLI 77. Tan of this Answer, a forth herein. 78. Tan disclosure of pate Statement with re characterize thos is required. To t	<b>ENENTECH'S SECOND CLAIM FOR RELIEF</b> <b>EGED INFRINGEMENT OF THE '037 PATENT)</b> vex repeats and realleges the responses in the foregoing paragraphs as set forth above, and incorporates them by reference as if fully set vex admits that Genentech included the '037 patent in its ents pursuant to 42 U.S.C. § $262(l)(3)(A)$ and provided a 3C espect to the '037 patent. To the extent that Genentech purports to a documents, the documents speak for themselves and no response
<ol> <li>16</li> <li>17</li> <li>18</li> <li>19</li> <li>20</li> <li>21</li> <li>22</li> <li>23</li> <li>24</li> <li>25</li> </ol>	GI (ALLI 77. Tan of this Answer, a forth herein. 78. Tan disclosure of pate Statement with re characterize thos is required. To the patent infringement	<b>ENENTECH'S SECOND CLAIM FOR RELIEF</b> <b>EGED INFRINGEMENT OF THE '037 PATENT)</b> vex repeats and realleges the responses in the foregoing paragraphs as set forth above, and incorporates them by reference as if fully set vex admits that Genentech included the '037 patent in its ents pursuant to 42 U.S.C. § $262(l)(3)(A)$ and provided a 3C espect to the '037 patent. To the extent that Genentech purports to a documents, the documents speak for themselves and no response the extent a response is required, Tanvex denies the allegations of

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1	truth of the a	Illegations regarding Genentech's beliefs in paragraph 78, and therefore
2		Tanvex denies any remaining allegations in paragraph 78.
3	79.	Tanvex admits that Tanvex BioPharma USA, Inc. submitted a BLA to
4	FDA throug	h which it is seeking approval from FDA for TX05. Tanvex denies any
5	remaining al	legations in paragraph 79.
6	80.	Denied.
7	81.	Tanvex admits that paragraph 81 contains the text of claim 1 of the
8	'037 patent.	Tanvex denies any remaining allegations in paragraph 81.
9	82.	Denied.
10	83.	Denied.
11	84.	Tanvex admits that on or about December 24, 2021, it received a letter
12	from Genent	eech listing the '037 patent. Tanvex denies any remaining allegations in
13	paragraph 84	4.
14	85.	Denied.
15	86.	Denied.
16		<b>GENENTECH'S THIRD CLAIM FOR RELIEF</b>
16 17	(A)	<u>GENENTECH'S THIRD CLAIM FOR RELIEF</u> LLEGED INFRINGEMENT OF THE '869 PATENT)
	(A) 87.	
17	87.	LLEGED INFRINGEMENT OF THE '869 PATENT)
17 18	87.	<b>LLEGED INFRINGEMENT OF THE '869 PATENT)</b> Tanvex repeats and realleges the responses in the foregoing paragraphs ver, as set forth above, and incorporates them by reference as if fully set
17 18 19	87. of this Answ	<b>LLEGED INFRINGEMENT OF THE '869 PATENT)</b> Tanvex repeats and realleges the responses in the foregoing paragraphs ver, as set forth above, and incorporates them by reference as if fully set
17 18 19 20	87. of this Answ forth herein. 88.	<b>LLEGED INFRINGEMENT OF THE '869 PATENT)</b> Tanvex repeats and realleges the responses in the foregoing paragraphs er, as set forth above, and incorporates them by reference as if fully set
17 18 19 20 21	87. of this Answ forth herein. 88. disclosure of	<b>LLEGED INFRINGEMENT OF THE '869 PATENT)</b> Tanvex repeats and realleges the responses in the foregoing paragraphs er, as set forth above, and incorporates them by reference as if fully set Tanvex admits that Genentech included the '869 patent in its
<ol> <li>17</li> <li>18</li> <li>19</li> <li>20</li> <li>21</li> <li>22</li> </ol>	87. of this Answ forth herein. 88. disclosure of Statement w	<b>LLEGED INFRINGEMENT OF THE '869 PATENT)</b> Tanvex repeats and realleges the responses in the foregoing paragraphs ver, as set forth above, and incorporates them by reference as if fully set Tanvex admits that Genentech included the '869 patent in its f patents pursuant to 42 U.S.C. § 262( <i>l</i> )(3)(A) and provided a 3C
<ol> <li>17</li> <li>18</li> <li>19</li> <li>20</li> <li>21</li> <li>22</li> <li>23</li> </ol>	87. of this Answ forth herein. 88. disclosure of Statement w characterize	<b>LLEGED INFRINGEMENT OF THE '869 PATENT)</b> Tanvex repeats and realleges the responses in the foregoing paragraphs er, as set forth above, and incorporates them by reference as if fully set Tanvex admits that Genentech included the '869 patent in its f patents pursuant to 42 U.S.C. § $262(l)(3)(A)$ and provided a 3C ith respect to the '869 patent. To the extent that Genentech purports to
<ol> <li>17</li> <li>18</li> <li>19</li> <li>20</li> <li>21</li> <li>22</li> <li>23</li> <li>24</li> </ol>	87. of this Answ forth herein. 88. disclosure of Statement w characterize is required.	<b>LLEGED INFRINGEMENT OF THE '869 PATENT)</b> Tanvex repeats and realleges the responses in the foregoing paragraphs eer, as set forth above, and incorporates them by reference as if fully set Tanvex admits that Genentech included the '869 patent in its f patents pursuant to 42 U.S.C. § $262(l)(3)(A)$ and provided a 3C ith respect to the '869 patent. To the extent that Genentech purports to those documents, the documents speak for themselves and no response
<ol> <li>17</li> <li>18</li> <li>19</li> <li>20</li> <li>21</li> <li>22</li> <li>23</li> <li>24</li> <li>25</li> </ol>	87. of this Answ forth herein. 88. disclosure of Statement w characterize is required. patent infring	<b>LLEGED INFRINGEMENT OF THE '869 PATENT)</b> Tanvex repeats and realleges the responses in the foregoing paragraphs ver, as set forth above, and incorporates them by reference as if fully set Tanvex admits that Genentech included the '869 patent in its f patents pursuant to 42 U.S.C. § $262(l)(3)(A)$ and provided a 3C ith respect to the '869 patent. To the extent that Genentech purports to those documents, the documents speak for themselves and no response To the extent a response is required, Tanvex denies the allegations of

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1	truth of the a	allegations regarding Genentech's beliefs in paragraph 88, and therefore
2		. Tanvex denies any remaining allegations of paragraph 88.
3	89.	Tanvex admits that Tanvex BioPharma USA, Inc. submitted a BLA to
4	FDA throug	h which it is seeking approval from the FDA for TX05. Tanvex denies
5	_	ng allegations in paragraph 89.
6	90.	Denied.
7	91.	Tanvex admits that paragraph 91 contains the text of claim 1 of the
8	'869 patent.	Tanvex denies any remaining allegations in paragraph 91.
9	92.	Denied.
10	93.	Denied.
11	94.	Tanvex admits that on or about December 24, 2021, it received a letter
12	from Genen	tech listing the '869 patent. Tanvex denies any remaining allegations in
13	paragraph 94	4.
14	95.	Denied.
15	96.	Denied.
16		* * *
17	Tanve	ex denies any remaining allegations not expressly admitted or
18	responded to	b herein. Tanvex further denies that Genentech is entitled to any relief
19	whatsoever, including the relief sought in paragraphs 1-6 of the Prayer for Relief.	
20	Tanvex resp	ectfully requests that the Court:
21	(a)	deny all relief requested by Genentech;
22	(b)	enter judgment in favor of Tanvex;
23	(c)	award Tanvex its reasonable attorneys' fees and costs of defending this
24		action pursuant to 35 U.S.C. § 285; and
25	(d)	award Tanvex such further relief as the Court deems just and
26		appropriate.
27		
28		
L LLP LAW		-14- DEFENDANTS' ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS; CASE NO. 3:22-cv-0809-RBM-JLB

1	AFFIRMATIVE DEFENSES	
2	97. Without prejudice to the denials set forth in the Answer, without	
3	admitting any averments in the Complaint not otherwise admitted, and without	
4	assuming any burden other than that imposed by operation of law or admitting that	
5	it bears the burden of proof with respect to any of the following, Tanvex states the	
6	following defenses to the allegations of the Complaint.	
7	FIRST AFFIRMATIVE DEFENSE	
8	NONINFRINGEMENT OF U.S. PATENT NO. 10,662,237	
9	98. Tanvex has not infringed and does not infringe, under any theory of	
10	infringement, including directly, indirectly, contributorily, or by inducement, and	
11	either literally or under the doctrine of equivalents, any valid and enforceable claim	
12	of the '237 patent.	
13	SECOND AFFIRMATIVE DEFENSE	
14	INVALIDITY OF U.S. PATENT NO. 10,662,237	
15	99. Each claim of the '237 patent is invalid for failure to satisfy one or	
16	more requirements for patentability set forth in the patent laws of the United States,	
17	Title 35, United States Code, including, without limitation, 35 U.S.C. §§ 101, 102,	
18	103, 112, and/or the doctrine of obviousness-type double patenting.	
19	THIRD AFFIRMATIVE DEFENSE	
20	NONINFRINGEMENT OF U.S. PATENT NO. 10,808,037	
21	100. Tanvex has not infringed and does not infringe, under any theory of	
22	infringement, including directly, indirectly, contributorily, or by inducement, and	
23	either literally or under the doctrine of equivalents, any valid and enforceable claim	
24	of the '037 patent.	
25	FOURTH AFFIRMATIVE DEFENSE	
26	INVALIDITY OF U.S. PATENT NO. 10,080,037	
27	101. Each claim of the '037 patent is invalid for failure to satisfy one or	
28	more requirements for patentability set forth in the patent laws of the United States,	
LLP	-15- DEFENDANTS' ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS; CASE NO. 3:22-cv-0809-RBM-JLB	

1	Title 35, United States Code, including, without limitation, 35 U.S.C. §§ 101, 102,	
2	103, 112, and/or the doctrine of obviousness-type double patenting.	
3	FIFTH AFFIRMATIVE DEFENSE	
4	NONINFRINGEMENT OF U.S. PATENT NO. 8,574,869	
5	102. Tanvex has not infringed and does not infringe, under any theory of	
6	infringement, including directly, indirectly, contributorily, or by inducement, and	
7	either literally or under the doctrine of equivalents, any valid and enforceable claim	
8	of the '869 patent.	
9	SIXTH AFFIRMATIVE DEFENSE	
10	<b>INVALIDITY OF U.S. PATENT NO. 8,574,869</b>	
11	103. Each claim of the '869 patent is invalid for failure to satisfy one or	
12	more requirements for patentability set forth in the patent laws of the United States,	
13	Title 35, United States Code, including, without limitation, 35 U.S.C. §§ 101, 102,	
14	103, 112, and/or the doctrine of obviousness-type double patenting.	
15	SEVENTH AFFIRMATIVE DEFENSE	
16	FAILURE TO STATE A CLAIM	
17	104. Genentech has failed to state a claim upon which relief can be granted.	
18	EIGHTH AFFIRMATIVE DEFENSE	
19	<b>PROSECUTION HISTORY ESTOPPEL</b>	
20	105. Genentech's infringement claims are barred as a result of prosecution	
21	history estoppel, prosecution disclaimer, and/or due to statements or amendments	
22	made during prosecution of the applications that issued as the Asserted Patents, or	
23	related patents and applications, or during any other proceedings in the U.S. Patent	
24	and Trademark Office or in any court.	
25		
26		
27		
28		
LP .aw	-16- DEFENDANTS' ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS; CASE NO. 3:22-cv-0809-RBM-JLB	

1	NINTH AFFIRMATIVE DEFENSE
2	NO DAMAGES
3	106. Plaintiff's claim for damages is statutorily limited by the patent laws of
4	the United States, including, without limitation, 35 U.S.C. §§ 271(e)(3), (4), 286,
5	287, and/or 288.
6	<b>TENTH AFFIRMATIVE DEFENSE</b>
7	NO WILLFUL INFRINGEMENT
8	107. Genentech cannot prove willful infringement and is not entitled to any
9	increased damages under 35 U.S.C. § 284 in this action related to an application
10	submitted to FDA pursuant to 21 U.S.C. § 262.
11	<b>ELEVENTH AFFIRMATIVE DEFENSE</b>
12	NO EXCEPTIONAL CASE
13	108. Genentech cannot prove that this is an exceptional case justifying an
14	award of any attorney fees or costs against Tanvex pursuant to 35 U.S.C. §
15	271(e)(4) and 35 U.S.C. § 285.
16	TWELFTH AFFIRMATIVE DEFENSE
17	35 U.S.C. § 271(e)(1) SAFE HARBOR
18	109. The manufacture, use, and importation of TX05 related to the
19	development and submission of information to FDA related to BLA No. 761266 is
20	exempt from liability under the safe harbor provision of 35 U.S.C. § 271(e)(1).
21	THIRTEENTH AFFIRMATIVE DEFENSE
22	<b>OTHER AFFIRMATIVE DEFENSES</b>
23	110. Tanvex reserves the right to assert any additional defenses or
24	counterclaims that discovery may reveal, including all affirmative defenses under
25	Rule 8(c) of the Federal Rules of Civil Procedure, the patent laws of the United
26	States, and any other defenses at law or in equity.
27	<b>COUNTERCLAIMS</b>
28	Tanvex BioPharma USA, Inc. brings counterclaims against Genentech, Inc.
LP	-17- DEFENDANTS' ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS; CASE NO. 3:22-cv-0809-RBM-JLB

1	("Genentech") under the patent laws of the United States, 35 U.S.C. § 1 et seq., and
2	the Declaratory Judgment Act, 28 U.S.C. § 2201 et seq., to obtain a declaratory
3	judgment that each and every claim of the '237, '037, and '869 patents is invalid
4	and/or not infringed.
5	THE PARTIES
6	1. Counterclaim-Plaintiff Tanvex BioPharma USA, Inc. is a California
7	corporation with a place of business at 10421 Pacific Center Court, Suite 100, San
8	Diego, California 92121.
9	2. Counterclaim-Defendant Genentech Inc. purports to be a company
10	organized and existing under the laws of Delaware, with its corporate headquarters
11	at 1 DNA Way, South San Francisco, California 94080.
12	JURISDICTION AND VENUE
13	3. The Court has subject matter jurisdiction over these Counterclaims
14	under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the patent
15	laws of the United States 35 U.S.C. § 101 et seq., including 28 U.S.C. §§ 1331 and
16	1338(a).
17	4. This Court has personal jurisdiction over Genentech because
18	Genentech commenced this action and continues to maintain it against Tanvex
19	BioPharma USA, Inc. in this judicial district, thus availing itself of the rights and
20	privileges and subjecting itself to jurisdiction in this forum.
21	5. The Court has personal jurisdiction over Genentech for the additional
22	reason that Genentech also regularly conducts business in this judicial district.
23	6. Venue is proper in this judicial district pursuant to, without limitation,
24	28 U.S.C. § 1400(b) and 28 U.S.C. §§ 1391(b) and (c), because this suit was filed
25	in this district by Genentech.
26	PATENTS AT ISSUE
27	7. U.S. Patent No. 10,662,237 ("the '237 patent") lists on its face an issue
28	date of May 26, 2020, and is entitled "Method to Improve Virus Filtration
.P	DEFENDANTS' ANSWER, AFFIRMATIVE DEFENSES -18- AND COUNTERCLAIMS:

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1	Capacity." Upon information and belief, Genentech purports to be the owner of all	
2	title, right, and interest in and to the '237 patent.	
3	8. U.S. Patent No. 10,808,037 ("the '037 patent") lists on its face an issue	
4	date of October 20, 2020, and is entitled "Prevention of Disulfide Bond Reduction	
5	During Recombinant Production of Polypeptides." Upon information and belief,	
6	Genentech purports to be the owner of all title, right, and interest in and to the '037	
7	patent.	
8	9. U.S. Patent No. 8,574,869 ("the '869 patent") lists on its face an issue	
9	date of November 5, 2013, and is entitled "Prevention of Disulfide Bond Reduction	
10	During Recombinant Production of Polypeptides." Upon information and belief,	
11	Genentech purports to be the owner of all title, right, and interest in and to the '869	
12	patent.	
13	10. Hereinafter, the '237 patent, '037 patent, and '869 patent, shall be	
14	collectively referred to as the "Asserted Patents."	
15	NATURE OF THE ACTION	
16	11. Tanvex BioPharma USA, Inc. asserts counterclaims under the Federal	
17	Declaratory Judgment Act, seeking declaratory judgments under the patent laws of	
18	the United States, United States Code Title 35, that each claim of the Asserted	
19	Patents is invalid and/or not infringed.	
20	THE PARTIES' BPCIA INFORMATION EXCHANGES	
21	12. The Biologics Price Competition and Innovation Act of 2009	
22	("BPCIA") sets forth a process whereby the reference product sponsor and the	
23	biosimilar applicant exchange information in advance of a specific and statutorily	
24	prescribed action for patent infringement.	
25	13. On or about July 21, 2021, Tanvex BioPharma USA, Inc. submitted to	
26	FDA its Biologics License Application ("BLA") No. 761266 for its trastuzumab	
27	product known as TX05. BLA No. 761266 lists Genentech's Herceptin® as the	
28	biological reference product.	

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CROWELL & MORING LLP Attorneys At Law

Pursuant to the BPCIA information exchange process, on October 20, 1 14. 2021, Tanvex BioPharma USA, Inc. notified Genentech that it had been notified by 2 FDA on September 30, 2021 that its BLA for TX05 had been accepted for review. 3 15. On October 27, 2021, Tanvex BioPharma USA, Inc. timely sent to 4 Genentech its disclosure under 42 U.S.C. & 262(l)(2)(A). 5 Tanvex BioPharma USA, Inc.'s October 27, 2021 disclosure included 6 16. a complete copy of BLA No. 761266. 7 17. Tanvex BioPharma USA, Inc.'s § 262(l)(2)(A) disclosure contained, 8 9 among other things, extensive information regarding the manufacturing processes used to make TX05. The copy of BLA No. 761266 contains extensive technical 10 details describing the manufacture of TX05. Tanvex BioPharma USA, Inc.'s 11 production contained sufficiently detailed information regarding its biosimilar 12 product and manufacturing processes, in compliance with 42 U.S.C. 262(l)(2)(A)-13 (B), which enabled Genentech to undertake its obligations under 42 U.S.C. 14 § 262(*l*)(3)(A). 15 18. Despite the fact that Tanvex BioPharma USA, Inc.'s October 27, 2021 16 disclosure fully met the requirements of 42 U.S.C. § 262(l)(2)(A), Tanvex 17 BioPharma USA, Inc. nonetheless produced thousands of pages of additional 18 19 documents on December 15, 2022. 19. 20 On December 24, 2021, Genentech provided Tanvex BioPharma USA, Inc. with its list of patents purporting to comply with 42 U.S.C.  $\leq 262(l)(3)(A)$  that 21 "it believe[d] reasonably could be asserted against Tanvex's proposed TX05 22 23 product" ("(3)(A) List"). Genentech's (3)(A) List included the Asserted Patents. On February 22, 2022, Tanvex BioPharma USA, Inc. responded to 20. 24 Genentech's (3)(A) List by timely providing Genentech a statement under 42 25

26 U.S.C. § 262(l)(3)(B)(ii) ("3B Statement") that describes on a claim-by-claim basis

27 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).

8 22. Although Tanvex BioPharma USA, Inc. believed – and continues to
9 believe – that the Asserted Patents are not infringed and/or are invalid or
10 unenforceable, on May 3, 2022, Tanvex BioPharma USA, Inc. sent correspondence
11 to Genentech stating that it agreed to Genentech's inclusion of the Asserted Patents
12 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

20 24. Tanvex BioPharma USA, Inc. incorporates by reference and realleges each of the allegations set forth in the foregoing paragraphs of these Counterclaims. 21 25. By virtue of Genentech's June 2, 2022 complaint for patent 22 23 infringement, there is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the submission of BLA No. 761266 and/or 24 the manufacture, use, offer to sell, sale, and/or importation into the United States of 25 TX05 prior to the expiration of the '237 patent will infringe any valid and 26 enforceable claim of the '237 patent. 27

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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.

Cunder 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.

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

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

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# <u>COUNTERCLAIM II</u>

# 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

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between the parties regarding he invalidity of the '237 patent.

28

32. 1 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 2 limited to 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrine of obviousness-type 3 4 double patenting.

One non-limiting example of how one or more claims of the '237 33. 5 6 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 7 person of ordinary skill in the art about the scope of the invention with reasonable 8 9 certainty based on at least the claim term reciting "having or suspected of having a parvovirus contaminant." 10

Another non-limiting example of how one or more claims of the '237 11 34. patent is invalid includes that the claims are invalid due to anticipation and/or 12 obviousness under 35 U.S.C. §§ 102 and/or 103 in view of prior art disclosing 13 processes for methods of for the production and purification of recombinant 14 proteins, including, but not limited to: Amit Mehta, et al., Purifying Therapeutic 15 16 Monoclonal Antibodies, 104(5), Chem. Eng'g. Prog. (CEP) S14-S20 (2008); Kenji Furuya, et al., Implementation of a 20-nm Pore-Size Filter in the Plasma Derived 17 Factor VIII Manufacturing Process, 91 Vox Sanguinis, 119-25 (2006); Barbra 18 Tipton, et al., Retrovirus and Parvovirus Clearance from an Affinity Column 19 20 Product Using Adsorptive Depth Filtration, 15(9) BioPharm 43-50 (2002); H. Abe, et al., Removal of Parvovirus Bl9 from Hemoglobin Solution by Nanofiltration, 21 28(5) Artificial Cells, Blood Subs. and Biotech. 375-83 (2000); and/or U.S. Patent 22 Publication No. 2007/0014724. The alleged invention of the '237 patent does no 23 more than combine familiar elements according to known methods to yield 24 predictable results. Any alleged improvement over the prior art set forth in the '237 25 patent is no more than the predictable use of prior art elements according to their 26 established functions. A person of skill in the art would have been motivated to 27

28

AND COUNTERCLAIMS;

1	combine the teachings of the prior art to achieve the alleged invention of the '237	
2	patent and would have had a reasonable expectation of success in doing so.	
3	35. Tanvex BioPharma USA, Inc. is entitled to a judgment that the claims	
4	of the '237 patent are invalid under one or more of 35 U.S.C. §§ 101, 102, 103,	
5	112, and/or the doctrine of obviousness-type double patenting.	
6	COUNTERCLAIM III	
7	Declaratory Judgment of Non-Infringement of U.S. Patent No. 10,808,037	
8	U.S. Patent No. 10,808,057	
9	36. Tanvex BioPharma USA, Inc. incorporates by reference and realleges	
10	each of the allegations set forth in the foregoing paragraphs of these Counterclaims.	
11	37. By virtue of Genentech's June 2, 2022 complaint for patent	
12	infringement, there is an actual, substantial, continuing, and justiciable controversy	
13	between the parties regarding whether the submission of BLA No. 761266 and/or	
14	the manufacture, use, offer to sell, sale, and/or importation into the United States of	
15	TX05 prior to the expiration of the '037 patent will infringe any valid and	
16	enforceable claim of the '037 patent.	
17	38. Tanvex BioPharma USA, Inc. has not infringed, contributed to the	
18	infringement of, or induced the infringement of any valid and enforceable claim of	
19	the '037 patent either literally or under the doctrine of equivalents and is not liable	
20	for such infringement, for at least the reasons set forth in Tanvex BioPharma USA,	
21	Inc.'s 3B Statement.	
22	39. Under 35 U.S.C. § 271(e)(1), Tanvex BioPharma USA, Inc. has not	
23	directly or indirectly infringed, and will not directly or indirectly infringe, any	
24	claim of the '037 patent because particular activities related to TX05, such as the	
25	manufacture and testing of TX05 related to the submission of BLA No. 761266,	
26	were and will be solely for uses reasonably related to the development and	
27	submission of information under a federal law that regulates the manufacture, use,	
28	or sale of drugs.	
Ъ	DEFENDANTS' ANSWER, AFFIRMATIVE DEFENSES	

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CROWELL & MORING LLP Attorneys At Law 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

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9

1	processes for methods of preventing the reduction of disulfide bonds via air			
2	sparging, including, but not limited to: U.S. Patent Publication No. 2004/0029229;			
3	S.H. de Kock, et al. Oxygen and Carbon Dioxide Kinetic Challenges for			
4	Thermophilic Mineral Bioleaching Processes, 32(2) Biochem. Soc. Trans. 273-75			
5	(2004); and Jason Christiansen, et al., Catalytic and Biophysical Properties of a			
6	Nitrogenase Apo-MoFe Protein Produced by a nifB-Deletion Mutant of			
7	Azotobacter vinelandii, 37 Biochem. 12611-23 (1998); Alvin W. Nienow, Reactor			
8	Engineering in Large Scale Animal Cell Culture, 50 Cytotech. 9-33 (2006); and			
9	John R. Birch & Andrew J. Racher, Antibody Production, 58 Adv. Drug Del. Rev's.			
10	671-85 (2006). The alleged invention of the '037 patent does no more than			
11	combine familiar elements according to known methods to yield predictable results.			
12	Any alleged improvement over the prior art set forth in the '037 patent is no more			
13	than the predictable use of prior art elements according to their established			
14	functions. A person of skill in the art would have been motivated to combine the			
15	teachings of the prior art to achieve the alleged invention of the '037 patent and			
16	would have had a reasonable expectation of success in doing so.			
17	47. Tanvex BioPharma USA, Inc. is entitled to a judgment that the claims			
18	of the '037 patent are invalid under one or more of 35 U.S.C. §§ 101, 102, 103,			
19	112, and/or the doctrine of obviousness-type double patenting.			
20	COUNTERCLAIM V			
21	Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,574,869			
22	U.S. Patent No. 8,5/4,869			
23	48. Tanvex BioPharma USA, Inc. incorporates by reference and realleges			
24	each of the allegations set forth in the foregoing paragraphs of these Counterclaims.			
25	49. By virtue of Genentech's June 2, 2022 complaint for patent			
26	infringement, there is an actual, substantial, continuing, and justiciable controversy			
27	between the parties regarding whether the submission of BLA No. 261266 and/or			
28	the manufacture, use, offer to sell, sale, and/or importation into the United States of			
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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.

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

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

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# **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.

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CROWELL & MORING LLP Attorneys At Law

55. By virtue of Genentech's June 2, 2022 complaint for patent infringement, there is an actual, substantial, continuing, and justiciable controversy 2 between the parties regarding he invalidity of the '869 patent. 3

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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.

One non-limiting example of how one or more claims of the '869 57. 8 9 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 10 11 "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 12 alone a post-fermentation, pre-harvest solution. 13

58. Another non-limiting example of how one or more claims of the '869 14 patent is invalid includes that the claims are invalid due to anticipation and/or 15 obviousness under 35 U.S.C. §§ 102 and/or 103 in view of prior art disclosing 16 processes for methods of preventing the reduction of disulfide bonds via air 17 sparging, including, but not limited to: U.S. Patent Publication No. 2004/0029229; 18 19 S.H. de Kock, et al. Oxygen and Carbon Dioxide Kinetic Challenges for 20 Thermophilic Mineral Bioleaching Processes, 32(2) Biochem. Soc. Trans. 273-75 (2004); Jason Christiansen, et al., Catalytic and Biophysical Properties of a 21 *Nitrogenase Apo-MoFe Protein Produced by a nifB-Deletion Mutant of* 22 23 Azotobacter vinelandii, 37 Biochem. 12611-23 (1998); Alvin W. Nienow, Reactor Engineering in Large Scale Animal Cell Culture, 50 Cytotech. 9-33 (2006); and 24 John R. Birch & Andrew J. Racher, *Antibody Production*, 58 Adv. Drug Del. Rev's. 25 671-85 (2006). The alleged invention of the '869 patent does no more than combine 26 27 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 28

1	the predictable use of prior art elements according to their established functions. A		
2	person of skill in the art would have been motivated to combine the teachings of the		
3	prior art to achieve the alleged invention of the '869 patent and would have had a		
4	reasonable expectation of success in doing so.		
5	59. Tanvex BioPharma USA, Inc. is entitled to a judgment that the claims		
6	of the '869 patent are invalid under one or more of 35 U.S.C. §§ 101, 102, 103,		
7	112, and/or the doctrine of obviousness-type double patenting.		
8	PRAYER FOR RELIEF		
9	WHEREFORE, Tanvex BioPharma USA, Inc. respectfully requests that the		
10	Court enter judgment as follows:		
11	a That the Complaint be dismissed with prejudice, and that all relief		
12	requested by Genentech therein be denied;		
13	b That Tanvex BioPharma USA, Inc. does not infringe, directly or		
14	indirectly, and has not infringed, directly or indirectly, any valid and enforceable		
15	claim of the '237, '037, and '869 patents;		
16	c That each claim of the '237, '037, and '869 patents is invalid;		
17	d That this is an exceptional case pursuant to 35 U.S.C. § 285, and		
18	therefore that Tanvex BioPharma USA, Inc. is entitled to an award of attorneys'		
19	fees, costs, and expenses in this action; and		
20	e That Tanvex BioPharma USA, Inc. be awarded such other and further		
21	relief that the Court may deem just and proper.		
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1	DEN	IAND FOR JURY TRIAL	
2	Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Tanvex		
3	demands a trial by jury of all issues so triable.		
4			
5	Dated: September 1, 2022	CROWELL & MORING LLP	
6			
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23		Corporation	
24			
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