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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

Genentech, Inc.,

Plaintiff,

v.

Tanvex BioPharma USA, Inc., Tanvex BioPharma, Inc., Tanvex Biologics, Inc., and Tanvex Biologics Corporation,

Defendants.

Case No. **'22CV0809 RBM JLB**

COMPLAINT

Demand for Jury Trial

For its Complaint against Defendants Tanvex BioPharma, Inc., Tanvex BioPharma USA, Inc., Tanvex Biologics, Inc., and Tanvex Biologics Corporation (collectively, "Tanvex"), Plaintiff Genentech, Inc. ("Genentech") alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement 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). Genentech asserts infringement of three patents in this lawsuit: U.S. Patent No. 10,662,237, U.S. Patent No. 10,808,037, U.S. Patent No. 8,574,869 (collectively, the "Patents-in-Suit"). *See* Exhibits 1-3. The BPCIA provides a pathway for resolving patent disputes relating to biosimilar products.

2. Tanvex is seeking FDA approval of a biosimilar version of Genentech's blockbuster antibody treatment for breast and gastric cancer called Herceptin®. Tanvex's proposed biosimilar product is called TX05. Upon information and belief, Tanvex will be engaged in the manufacture, marketing, and distribution of TX05 in the United States upon FDA approval.

3. As described further below, the parties exchanged information under the BPCIA and agreed upon three patents to litigate with respect to Tanvex's abbreviated biologic license agreement ("aBLA") submission for TX05. Genentech thus brings this action for infringement of three patents pursuant to 35 U.S.C. § 271(e)(2) based upon Tanvex's submission of its aBLA for TX05. Genentech also seeks a declaratory judgment that the manufacture, use, offer to sell, sale, or importation into the United States of Tanvex's biosimilar product

would infringe the Patents-in-Suit. In the event that Tanvex imports or launches its biosimilar product and/or otherwise practices the patented inventions in the United States prior to the expiration of those patents, Genentech also seeks monetary damages, including lost profits, and any further relief as this Court may deem just and proper.

THE PARTIES

4. Plaintiff Genentech is a corporation organized and existing under the laws of the State of Delaware with its corporate headquarters at 1 DNA Way, South San Francisco, CA 94080. The company is dedicated to discovering, developing, and commercializing medicines to treat patients with debilitating and life-threatening diseases. Genentech developed and markets Herceptin® as an antibody therapy for breast and gastric cancer.

5. Upon information and belief, Defendant Tanvex BioPharma USA, Inc. is a corporation organized and existing under the laws of the State of California, with its principal place of business in San Diego, California at 10394 Pacific Center Court, San Diego, CA 92121. Tanvex BioPharma USA, Inc. filed the aBLA for Tanvex's TX05, which is a proposed biosimilar product to Genentech's Herceptin®. Upon information and belief, Tanvex BioPharma USA, Inc., developed TX05 and will manufacture TX05, import TX05 into the United States, and market and distribute TX05 in California and throughout the United States.

6. Upon information and belief, Tanvex BioPharma, Inc. is a corporation organized and existing under the laws of the Cayman Islands, with its principal 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. Upon information and belief, Tanvex BioPharma, Inc. exercises considerable control over the other Defendants with respect to the filing of the TX05 aBLA, development and

manufacture of TX05, importation of TX05 into the United States, and marketing and distribution of TX05 in California and throughout the United States.

7. Upon information and belief, Defendant Tanvex Biologics, Inc. is a corporation organized and existing under the laws of the State of California, with its principal place of business in Irvine, California at 2030 Main Street, #1050, Irvine, CA 92614. Upon information and belief, Tanvex Biologics, Inc. collaborates with each of the other Defendants with respect to the filing of the TX05 aBLA, development and manufacture of TX05, importation of TX05 into the United States, and marketing and distribution of TX05 in California and throughout the United States.

8. Upon information and belief, Tanvex Biologics Corporation is a corporation organized and existing under the laws of Taiwan with its principal 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. Upon information and belief, Tanvex Biologics, Inc. collaborates with each of the other Defendants with respect to the filing of the TX05 aBLA, development and manufacture of TX05, importation of TX05 into the United States, and marketing and distribution of TX05 in California and throughout the United States.

JURISDICTION AND VENUE

9. This action arises 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. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1332, and 1338.

10. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c), and 28 U.S.C. § 1400(b).

11. This Court has personal jurisdiction over each of the Defendants for the reasons set forth below.

A. Tanvex BioPharma USA, Inc.

12. Venue is proper with respect to Tanvex BioPharma USA, Inc. pursuant to 28 U.S.C. § 1400(b) because Tanvex BioPharma USA, Inc. is a corporation organized and existing under the laws of the State of California, with its principal place of business in San Diego, California at 10394 Pacific Center Court, San Diego, CA 92121 and an office in Irvine, California at 2030 Main Street, #1050, Irvine, CA 92614. Upon information and belief, Tanvex BioPharma USA, Inc. develops, manufactures, imports, seeks regulatory approval to market, distribute, and sell biopharmaceuticals for sale and use throughout the United States, including in California and this federal judicial District.

13. Personal jurisdiction over Tanvex BioPharma USA, Inc. exists because it is a California corporation with its principal place of business at 10394 Pacific Center Court, San Diego, CA 92121.

14. Upon information and belief, Tanvex BioPharma USA, Inc. maintains offices and manufacturing facilities at 10421 Pacific Center Court, Suite 100 and San Diego, CA 92121 and 10394 Pacific Center Court, San Diego, CA 92121.

15. Moreover, upon information and belief, Tanvex BioPharma USA, Inc., following any FDA approval of the Tanvex TX05 Product, will import, make, and sell the Tanvex TX05 Product in California and throughout the United States.

16. Tanvex BioPharma, Inc.'s 2020 Annual Report lists under its "technical operations" that cell culture development, purification, upstream and

downstream scale up, and commercialization operations are performed by Tanvex BioPharma USA, Inc. *See* Tanvex 2020 Annual Report at 10, Exhibit 4.

17. Tanvex BioPharma USA, Inc. is a wholly owned subsidiary of Tanvex BioPharma, Inc., and upon information and belief, Tanvex BioPharma, Inc. exercises considerable control over Tanvex BioPharma USA, Inc.

B. Tanvex BioPharma, Inc.

18. Personal jurisdiction over Tanvex BioPharma, Inc. exists because upon information and belief, Tanvex BioPharma USA, Inc., Tanvex Biologics, Inc., Tanvex BioPharma, Inc., and Tanvex Biologics Corporation hold themselves out as a unitary entity and represent to the public that their activities are directed, controlled, and carried out as a single entity. *See, e.g.*, Tanvex 2020 Annual Report at 105, Exhibit 4 ("The Company [Tanvex BioPharma, Inc.] and its subsidiaries (the 'Group') are primarily engaged in the research, development, manufacture and sale of biosimilar products. The Group is currently engaged in conducting research and development of biosimilar products, biological production procedures[.]").

19. Personal jurisdiction further exists for Tanvex BioPharma, Inc. because, upon information and belief, Tanvex BioPharma, Inc. exercises control over each of the other Defendants (or at least collaborates with each of the other Defendants) with respect to the filing of the TX05 aBLA, development and manufacture of TX05, importation of TX05 into the United States, and sale, marketing, and distribution of TX05 in California and throughout the United States.

20. Upon information and belief, Tanvex BioPharma, Inc. is actively involved with planning Tanvex BioPharma USA, Inc.'s new products and filing the Tanvex aBLA for the proposed biosimilar product in dispute. For example, Tanvex BioPharma, Inc. released a press release about the submission of the

Tanvex aBLA to the FDA. *See* October 4, 2021 Press Release, FDA Accepts TX05 BLA Filing, Exhibit 5.

21. According to Tanvex BioPharma, Inc.'s 2020 Annual Report, there is a 100% overlap between the directors, supervisors, chairman and presidents between Tanvex BioPharma USA, Inc. and Tanvex Biologics Corporation. *See* Tanvex 2020 Annual Report at 88, Exhibit 4.

22. According to Tanvex BioPharma, Inc.'s 2020 Annual Report, Tanvex BioPharma, Inc., Tanvex BioPharma USA, Inc., and Tanvex Biologics Corporation have the same CEO and Chairman: Ling-Cheng Chen; these entities further share Allen Chao as a chairman and director. *See* Tanvex 2020 Annual Report at 3 & 88, Exhibit 4.

23. Tanvex BioPharma, Inc.'s 2020 Annual Report includes a 2020 Statement of Internal Control System, dated March 25, 2021, that identifies five key components of managerial control, including "control activities," "information and monitoring," and "communication," and further states that as of "December 31, 2020, it has maintained in all material respects an effective internal control system (that includes the supervision and management of our subsidiaries)." *See* Tanvex 2020 Annual Report at 46, Exhibit 4.

24. Upon information and belief, Defendants Tanvex BioPharma USA, Inc., Tanvex BioPharma, Inc., and Tanvex Biologics Corporation were represented by the same legal counsel in *Amgen Inc. et al. v. Tanvex BioPharma USA, Inc. et al.*, No. 19-cv-1374-H-AHG (S.D. Cal.).

25. Tanvex BioPharma, Inc.'s 2016 Annual Report lists as a "Material Contract[]" the "Service Agreement" between Tanvex BioPharma USA, Inc. (formerly known as "La Jolla Biologics," abbreviated as "LJB") and Tanvex Biologics Corporation under which Tanvex BioPharma USA, Inc. "provides

R&D services to Tanvex Taiwan" (i.e., Tanvex Biologics Corporation). *See* Tanvex 2016 Annual Report, Exhibit 6.

26. Tanvex BioPharma, Inc's 2020 Annual Report lists as a "Material Contract[]" the "Master Collaboration Agreement and SOW" between Tanvex BioPharma USA, Inc. and "Tanvex TW" (i.e., Tanvex Biologics Corporation) for "Collaboration on the biosimilar products development" and which spans from January 1, 2018 to December 31, 2023. *See* Tanvex 2020 Annual Report at 71, Exhibit 4. *See also id*. at 7 (stating that in January 2018, La Jolla Biologics, Inc. changed name to Tanvex BioPharma USA, Inc.).

27. Upon information and belief, Tanvex BioPharma, Inc.—as evidenced, *inter alia*, by its inter-company agreements, total ownership, overlap of officers and directors, sharing of legal counsel, its website, its press releases, its financial statements, its aBLA materials, and its pervasive, day-to-day control of its subsidiaries—exercises complete dominion over Tanvex BioPharma USA, Inc. and Tanvex Biologics Corporation, rendering them Tanvex BioPharma, Inc.'s alter-ego and/or its agents.

28. Upon information and belief, Tanvex BioPharma, Inc. aids, abets, and/or ratifies Tanvex BioPharma USA, Inc. and Tanvex Biologics Corporation's making, using, and selling of Tanvex's aBLA Product, TX05—as evidenced, *inter alia*, by its inter-company agreements, total ownership, sharing of legal counsel, its aBLA materials, overlap of officers and directors, its website, its press releases, and its financial statements.

29. To the extent Tanvex BioPharma, Inc. is not subject to the jurisdiction of the courts of general jurisdiction of the State of California, it is thus not subject to the jurisdiction of the courts of general jurisdiction of any state, and accordingly is amenable to service of process based on its aggregate

contacts with the United States, including but not limited to the above-described contacts, as authorized by Rule 4(k)(2) of the Federal Rules of Civil Procedure.

30. Venue is proper with respect to Tanvex BioPharma, Inc., a Taiwanese company, pursuant to 28 U.S.C. § 1391(b), (c)(3) and 28 U.S.C. § 1400(b). Upon information and belief, Tanvex BioPharma, Inc. collaborates with Tanvex BioPharma USA, Inc., Tanvex Biologics, Inc., and Tanvex Biologics Corporation to develop, manufacture, import into the United States, and seek approval to sell FDA-approved biopharmaceutical drugs, which are to be marketed, distributed, and sold in California and throughout the United States.

C. Tanvex Biologics, Inc.

31. Venue is proper with respect to Tanvex Biologics, Inc., a corporation organized and existing under the laws of the State of California, with its principal place of business in Irvine, California at 2030 Main Street, #1050, Irvine, CA 92614, pursuant to 28 U.S.C. § 1391(b)(2), (c)(2) and 28 U.S.C. § 1400(b). Upon information and belief, Tanvex Biologics, Inc. collaborates with Tanvex BioPharma USA, Inc., Tanvex BioPharma, Inc., and Tanvex Biologics Corporation to develop, manufacture, import into the United States, and seek approval to sell FDA-approved biopharmaceutical drugs, which are to be marketed, distributed, and sold in California and throughout the United States.

32. Personal jurisdiction over Tanvex Biologics, Inc. exists because it is a California corporation and its principal place of business is at 2030 Main Street, #1050, Irvine, CA 92614.

33. Upon information and belief, Tanvex BioPharma USA, Inc., Tanvex Biologics, Inc., Tanvex BioPharma, Inc., and Tanvex Biologics Corporation hold themselves out as a unitary entity and represent to the public that their activities are directed, controlled, and carried out as a single entity. *See, e.g.*,

Tanvex 2020 Annual Report at 105, Exhibit 4 ("The Company [Tanvex BioPharma, Inc.] and its subsidiaries (the 'Group') are primarily engaged in the research, development, manufacture and sale of biosimilar products. The Group is currently engaged in conducting research and development of biosimilar products, biological production procedures[.]")

34. Moreover, upon information and belief, Tanvex Biologics, Inc., following any FDA approval of the Tanvex TX05 Product, will sell the Tanvex TX05 Product in California and throughout the United States.

D. Tanvex Biologics Corporation

35. Venue is proper with respect to Tanvex Biologics Corporation, a Taiwanese company, pursuant to 28 U.S.C. § 1391(b), (c)(3) and 28 U.S.C. § 1400(b). Upon information and belief, Tanvex Biologics Corporation collaborates with Tanvex BioPharma USA, Inc., Tanvex BioPharma, Inc., and Tanvex Biologics, Inc. to develop, manufacture, import into the United States, and seek approval to sell FDA-approved biopharmaceutical drugs, which are intended to be marketed, distributed, and sold in California and throughout the United States.

36. Personal jurisdiction over Tanvex Biologics Corporation exists because upon information and belief, Tanvex BioPharma USA, Inc., Tanvex BioPharma, Inc., Tanvex Biologics, Inc., and Tanvex Biologics Corp. hold themselves out as a unitary entity and represent to the public that their activities are directed, controlled, and carried out as a single entity.

37. Personal jurisdiction over Tanvex Biologics Corporation further exists because upon information and belief, Tanvex Biologics Corporation collaborates with each of the other Defendants with respect to the filing of the TX05 aBLA, development and manufacture of TX05, importation of TX05 into

the United States, and marketing and distribution of TX05 in California and throughout the United States.

38. Tanvex BioPharma, Inc.'s 2020 Annual Report lists under its "technical operations" that cell line development, cell cultivation, and purification will be performed by Tanvex Biologics Corporation. *See* Tanvex 2020 Annual Report at 10, Exhibit 4.

39. To the extent Tanvex Biologics Corporation is not subject to the jurisdiction of the courts of general jurisdiction of the State of California, it is thus not subject to the jurisdiction of the courts of general jurisdiction of any state, and accordingly is amenable to service of process based on its aggregate contacts with the United States, including but not limited to the above-described contacts, as authorized by Rule 4(k)(2) of the Federal Rules of Civil Procedure.

40. Upon information and belief, Defendants are in agreement—both express and implied—to make, use, and sell TX05.

FACTUAL ALLEGATIONS

A. Genentech & Herceptin®

41. Genentech was founded in 1976 and for four decades has been at the forefront of innovation in the field of therapeutic biotechnology. Today, Genentech employs a large number of researchers, scientists, and post-doctoral staff members who routinely publish in top peer-reviewed journals and are among the leaders in total citations to their work by researchers. Genentech currently markets numerous approved pharmaceutical and biologic drugs for a range of serious or life-threatening medical conditions, including various forms of cancer, heart attacks, strokes, rheumatoid arthritis, and respiratory diseases. Among these life-saving drugs, Genentech invented its biologic drug, Herceptin®.

42. Herceptin® contains a genetically engineered antibody, trastuzumab, which works by attaching to receptors that in large amounts lead to certain cancers, like breast cancer. By attaching to these receptors, trastuzumab stops the cancer cells from growing and dividing. The Food and Drug Administration ("FDA") approved Herceptin® in 1998. Based on extensive clinical testing by Genentech, Herceptin® is now approved for use in treating breast cancer and gastric cancer. It is one of the top selling medicines in the United States.

43. Biologic medicines are complex and complicated to manufacture. Genentech's innovative work in developing trastuzumab and other antibody drugs has been recognized by the United States Patent and Trademark Office with patents covering the processes for the manufacture of therapeutic antibodies. These issued patents include the three Patents-in-Suit.

B. Tanvex's aBLA , Manufacture, Importation, and Sale of TX05

44. On August 3, 2021, Tanvex filed aBLA No. 761266 with the FDA seeking approval to market its TX05 product in the United States. On October 4, 2021, Tanvex announced that the FDA had accepted its aBLA for review.

45. As Tanvex has publicly stated, TX05 is a biosimilar to Herceptin®. *See* Exhibit 5, October 4, 2021 Press Release, FDA Accepts TX05 BLA Filing. Accordingly, under 35 U.S.C. § 271(e)(2)(C), Tanvex has committed a statutory act of patent infringement with respect to patents identified by Genentech under 42 U.S.C. § 262(*l*)(3), through the submission of its aBLA application for TX05.

46. Defendants work in concert and/or will work in concert as a single entity to make, use, import, sell, and offer for sale TX05.

47. Upon information and belief, Tanvex has and continues to encourage, aid, abet, and/or induce infringement of the Patents-in-Suit of entities involved in making, using, selling, and testing TX05.

48. According to Tanvex's website, attached hereto as Exhibit 7, "[s]train and cell line construction takes place in our Research Lab in Taipei, Taiwan … Master cell selection and 'seed' development also take place in our Taiwan-based facilities … [And p]rocess and drug product development are carried out in our San Diego, California facility."

49. According to Tanvex's website, attached hereto as Exhibit 8, manufacturing occurs in Taiwan and its United States facilities, and distribution and sales operations occur at its United States facilities.

50. Upon information and belief, Tanvex imports into the United States components of TX05—including but not limited to downstream components of TX05—that are material to the TX05 drug product and substance and are not staple articles. The downstream components of TX05 that are imported by Tanvex into the United States have no substantial non-infringing use besides to be further processed into the TX05 drug product and substance.

51. Tanvex filed an aBLA, manufactured, imported, and has and/or plans to distribute and sell TX05 in the United States.

52. Upon information and belief, Tanvex encourages, aids, abets, and/or induces third parties to partake in the commercial manufacture of TX05, use TX05, and/or sell or offer for sale TX05 in the United States.

C. The Parties' Exchanges Under the BPCIA

53. On October 4, 2021, Tanvex announced that the FDA had accepted its aBLA No. 761266 for review.

54. On October 27, 2021, Tanvex provided Genentech with a copy of its aBLA. By providing its aBLA only, Tanvex did not provide all of manufacturing information for TX05 required by 42 U.S.C. § 262(*l*)(2)(A).

55. On November 12, 2021, Genentech responded by identifying deficiencies in Tanvex's production of manufacturing information and

requesting specific information concerning the manufacturing of Tanvex's biosimilar product. Genentech further explained that Tanvex's production was deficient because it failed to provide all of the requested information in contravention of 42 U.S.C. § 262(*l*)(2).

56. Tanvex did not correct these deficiencies, and did not disclose all the information relevant to establishing whether the manufacture of Tanvex's aBLA product will infringe each of the patents identified on Genentech's operative list pursuant to 42 U.S.C. § 262(*l*)(3)(A).

57. Despite Tanvex's non-compliance (and without waiving Genentech's objection to such non-compliance), Genentech provided its operative list of seven patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) on December 24, 2021. Tanvex's failure to provide sufficient information under those circumstances justifies Genentech's contention that manufacturing Tanvex's aBLA product will infringe such patents.

58. On February 22, 2022, Tanvex purported to provide its detailed statement concerning non-infringement and invalidity pursuant to 42 U.S.C. § 262(*l*)(3)(B) ("Tanvex's 3B Statement"). Tanvex's 3B Statement was deficient in numerous ways. For example, it—like Tanvex's document productions—failed to fully describe Tanvex's manufacturing process, such that Genentech was unable to evaluate many of Tanvex's non-infringement arguments. Tanvex's 3B Statement also failed to provide any statements of invalidity pursuant to 42 U.S.C. § 262(*l*)(3)(B) for any of the patents on Genentech's 3A list.

59. On April 21, 2022, and subject to its objections, Genentech provided its response pursuant to 42 U.S.C. § 262(*l*)(3)(C) ("Genentech's 3C Statement") and stated that Tanvex's vague incorporation of indiscriminate arguments and legal concepts was insufficient under 42 U.S.C. § 262(*l*)(3)(B), and that it further

thwarted Genentech's ability to respond. Genentech also stated that "[w]here Tanvex could have, but did not, provide the required detailed statement on invalidity, Tanvex has waived any invalidity arguments in future litigation or in an administrative proceeding based on information that was available when Tanvex served its contentions."[1]

60. Genentech's 3C Statement included responses to Tanvex's non-infringement statements and addressed Tanvex's failure to identify invalidity positions for each of the patents addressed in its 3B Statement and maintained that TX05 will infringe at least three Genentech patents, the Patents-in-Suit. With its 3C Statement, Genentech proposed that Tanvex agree that all three of these patents be included in a first-phase infringement action under § 262(*l*)(6).

61. After Genentech served its 3C Statement, Tanvex sent correspondence on May 3, 2022 that it agreed that the Patents-in-Suit should be included in an infringement action.

62. In light of the parties' agreement, § 262(*l*)(6)(A) required Genentech to bring an action for patent infringement with respect to each of the three patents that were part of the parties' agreement. This action is Genentech's action pursuant to § 262(*l*)(6)(A), and is brought within 30 days of the parties' Tanvex's May 3, 2022 letter.

D. Genentech's Patents-in-Suit

63. Upon information and belief, Tanvex's aBLA product will infringe at least the following patents, which Genentech asserts in this lawsuit the Patents-in-Suit: U.S. Patent No. 10,662,237, U.S. Patent No. 10,808,037, U.S. Patent No. 8,574,869. The Patents-in-Suit claim novel techniques developed by Genentech relating to various aspects of cell culture and antibody purification.

[1] To the extent Tanvex has not waived its invalidity arguments, Genentech's 3C Statement stated that it reserved its right to respond to such challenges on the merits at that time.

64. U.S. Patent No. 10,662,237 ("the '237 patent"), titled "Method to Improve Virus Filtration Capacity," was duly and legally issued by the Patent Office on May 26, 2020. A true and correct copy of the '237 patent is attached as Exhibit 1. Genentech is the owner by assignment of the '237 patent. The '237 patent claims methods of viral filtration used in the manufacture of a biological product.

65. U.S. Patent No. 10,808,037 ("the '037 patent"), titled "Prevention of Disulfide Bond Reduction During Recombinant Production of Polypeptides," was duly and legally issued by the Patent Office on October 20, 2020. A true and correct copy of the '037 patent is attached as Exhibit 2. Genentech is the owner by assignment of the '037 patent. The '037 patent claim methods of reducing certain molecular bonds in recombinant proteins used in the manufacture of a biological product.

66. U.S. Patent No. 8,574,869 ("the '869 patent"), titled "Prevention of Disulfide Bond Reduction During Recombinant Production of Polypeptides," was duly and legally issued by the Patent Office on November 5, 2013. A true and correct copy of the '869 patent is attached as Exhibit 3. Genentech is the owner by assignment of the '869 patent. The '869 patent claim methods of reducing certain molecular bonds in recombinant proteins used in the manufacture of a biological product.

FIRST CLAIM FOR RELIEF

(INFRINGEMENT OF THE '237 PATENT)

67. Genentech incorporates by reference paragraphs 1-66 as if fully set forth therein.

68. Upon review of publicly available information and/or information provided by Tanvex pursuant to 42 U.S.C. § 262(*l*)(2), Genentech believes that a claim of patent infringement, either literally or under the doctrine of equivalents,

could reasonably be asserted by Genentech if a person not licensed by Genentech engaged in the making, using, offering to sell, selling, or importing into the United States of TX05 prior to the expiration of the '237 patent. Genentech included the '237 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). Genentech also provided Tanvex with a detailed statement that describes, on a claim-by-claim basis, the factual and legal basis of its belief that at least claims 1-22 of the '237 patent will be infringed by the commercial marketing of TX05, pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

69. Tanvex submitted its aBLA to obtain approval to engage in the commercial manufacture, use, or sale of TX05 before the expiration of the '237 patent. Tanvex has therefore committed a technical act of infringement of one or more claims of the '237 patent under 35 U.S.C. § 271(e)(2)(C)(i).

70. Likewise, based on publicly available information and/or information provided by Tanvex pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Tanvex will infringe at least claims 1-22 of the '237 patent in violation of 35 U.S.C. §§ 271(a), (b), (c), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the TX05 drug substance and its proposed TX05 product, as explained in Genentech's 3C Statement.

71. Representative Claim 1 of the '237 patent recites:

> A method of virus filtration comprising subjecting a composition comprising
>
> > a recombinant protein produced in a mammalian host cell and having or suspected of having a parvovirus contaminant
> >
> > to a virus filtration process comprising a cation exchange step and an endotoxin removal step, simultaneously or in either order, immediately

> preceding a virus filter capable of removing a parvovirus,
>
> and wherein said virus filter's filtration capacity in kg/m2 is improved between 1.5 to 20 fold, as compared to no prefiltration step or using either cation exchange step or endotoxin removal step alone.

72. Upon information and belief as set forth in Tanvex's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C) that relies on the confidential information that Tanvex was willing to provide to Genentech pursuant to 42 U.S.C. § 262(*l*)(2), the process by which Defendants manufacture and/or seek to manufacture the Tanvex TX05 Product satisfies each limitation of at least claims 1-22 of the '237 patent, literally or under the doctrine of equivalents. Defendants practice a method of virus filtration of the recombinant protein TX05, suspected of having parvovirus contamination, wherein they employ a cation exchange step and an endotoxin removal step—simultaneously and/or in either order—immediately preceding a filter capable of removing parvovirus; the result of this method of virus filtration is a 1.5 to 20 fold improved capacity in kg/m2 as compared to no prefiltration or using the cation or endotoxin steps alone. Each of these claim elements is met literally or equivalently in Defendants' process.

73. Pursuant to 28 U.S.C. § 2201, Genentech is entitled to a declaratory judgment that Tanvex's manufacture, importation, sale, offer for sale, use, and promotion of the use of the TX05 drug substance and Tanvex's proposed TX05 drug product will infringe the '237 patent pursuant to 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

74. Tanvex has knowledge of and is aware of the '237 patent, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A)

and the filing of this Complaint. Tanvex's infringement of the '237 patent is willful.

75. To the extent Defendants commercialize their product prior to the expiration of the '237 patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

76. The manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Tanvex TX05 product before the expiration of the '237 patent will cause injury to Genentech, entitling it to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

SECOND CLAIM FOR RELIEF

(INFRINGEMENT OF THE '037 PATENT)

77. Genentech incorporates by reference paragraphs 1-66 as if fully set forth therein.

78. Upon review of publicly available information and/or information provided by Tanvex pursuant to 42 U.S.C. § 262(*l*)(2), Genentech believes that a claim of patent infringement, either literally or under the doctrine of equivalents, could reasonably be asserted by Genentech if a person not licensed by Genentech engaged in the making, using, offering to sell, selling, or importing into the United States of TX05 prior to the expiration of the '037 patent. Genentech included the '037 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). Genentech also provided Tanvex with a detailed statement that describes, on a claim-by-claim basis, the factual and legal basis of its belief that at least claims 1, 3, and 5-9 of the '037 patent will be infringed by the commercial marketing of TX05, pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

79. Tanvex submitted its aBLA to obtain approval to engage in the commercial manufacture, use, or sale of TX05 before the expiration of the '037

patent. Tanvex has therefore committed a technical act of infringement of one or more claims of the '037 patent under 35 U.S.C. § 271(e)(2)(C)(i).

80. Likewise, based on publicly available information and/or information provided by Tanvex pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Tanvex will infringe at least claims 1, 3, and 5-9 of the '037 patent in violation of 35 U.S.C. §§ 271(a), (b), (c) and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the TX05 drug substance and its proposed TX05 product, as explained in Genentech's 3C Statement.

81. Representative Claim 1 of the '037 patent recites:

> A method for producing an antibody, comprising
>
> > expressing the antibody in a Chinese Hamster Ovary (CHO) recombinant host cell culture,
> >
> > and following a production phase of the cell culture,
> >
> > sparging the pre-harvest cell culture fluid of the recombinant host cell with air to inhibit reduction of a disulfide bond in the antibody during processing,
> >
> > wherein the antibody is a therapeutic monoclonal antibody that binds to human epidermal growth factor receptor 2 (HER2),
> >
> > and wherein the air sparging is continued until the amount of dissolved oxygen (dO2) in the pre-harvest cell culture fluid is at least 10%.

82. Upon information and belief as set forth in Tanvex's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C) that relies on the confidential information that Tanvex was willing to provide to Genentech pursuant to 42 U.S.C. § 262(*l*)(2), the process by which Defendants manufacture and/or seek to

manufacture the Tanvex TX05 Product satisfies each limitation of at least claims 1-22 of the '037 patent, literally or under the doctrine of equivalents. Defendants practice a method of producing the antibody TX05 (trastuzumab), expressed through a Chinese Hamster Ovary (CHO) recombinant host cell; following a production phase of the cell culture in which TX05 is expressed, Defendants inhibit reduction in disulfide bonds in TX05 by sparging the pre-harvest cell culture fluid of the recombinant host cell with air; Defendants continue that sparging until the amount of dissolved oxygen is at least of 10% to 30%. Each of these claim elements is met literally or equivalently in Defendants' process.

83. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is entitled to a declaratory judgment that Tanvex's manufacture, importation, sale, offer for sale, use, and promotion of the use of the TX05 drug substance and Tanvex's proposed TX05 drug product will infringe the '037 patent pursuant to 35 U.S.C. §§ 271(a), (b), (c) and/or (g).

84. Tanvex has knowledge of and is aware of the '037 patent, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. Tanvex's infringement of the '037 patent is willful.

85. To the extent Defendants commercialize their product prior to the expiration of the '037 patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

86. The manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Tanvex TX05 product before the expiration of the '037 patent will cause injury to Genentech, entitling it to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

THIRD CLAIM FOR RELIEF

(INFRINGEMENT OF THE '869 PATENT)

87. Genentech incorporates by reference paragraphs 1-66 as if fully set forth therein.

88. Upon review of publicly available information and/or information provided by Tanvex pursuant to 42 U.S.C. § 262(*l*)(2), Genentech believes that a claim of patent infringement, either literally or under the doctrine of equivalents, could reasonably be asserted by Genentech if a person not licensed by Genentech engaged in the making, using, offering to sell, selling, or importing into the United States of TX05 prior to the expiration of the '869 patent. Genentech included the '869 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). Genentech also provided Tanvex with a detailed statement that describes, on a claim-by-claim basis, the factual and legal basis of its belief that at least claims 1, 4-5, and 7-8 of the '869 patent will be infringed by the commercial marketing of TX05, pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

89. Tanvex submitted its aBLA to obtain approval to engage in the commercial manufacture, use, or sale of TX05 before the expiration of the '869 patent. Tanvex has therefore committed a technical act of infringement of one or more claims of the '869 patent under 35 U.S.C. § 271(e)(2)(C)(i).

90. Likewise, based on publicly available information and/or information provided by Tanvex pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Tanvex will infringe at least claims 1, 4-5, and 7-8 of the '869 patent in violation of 35 U.S.C. §§ 271(a), (b), (c), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the TX05 drug substance and its proposed TX05 product, as explained in Genentech's 3C Statement.

91. Representative Claim 1 of the '869 patent recites:

> A method for the prevention of the reduction of a disulfide bond in an antibody expressed in a recombinant host cell, comprising,
>
> following fermentation,
>
> sparging the pre-harvest or harvested culture fluid of said recombinant host cell with air,
>
> wherein the amount of dissolved oxygen (dO2) in the pre-harvest or harvested culture fluid is at least 10%.

92. Upon information and belief as set forth in Tanvex's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(C) that relies on the confidential information that Tanvex was willing to provide to Genentech pursuant to 42 U.S.C. § 262(*l*)(2), the process by which Defendants manufacture and/or seek to manufacture the Tanvex TX05 Product satisfies each limitation of at least claims 1-22 of the '869 patent, literally or under the doctrine of equivalents. Defendants practice a method of preventing the reduction of a disulfide bond in is antibody TX05 trastuzumab product, which is expressed in a recombinant host cell; Defendants prevent the reduction of a disulfide bond following fermentation by sparging with air the pre-harvest culture fluid of the recombinant host cell; Defendants sparge the pre-harvest culture fluid with air until the amount of dissolved oxygen is at least 10% to 30%. Each of these claim elements is met literally or equivalently in Defendants' process.

93. Pursuant to 28 U.S.C. § 2201, Genentech is entitled to a declaratory judgment that Tanvex's manufacture, importation, sale, offer for sale, use, and promotion of the use of the TX05 drug substance and Tanvex's proposed TX05 drug product will infringe at least claims 1, 4-5, and 7-8 of the '869 patent pursuant to 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

94. Tanvex has knowledge of and is aware of the '869 patent, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. Tanvex's infringement of the '869 patent is willful.

95. To the extent Defendants commercialize their product prior to the expiration of the '869 patent, Genentech will also be entitled to damages under 35 U.S.C. § 284.

96. The manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the Tanvex TX05 product before the expiration of the '869 patent will cause injury to Genentech, entitling it to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

PRAYER FOR RELIEF

Wherefore, Genentech respectfully request that this Court enter judgment in its favor against Tanvex and grant the following relief:

1. a judgment that Tanvex has infringed directly, by divided infringement, or contributorily or induced infringement of one or more claims of the asserted patents under 35 U.S.C. § 271(e)(2)(C);
2. a judgment that Tanvex has infringed or will infringe directly, by divided infringement, or contributorily, or has induced or will induce infringement, of one or more claims of the asserted patents by engaging in the manufacture, import, offer for sale, sale, or use within the United States of the Tanvex aBLA product before the expirations of the asserted patents under 35 U.S.C. §§ 271(a), (b), (c), and/or (g);
3. monetary damages in the event that Tanvex imports, manufactures, or launches its biosimilar product and/or otherwise practices the patented inventions in the United States prior to the expiration of the asserted patents, including lost profits and/or a reasonable royalty, and an accounting and/or ongoing royalty for any post-judgment infringement;
4. a judgment that Tanvex's infringement was willful and enhancement of any monetary damages pursuant to 35 U.S.C. § 284;
5. a declaration that this is an exceptional case and an award to Genentech of its attorneys' fees, costs, and expenses pursuant to 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285; and
6. such other relief as this Court may deem just and proper.

JURY TRIAL DEMAND

Genentech hereby demands a jury trial pursuant to Rule 38 of the Federal Rules of Civil Procedure as to all issues so triable.

Dated: June 2, 2022

WILMER CUTLER PICKERING HALE AND DORR LLP

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