'11 CIV 9463

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

GENENTECH, INC.,

Plaintiff,

v.

REGENERON PHARMACEUTICALS, INC., SANOFI-AVENTIS U.S. LLC, SANOFI-AVENTIS U.S. INC., SANOFI-AVENTIS AMÉRIQUE DU NORD S.N.C., AND SANOFI

Defendants.

Civil Action No. _____

ECF Case

Jury Demand

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff Genentech, Inc. ("Genentech"), for its complaint against Defendants Sanofi-Aventis US Inc. ("Sanofi Inc."), Sanofi-Aventis U.S. LLC ("Sanofi LLC"), Sanofi-Aventis Amérique du Nord S.A.S. ("Sanofi Amérique"), and Sanofi ("Sanofi Parent") (collectively, the "Sanofi entities"), and Regeneron Pharmaceuticals, Inc. ("Regeneron") (all defendants collectively, "Defendants"), alleges as follows:

JURISDICTION AND VENUE

1. This action arises under the patent laws of the United States of America, 35 U.S.C. §§ 1 *et. seq.*, and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et. seq.* and jurisdiction is therefore properly based on Title 35 of the United States Code, § 271, and Title 28 of the United States Code, § 1338(a).

2. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b).

THE PARTIES

3. Plaintiff Genentech is a corporation organized under the laws of the State of Delaware, with its principal place of business in South San Francisco, California. Genentech is registered to do business and is doing business in the State of New York.

4. Defendant Regeneron is a corporation organized under the laws of the State of New York, with its principal place of business in Tarrytown, New York.

5. Defendant Sanofi LLC is a corporation organized under the laws of the State of Delaware, with its principal place of business in Bridgewater, New Jersey.

6. Defendant Sanofi Inc. is a corporation organized under the laws of the State of Delaware, with its principal place of business in Bridgewater, New Jersey.

7. Defendant Sanofi Amérique is a partnership organized under the laws of France, with its principal place of business in Paris, France.

8. Defendant Sanofi Parent is a corporation organized under the laws of France, with its principal place of business in Paris, France, and is the direct or indirect corporate parent of Sanofi Inc., Sanofi LLC, and Sanofi Amérique.

9. This Court has personal jurisdiction over Regeneron because, *inter alia*, Regeneron resides in the State of New York.

10. On information and belief, this Court has personal jurisdiction over Sanofi LLC because, *inter alia*, Sanofi LLC has, in its own right or by virtue its being in privity with one or more of the other Defendants (*e.g.*, by virtue of an agency or alter ego relationship, or being under common control or direction), availed itself of the rights and benefits of New York law, has transacted business inside the State of New York, including within this judicial district, which transactions have given rise to the claims asserted by Genentech herein, and has

systematic and continuous contacts with the State of New York, including within this judicial district.

11. On information and belief, this Court has personal jurisdiction over Sanofi Inc. because, *inter alia*, Sanofi Inc. has, in its own right or by virtue its being in privity with one or more of the other Defendants (*e.g.*, by virtue of an agency or alter ego relationship, or being under common control or direction), availed itself of the rights and benefits of New York law, has transacted business inside the State of New York, including within this judicial district, which transactions have given rise to the claims asserted by Genentech herein, and has systematic and continuous contacts with the State of New York, including within this judicial district.

12. On information and belief, this Court has personal jurisdiction over Sanofi Amérique because, *inter alia*, Sanofi Amérique has, in its own right or by virtue its being in privity with one or more of the other Defendants (*e.g.*, by virtue of an agency or alter ego relationship, or being under common control or direction), availed itself of the rights and benefits of New York law, has transacted business inside the State of New York, including within this judicial district, which transactions have given rise to the claims asserted by Genentech herein, and has systematic and continuous contacts with the State of New York, including within this judicial district.

13. On information and belief, this Court has personal jurisdiction over Sanofi Parent because, *inter alia*, Sanofi Parent has, in its own right or by virtue its being in privity with one or more of the other Defendants (*e.g.*, by virtue of an agency or alter ego relationship, or being under common control or direction), availed itself of the rights and benefits of New York law, has transacted business inside the State of New York, including within this judicial district,

which transactions have given rise to the claims asserted by Genentech herein, and has systematic and continuous contacts with the State of New York, including within this judicial district.

INTRA-DISTRICT ASSIGNMENT

14. Assignment to White Plains is proper pursuant to Local Rule 16 for the Division of Business Among District Judges. There is a related case pending in White Plains, *Regeneron Pharmaceuticals, Inc. v. Genentech Inc.*, No. 11-CIV-01156-VB. The complaint in the related case alleges that Regeneron resides in Westchester County, and the claims asserted herein arose in major part in Westchester County.

BACKGROUND

THE DAVIS-SMYTH PATENTS

15. U.S. Patent No. 6,100,071, titled Receptors as Novel Inhibitors of Vascular Endothelial Growth Factor Activity And Processes for Their Production, was issued by the U.S. Patent and Trademark Office on August 8, 2000. The inventors on the patent are Terri Lynn Davis-Smyth, Helen Hsifei Chen, Leonard Presta, and Napoleone Ferrara, all of whom are or were Genentech employees.

16. U.S. Patent No. 6,383,486, titled Inhibitors of Vascular Endothelial Growth Factor Activity, Their Uses And Processes for Their Production, was issued by the U.S. Patent and Trademark Office on May 7, 2002. The inventors on the patent are Terri Lynn Davis-Smyth, Helen Hsifei Chen, Leonard Presta, and Napoleone Ferrara, all of whom are or were Genentech employees.

17. U.S. Patent No. 6,897,294, titled Inhibitors of Vascular Endothelial Growth Factor Activity, Their Uses And Processes for Their Production, was issued by the U.S. Patent

and Trademark Office on May 24, 2005. The inventors on the patent are Terri Lynn Davis-Smyth, Helen Hsifei Chen, Leonard Presta, and Napoleone Ferrara, all of whom are or were Genentech employees.

18. U.S. Patent No. 7,771,721, titled Methods for Using Chimeric Vascular Endothelial Growth Factor Receptor Proteins, was issued by the U.S. Patent and Trademark Office on August 10, 2010. The inventors on the patent are Terri Lynn Davis-Smyth, Helen Hsifei Chen, Leonard Presta, and Napoleone Ferrara, all of whom are or were Genentech employees.

19. The 6,100,071, 6,383,486, 6,897,294, and 7,771,721 patents will be referred to herein as the "Davis-Smyth patents."

20. Genentech owns all rights, title, and interest in and to the Davis-Smyth patents.

21. On information and belief, Regeneron has known about the '071 and/or '486 patents at least since March 3, 2005 and has known about the '294 and '721 patents at least since they issued on May 24, 2005 and August 10, 2010, respectively.

22. On information and belief, the Sanofi entities have individually and collectively known about the '071, '486, '294, and/or '721 patents well before the filing of this action.

DEFENDANTS' VEGF INHIBITOR MOLECULES

23. Regeneron and Aventis Pharmaceuticals Inc. entered into a collaboration agreement on September 5, 2003 (the "Collaboration Agreement") for the development, promotion, marketing, commercialization, and manufacture of certain Vascular Endothelial Growth Factor ("VEGF") inhibitor molecules. Sanofi LLC is the successor-in-interest to the Collaboration Agreement. In that Collaboration Agreement, Sanofi LLC stipulated to

jurisdiction for all disputes relating to and arising from that Collaboration Agreement in the United States District Court for the Southern District of New York.

24. On information and belief, Zaltrap™, also known as VEGF Trap-Oncology, is or contains a VEGF inhibitor molecule developed by Regeneron and Sanofi LLC pursuant to the Collaboration Agreement and is an inhibitor of VEGF-A.

25. On information and belief, Zaltrap™ is or contains a fusion protein designed to bind VEGF-A and prevent its interactions with cell surface receptors. VEGF-A mediates the growth of new blood vessels (a process known as angiogenesis) that supports tumor growth.

26. On February 18, 2011, Regeneron filed a Biologics License Application ("BLA") to the United States Food and Drug Administration ("FDA"), through which Regeneron sought approval to market a VEGF Trap-Eye product (Eylea™) for treatment of a degenerative eye disorder called wet age-related macular degeneration. That same day, Regeneron filed a complaint for a lawsuit currently pending in this Court, *Regeneron Pharmaceuticals, Inc. v. Genentech Inc.*, No. 11-CIV-01156-VB (hereinafter the "related case"), in which Regeneron seeks declaratory judgment of non-infringement and invalidity relating to the Davis-Smyth patents on February 18, 2011 and its development of a VEGF Trap product. That complaint contains no reference to Regeneron's use or development of VEGF Trap product for any specific indications except for wet age-related macular degeneration.

27. Genentech filed a counter-claim in the predecessor lawsuit on April 25, 2011 (amended on May 11, 2011), alleging, *inter alia*, infringement by Regeneron of Genentech's patents, with respect to Regeneron's VEGF Trap-Eye product (Eylea™) for treatment of age-related macular degeneration. Until recently, Eylea™ was the only VEGF Trap product for

which a BLA had been filed by any of the Defendants, and therefore for which subject matter jurisdiction was properly vested in this Court.

28. On information and belief, in or about October of 2011, one or more of the Sanofi entities submitted BLA for Zaltrap™ to the FDA seeking approval to engage in the commercial manufacture, use, marketing, and sale of Zaltrap™ throughout the United States for use in treating certain types of cancer.

29. On information and belief, in or about December of 2011, the BLA for Zaltrap™ was voluntarily withdrawn so that additional information can be provided in the Chemistry Manufacturing and Controls section of the BLA about the nature of Zaltrap™, the manner in which it is made, and/or the manner in which the manufacturing process is controlled.

30. On information and belief, the BLA was not voluntarily withdrawn so that additional testing could be conducted to support the re-filing of the BLA.

31. On information and belief, the BLA for Zaltrap™ will be resubmitted to the FDA in early 2012.

32. On information and belief, both Eylea™ and Zaltrap™ are or contain the same active ingredient, namely aflibercept, which is a protein that comprises domains 2 from VEGF-A receptor Flt1 and 3 from VEGF-A receptor KDR fused to an Fc portion of an immunoglobulin of IgG origin.

33. On information and belief, the Sanofi entities, acting alone and/or under principles of privity (*e.g.*, agency, alter ego, common control or direction), will introduce Zaltrap™ into the stream of commerce in the United States knowing that Zaltrap™ will be sold in the State of New York, including within this judicial district.

34. On information and belief, Defendants, acting alone and/or under principles of privity: a) have made, used, offered for sale, sold and/or marketed; b) are making, using, offering for sale, selling and/or marketing; and/or c) are preparing to make, use, offer for sale, sell, and/or market VEGF inhibitor molecules, the amino acid sequence of which is derived in whole or part from the amino acid sequence of one or more VEGF-A receptors, and enables the inhibitor molecules to bind to and inhibit VEGF-A (hereinafter, the "Accused Products," which phrase, for purposes of this Complaint, includes Zaltrap™ but excludes Eylea™), in the United States, including within this judicial district.

35. On information and belief, Defendants, acting alone or under principles of privity, have taken concrete and substantial steps to prepare for commercial manufacturing, use, marketing, and selling of Zaltrap™ throughout the United States, including within this judicial district.

36. Beyond the foregoing allegations, a further indicia that such substantial and concrete steps have been taken is the fact that one or more of the Defendants wanted to qualify an in-house Sanofi attorney under the protective order recently submitted in the related case brought by Regeneron—even though no Sanofi entity is a party to that suit.

37. On information and belief, that Sanofi attorney is an-house patent attorney and Vice President within the Sanofi family of companies and has U.S. patent litigation oversight responsibilities for one or more of the Sanofi entities named herein.

COUNT I
(Infringement and Declaratory Judgment of Infringement of the '071 Patent)

38. Genentech incorporates the allegations in Paragraphs 1-37 as if fully set forth herein.

39. By virtue of Defendants individually or under principles of privity: a) having made, used, offered for sale, sold and/or marketed; b) making, using, offering for sale, selling and/or marketing; and/or c) preparing to make, use, offer for sale, sell, and/or market Accused Products, including Zaltrap™ (but excluding Eylea™, which is addressed in the related case), in the United States, Defendants have infringed, are infringing and/or will infringe—directly, and/or by contributing to others' infringement of and/or by inducing others to infringe—one or more claims of the '071 patent, either literally and/or under the doctrine of equivalents.

40. Defendants' past, ongoing, and/or future infringement has damaged, is damaging, and/or will damage Genentech, which is entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts, including in loss of sales and profits, in an amount to be determined at trial, and in any event no less than a reasonable royalty.

41. Defendants' infringement has been, is, and/or will be willful, justifying an award to Genentech of increased damages under 35 U.S.C. § 284 and attorney's fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

42. Defendants' infringing activities have caused, are causing, and/or will cause Genentech to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Defendants' infringement is enjoined by this Court.

COUNT II
(Infringement and Declaratory Judgment of Infringement of the '486 Patent)

43. Genentech incorporates the allegations in Paragraphs 1-42 as if fully set forth herein.

44. By virtue of Defendants individually or under principles of privity: a) having made, used, offered for sale, sold and/or marketed; b) making, using, offering for sale, selling and/or marketing; and/or c) preparing to make, use, offer for sale, sell, and/or market Accused

Products, including Zaltrap™ (but excluding Eylea™, which is addressed in the related case), in the United States, Defendants have infringed, are infringing and/or will infringe—directly, and/or by contributing to others' infringement of and/or by inducing others to infringe—one or more claims of the '486 patent, either literally and/or under the doctrine of equivalents.

45. Defendants' past, ongoing, and/or future infringement has damaged, is damaging, and/or will damage Genentech, which is entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts, including in loss of sales and profits, in an amount to be determined at trial, and in any event no less than a reasonable royalty.

46. Defendants' infringement has been, is, and/or will be willful, justifying an award to Genentech of increased damages under 35 U.S.C. § 284 and attorney's fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

47. Defendants' infringing activities have caused, are causing, and/or will cause Genentech to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Defendants' infringement is enjoined by this Court.

COUNT III
(Infringement and Declaratory Judgment of Infringement of the '294 Patent)

48. Genentech incorporates the allegations in Paragraphs 1-47 as if fully set forth herein.

49. By virtue of Defendants individually or under principles of privity: a) having made, used, offered for sale, sold and/or marketed; b) making, using, offering for sale, selling and/or marketing; and/or c) preparing to make, use, offer for sale, sell, and/or market Accused Products, including Zaltrap™ (but excluding Eylea™, which is addressed in the related case), in the United States, Defendants have infringed, are infringing and/or will infringe—directly,

and/or by contributing to others' infringement of and/or by inducing others to infringe—one or more claims of the '294 patent, either literally and/or under the doctrine of equivalents.

50. Defendants' past, ongoing, and/or future infringement has damaged, is damaging, and/or will damage Genentech, which is entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts, including in loss of sales and profits, in an amount to be determined at trial, and in any event no less than a reasonable royalty.

51. Defendants' infringement has been, is, and/or will be willful, justifying an award to Genentech of increased damages under 35 U.S.C. § 284 and attorney's fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

52. Defendants' infringing activities have caused, are causing, and/or will cause Genentech to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Defendants' infringement is enjoined by this Court.

COUNT IV
(Infringement and Declaratory Judgment of Infringement of the '721 Patent)

53. Genentech incorporates the allegations in Paragraphs 1-52 as if fully set forth herein.

54. By virtue of Defendants individually or under principles of privity: a) having made, used, offered for sale, sold and/or marketed; b) making, using, offering for sale, selling and/or marketing; and/or c) preparing to make, use, offer for sale, sell, and/or market Accused Products, including Zaltrap™ (but excluding Eylea™, which is addressed in the related case), in the United States, Defendants have infringed, are infringing and/or will infringe—directly, and/or by contributing to others' infringement of and/or by inducing others to infringe—one or more claims of the '721 patent, either literally and/or under the doctrine of equivalents.

55. Defendants' past, ongoing, and/or future infringement has damaged, is damaging, and/or will damage Genentech, which is entitled to recover jointly or severally from Defendants the damages resulting from Defendants' wrongful acts, including in loss of sales and profits, in an amount to be determined at trial, and in any event no less than a reasonable royalty.

56. Defendants' infringement has been, is, and/or will be willful, justifying an award to Genentech of increased damages under 35 U.S.C. § 284 and attorney's fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

57. Defendants' infringing activities have caused, are causing, and/or will cause Genentech to suffer irreparable harm for which there is no adequate remedy at law. This harm will continue unless and until Defendants' infringement is enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Genentech requests that judgment be entered in its favor against Defendants:

1. Finding that Defendants: a) have directly infringed and/or will directly infringe; b) have actively induced and/or will actively induce others to infringe, and/or c) have engaged and/or will engage in acts that contribute to others infringing one or more claims of the '071, '486, '294, and '721 patents;

2. Finding that Defendants' infringement of the '071, '486, '294, and '721 patents was and/or is willful and deliberate;

3. If appropriate, taking into account the public interest in this controversy, such as the interests of medical practitioners and patients, enjoining Regeneron, the Sanofi entities, and their officers, agents, servants, employees, parents, subsidiaries, affiliates, successors, assignees, licensees, and attorneys, and all persons acting in concert or participation with them, from

infringing the '071, '486, '294, and '721 patents directly, by contributory infringement, and/or by actively inducing infringement;

4. Ordering Defendants to account for and pay to Genentech any and all damages caused by the infringement of one or more claims of the '071, '486, '294, and '721 patents;

5. Ordering Defendants to pay increased damages, up to treble damages to Genentech because of the willful nature of Defendants' infringement of one or more claims of the '071, '486, '294, and '721 patents;

6. Ordering that this case be declared an exceptional case under 35 U.S.C. § 285 and that Genentech be awarded its attorney's fees incurred in this action;

7. Ordering an award of Genentech's costs and expenses for this action, pre- and post-judgment interest on any money damages award, and any other charges to the maximum extent permitted;

8. Ordering such future relief as the Court deems just and proper under the circumstances.

JURY TRIAL DEMAND

Genentech demands a trial by jury of all issues so triable.

Dated: December 22, 2011

PAUL, WEISS, RIFKIND, WHARTON & GARRISON LLP

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