IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC., a Delaware corporation, Plaintiff, v. SANOFI, a French company; SANOFI-AVENTIS U.S. LLC, a Delaware limited liability company; AVENTISUB LLC, a Delaware limited liability company f/d/b/a AVENTIS PHARMACEUTICALS INC., a Delaware corporation; and REGENERON PHARMACEUTICALS, INC., a New York corporation, Defendants.	C.A. No. 14-1349-SLR JURY TRIAL DEMANDED

AMENDED COMPLAINT FOR PATENT INFRINGEMENT AND DECLARATORY JUDGMENT OF PATENT INFRINGEMENT

Plaintiff Amgen Inc. ("Amgen"), by its attorneys, alleges as follows for its Complaint for Patent Infringement and for a Declaratory Judgment of Patent Infringement against Sanofi; Sanofi-Aventis U.S. LLC; Aventisub LLC, formerly doing business as Aventis Pharmaceuticals Inc.; and Regeneron Pharmaceuticals, Inc. (collectively "Defendants"):

NATURE OF THE ACTION

1. This is an action for patent infringement and for a declaratory judgment of patent infringement of United States Patent Nos. 8,871,913 and 8,871,914. This action arises out of Defendants' current and/or imminent manufacture, use, sale, offer to sell within the United States, and/or importation to the United States, of Defendants' anti-PCSK9 antibody developed under the compound name "alirocumab" for treatment of dyslipidemia and other cholesterol disorders.

THE PARTIES

2. Plaintiff Amgen is a corporation organized under the laws of the State of Delaware with its principal place of business at One Amgen Center Drive, Thousand Oaks, California.

3. Amgen is a global biotechnology company committed to using discoveries in human biology to invent and develop new therapeutic products for the benefit of patients suffering from serious illness in areas of high unmet medical need. A biotechnology pioneer since 1980, Amgen's products are used by millions of patients around the world. Amgen has long been a leader in research and development of human therapeutics in the areas of metabolic disorders, nephrology, oncology, inflammation, and neurology. Amgen is extending its experience and leadership in these human therapeutic areas to address unmet medical needs in cardiovascular disease. Toward that end, Amgen has been investing in research and development to address important scientific questions, and to build a robust cardiology pipeline consisting of several investigational molecules, with the vision of improving the lives of patients with cardiovascular disease.

4. Upon information and belief, Defendant Sanofi ("Sanofi") is a company organized under the laws of France with its principal headquarters at 54 rue La Boétie, 75008 Paris, France.

5. Upon information and belief, Defendant Sanofi-Aventis U.S. LLC ("Sanofi U.S.") is a company organized under the laws of the State of Delaware with its principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807.

6. Upon information and belief, Defendant Aventisub LLC ("Aventisub") is a company organized under the laws of the State of Delaware having its principal place of business at 3711 Kennett Pike, Suite 200, Greenville, Delaware 19807. Upon information and belief,

Aventisub is the surviving entity from a June 2014 merger involving Aventis Pharmaceuticals Inc. (*see* Certificate of Merger attached as Exhibit 1 hereto) and has assumed the assets, liabilities, and/or responsibilities of Aventis Pharmaceuticals Inc. Upon information and belief, Aventis Pharmaceuticals Inc. was a corporation organized under the laws of the State of Delaware having a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Upon information and belief, the sole member of Aventisub is Aventis Inc., which operates as a subsidiary of Sanofi. This complaint refers to Aventisub and Aventis Pharmaceuticals Inc. collectively as "Aventis."

7. Upon information and belief, Sanofi U.S. is a wholly owned subsidiary of Defendant Sanofi.

8. Upon information and belief, Aventis is an indirect wholly owned subsidiary of Defendant Sanofi.

9. This complaint refers to Sanofi, Sanofi U.S., and Aventis collectively as "Sanofi Group."

10. Upon information and belief, Defendant Regeneron Pharmaceuticals, Inc. ("Regeneron") is a corporation organized under the laws of the State of New York with its principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591-6707.

JURISDICTION AND VENUE

11. This civil action for patent infringement arises under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.*, and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.*

12. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

13. This Court has personal jurisdiction over the Defendants at least by virtue of the fact that Defendants conduct business in the State of Delaware, have availed themselves of the rights and benefits under Delaware law, and have engaged in substantial and continuous contacts in the State of Delaware.

14. Upon information and belief, Sanofi is in the business of developing, formulating, manufacturing, marketing, and selling pharmaceutical drug products, including antibody products. Upon information and belief, Sanofi, directly or indirectly through its affiliates and agents, including but not limited to Sanofi U.S. and Aventis, markets and sells pharmaceutical products throughout the United States and in this judicial district. Upon information and belief, Sanofi has availed itself of this forum by filing suit in the District of Delaware, including, for example, *Sanofi v. Alembic Pharma. Ltd.*, 1:14-CV-00424-RGA; *Sanofi v. Alkem Labs Ltd.*, 1:14-CV-00292-RGA; *Sanofi v. Watson Labs., Inc.*, 1:14-CV-00265-RGA; *Sanofi v. Glenmark Generics Inc., USA*, 1:14-CV-00264-RGA; *Sanofi v. First Time US Generics LLC*, 1:14-CV-00293-RGA; *Sanofi v. Sun Pharma Global FZE*, 1:14-CV-00294-RGA; *Sanofi v. Amneal Pharma. LLC*, 1:14-CV-00875-RGA; and *Sanofi v. Unimark Remedies Ltd.*, 1:14-CV-00876-RGA.

15. Upon information and belief, Sanofi U.S. is organized in the State of Delaware.

16. Upon information and belief, Aventisub is organized in the State of Delaware and has its principal place of business in Delaware.

17. Upon information and belief, Aventisub's predecessor, Aventis Pharmaceuticals Inc., previously availed itself of this forum by filing suit in the District of Delaware, including, for example, *Aventis Pharmaceuticals Inc. v. Barr Labs, Inc.*, 1:06-CV-00286-GMS. Upon information and belief, Aventis Pharmaceuticals Inc. was incorporated in the State of Delaware.

18. Upon information and belief, Sanofi has directed or authorized the infringing activities of Sanofi U.S. and Aventis such that the infringing conduct by Sanofi U.S. and Aventis is attributable to Sanofi. Upon information and belief, the Sanofi Group defendants were at all times relevant the partners, officers, agents, assignees, successors-in-interest, co-conspirators, principals, alter egos, or employees of each other or were otherwise responsible for, contributed to, or participated in the acts of infringement alleged herein, and thereby incurred liability therefore. For example, as detailed further in paragraphs 38-44, *infra*, the collaboration and license agreements between Aventis and Regeneron state that Aventis is a wholly owned subsidiary of Sanofi, which is a statement that Sanofi exercises dominion and control over Aventis.

19. Upon information and belief, Regeneron is registered as a foreign corporation to conduct business in the State of Delaware. Per its registration, Regeneron has a Registered Office in the State of Delaware, is in good standing, and filed an annual report in 2013.

20. Upon information and belief, Regeneron is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug and biologic products, including antibody products. Upon information and belief, Regeneron, directly or indirectly, including through its affiliates and agents including Sanofi Group, currently markets and sells pharmaceutical drug and biologics products throughout the United States and in this judicial district.

21. Upon information and belief, Regeneron, directly or indirectly, through its affiliates and agents including Sanofi Group, intends to market and sell alirocumab throughout the United States and in this judicial district.

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

THE PATENTS-IN-SUIT

23. On October 28, 2014, United States Patent No. 8,871,913 ("the '913 Patent") entitled "Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9)" issued to Amgen as assignee of the named inventors Simon Mark Jackson, Nigel Pelham Clinton Walker, Derek Evan Piper, Wenyan Shen, Chadwick Terence King, Randal Robert Ketchem, Christopher Mehlin, and Teresa Arazas Carabeo. A copy of the '913 Patent is attached as Exhibit 2.

24. On October 28, 2014, United States Patent No. 8,871,914 ("the '914 Patent") entitled "Antigen binding proteins to proprotein convertase subtilisin kexin type 9 (PCSK9)" issued to Amgen as assignee of the named inventors Simon Mark Jackson, Nigel Pelham Clinton Walker, Derek Evan Piper, Wenyan Shen, Chadwick Terence King, Randal Robert Ketchem, Christopher Mehlin, and Teresa Arazas Carabeo. A copy of the '914 Patent is attached as Exhibit 3.

25. The '913 and '914 Patents (collectively the "patents-in-suit") have been owned by Amgen at all times, are fully maintained, and are valid and enforceable.

BACKGROUND

A. DYSLIPIDEMIA AND AMGEN'S ANTI-PCSK9 ANTIBODY PRODUCT FOR TREATMENT OF HIGH CHOLESTEROL: EVOLOCUMAB

26. Dyslipidemia is a condition that contributes to the development of atherosclerosis. Dyslipidemia is marked by elevated blood plasma levels of low-density lipoprotein cholesterol ("LDL-C" or "bad cholesterol"), triglycerides, or both, or a low high-density lipoprotein level. Some dyslipidemia patients carry a genetic risk for this condition. There are approximately 300 million cases of dyslipidemia in the United States, Japan, and Western Europe. More than 71

million American adults have high LDL-C, which is recognized as a major risk factor for cardiovascular disease.

27. For the last two decades, a primary treatment for dyslipidemia has included administration of a class of drugs known as statins. There has remained, however, an unmet medical need for improved dyslipidemia therapy because a large residual risk remains for the development of atherosclerotic cardiovascular disease in patients taking statins. Moreover, a significant percentage of patients taking statins experience intolerable or dose-limiting side effects that preclude those patients from reaching their cholesterol-lowering goals.

28. More than nine years ago, Amgen embarked on a research path that led to the innovative work behind the design and elucidation of fully human monoclonal antibodies to treat dyslipidemia.

29. This new class of potential therapeutic targets proprotein convertase subtilisin/kexin type 9 ("PCSK9"). PCSK9 is a protein found in the human body that reduces the liver's ability to remove LDL-C from the blood. PCSK9 does this by targeting for degradation a protein found on the surface of the liver called the low-density lipoprotein receptor ("LDL-receptor" or "LDL-R"). When LDL-receptors are degraded, they are no longer available to remove LDL-C from the blood. By contrast, when PCSK9 is removed, there is an increase in the number of LDL-receptors available to remove LDL-C from the blood, thus lowering the "bad cholesterol."

30. Amgen's investigational therapeutic antibody prevents PCSK9 from productively interacting with LDL-receptors on the liver surface. The number of LDL-receptors on the surface of the liver thereby increases. And with that increase, improved LDL-C removal from the blood can be achieved.

31. The compound name for Amgen's antibody product is "evolocumab." Clinical evaluations evidencing LDL-C lowering have been completed with respect to several patient populations, including those who cannot achieve LDL-C lowering objectives with statins alone, those whose cannot tolerate statins, and those with genetic diseases such as familial hypercholesterolemia. For example, one clinical study showed that the addition of evolocumab to moderate or high doses of statins lowers LDL-C levels over administration of statins alone. Another study showed that the mean LDL-C in patients with high cholesterol who cannot tolerate effective doses of statins was significantly reduced with evolocumab when compared to statin. Yet another study showed that patients with homozygous familial hypercholesterolemia, a rare and serious genetic disorder characterized by severely elevated LDL-C at an early age, showed clinically meaningful and statistically significant reduction in LDL-C with evolocumab in combination with a stable dose of statin therapy or other lipid-lowering medication, as compared to placebo.

32. Through additional on-going clinical testing, Amgen is further developing evolocumab as a potential treatment that, when used in conjunction with other treatments for dyslipidemia, will be well tolerated and decreases the risk of cardiovascular death, myocardial infarction, hospitalization for unstable angina, stroke, or coronary revascularization in subjects with clinically evident cardiovascular disease.

B. AMGEN'S COMMITMENT TO SUPPLYING THE U.S. PATIENT POPULATION WITH EVOLOCUMAB UPON FDA APPROVAL

33. A company seeking to market a biological product for human therapeutic use in the United States must first obtain a license from the U.S. Food and Drug Administration ("FDA"), typically through the filing of a Biologics License Application ("BLA"). *See* 42 U.S.C. § 262. The BLA, among other things, comprises technical data on the composition of the

biologic, the means for its manufacturing, clinical trial results to establish the safety and efficacy of the biologic, and labeling for use of the biologic for which approval is requested. *See* 21 C.F.R. §§ 601 *et seq.*

34. On August 28, 2014, Amgen submitted a Biologics License Application to the FDA seeking approval to market evolocumab for the treatment of high cholesterol. According to FDA performance goals, the standard time for FDA to review and act on new BLAs is ten months from FDA acceptance of the BLA for review.

35. Amgen's regulatory submission for evolocumab in the United States reflects the achievement of an important milestone in the clinical development of this antibody product candidate. Indeed, the evolocumab BLA contains data from approximately 6,800 patients, including more than 4,500 patients with high cholesterol across ten Phase 3 clinical trials. Those Phase 3 studies evaluated the safety and efficacy of evolocumab in patients with elevated cholesterol on statins with or without other lipid-lowering therapies; patients who cannot tolerate statins; patients with heterozygous familial hypercholesterolemia; and patients with homozygous familial hypercholesterolemia, a rare and serious genetic disorder.

36. Amgen leverages its biologics manufacturing expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. This circumstance is particularly true in the case of evolocumab. Amgen has made significant investments in its manufacturing facilities for evolocumab and is prepared and equipped to supply evolocumab to meet the US marketplace demand for therapeutic monoclonal antibodies to PCSK9.

37. In addition, Amgen has made meaningful preparations to commercialize evolocumab once it is approved, including the development of an in-house marketing team for evolocumab and hiring a dedicated sales force. Finally, Amgen is continuing its clinical development program for evolocumab with the goal of ultimately reaching other U.S. patients

suffering from cardiovascular disease who might benefit from evolocumab's cholesterol-lowering capabilities.

C. DEFENDANTS' CURRENT STOCKPILING AND IMMINENT COMMERCIAL SALE IN THE UNITED STATES HAS CREATED A REAL AND IMMEDIATE CONTROVERSY BETWEEN DEFENDANTS AND AMGEN

1. Sanofi Group and Regeneron's Intentions to Market a Competing Anti-PCSK9 Antibody Known as Alirocumab in the United States

38. Upon information and belief, since at least November 2007, Sanofi Group and Regeneron have collaborated on the research and development of antibody product candidates for commercial sale in the United States upon FDA licensure. That collaboration was initially governed by a License and Collaboration Agreement executed on November 28, 2007 by Regeneron on the one hand, and Aventis Pharmaceuticals Inc. and a third entity, Sanofi Amérique du Nord, on the other. Upon information and belief, Sanofi Amérique du Nord is a partnership organized under the laws of France that was and is responsible for causing Regeneron to be paid whatever monies are owed to Regeneron under the terms of this agreement. Concurrently with the execution and delivery of that agreement on November 28, 2007, Regeneron and Aventis Pharmaceuticals Inc. also entered into a Discovery and Preclinical Development Agreement. Pursuant to these agreements, and upon information and belief, Regeneron uses its VelocImmune® technology and related technologies to discover product candidates that Sanofi Group may elect to advance into further development.

39. Upon information and belief, on November 10, 2009, Regeneron and Aventis Pharmaceuticals executed an "Amended and Restated License and Collaboration Agreement" setting forth amended terms under which Sanofi Group and Regeneron would jointly develop antibody product candidates. Also upon information and belief, Regeneron, Aventis

Pharmaceuticals Inc., and Sanofi Amérique du Nord concurrently executed an "Amended and Restated Discovery and Preclinical Development Agreement" on November 10, 2009.

40. This complaint collectively refers to the 2007 and 2009 agreements referenced in paragraphs 38-39 above as the "2007 and 2009 Agreements."

41. Upon information and belief, the 2007 and 2009 Agreements state that Aventis Pharmaceuticals Inc. (which the agreements abbreviate as "Sanofi") is an indirect wholly owned subsidiary of Sanofi.

42. Upon information and belief, subsequent to Amgen beginning its research efforts that ultimately led to evolocumab, Sanofi Group and Regeneron initiated development of a fully human monoclonal antibody product candidate against PCSK9 called "alirocumab" (also called "REGN727" and "SAR236553") as a co-developed drug candidate under the 2007 and 2009 Agreements.

43. Upon information and belief, alirocumab is a monoclonal antibody to PCSK9 that is reported to block the interaction of PCSK9 with LDL receptors and increase the recycling of LDL receptors and reduces LDL cholesterol levels in the blood.

44. Upon information and belief, alirocumab is a monoclonal antibody as claimed in Amgen's '913 and '914 Patents.

2. Defendants' Manufacture of Alirocumab for Commercial Sale and Seeking of FDA Approval of Alirocumab on an Expedited Timeline for Sale within the United States

45. Upon information and belief, Sanofi Group and Regeneron have pursued the clinical development of alirocumab with the goal of launching it for sale in the United States and worldwide marketplace. For example, as early as July 20, 2012, Sanofi Group announced the creation of a dedicated PCSK9 Development and Launch Unit in tandem with beginning its Phase 3 clinical trial program.

46. Defendants have hailed the creation of the dedicated PCSK9 Development and Launch Unit as underscoring Sanofi's commitment to develop alirocumab.

47. Upon information and belief, Sanofi Group and Regeneron initially intended to seek regulatory approval for alirocumab in 2015 in the United States and Europe upon receiving positive clinical trial data during 2014. But on July 30, 2014, the companies announced that regulatory submissions are expected in the U.S. and EU by the end of 2014. Submission of a BLA for approval by FDA is a necessary prerequisite to offering alirocumab for sale in the United States. (*See* paragraph 33, *supra*.)

48. Also on July 30, 2014, Sanofi Group and Regeneron announced they had taken the unusual step of jointly purchasing for $67.5 million a special FDA priority review voucher from BioMarin Pharmaceuticals Inc., a third party that had obtained the voucher under an FDA program intended to encourage the development of treatments for rare pediatric diseases. Defendants further announced their intent to use that voucher to expedite Agency consideration of the BLA for alirocumab. According to Sanofi Group and Regeneron, use of this priority review voucher will require the FDA to respond to the BLA submission for alirocumab within six months from the filing date instead of the standard ten-month review.

49. Upon information and belief, Sanofi Group and Regeneron announced on August 31, 2014 that the companies had successfully concluded ten Phase 3 clinical trials on alirocumab encompassing more than 5,000 patients.

50. Upon information and belief, Sanofi Group and Regeneron have completed all of the Phase 3 clinical trials that the companies believe they need for a BLA submission covering alirocumab. For example, on September 3, 2014, Regeneron's Founder, President, and Chief Executive Officer, Dr. Len Schleifer, informed the investing public:

> Basically, alirocumab, we have completed the basic Phase 3 program that we will need, we believe, for filing, which we will file before the end of the year. We expect to use our recently-acquired voucher to get us a priority review. Therefore, if all goes well, sometime the second half of next year we might be able to launch the product in the United States.

51. Taken together, and upon information and belief, Sanofi Group and Regeneron will submit a Biologics License Application to FDA before the end of 2014 seeking approval to market alirocumab in the United States. When making that submission, the companies will use the $67.5 million priority review voucher to reduce the FDA review time and thereby even further accelerate actual entry of alirocumab to the domestic marketplace.

52. Upon information and belief, Sanofi Executive Vice President and Chief Operating Officer Jerome Contamine recently informed the investing public that:

> We plan to file both in the US and the EU by the end of 2014. We have also acquired a voucher which gives us priority review in the US, so we think that we really can accelerate to the maximum possible not only the filing but hopefully the approval to be ready to launch somewhere in 2015.

53. Upon information and belief, Sanofi Group and Regeneron are now preparing to launch alirocumab for commercial sale in the United States marketplace with the intention of doing so by the second half of 2015.

54. Upon information and belief, Regeneron's Senior Vice President of Finance and Chief Financial Officer, Bob Landry, informed the investing public on September 8, 2014 that "the launch of alirocumab [is] coming up."

55. Upon information and belief, on June 24, 2014, Sanofi filed with the U.S. Trademark Office an application for its intent to use the mark "Praluent" in commerce in connection with a cardiovascular pharmaceutical product or service. Upon information and belief, Defendants intend to market alirocumab to doctors and patients under the brand name "Praluent."

56. Upon information and belief, Defendants' current preparations for the launch of alirocumab in the United States at least include manufacturing alirocumab product for commercial sale in the United States.

57. Upon information and belief, Sanofi Executive Vice President and Chief Operating Officer Mr. Contamine informed the investing public on September 18, 2014 that "[w]e are building inventory just now so that we can take care of a few hundred thousand [patients] in the first two years" after launch.

58. Mr. Contamine also informed the investing public that Sanofi is readying a U.S.-based salesforce to sell and offer to sell alirocumab into the domestic marketplace. He stated that Sanofi "can leverage our diabetes salesforce" and to "[k]eep in mind that, in the US, we have kept the salesforce intact."

59. Upon information and belief, and as stated in regulatory filings and in statements to the investing public, Sanofi Group and Regeneron assert that Amgen's evolocumab is a competitor molecule to its clinical candidate to PCSK9, *i.e.*, alirocumab.

60. In sum, Regeneron and its development and commercialization partner Sanofi have, within the United States, manufactured the alirocumab antibody product that infringes Amgen's '913 and '914 Patents. Upon information and belief, Defendants intend to use that manufactured product for commercial sale in the United States.

61. Further, Regeneron and its development and commercialization partner Sanofi Group have made actual and real preparations to file a Biologics License Application with FDA this quarter (Q4 2014) seeking approval to market alirocumab in the United States utilizing its priority review voucher, which provides for FDA review on an accelerated basis. Upon information and belief, FDA approval of that Biologics License Application would permit Defendants to further infringe Amgen's '913 and '914 Patents by making, using, offering to sell,

and selling alirocumab within the United States, and by importing alirocumab into the United States, before the expiration of the Amgen patents. Upon FDA approval, the infringing alirocumab product will compete with Amgen's evolocumab in the domestic marketplace.

62. Upon offering to sell and selling alirocumab in the United States, Defendants' infringing acts as described herein will immediately and irreparably harm Amgen.

FIRST CAUSE OF ACTION
(Infringement of the '913 Patent)

63. Amgen realleges and incorporates by reference the allegations contained in paragraphs 1 – 62.

64. On information and belief, Defendants have infringed the '913 Patent, pursuant to 35 U.S.C. § 271(a), (b), or (c) by engaging in the commercial manufacture, use, offer to sell, sale, or importation of alirocumab prior to the expiration of the '913 Patent.

65. Amgen will be substantially and irreparably harmed if Defendants are not enjoined from infringing the '913 Patent.

66. Amgen has no adequate remedy at law.

67. This case is exceptional, and Amgen is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

SECOND CAUSE OF ACTION
(Infringement of the '914 Patent)

68. Amgen realleges and incorporates by reference the allegations contained in paragraphs 1 – 62.

69. On information and belief, Defendants have infringed the '914 Patent, pursuant to 35 U.S.C. § 271(a), (b), or (c) by engaging in the commercial manufacture, use, offer to sell, sale, or importation of alirocumab prior to the expiration of the '914 Patent.

70. Amgen will be substantially and irreparably harmed if Defendants are not enjoined from infringing the '914 Patent.

71. Amgen has no adequate remedy at law.

72. This case is exceptional, and Amgen is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

THIRD CAUSE OF ACTION
(Declaratory Judgment of Infringement of the '913 Patent)

73. Amgen realleges and incorporates by reference the allegations contained in paragraphs 1 – 62.

74. On information and belief, Defendants' contemplated imminent submission of a Biologics License Application to FDA seeking approval to market alirocumab in the United States on an accelerated basis, coupled with Defendants' preparations to actually launch alirocumab for sale to the domestic marketplace upon receiving that approval, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Defendants will directly or indirectly infringe valid and enforceable claims of the '913 Patent prior to its expiration.

75. A judicial declaration of infringement is necessary and appropriate to resolve this controversy.

76. Amgen will be substantially and irreparably harmed if Defendants are not enjoined from infringing the '913 Patent.

77. Amgen has no adequate remedy at law.

78. This case is exceptional, and Amgen is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

FOURTH CAUSE OF ACTION
(Declaratory Judgment of Infringement of the '914 Patent)

79. Amgen realleges and incorporates by reference the allegations contained in paragraphs 1 – 62.

80. On information and belief, Defendants' contemplated imminent submission of a Biologics License Application to FDA seeking approval to market alirocumab in the United States on an accelerated basis, coupled with Defendants' preparations to actually launch alirocumab for sale to the domestic marketplace upon receiving that approval, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Defendants will directly or indirectly infringe valid and enforceable claims of the '914 Patent prior to its expiration.

81. A judicial declaration of infringement is necessary and appropriate to resolve this controversy.

82. Amgen will be substantially and irreparably harmed if Defendants are not enjoined from infringing the '914 Patent.

83. Amgen has no adequate remedy at law.

84. This case is exceptional, and Amgen is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Amgen prays for judgment against Defendants Sanofi; Sanofi-Aventis U.S. LLC; Aventisub LLC, formerly doing business as Aventis Pharmaceuticals Inc.; and Regeneron Pharmaceuticals, Inc., and respectfully requests the following relief:

1. A judgment that the '913 and '914 Patents have been infringed and will be infringed by Defendants;

2. A judgment for an injunction enjoining each Defendant, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from manufacturing, using, offering to sell, or selling alirocumab within the United States, or importing alirocumab into the United States, prior to the expiration of the '913 and/or '914 Patents pursuant to 35 U.S.C. § 283;

3. To the extent that Defendants have or will commercially manufacture, use, offer to sell, or sell alirocumab within the United States, or import alirocumab into the United States, prior to the expiration of any of the '913 and/or '914 Patents, including any extensions, a judgment awarding Amgen monetary relief together with interest;

4. A judgment that this is an exceptional case and that Amgen be awarded its attorneys' fees incurred in this action pursuant to 35 U.S.C. § 285;

5. Costs and expenses in this action; and

6. Such other and further relief as the Court deems just and appropriate.

JURY DEMAND

Amgen hereby demands a jury trial on all issues appropriately triable by a jury.

/s/ Melanie K. Sharp

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