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AMGEN INC.

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

AMGEN INC.,

Plaintiff,

v.

GENENTECH, INC. and CITY OF HOPE,

Defendants.

Case No. 17-cv-7349

COMPLAINT FOR DECLARATORY JUDGMENT OF PATENT NON-INFRINGEMENT, INVALIDITY, AND UNENFORCEABILITY

Plaintiff Amgen Inc. ("Amgen") brings this action for declaratory judgment of patent non-infringement, invalidity, and unenforceability against Defendants Genentech, Inc. ("Genentech") and City of Hope. Amgen alleges as follows:

NATURE OF THE CASE

1. This is an action for declaratory judgment of non-infringement, invalidity, and unenforceability relating to the following patents:

(i) U.S. Patent No. 6,054,297 ("the '297 patent");

(ii) U.S. Patent No. 6,121,428 ("the '428 patent");

(iii) U.S. Patent No. 6,242,177 ("the '177 patent");

(iv) U.S. Patent No. 6,331,415 ("the '415 patent");

(v) U.S. Patent No. 6,407,213 ("the '213 patent");

(vi) U.S. Patent No. 6,417,335 ("the '335 patent");

(vii) U.S. Patent No. 6,586,206 ("the '206 patent");

(viii) U.S. Patent No. 6,610,516 ("the '516 patent");

(ix) U.S. Patent No. 6,620,918 ("the '918 patent");

(x) U.S. Patent No. 6,870,034 ("the '034 patent");

(xi) U.S. Patent No. 6,884,879 ("the '879 patent");

(xii) U.S. Patent No. 7,060,269 ("the '269 patent");

(xiii) U.S. Patent No. 7,169,901 ("the '901 patent");

(xiv) U.S. Patent No. 7,297,334 ("the '334 patent");

(xv) U.S. Patent No. 7,323,553 ("the '553 patent");

(xvi) U.S. Patent No. 7,375,193 ("the '193 patent");

(xvii) U.S. Patent No. 7,622,115 ("the '115 patent");

(xviii) U.S. Patent No. 7,807,799 ("the '799 patent");

(xix) U.S. Patent No. 7,923,221 ("the '221 patent");

(xx) U.S. Patent No. 8,044,017 ("the '017 patent");

(xxi) U.S. Patent No. 8,460,895 ("the '895 patent");

(xxii) U.S. Patent No. 8,512,983 ("the '983 patent");

(xxiii) U.S. Patent No. 8,574,869 ("the '869 patent");

(xxiv) U.S. Patent No. 8,633,302 ("the '302 patent");

(xxv) U.S. Patent No. 8,710,196 ("the '196 patent");

(xxvi) U.S. Patent No. 9,441,035 ("the '035 patent"); and

(xxvii) U.S. Patent No. 9,487,809 ("the '809 patent") (collectively, "the patents-in-suit").

2. According to Genentech, the patents-in-suit relate to an antibody product called bevacizumab, which Genentech markets under the brand name Avastin®. Avastin® is approved by the FDA for the treatment of several types of cancer.

3. A substantial controversy exists between Amgen, on the one hand, and Genentech and City of Hope, on the other hand, in which the parties have adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. Amgen submitted an application to the FDA under 42 U.S.C. § 262(k) for licensure of a bevacizumab biological product (hereinafter, "biosimilar product," "ABP 215," or "Mvasi™") that is highly similar to the Avastin® brand of bevacizumab. Amgen provided Genentech with a copy of its application and in response, Genentech identified the patents-in-suit, which Genentech alleges could reasonably be asserted against Amgen if it were to manufacture, use, offer for sale, or sell in the United States, or import into the United States, its biosimilar product. In addition, Genentech provided Amgen with a statement purporting to contain the factual and legal basis of Genentech's opinion that the patents-in-suit would be infringed by the commercial marketing of Amgen's biosimilar product. Finally, Genentech has asserted that patents-in-suit have been infringed by the manufacture and/or use of Amgen's bevacizumab biological product for uses that were not reasonably related to the development and submission of information to the FDA.

The FDA approved Amgen's biosimilar product, Mvasi™, for commercial marketing on September 14, 2017. Pursuant to 42 U.S.C. § 262(*l*)(8)(A) and on October 6, 2017, Amgen provided Genentech with notice that the first commercial marketing of Amgen's Mvasi™ brand of bevacizumab will commence not earlier than 180 days from the date of notice.

PARTIES

4. Amgen Inc. 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, CA 91320.

5. Genentech, Inc. is a corporation organized under the laws of the State of Delaware, with its principal place of business at 1 DNA Way, South San Francisco, CA 94080.

6. On information and belief, Defendant City of Hope is a not-for-profit organization organized and existing under the laws of California, having its principal place of business in this District at 1500 East Duarte Road, Duarte, California 91010.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202, as well as 35 U.S.C. § 271(e)(2). Amgen provided to Genentech the application and information required under 42 U.S.C. § 262(*l*)(2)(A). And in response, Genentech identified the patents-in-suit pursuant to 42 U.S.C. § 262(*l*)(3)(A), which Genentech alleges could reasonably be asserted against Amgen if it were to manufacture, use, offer for sale, or sell in the United States, or import into the United States, its biosimilar product. On October 6, 2017, Amgen provided notice of commercial marketing to Genentech pursuant to 42 U.S.C. § 262(*l*)(8)(A).

8. The Court has personal jurisdiction over Genentech because Genentech has its headquarters and principal place of business in the State of California. Genentech also maintains multiple other facilities in California. Upon information and belief, Genentech markets, distributes and sells pharmaceutical products, including Avastin®, in California. Genentech's continuous corporate operations within California are so substantial and of such a nature to justify suit against it on causes of action arising from dealings entirely distinct from those activities.

9. The Court also has personal jurisdiction over Genentech because, among other reasons, Genentech's activities in California are continuous and systematic and gave rise to this action. For example, Genentech has sent to Amgen (i) notice letters, (ii) a list of patents that it purports could reasonably be asserted against Amgen, and (iii) a statement that purports to describe, among other things, the factual and legal basis of Genentech's opinion that patents that it owns, or for which it is an exclusive licensee, will be infringed by the commercial marketing of Amgen's biosimilar product, all within this District and the State of California. Genentech has also engaged in other activities in California relating to the enforcement of the patents-in-suit, including an in-person meeting with Amgen in this District to determine which, if any, patents should be the subject of an action for patent infringement under 42 U.S.C. § 262(*l*)(6).

10. The Court has personal jurisdiction over City of Hope because, among other reasons, upon information and belief, it is organized under the laws of the State of California and has its principal place of operations in this District in California. Upon information and belief, City of Hope is the co-owner of one or more patents-in-suit.

11. Venue is proper in this district pursuant to 28 U.S.C. § 1391 because, among other reasons, upon information and belief, City of Hope resides in this judicial district. Also, Genentech has directed at Amgen certain activities in this

District relating to the enforcement of the patents-in-suit, including the transmission of (i) notice letters, (ii) a list identifying the patents-in-suit among those patents that Genentech believes could reasonably be asserted against Amgen following the submission of its subsection (k) application, and (iii) a statement that purports to describe Genentech's opinions regarding the infringement, validity, and enforceability of the patents-in-suit. Genentech also attended an in-person meeting with Amgen in this District to determine which, if any, patents should be the subject of an action for patent infringement. Both Genentech and City of Hope have litigated in this District at least 11 separate actions relating to patents-in-suit, including those having civil action numbers 2-16-cv-04992, 2-15-cv-09991, 2-15-cv-05685, 2-13-cv-07248, 2-13-cv-05400, 2-11-cv-06594, 2-11-cv-03065, 2-11-cv-06519, 2-10-cv-02764, 2-08-cv-03573, and 2-03-cv-02567. Furthermore, a substantial part of the events giving rise to Genentech's assertions that Amgen has infringed the patents-in-suit occurred in this District. Amgen, a resident of this District, prepared and filed its application for its biosimilar product pursuant to 42 U.S.C. § 262(k) ("subsection (k)" application) from within this District. Amgen also has conducted substantial activities, including correspondence with the FDA, in furtherance of its subsection (k) application from within this District. Amgen also has performed substantial activities in this District relating to the development, manufacture, and future commercial marketing of its biosimilar product.

FACTUAL BACKGROUND

12. Amgen has been a biotechnology pioneer since 1980, discovering, developing, manufacturing, and delivering innovative and important human therapeutic products. Since its inception, Amgen has focused on the development of biologic drugs. Unlike most traditional drugs that are synthesized chemically and have a known structure, biologic drugs are "complex mixtures that are not easily identified or characterized" and represent "the cutting-edge of biomedical research."

FDA, What are "Biologics" Questions and Answers (Aug. 5, 2015), http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cber/ucm133077.htm. Because of their complexity, biologic drugs require substantially more effort, monetary resources and technical expertise to develop than traditional drugs that are synthesized chemically.

13. Over the last nearly 40 years and still today, Amgen's unparalleled experience and expertise in biologics research, development and manufacture has enabled it to develop biologic drugs to treat serious illnesses where there has previously been unmet medical needs and limited treatment options. These medicines have dramatically changed the treatment of disease and the lives of patients with these life-altering and life-threatening diseases. Since its inception, Amgen has developed a number of biologic medicines that have changed the standard of care, two of which have been named Product of the Year by Fortune Magazine and many which have received scientific and industry awards in recognition of Amgen's innovation. Over the last twenty years alone, Amgen received FDA approval of at least thirteen drugs that have addressed serious illnesses of patients.

14. In 2011, Amgen announced that it would develop and commercialize several oncology antibody biosimilar drugs, including biosimilar versions of Genentech's Avastin®, Herceptin®, and Rituxan®. In the announcement, Amgen recognized that "the development and commercialization of biosimilar products will not follow a pure brand or generic model, and will require significant expertise, infrastructure, and investment to ensure safe, reliably supplied therapies for patients." Amgen and Watson Announce Collaboration to Develop and Commercialize Oncology Biosimilars, Media Release (Dec. 19, 2011), http://www.amgenbiosimilars.com/media/media-releases/2011/12/amgen-and-

watson-announce-collaboration-to-develop-and-commercialize-oncology-biosimilars/.

15. Since its original announcement regarding biosimilars, Amgen has devoted significant time, effort, and substantial monetary resources to the development of Mvasi™. With its deep experience in biologics development and manufacture, Amgen developed materials that have been and will be used to make Mvasi™, including its proprietary cell line and cell culture used to produce the antibody that is the active ingredient of Mvasi™ ("Mvasi™ antibody"). Amgen also designed the manufacturing process and process controls that have been and will be used to make Mvasi™, including, among other things, developing the cell culture, harvest, and numerous purification steps to manufacture and purify the Mvasi™ antibody. Amgen also conducted numerous clinical studies in which it successfully tested Mvasi™ in humans. In the end, Amgen generated comprehensive analytical, pharmacokinetic, pharmacodynamic and clinical data that was submitted to the FDA as part of the FDA-approval process and that is the basis for the FDA's ultimate approval of Mvasi™.

Congress Enacts Legislation Creating a Regulatory Pathway for Biosimilar Biological Products

16. By amending the Public Health Service Act, the Patent Act, and the Declaratory Judgment Act, and through the Biologics Price Competition and Innovation Act of 2009 (the "BPCIA"), Congress created a new pathway for FDA review and approval of "biosimilar" biological products, as well as new mechanisms to resolve patent disputes that may arise with respect to such products.

17. "The BPCIA governs a type of drug called a biosimilar, which is a biologic product that is highly similar to a biologic product that has already been approved by the Food and Drug Administration (FDA)." *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1669 (2017).

18. The BPCIA sets forth an abbreviated pathway for FDA approval of biosimilars. 42 U.S.C. § 262(k). To obtain approval through the BPCIA's abbreviated process, an applicant must show that its biosimilar product is "highly similar" to the reference product and that there are no "clinically meaningful differences" between the two products in terms of "safety, purity, and potency." 42 U.S.C. § 262(k)(2). Under the BPCIA, an applicant may not submit an application until 4 years after the reference product is first licensed, and the FDA may not license a biosimilar until 12 years after the reference product is first licensed. 42 U.S.C. § 262(k)(7).

19. The reference product sponsor may have patents relating to the biological product, as well as therapeutic uses for and/or processes used to manufacture the biological product, that it believes may be relevant to the biosimilar product. In recognition that there may be patent disputes between the reference product sponsor and the biosimilar applicant, "[t]he BPCIA sets forth a carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of [patent] infringement." *Sandoz*, 137 S. Ct. at 1671 (citing 42 U.S.C. § 262(*l*)).

20. The BPCIA describes a process whereby the reference product sponsor and the biosimilar applicant exchange information in advance of a specific and statutorily prescribed action for patent infringement. *First*, the process begins when the applicant provides "a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application." 42 U.S.C. § 262(*l*)(2)(A). In addition, the applicant "may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor." 42 U.S.C. § 262(*l*)(2)(B). *Second*, the BPCIA states that the reference product sponsor shall provide "a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be

asserted by the reference product sponsor . . . if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application." 42 U.S.C. § 262(*l*)(3)(A). *Third*, the BPCIA requires the applicant to provide a "detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application." 42 U.S.C. § 262(*l*)(3)(B)(ii)(I). Alternatively, the applicant can provide "a statement that the subsection (k) applicant does not intend to begin commercial marketing of the biological product before the date that such patent expires." 42 U.S.C. § 262(*l*)(3)(B)(ii)(II). *Last*, the BPCIA states that the reference product sponsor "shall provide to the subsection (k) applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I)." 42 U.S.C. § 262(*l*)(3)(C).

21. Following the information exchange, the BPCIA requires the reference product sponsor and the applicant to engage in "good faith negotiations to agree on which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6) [of the statute]." 42 U.S.C. § 262(*l*)(4). If agreement cannot be reached, the statute provides for a mechanism of further exchanges to determine which patent(s) will be the subject of a paragraph (6) patent litigation. 42 U.S.C. § 262(*l*)(4)(B)-(5). While the procedure and timing depend on

whether the reference product sponsor and the applicant can reach agreement, the process may result in a statutorily defined action for patent infringement. 42 U.S.C. § 262(*l*)(6).

22. Paragraph (*l*)(8) of the BPCIA states that "[t]he subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A). Once the applicant's notice of commercial marketing is received by the reference product sponsor, any limitation under the BPCIA on bringing an action under section 2201 of title 28 for a declaration of rights concerning patent infringement, validity and/or enforceability is lifted. 42 U.S.C. § 262(*l*)(9).

The Parties' Exchanges Following the Filing of Amgen's Subsection (k) Application for Approval of Its Biosimilar Product

23. According to the FDA's "Purple Book," Genentech's Avastin® brand of bevacizumab was first approved on February 26, 2004.

24. On November 14, 2016, Amgen filed its Biologics License Application ("BLA") for Mvasi™ pursuant to 42 U.S.C. § 262(k). Amgen's BLA was filed after the expiration of the 4 year and 12 year statutory periods provided by 42 U.S.C. § 262(k)(7). Amgen received notification from the FDA that its BLA had been accepted for review on January 4, 2017.

25. Genentech wrote a letter to Amgen following the FDA's acceptance of Amgen's BLA. In this letter, dated January 13, 2017, Genentech requested vaguely defined information relating to the processes used in the production of Mvasi™ "irrespective of whether it is contained in the aBLA." The letter also purported to include "exemplary citations" to approximately 30 patents, including several which, upon information and belief, were not assigned or exclusively licensed to Genentech.

26. One week later, on January 20, 2017, Amgen timely sent to Genentech its disclosure pursuant to 42 U.S.C. § 262(*l*)(2)(A). Amgen's § 262(*l*)(2)(A) disclosure contained, *inter alia*, extensive information regarding the manufacturing processes used to make Mvasi™. In fact, Amgen provided Genentech more than a million pages of technical details and batch records describing, among other things, (i) the source, history, and generation of the cell substrate, (ii) the cell culture and harvest process, (iii) each and every purification process step, and (iv) the raw materials used during the manufacture of Mvasi™.

27. Together with Amgen's § 262(*l*)(2)(A) disclosure, Amgen sent a letter to Genentech communicating Amgen's good-faith belief that its disclosure contained sufficiently detailed information regarding its biosimilar product and manufacturing processes, which "satisfie[d] Amgen's production obligations under 42 U.S.C. § 262(*l*)(2)(A) and enable[d] Genentech to undertake its obligations under 42 U.S.C. § 262(*l*)(3)(A)."

28. Thereafter, the parties exchanged additional correspondence. Genentech continued to insist that Amgen had an obligation to produce "all" documents relating to its manufacturing processes, regardless of whether the information was provided in or duplicative of the information already provided in Amgen's § 262(*l*)(2)(A) disclosure.

29. Amgen communicated its willingness to reasonably cooperate with Genentech in response to specific requests for non-cumulative information if Genentech believed it needed additional information to assist it in fulfilling its § 262(*l*)(3)(A) duties. Amgen wrote the following to Genentech in a letter dated January, 25, 2017:

> Amgen believes that its disclosure contains the information sufficient for Genentech to determine for which patents it can reasonably assert a claim of patent

> infringement pursuant to § 262(*l*)(3)(A). If, however, in your evaluation of Amgen's disclosure you believe that additional targeted information not already provided in Amgen's § 262(*l*)(2)(A) disclosure would be helpful to Genentech in making its determination under § 262(*l*)(3)(A), we would be happy to discuss the production of such information if it is reasonably available to Amgen.

30. Instead of making any requests for targeted information as Amgen invited Genentech to do, Genentech filed suit against Amgen on February 15, 2017, in the District of Delaware, alleging that Amgen had violated the BPCIA, including alleged violations of 42 U.S.C. § 262(*l*)(2)(A). The Court dismissed Genentech's Complaint two weeks later. In its March 1, 2017 Order, the Court provided Genentech with 45 days to file an amended Complaint alleging patent infringement pursuant to 42 U.S.C. § 262(*l*)(9)(C) if Genentech, in fact, believed that Amgen had violated the BPCIA. As discussed further below, Genentech did not file an amended complaint.

31. Meanwhile, on March 24, 2017, Genentech provided Amgen with its list of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) ("the (3)(A) list") that Genentech "believe[d] could reasonably be asserted against Amgen's proposed ABP 215 product based upon a review of the product's aBLA filing." Genentech's (3)(A) list included a total of 27 patents, including the patents-in-suit.

32. On April 14, 2017, Genentech told the Court in the Delaware action that Genentech would not be filing an amended Complaint because "[w]e believe it is more efficient for the Court and the parties to address both the patent merits and Amgen's continued noncompliance with its statutory production obligations . . . after the Supreme Court's expected decision in June in *Amgen v. Sandoz*."

Genentech, however, failed to inform the Court that it had already provided Amgen with its (3)(A) list. The Supreme Court subsequently issued its decision in the *Amgen v. Sandoz* case on June 12, 2017. Following the decision, Genentech again did not file a declaratory judgment action for patent infringement pursuant to 42 U.S.C. § 262(*l*)(9)(C), which, according to the Supreme Court, "excludes all other federal remedies, including injunctive relief," for any alleged noncompliance with § 262(*l*)(2)(A).

33. Amgen fully responded to Genentech's (3)(A) list by providing Genentech a statement pursuant to 42 U.S.C. § 262(*l*)(3)(B)(ii)(II), and further providing Genentech, pursuant to 42 U.S.C. § 262(*l*)(3)(B)(ii)(I), a 778-page detailed statement that describes on a claim-by-claim basis the factual and legal bases for Amgen's opinion that patents included on Genentech's (3)(A) list are not infringed and/or are invalid or unenforceable (Amgen's "(3)(B) statement"). Amgen annotated its non-infringement contentions with detailed citations to its BLA. Amgen timely provided its detailed statement to Genentech on May 23, 2017.

34. On July 22, 2017, Amgen received Genentech's alleged statement pursuant to § 262(*l*)(3)(C) (Genentech's "(3)(C) statement"). Even though the BPCIA required Genentech to provide, among other things, "on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that [each] patent [identified in Amgen's (3)(B) statement] will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application," Genentech did not address all of the patents identified in Amgen's (3)(B) statement. Specifically, Genentech did not provide any response to Amgen's contentions for the '553 patent or the '516 patent, or claim 4 of the '017 patent. In addition, Genentech provided no factual or legal basis to support a claim of infringement for 11 patents, and 2 claims of a twelfth patent, on its (3)(A) list, relying instead on its own unsupported assertion that Amgen violated § 262(*l*)(2)(A)

to "justify" contentions that Amgen's commercial marketing of Mvasi™ would somehow infringe Genentech's patents.

35. On September 6, 2017, Amgen wrote to Genentech regarding its non-compliance with § 262(*l*)(3)(C). For example, Amgen explained that "Genentech's § 262(*l*)(3)(C) statement fails to provide the requisite detailed factual and legal basis for its infringement contentions when . . . Genentech relies on Amgen's alleged § 262(*l*)(2)(A) violation." Amgen also explained that, according to recent Supreme Court precedent, any purported or perceived violation of § 262(*l*)(2)(A) is not an act of patent infringement and, therefore, cannot serve as the basis for Genentech's continued assertion of 11 patents and 2 claims of a twelfth patent. *See Sandoz Inc. v. Amgen Inc.*, 137 S.Ct. 1664, 1674 (2017) ("Failing to disclose the application and manufacturing information under § 262(l)(2)(A) does not [constitute an act of infringement under 35 U.S.C. § 271(e)(2)].") In view of Genentech's failure to properly address the 13 patents and 3 claims described in Paragraph 34 above, Amgen requested that Genentech confirm that it would remove them from its (3)(A) list, or otherwise covenant that it would not assert them with respect to Mvasi™.

36. Genentech responded on September 8, 2017. In its letter, Genentech refused to withdraw any patents or claims from its (3)(A) list as previously requested by Amgen. Genentech also stated that, in spite of the issues raised regarding its compliance with § 262(*l*)(3)(C), "[w]e believe those contentions suffice."

37. On September 14, 2017, the parties held an in-person meeting in Los Angeles, California to engage in good-faith negotiations under § 262(*l*)(4) regarding which patents on Genentech's (3)(A) list shall be the subject of an action for patent infringement under § 262(*l*)(6). Genentech again told Amgen that it refused to withdraw any patents or claims from its (3)(A) list.

38. On the same day, the FDA approved Amgen's Mvasi™ as a biosimilar to Genentech's Avastin®, making it the first biosimilar approved in the United States for the treatment of cancer.

39. On September 29, 2017, the parties' negotiations under § 262(*l*)(4) ended without an agreement on a final and complete list of which, if any, patents on Genentech's (3)(A) list shall be the subject of an action for patent infringement under § 262(*l*)(6).

THE PATENTS-IN-SUIT

40. U.S. Patent No. 6,054,297, titled "Humanized Antibodies and Methods for Making Them," issued on April 25, 2000. Upon information and belief, Genentech owns the '297 patent. The earliest possible priority date for the '297 patent is June 14, 1991. Upon information and belief, the '297 patent expires on February 26, 2018.

41. U.S. Patent No. 6,121,428, titled "Protein Recovery," issued on September 19, 2000. Upon information and belief, Genentech owns the '428 patent. The earliest possible priority date for the '428 patent is June 13, 1997. Upon information and belief, the '428 patent expires on June 12, 2018.

42. U.S. Patent No. 6,242,177, titled "Methods and Compositions for Secretion of Heterologous Polypeptides," issued on June 5, 2001. Upon information and belief, Genentech owns the '177 patent. The earliest possible priority date for the '177 patent is March 1, 1995. Upon information and belief, the '177 patent expires on June 5, 2018.

43. U.S. Patent No. 6,331,415, titled "Methods of Producing Immunoglobulins, Vectors and Transformed Host Cells for Use Therein," issued on December 18, 2001. Upon information and belief, Genentech and City of Hope co-own the '415 patent. The earliest possible priority date for the '415 patent is April

8, 1983. Upon information and belief, the '415 patent expires on December 18, 2018.

44. U.S. Patent No. 6,407,213, titled "Method for Making Humanized Antibodies," issued on June 18, 2002. Upon information and belief, Genentech owns the '213 patent. The earliest possible priority date for the '213 patent is June 14, 1991. Upon information and belief, the '213 patent expires on June 18, 2019.

45. U.S. Patent No. 6,417,335, titled "Protein Purification," issued on July 9, 2002. Upon information and belief, Genentech owns the '335 patent. The earliest possible priority date for the '335 patent is May 6, 1998. Upon information and belief, the '213 patent expires on May 3, 2019.

46. U.S. Patent No. 6,586,206, titled "Methods for Making Recombinant Proteins Using Apoptosis Inhibitors," issued on July 1, 2003. Upon information and belief, Genentech owns the '206 patent. The earliest possible priority date for the '206 patent is September 27, 1999. Upon information and belief, the '206 patent expires on September 25, 2020.

47. U.S. Patent No. 6,610,516, titled "Cell Culture Process," issued on August 26, 2003. Upon information and belief, Genentech owns the '516 patent. The earliest possible priority date for the '516 patent is April 26, 1999. Upon information and belief, the '516 patent expires on April 21, 2020.

48. U.S. Patent No. 6,620,918, titled "Separation of Polypeptide Monomers," issued on September 16, 2003. Upon information and belief, Genentech owns the '918 patent. The earliest possible priority date for the '918 patent is June 1, 1998. Upon information and belief, the '918 patent expires on May 26, 2019.

49. U.S. Patent No. 6,870,034, titled "Protein Purification," issued on March 22, 2005. Upon information and belief, Genentech owns the '034 patent.

The earliest possible priority date for the '034 patent is February 5, 2002. Upon information and belief, the '034 patent expires on February 3, 2023.

50. U.S. Patent No. 6,884,879, titled "Anti-VEGF Antibodies," issued on April 26, 2005. Upon information and belief, Genentech owns the '879 patent. The earliest possible priority date of the '879 patent is August 7, 1997. Upon information and belief, the '879 patent expired on August 7, 2017.

51. U.S. Patent No. 7,060,269, titled "Anti-VEGF Antibodies," issued on June 13, 2006. Upon information and belief, Genentech owns the '269 patent. The earliest possible priority date of the '269 patent is August 6, 1997. Upon information and belief, the '269 patent expires on July 4, 2019. Genentech contends that the '269 patent covers bevacizumab.

52. U.S. Patent No. 7,169,901, titled "Anti-VEGF Antibodies," issued on January 30, 2007. Upon information and belief, Genentech owns the '901 patent. The earliest possible priority date of the '901 patent is April 7, 1997. Upon information and belief, the '901 patent expires on March 23, 2019. Genentech contends that the '901 patent covers bevacizumab.

53. U.S. Patent No. 7,297,334, titled "Anti-VEGF Antibodies," issued on November 20, 2007. Upon information and belief, Genentech owns the '334 patent. The earliest possible priority date of the '334 patent is August 7, 1997. Upon information and belief, the '334 patent expired on August 7, 2017.

54. U.S. Patent No. 7,323,553, titled "Non-Affinity Purification of Proteins," issued on January 29, 2008. Upon information and belief, Genentech owns the '553 patent. The earliest possible priority date for the '553 patent is April 26, 2002. Upon information and belief, the '553 patent expires on April 25, 2023.

55. U.S. Patent No. 7,375,193, titled "Anti-VEGF Antibodies," issued on May 20, 2008. Upon information and belief, Genentech owns the '193 patent. The

earliest possible priority date of the '193 patent is August 7, 1997. Upon information and belief, the '193 patent expired on August 7, 2017.

56. U.S. Patent No. 7,622,115, titled "Treatment with Anti-VEGF Antibodies," issued on November 24, 2009. Upon information and belief, Genentech owns the '115 patent. The earliest possible priority date for the '115 patent is May 30, 2003. Upon information and belief, the '115 patent expires on May 28, 2024.

57. U.S. Patent No. 7,807,799, titled "Reducing Protein A Leaching During Protein A Affinity Chromatography," issued on October 5, 2010. Upon information and belief, Genentech owns the '799 patent. The earliest possible priority date for the '799 patent is July 28, 2003. Upon information and belief, the '799 patent expires on June 24, 2024.

58. U.S. Patent No. 7,923,221, titled "Methods of Making Antibody Heavy and Light Chains Having Specificity for a Desired Antigen," issued on April 12, 2011. Upon information and belief, Genentech and City of Hope co-own the '221 patent. The earliest possible priority date of the '221 patent is April 8, 1983. Upon information and belief, the '221 patent expires on December 18, 2018.

59. U.S. Patent No. 8,044,017, titled "Protein Purification," issued on October 25, 2011. Upon information and belief, Genentech owns the '017 patent. The earliest possible priority date for the '017 patent is September 11, 2002. Upon information and belief, the '017 patent expires on March 28, 2026.

60. U.S. Patent No. 8,460,895, titled "Method for Producing Recombinant Proteins with a Constant Content of pCO_2 in the Medium," issued on June 11, 2013. Upon information and belief, the '895 patent is owned by Hoffman-La Roche, Inc. with all substantial rights exclusively licensed to Genentech. The earliest possible priority date for the '895 patent is March 12, 2008. Upon information and belief, the '895 patent expires on August 8, 2029.

61. U.S. Patent No. 8,512,983, titled "Production of Proteins in Glutamine-Free Cell Culture Media," issued on August 20, 2013. Upon information and belief, the '983 patent is owned by F. Hoffmann-La Roche AG with all substantial rights exclusively licensed to Genentech. The earliest possible priority date for the '983 patent is August 11, 2009. Upon information and belief, the '983 patent expires on January 4, 2031.

62. U.S. Patent No. 8,574,869, titled "Prevention of Disulfide Bond Reduction During Recombinant Production of Polypeptides," issued on November 5, 2013. Upon information and belief, Genentech owns the '869 patent. The earliest possible priority date for the '869 patent is July 9, 2007. Upon information and belief, the '869 patent expires on July 8, 2028.

63. U.S. Patent No. 8,633,302, titled "Variable Tangential Flow Filtration," issued on January 21, 2014. Upon information and belief, the '302 patent is owned Hoffman-LaRoche, Inc. with all substantial rights exclusively licensed to Genentech. The earliest possible priority date for the '302 patent is July 17, 2007. Upon information and belief, the '302 patent expires on July 23, 2030.

64. U.S. Patent No. 8,710,196, titled "Protein Purification," issued on April 29, 2014. Upon information and belief, Genentech owns the '196 patent. The earliest possible priority date for the '196 patent is September 11, 2002. Upon information and belief, the '196 patent expires on September 10, 2023.

65. U.S. Patent No. 9,441,035, titled "Cell Culture Media and Methods of Antibody Production," issued on September 13, 2016. Upon information and belief, Genentech owns the '035 patent. The earliest possible priority date for the '035 patent is March 15, 2013. Upon information and belief, the '035 patent expires on April 23, 2034.

66. U.S. Patent No. 9,487,809, titled "Decreasing Lactate Level and Increasing Polypeptide Production by Downregulating the Expression of Lactate

Dehydrogenase and Pyruvate Dehydrogenase Kinase," issued on November 8, 2016. Upon information and belief, Genentech owns the '809 patent. The earliest possible priority date for the '809 patent is May 28, 2010. Upon information and belief, the '809 patent expires on January 14, 2032.

COUNT I

Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,054,297

67. Amgen restates and incorporates by reference the allegations in paragraphs 1–66 above as if fully set forth herein.

68. To the extent there is an invention which is properly the subject of a United States patent, any manufacture, use, sale, offer for sale or import into the United States of ABP 215 by Amgen prior to the expiration date of the '297 patent was not an infringement of the '297 patent. Any manufacture and use of ABP 215 by Amgen prior to the expiration date of the '297 patent was solely for uses reasonably related to the development and submission of information under a Federal law, for example to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k), which regulates biological products. These are not acts of infringement. 35 U.S.C. § 271(e)(1). In addition, Amgen cannot infringe the '297 patent because it is invalid. *See Commil USA, LLC v. Cisco Systems, Inc.*, 135 S. Ct. 1920, 1929 (2015) ("To say that an invalid patent cannot be infringed, or that someone cannot be induced to infringe an invalid patent, is in one sense a simple truth, both as a matter of logic and semantics . . . To be sure, if at the end of the day, an act that would have been an infringement or an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed.").

69. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether Amgen has infringed any valid and enforceable claim of the '297 patent.

70. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

71. Amgen is entitled to a judicial declaration that Amgen has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '297 patent.

COUNT II

Declaratory Judgment of Invalidity of U.S. Patent No. 6,054,297

72. Amgen restates and incorporates by reference the allegations in paragraphs 1–71 above as if fully set forth herein.

73. Among other reasons, the claims of the '297 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '297 patent.

74. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether the claims of the '297 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

75. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

76. Amgen is entitled to a judicial declaration that all claims of the '297 patent are invalid.

COUNT III

Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,121,428

77. Amgen restates and incorporates by reference the allegations in paragraphs 1–76 above as if fully set forth herein.

78. To the extent there is an invention which is properly the subject of a United States patent, any manufacture, use, sale, offer for sale or import into the

United States of ABP 215 by Amgen prior to the expiration date of the '428 patent was not an infringement of the '428 patent. Any manufacture and use of ABP 215 by Amgen prior to the expiration date of the '428 patent was solely for uses reasonably related to the development and submission of information under a Federal law, for example to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k), which regulates biological products. These are not acts of infringement. 35 U.S.C. § 271(e)(1). In addition, Amgen cannot infringe the '428 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 ("To say that an invalid patent cannot be infringed, or that someone cannot be induced to infringe an invalid patent, is in one sense a simple truth, both as a matter of logic and semantics . . . To be sure, if at the end of the day, an act that would have been an infringement or an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed.").

79. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether Amgen has infringed any valid and enforceable claim of the '428 patent.

80. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

81. Amgen is entitled to a judicial declaration that Amgen has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '428 patent.

COUNT IV

Declaratory Judgment of Invalidity of U.S. Patent No. 6,121,428

82. Amgen restates and incorporates by reference the allegations in paragraphs 1–81 above as if fully set forth herein.

83. Among other reasons, the claims of the '428 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '428 patent.

84. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether the claims of the '428 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

85. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

86. Amgen is entitled to a judicial declaration that all claims of the '428 patent are invalid.

COUNT V

Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,242,177

87. Amgen restates and incorporates by reference the allegations in paragraphs 1–86 above as if fully set forth herein.

88. To the extent there is an invention which is properly the subject of a United States patent, any manufacture, use, sale, offer for sale or import into the United States of ABP 215 by Amgen prior to the expiration date of the '177 patent was not an infringement of the '177 patent. Any manufacture and use of ABP 215 by Amgen prior to the expiration date of the '177 patent was solely for uses reasonably related to the development and submission of information under a Federal law, for example to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k), which regulates biological products. These are not acts of infringement. 35 U.S.C. § 271(e)(1). In addition, Amgen cannot infringe the '177 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 ("To say that an invalid patent cannot be infringed, or that someone cannot be induced to infringe an invalid

patent, is in one sense a simple truth, both as a matter of logic and semantics . . . To be sure, if at the end of the day, an act that would have been an infringement or an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed.").

89. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether Amgen has infringed any valid and enforceable claim of the '177 patent.

90. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

91. Amgen is entitled to a judicial declaration that Amgen has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '177 patent.

COUNT VI

Declaratory Judgment of Invalidity of U.S. Patent No. 6,242,177

92. Amgen restates and incorporates by reference the allegations in paragraphs 1–91 above as if fully set forth herein.

93. Among other reasons, the claims of the '177 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '177 patent.

94. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether the claims of the '177 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

95. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

96. Amgen is entitled to a judicial declaration that all claims of the '177 patent are invalid.

COUNT VII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,331,415

97. Amgen restates and incorporates by reference the allegations in paragraphs 1–96 above as if fully set forth herein.

98. To the extent there is an invention which is properly the subject of a United States patent, any manufacture, use, sale, offer for sale or import into the United States of ABP 215 by Amgen prior to the expiration date of the '415 patent was not an infringement of the '415 patent. Any manufacture and use of ABP 215 by Amgen prior to the expiration date of the '415 patent was solely for uses reasonably related to the development and submission of information under a Federal law, for example to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k), which regulates biological products. These are not acts of infringement. 35 U.S.C. § 271(e)(1). In addition, Amgen cannot infringe the '415 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 ("To say that an invalid patent cannot be infringed, or that someone cannot be induced to infringe an invalid patent, is in one sense a simple truth, both as a matter of logic and semantics . . . To be sure, if at the end of the day, an act that would have been an infringement or an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed.").

99. There is a real, substantial, and justiciable controversy between Amgen, on the one hand, and Genentech and City of Hope, on the other hand, concerning whether Amgen has infringed any valid and enforceable claim of the '415 patent.

100. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

101. Amgen is entitled to a judicial declaration that Amgen has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '415 patent.

COUNT VIII

Declaratory Judgment of Invalidity of U.S. Patent No. 6,331,415

102. Amgen restates and incorporates by reference the allegations in paragraphs 1–101 above as if fully set forth herein.

103. Among other reasons, the claims of the '415 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '415 patent.

104. There is a real, substantial, and justiciable controversy between Amgen, on the one hand, and Genentech and City of Hope, on the other hand, concerning whether the claims of the '415 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

105. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

106. Amgen is entitled to a judicial declaration that all claims of the '415 patent are invalid.

COUNT IX

Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,407,213

107. Amgen restates and incorporates by reference the allegations in paragraphs 1–106 above as if fully set forth herein.

108. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. §§ 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '213 patent would not be infringed by

the commercial marketing of ABP 215. For example, the claims of the '213 patent recite amino acid substitutions at specific sites in the framework region(s) which Amgen's ABP 215 biological product does not satisfy. In addition, Amgen cannot infringe the '213 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 ("To say that an invalid patent cannot be infringed, or that someone cannot be induced to infringe an invalid patent, is in one sense a simple truth, both as a matter of logic and semantics . . . To be sure, if at the end of the day, an act that would have been an infringement or an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed."). To the extent there is an invention which is properly the subject of a United States patent, any manufacture, use, sale, offer for sale or import into the United States of ABP 215 by Amgen prior to the expiration date of the '213 patent was not an infringement of the '213 patent. Any manufacture and use of ABP 215 by Amgen prior to the expiration date of the '213 patent was solely for uses reasonably related to the development and submission of information under a Federal law, for example to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k), which regulates biological products. These are not acts of infringement. 35 U.S.C. § 271(e)(1).

109. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether commercial marketing of the biological product that is the subject of Amgen's BLA would infringe any valid and enforceable claim of the '213 patent.

110. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

111. Amgen is entitled to a judicial declaration that Amgen has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '213 patent.

COUNT X

Declaratory Judgment of Invalidity of U.S. Patent No. 6,407,213

112. Amgen restates and incorporates by reference the allegations in paragraphs 1–111 above as if fully set forth herein.

113. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '213 patent is invalid. Among other reasons, the claims of the '213 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '213 patent.

114. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether the claims of the '213 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

115. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

116. Amgen is entitled to a judicial declaration that all claims of the '213 patent are invalid.

COUNT XI

Declaratory Judgment of Unenforceability of U.S. Patent No. 6,407,213

117. Amgen restates and incorporates by reference the allegations in paragraphs 1–116 above as if fully set forth herein.

118. During the prosecution of the '213 patent, Genentech made misrepresentations and omissions material to patentability and did so with the specific intent to mislead or deceive the Patent Office.

119. Genentech deliberately misrepresented the teachings of U.S. Patent No. 5,530,101 ("'101 patent") to the Patent Office in order to overcome a rejection based on that reference. Specifically, Genentech told the Examiner that the '101 patent does not use the Kabat numbering system, despite its repeated references to "numbering according to Kabat" and "the Kabat system."

120. Genentech also made deliberate misrepresentations and omissions regarding Queen 1989, including (i) falsely distinguishing Queen 1989 on the ground that it used "sequential numbering," as opposed to the Kabat numbering system; and (ii) providing information at the request of the Examiner that conspicuously omitted a key residue ("62L") disclosed in the prior art. Deceptive intent by Genentech is the single most reasonable inference to be drawn from the prosecution history and all other available evidence.

121. On November 17, 1993, Genentech filed its patent application with claims requiring substitutions at specific locations, including positions "62L" and "93H." On December 9, 1994, the Examiner issued a Non-Final Rejection, rejecting the claims as obvious under § 103 over EP 0239400, Queen 1989, Riechmann 1988.

122. On June 12, 1995, Genentech amended the pending claims and deleted references to amino acid position "62L."

123. Following a final rejection and an Examiner interview, the case was transferred to a different Examiner and a new non-final rejection issued on December 23, 1996. The new Examiner maintained all prior rejections and further rejected the pending claims as anticipated by the '101 patent.

124. In response to the non-final rejection, Genentech once again amended the pending claims on June 27, 1997, adding amino acid position "62L" back into the claims.

125. On October 7, 1997, Genentech argued in its remarks to the Patent Office that Queen 1989 and the '101 patent were distinguishable because they "use

sequential numbering for the variable domain residues of the antibodies described in these references, whereas the claims of the instant application use Kabat numbering for the framework region residues." Genentech repeated the same argument later in the prosecution of the '213 patent to distinguish Queen 1989 and the '101 patent with specific reference to residue "93H":

> Applicants point out that – as explained earlier in prosecution – the substituted 93 FR residue in the cited references [Queen 1989 and the '101 patent] is not 93H 'utilizing the numbering system set forth in Kabat' (see page 13, line 33 through to line 22 on page 14 of the present application) as required by claims 115-117, 123 and 127 of the present application. In particular, as noted on page 6 of the amendment hand carried to the Office on 10/7/97, residue no. 93 in the heavy chain of the anti-Tac antibody in the cited references, is actually 89H utilizing the numbering system set forth in Kabat. The cited references use a sequential numbering system, rather than the Kabat numbering system claimed herein.

(*See* Applicant Remarks, dated Apr. 26, 2001, at 7.)

126. On December 11, 2001, the Examiner indicated during an interview that the pending claims were allowable.

127. Contrary to Genentech's representations to the Patent Office—namely, that the '101 patent does not use the Kabat numbering system—the '101 patent states: "Residues are numbered according to the Kabat system (E. A. Kabat et al., Sequences of Proteins of Immunological Interest (National Institutes of Health, Bethesda, Md.) (1987)." ('101 patent at 9:13–18.) In addition, the '101 patent expressly refers to "numbering according to Kabat, op. cit." with specific reference

to position 93 in the heavy chain. (*See id.* at 15:17–37.) Moreover, Table 5 of the '101 patent refers to residue "H93," with explicit reference to numbering "according to the Kabat system," as shown below:

TABLE 5

Residues in the framework sequence showing contacts with residues in the hypervariable regions.

Residue No.[1]	Amino Acid	Contacting CDR residues[2]
Fd79		
L49	Lys	L50Y, L53N, L55E, H99D, H100Y
H93	Leu	H35S, H37V, H100CF
Fd138-80		
L36	His	L34V, L89Q
H27	Tyr	H32H, H34I
H30	Tyr	H32H, H53R
H48	Phe	H63F
H66	Lys	H63F
H67	Ala	H63F

1. The amino acid residues are numbered according to the Kabat system (E. A. Kabat et al., Sequences of Proteins of Immunological Interest, National Institutes of Health, Bethesda, MD (1987)): the first letter (H or L) stands for the heavy chain or light chain. The following number is the residue number. The last letter is the amino acid one letter code.
2. The hypervariable regions are defined according to Kabat: Light chain CDR1: residue 24–34; CDR2: 50–56; CDR3: 89–97. Heavy chain CDR1: 31–35; CDR2: 50–65; CDR3: 95–102.

128. In order to overcome the § 102 rejection based on the '101 patent, Genentech falsely represented to the Patent Office that the '101 patent used sequential numbering, while arguing that the "claims of the instant application use Kabat numbering for the framework region residues." Genentech misrepresented the teachings of the '101 patent, despite clear and repeated references in the '101 patent to the Kabat numbering system. Absent Genentech's false and misleading distinction, the Examiner had no reason to withdraw the § 102 rejection based on the '101 patent.

129. Genentech also made deliberate and material misrepresentations and omissions regarding Queen 1989 during the prosecution of the '213 patent. Genentech distinguished Queen 1989 on the ground that it used "sequential

numbering," as opposed to the Kabat numbering system. At the Examiner's request, Genentech submitted a comparison of the different numbering systems purportedly utilized in Queen 1989 and the pending claims.[1] The alignments provided by Genentech to the Examiner conspicuously omitted the "62L" residue in both numbering systems. As noted above, residue "62L" was recited in then-pending claims of the '213 patent, and Queen 1989 expressly discloses "residues at positions corresponding to . . . 47 and 62 of the light chain (Fig. 2)." (*See* Queen 1989 at 10032.) Importantly, Queen 1989 discloses residues in the Kabat numbering system and, in particular, residue "62 of the light chain."

130. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether the claims of the '213 patent are enforceable in view of Genentech's inequitable conduct before the Patent Office.

131. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

132. Amgen is entitled to a judicial declaration that all claims of the '213 patent are unenforceable.

COUNT XII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,417,335

133. Amgen restates and incorporates by reference the allegations in paragraphs 1–132 above as if fully set forth herein.

134. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '335 patent would not be infringed by the

[1] *See* 10/7/97 Applicant Remarks at 6–10 ("As requested by the Examiner in the interview, alignments of heavy chain variable domain (Exhibit A) and light chain variable domain (Exhibit B) sequences of the 101 patent (including the sequences for the murine and humanized anti-Tac antibody of Queen *et al.*) with sequential and Kabat residue numbering is attached.").

commercial marketing of ABP 215. For example, the claims of the '335 patent recite an "anti-HER2 antibody," which Amgen's ABP 215 biological product does not satisfy. In addition, Amgen cannot infringe the '335 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 ("To say that an invalid patent cannot be infringed, or that someone cannot be induced to infringe an invalid patent, is in one sense a simple truth, both as a matter of logic and semantics . . . To be sure, if at the end of the day, an act that would have been an infringement or an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed."). To the extent there is an invention which is properly the subject of a United States patent, any manufacture, use, sale, offer for sale or import into the United States of ABP 215 by Amgen prior to the expiration date of the '335 patent was not an infringement of the '335 patent. Any manufacture and use of ABP 215 by Amgen prior to the expiration date of the '335 patent was solely for uses reasonably related to the development and submission of information under a Federal law, for example to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k), which regulates biological products. These are not acts of infringement. 35 U.S.C. § 271(e)(1).

135. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether commercial marketing of the biological product that is the subject of Amgen's BLA for ABP 215 would infringe any valid and enforceable claim of the '335 patent.

136. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

137. Amgen is entitled to a judicial declaration that Amgen has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '335 patent.

COUNT XIII

Declaratory Judgment of Invalidity of U.S. Patent No. 6,417,335

138. Amgen restates and incorporates by reference the allegations in paragraphs 1–137 above as if fully set forth herein.

139. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '335 patent is invalid. Among other reasons, the claims of the '335 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '335 patent.

140. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether the claims of the '335 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

141. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

142. Amgen is entitled to a judicial declaration that all claims of the '335 patent are invalid.

COUNT XIV

Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,586,206

143. Amgen restates and incorporates by reference the allegations in paragraphs 1–142 above as if fully set forth herein.

144. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '206 patent would not be infringed by the commercial marketing of ABP 215. For example, the claims of the '206 patent

recite "provid[ing] a vector comprising a gene encoding caspase-9 dominant negative protein," "provid[ing] a Chinese hamster ovary (CHO) host cell comprising a gene encoding caspase-9 dominant negative protein," or "provid[ing] an amount of caspase inhibitor z-VAD-fmk," which Amgen's ABP 215 biological product and associated manufacturing processes do not satisfy. In addition, Amgen cannot infringe the '206 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 ("To say that an invalid patent cannot be infringed, or that someone cannot be induced to infringe an invalid patent, is in one sense a simple truth, both as a matter of logic and semantics . . . To be sure, if at the end of the day, an act that would have been an infringement or an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed."). To the extent there is an invention which is properly the subject of a United States patent, any manufacture, use, sale, offer for sale or import into the United States of ABP 215 by Amgen prior to the expiration date of the '206 patent was not an infringement of the '206 patent. Any manufacture and use of ABP 215 by Amgen prior to the expiration date of the '206 patent was solely for uses reasonably related to the development and submission of information under a Federal law, for example to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k), which regulates biological products. These are not acts of infringement. 35 U.S.C. § 271(e)(1).

145. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether commercial marketing of the biological product that is the subject of Amgen's BLA for ABP 215 would infringe any valid and enforceable claim of the '206 patent.

146. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

147. Amgen is entitled to a judicial declaration that Amgen has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '206 patent.

COUNT XV

Declaratory Judgment of Invalidity of U.S. Patent No. 6,586,206

148. Amgen restates and incorporates by reference the allegations in paragraphs 1–147 above as if fully set forth herein.

149. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '206 patent is invalid. Among other reasons, the claims of the '206 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '206 patent.

150. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether the claims of the '206 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

151. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

152. Amgen is entitled to a judicial declaration that all claims of the '206 patent are invalid.

COUNT XVI

Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,610,516

153. Amgen restates and incorporates by reference the allegations in paragraphs 1–152 above as if fully set forth herein.

154. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '516 patent would not be infringed by the commercial marketing of ABP 215. For example, the claims of the '516 patent recite a "process for producing a human glycoprotein having multiple glycoforms," and culturing cells "in the presence of about 0 to 2 mM of a butyrate salt," which Amgen's ABP 215 biological product and associated manufacturing processes do not satisfy. In addition, Amgen cannot infringe the '516 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 ("To say that an invalid patent cannot be infringed, or that someone cannot be induced to infringe an invalid patent, is in one sense a simple truth, both as a matter of logic and semantics . . . To be sure, if at the end of the day, an act that would have been an infringement or an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed."). To the extent there is an invention which is properly the subject of a United States patent, any manufacture, use, sale, offer for sale or import into the United States of ABP 215 by Amgen prior to the expiration date of the '516 patent was not an infringement of the '516 patent. Any manufacture and use of ABP 215 by Amgen prior to the expiration date of the '516 patent was solely for uses reasonably related to the development and submission of information under a Federal law, for example to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k), which regulates biological products. These are not acts of infringement. 35 U.S.C. § 271(e)(1).

155. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether commercial marketing of the biological product that is the subject of Amgen's BLA for ABP 215 would infringe any valid and enforceable claim of the '516 patent.

156. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

157. Amgen is entitled to a judicial declaration that Amgen has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '516 patent.

COUNT XVII

Declaratory Judgment of Invalidity of U.S. Patent No. 6,610,516

158. Amgen restates and incorporates by reference the allegations in paragraphs 1–157 above as if fully set forth herein.

159. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '516 patent is invalid. Among other reasons, the claims of the '516 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '516 patent.

160. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether the claims of the '516 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

161. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

162. Amgen is entitled to a judicial declaration that all claims of the '516 patent are invalid.

COUNT XVIII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,620,918

163. Amgen restates and incorporates by reference the allegations in paragraphs 1–162 above as if fully set forth herein.

164. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '918 patent would not be infringed by the commercial marketing of ABP 215. For example, the claims of the '918 patent recite purifying "polypeptide monomers from a mixture consisting essentially of said polypeptide monomers, and dimers or multimers of said polypeptide monomers or both dimers and multimers of said polypeptide monomers" or use a purification method that "consists essentially of applying the mixture to a cation-exchange or anion-exchange chromatography resin in a buffer," which Amgen's ABP 215 biological product and associated manufacturing processes do not satisfy. In addition, Amgen cannot infringe the '918 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 ("To say that an invalid patent cannot be infringed, or that someone cannot be induced to infringe an invalid patent, is in one sense a simple truth, both as a matter of logic and semantics . . . To be sure, if at the end of the day, an act that would have been an infringement or an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed."). To the extent there is an invention which is properly the subject of a United States patent, any manufacture, use, sale, offer for sale or import into the United States of ABP 215 by Amgen prior to the expiration date of the '918 patent was not an infringement of the '918 patent. Any manufacture and use of ABP 215 by Amgen prior to the expiration date of the '918 patent was solely for uses reasonably related to the development and submission of information under a Federal law, for example to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k),

which regulates biological products. These are not acts of infringement. 35 U.S.C. § 271(e)(1).

165. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether commercial marketing of the biological product that is the subject of Amgen's BLA for ABP 215 would infringe any valid and enforceable claim of the '918 patent.

166. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

167. Amgen is entitled to a judicial declaration that Amgen has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '918 patent.

COUNT XIX

Declaratory Judgment of Invalidity of U.S. Patent No. 6,620,918

168. Amgen restates and incorporates by reference the allegations in paragraphs 1–167 above as if fully set forth herein.

169. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '918 patent is invalid. Among other reasons, the claims of the '918 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '918 patent.

170. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether the claims of the '918 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

171. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

172. Amgen is entitled to a judicial declaration that all claims of the '918 patent are invalid.

COUNT XX

Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,870,034

173. Amgen restates and incorporates by reference the allegations in paragraphs 1–172 above as if fully set forth herein.

174. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '034 patent would not be infringed by the commercial marketing of ABP 215. For example, the claims of the '034 patent recite (i) "wash[] the solid phase with a composition comprising detergent," (ii) "wash[] the solid phase with a composition comprising . . . a solvent selected from the group consisting of ethanol, methanol, isopropanol, acetonitrile, hexylene glycol, propylene glycol, and 2,2-thiodiglycol," (iii) "wash[] the solid phase with a composition comprising a buffer at a concentration of greater than about 0.8M," or (iv) "wash[] the solid phase with a composition comprising . . . a polymer selected from the group consisting of polyethylene glycol, polypropyl glycol, and copolymers of ethylene and propylene glycol," which Amgen's ABP 215 biological product and associated manufacturing processes do not satisfy. In addition, Amgen cannot infringe the '034 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 ("To say that an invalid patent cannot be infringed, or that someone cannot be induced to infringe an invalid patent, is in one sense a simple truth, both as a matter of logic and semantics . . . To be sure, if at the end of the day, an act that would have been an infringement or an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed."). To the extent there is an invention

which is properly the subject of a United States patent, any manufacture, use, sale, offer for sale or import into the United States of ABP 215 by Amgen prior to the expiration date of the '034 patent was not an infringement of the '034 patent. Any manufacture and use of ABP 215 by Amgen prior to the expiration date of the '034 patent was solely for uses reasonably related to the development and submission of information under a Federal law, for example to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k), which regulates biological products. These are not acts of infringement. 35 U.S.C. § 271(e)(1).

175. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether commercial marketing of the biological product that is the subject of Amgen's BLA for ABP 215 would infringe any valid and enforceable claim of the '034 patent.

176. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

177. Amgen is entitled to a judicial declaration that Amgen has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '034 patent.

COUNT XXI

Declaratory Judgment of Invalidity of U.S. Patent No. 6,870,034

178. Amgen restates and incorporates by reference the allegations in paragraphs 1–177 above as if fully set forth herein.

179. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '034 patent is invalid. Among other reasons, the claims of the '034 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '034 patent.

180. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether the claims of the '034 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

181. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

182. Amgen is entitled to a judicial declaration that all claims of the '034 patent are invalid.

COUNT XXII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 6,884,879

183. Amgen restates and incorporates by reference the allegations in paragraphs 1–182 above as if fully set forth herein.

184. To the extent there is an invention which is properly the subject of a United States patent, any manufacture, use, sale, offer for sale or import into the United States of ABP 215 by Amgen prior to the expiration date of the '879 patent was not an infringement of the '879 patent. Any manufacture and use of ABP 215 by Amgen prior to the expiration date of the '879 patent was solely for uses reasonably related to the development and submission of information under a Federal law, for example to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k), which regulates biological products. These are not acts of infringement. 35 U.S.C. § 271(e)(1). In addition, Amgen cannot infringe the '879 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 ("To say that an invalid patent cannot be infringed, or that someone cannot be induced to infringe an invalid patent, is in one sense a simple truth, both as a matter of logic and semantics . . . To be sure, if at the end of the day, an act that would have been an infringement or an

inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed.").

185. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether Amgen has infringed any valid and enforceable claim of the '879 patent.

186. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

187. Amgen is entitled to a judicial declaration that Amgen has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '879 patent.

COUNT XXIII

Declaratory Judgment of Invalidity of U.S. Patent No. 6,884,879

188. Amgen restates and incorporates by reference the allegations in paragraphs 1–187 above as if fully set forth herein.

189. Among other reasons, the claims of the '879 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '879 patent.

190. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether the claims of the '879 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

191. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

192. Amgen is entitled to a judicial declaration that all claims of the '879 patent are invalid.

COUNT XXIV

Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,060,269

193. Amgen restates and incorporates by reference the allegations in paragraphs 1–192 above as if fully set forth herein.

194. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '269 patent would not be infringed by the commercial marketing of ABP 215. For example, the claims of the '269 patent recite "a heavy chain variable domain sequence of SEQ ID NO: 116" or "a light chain variable domain sequence of SEQ ID NO:115," which Amgen's ABP 215 biological product does not satisfy. In addition, Amgen cannot infringe the '269 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 ("To say that an invalid patent cannot be infringed, or that someone cannot be induced to infringe an invalid patent, is in one sense a simple truth, both as a matter of logic and semantics . . . To be sure, if at the end of the day, an act that would have been an infringement or an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed."). To the extent there is an invention which is properly the subject of a United States patent, any manufacture, use, sale, offer for sale or import into the United States of ABP 215 by Amgen prior to the expiration date of the '269 patent was not an infringement of the '269 patent. Any manufacture and use of ABP 215 by Amgen prior to the expiration date of the '269 patent was solely for uses reasonably related to the development and submission of information under a Federal law, for example to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k), which regulates biological products. These are not acts of infringement. 35 U.S.C. § 271(e)(1).

195. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether commercial marketing of the biological product

that is the subject of Amgen's BLA for ABP 215 would infringe any valid and enforceable claim of the '269 patent.

196. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

197. Amgen is entitled to a judicial declaration that Amgen has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '269 patent.

COUNT XXV

Declaratory Judgment of Invalidity of U.S. Patent No. 7,060,269

198. Amgen restates and incorporates by reference the allegations in paragraphs 1–197 above as if fully set forth herein.

199. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '269 patent is invalid. Among other reasons, the claims of the '269 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '269 patent.

200. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether the claims of the '269 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

201. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

202. Amgen is entitled to a judicial declaration that all claims of the '269 patent are invalid.

COUNT XXVI

Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,169,901

203. Amgen restates and incorporates by reference the allegations in paragraphs 1–202 above as if fully set forth herein.

204. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '901 patent would not be infringed by the commercial marketing of ABP 215. For example, the claims of the '901 patent recite "an antigen binding fragment," "a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO:118," or a "light chain variable domain comprising the amino acid sequence of SEQ ID NO:117," which Amgen's ABP 215 biological product does not satisfy. In addition, Amgen cannot infringe the '901 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 ("To say that an invalid patent cannot be infringed, or that someone cannot be induced to infringe an invalid patent, is in one sense a simple truth, both as a matter of logic and semantics . . . To be sure, if at the end of the day, an act that would have been an infringement or an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed."). To the extent there is an invention which is properly the subject of a United States patent, any manufacture, use, sale, offer for sale or import into the United States of ABP 215 by Amgen prior to the expiration date of the '901 patent was not an infringement of the '901 patent. Any manufacture and use of ABP 215 by Amgen prior to the expiration date of the '901 patent was solely for uses reasonably related to the development and submission of information under a Federal law, for example to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k), which regulates biological products. These are not acts of infringement. 35 U.S.C. § 271(e)(1).

205. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether commercial marketing of the biological product that is the subject of Amgen's BLA for ABP 215 would infringe any valid and enforceable claim of the '901 patent.

206. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

207. Amgen is entitled to a judicial declaration that Amgen has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '901 patent.

COUNT XXVII

Declaratory Judgment of Invalidity of U.S. Patent No. 7,169,901

208. Amgen restates and incorporates by reference the allegations in paragraphs 1–207 above as if fully set forth herein.

209. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '901 patent is invalid. Among other reasons, the claims of the '901 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '901 patent.

210. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether the claims of the '901 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

211. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

212. Amgen is entitled to a judicial declaration that all claims of the '901 patent are invalid.

COUNT XXVIII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,297,334

213. Amgen restates and incorporates by reference the allegations in paragraphs 1–212 above as if fully set forth herein.

214. To the extent there is an invention which is properly the subject of a United States patent, any manufacture, use, sale, offer for sale or import into the United States of ABP 215 by Amgen prior to the expiration date of the '334 patent was not an infringement of the '334 patent. Any manufacture and use of ABP 215 by Amgen prior to the expiration date of the '334 patent was solely for uses reasonably related to the development and submission of information under a Federal law, for example to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k), which regulates biological products. These are not acts of infringement. 35 U.S.C. § 271(e)(1). In addition, Amgen cannot infringe the '334 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 ("To say that an invalid patent cannot be infringed, or that someone cannot be induced to infringe an invalid patent, is in one sense a simple truth, both as a matter of logic and semantics . . . To be sure, if at the end of the day, an act that would have been an infringement or an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed.").

215. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether Amgen has infringed any valid and enforceable claim of the '334 patent.

216. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

217. Amgen is entitled to a judicial declaration that Amgen has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '334 patent.

COUNT XXIX

Declaratory Judgment of Invalidity of U.S. Patent No. 7,297,334

218. Amgen restates and incorporates by reference the allegations in paragraphs 1–217 above as if fully set forth herein.

219. Among other reasons, the claims of the '334 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '334 patent.

220. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether the claims of the '334 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

221. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

222. Amgen is entitled to a judicial declaration that all claims of the '334 patent are invalid.

COUNT XXX

Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,323,553

223. Amgen restates and incorporates by reference the allegations in paragraphs 1–222 above as if fully set forth herein.

224. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '553 patent would not be infringed by the commercial marketing of ABP 215. For example, the claims of the '553 patent

recite "wherein said method includes no affinity purification step," which Amgen's ABP 215 biological product and associated manufacturing processes do not satisfy. In addition, Amgen cannot infringe the '553 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 ("To say that an invalid patent cannot be infringed, or that someone cannot be induced to infringe an invalid patent, is in one sense a simple truth, both as a matter of logic and semantics . . . To be sure, if at the end of the day, an act that would have been an infringement or an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed."). To the extent there is an invention which is properly the subject of a United States patent, any manufacture, use, sale, offer for sale or import into the United States of ABP 215 by Amgen prior to the expiration date of the '553 patent was not an infringement of the '553 patent. Any manufacture and use of ABP 215 by Amgen prior to the expiration date of the '553 patent was solely for uses reasonably related to the development and submission of information under a Federal law, for example to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k), which regulates biological products. These are not acts of infringement. 35 U.S.C. § 271(e)(1).

225. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether commercial marketing of the biological product that is the subject of Amgen's BLA for ABP 215 would infringe any valid and enforceable claim of the '553 patent.

226. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

227. Amgen is entitled to a judicial declaration that Amgen has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '553 patent.

COUNT XXXI

Declaratory Judgment of Invalidity of U.S. Patent No. 7,323,553

228. Amgen restates and incorporates by reference the allegations in paragraphs 1–227 above as if fully set forth herein.

229. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '553 patent is invalid. Among other reasons, the claims of the '553 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '553 patent.

230. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether the claims of the '553 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

231. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

232. Amgen is entitled to a judicial declaration that all claims of the '553 patent are invalid.

COUNT XXXII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,375,193

233. Amgen restates and incorporates by reference the allegations in paragraphs 1–232 above as if fully set forth herein.

234. To the extent there is an invention which is properly the subject of a United States patent, any manufacture, use, sale, offer for sale or import into the United States of ABP 215 by Amgen prior to the expiration date of the '193 patent was not an infringement of the '193 patent. Any manufacture and use of ABP 215

by Amgen prior to the expiration date of the '193 patent was solely for uses reasonably related to the development and submission of information under a Federal law, for example to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k), which regulates biological products. These are not acts of infringement. 35 U.S.C. § 271(e)(1). In addition, Amgen cannot infringe the '193 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 ("To say that an invalid patent cannot be infringed, or that someone cannot be induced to infringe an invalid patent, is in one sense a simple truth, both as a matter of logic and semantics . . . To be sure, if at the end of the day, an act that would have been an infringement or an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed.").

235. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether Amgen has infringed any valid and enforceable claim of the '193 patent.

236. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

237. Amgen is entitled to a judicial declaration that Amgen has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '193 patent.

COUNT XXXIII

Declaratory Judgment of Invalidity of U.S. Patent No. 7,375,193

238. Amgen restates and incorporates by reference the allegations in paragraphs 1–237 above as if fully set forth herein.

239. Among other reasons, the claims of the '193 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '193 patent.

240. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether the claims of the '193 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

241. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

242. Amgen is entitled to a judicial declaration that all claims of the '193 patent are invalid.

COUNT XXXIV

Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,622,115

243. Amgen restates and incorporates by reference the allegations in paragraphs 1–242 above as if fully set forth herein.

244. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '115 patent would not be infringed by the commercial marketing of ABP 215. For example, the claims of the '115 patent recite "assess[] the patient for gastrointestinal perforation during treatment with bevacizumab," which Amgen does not directly or indirectly satisfy. In addition, Amgen cannot infringe the '115 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 ("To say that an invalid patent cannot be infringed, or that someone cannot be induced to infringe an invalid patent, is in one sense a simple truth, both as a matter of logic and semantics . . . To be sure, if at the end of the day, an act that would have been an infringement or an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed."). To the extent there is an invention which is properly the subject of a United States patent, any manufacture, use, sale, offer for sale or import into the United States of ABP 215 by

Amgen prior to the expiration date of the '115 patent was not an infringement of the '115 patent. Any manufacture and use of ABP 215 by Amgen prior to the expiration date of the '115 patent was solely for uses reasonably related to the development and submission of information under a Federal law, for example to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k), which regulates biological products. These are not acts of infringement. 35 U.S.C. § 271(e)(1).

245. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether commercial marketing of the biological product that is the subject of Amgen's BLA for ABP 215 would infringe any valid and enforceable claim of the '115 patent.

246. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

247. Amgen is entitled to a judicial declaration that Amgen has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '115 patent.

COUNT XXXV

Declaratory Judgment of Invalidity of U.S. Patent No. 7,622,115

248. Amgen restates and incorporates by reference the allegations in paragraphs 1–247 above as if fully set forth herein.

249. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '115 patent is invalid. Among other reasons, the claims of the '115 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '115 patent.

250. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether the claims of the '115 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

251. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

252. Amgen is entitled to a judicial declaration that all claims of the '115 patent are invalid.

COUNT XXXVI

Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,807,799

253. Amgen restates and incorporates by reference the allegations in paragraphs 1–252 above as if fully set forth herein.

254. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '799 patent would not be infringed by the commercial marketing of ABP 215. For example, the claims of the '799 patent recite a "protease inhibitor" during protein A affinity chromatography, "trastuzumab" or "an immunoadhesin," which Amgen's ABP 215 biological product and associated manufacturing processes do not satisfy. In addition, Amgen cannot infringe the '799 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 ("To say that an invalid patent cannot be infringed, or that someone cannot be induced to infringe an invalid patent, is in one sense a simple truth, both as a matter of logic and semantics . . . To be sure, if at the end of the day, an act that would have been an infringement or an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed."). To the extent there is an invention which is properly the subject of a United States patent, any manufacture, use, sale,

offer for sale or import into the United States of ABP 215 by Amgen prior to the expiration date of the '799 patent was not an infringement of the '799 patent. Any manufacture and use of ABP 215 by Amgen prior to the expiration date of the '799 patent was solely for uses reasonably related to the development and submission of information under a Federal law, for example to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k), which regulates biological products. These are not acts of infringement. 35 U.S.C. § 271(e)(1).

255. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether commercial marketing of the biological product that is the subject of Amgen's BLA for ABP 215 would infringe any valid and enforceable claim of the '799 patent.

256. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

257. Amgen is entitled to a judicial declaration that Amgen has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '799 patent.

COUNT XXXVII

Declaratory Judgment of Invalidity of U.S. Patent No. 7,807,799

258. Amgen restates and incorporates by reference the allegations in paragraphs 1–257 above as if fully set forth herein.

259. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '799 patent is invalid. Among other reasons, the claims of the '799 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '799 patent.

260. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether the claims of the '799 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

261. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

262. Amgen is entitled to a judicial declaration that all claims of the '799 patent are invalid.

COUNT XXXVIII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 7,923,221

263. Amgen restates and incorporates by reference the allegations in paragraphs 1–262 above as if fully set forth herein.

264. To the extent there is an invention which is properly the subject of a United States patent, any manufacture, use, sale, offer for sale or import into the United States of ABP 215 by Amgen prior to the expiration date of the '221 patent was not an infringement of the '221 patent. Any manufacture and use of ABP 215 by Amgen prior to the expiration date of the '221 patent was solely for uses reasonably related to the development and submission of information under a Federal law, for example to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k), which regulates biological products. These are not acts of infringement. 35 U.S.C. § 271(e)(1). In addition, Amgen cannot infringe the '221 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 ("To say that an invalid patent cannot be infringed, or that someone cannot be induced to infringe an invalid patent, is in one sense a simple truth, both as a matter of logic and semantics . . . To be sure, if at the end of the day, an act that would have been an infringement or an

inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed.").

265. There is a real, substantial, and justiciable controversy between Amgen, on the one hand, and Genentech and City of Hope, on the other hand, concerning whether Amgen has infringed any valid and enforceable claim of the '221 patent.

266. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

267. Amgen is entitled to a judicial declaration that Amgen has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '221 patent.

COUNT XXXIX

Declaratory Judgment of Invalidity of U.S. Patent No. 7,923,221

268. Amgen restates and incorporates by reference the allegations in paragraphs 1–267 above as if fully set forth herein.

269. Among other reasons, the claims of the '221 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '221 patent.

270. There is a real, substantial, and justiciable controversy between Amgen, on the one hand, and Genentech and City of Hope, on the other hand, concerning whether the claims of the '221 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

271. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

272. Amgen is entitled to a judicial declaration that all claims of the '221 patent are invalid.

COUNT XL

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,044,017

273. Amgen restates and incorporates by reference the allegations in paragraphs 1–272 above as if fully set forth herein.

274. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '017 patent would not be infringed by the commercial marketing of ABP 215. For example, the claims of the '017 patent recite "wash[ing] the ion exchange resin with a wash buffer until a predetermined protein concentration is measured in the flowthrough," and the salt concentration of the wash buffer does not "increase[] from an initial, second salt concentration that is greater than the salt concentration of the equilibration buffer, to a final, third salt concentration," which Amgen's ABP 215 biological product and associated manufacturing processes do not satisfy. In addition, Amgen cannot infringe the '017 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 ("To say that an invalid patent cannot be infringed, or that someone cannot be induced to infringe an invalid patent, is in one sense a simple truth, both as a matter of logic and semantics . . . To be sure, if at the end of the day, an act that would have been an infringement or an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed."). To the extent there is an invention which is properly the subject of a United States patent, any manufacture, use, sale, offer for sale or import into the United States of ABP 215 by Amgen prior to the expiration date of the '017 patent was not an infringement of the '017 patent. Any manufacture and use of ABP 215 by Amgen prior to the expiration date of the '017 patent was solely for uses reasonably related to the development and submission of information under a Federal law, for example to the FDA under the Public Health Service Act

including 42 U.S.C. § 262(k), which regulates biological products. These are not acts of infringement. 35 U.S.C. § 271(e)(1).

275. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether commercial marketing of the biological product that is the subject of Amgen's BLA for ABP 215 would infringe any valid and enforceable claim of the '017 patent.

276. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

277. Amgen is entitled to a judicial declaration that Amgen has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '017 patent.

COUNT XLI

Declaratory Judgment of Invalidity of U.S. Patent No. 8,044,017

278. Amgen restates and incorporates by reference the allegations in paragraphs 1–277 above as if fully set forth herein.

279. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '017 patent is invalid. Among other reasons, the claims of the '017 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '017 patent.

280. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether the claims of the '017 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

281. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

282. Amgen is entitled to a judicial declaration that all claims of the '017 patent are invalid.

COUNT XLII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,460,895

283. Amgen restates and incorporates by reference the allegations in paragraphs 1–282 above as if fully set forth herein.

284. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '895 patent would not be infringed by the commercial marketing of ABP 215. For example, the claims of the '895 patent recite a "method for the recombinant production of a polypeptide in a eukaryotic host cell modified in the citrate cycle to express a cystosolic pyruvate carboxylase," which Amgen's ABP 215 biological product and associated manufacturing processes do not satisfy. In addition, Amgen cannot infringe the '895 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 ("To say that an invalid patent cannot be infringed, or that someone cannot be induced to infringe an invalid patent, is in one sense a simple truth, both as a matter of logic and semantics . . . To be sure, if at the end of the day, an act that would have been an infringement or an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed."). To the extent there is an invention which is properly the subject of a United States patent, any manufacture, use, sale, offer for sale or import into the United States of ABP 215 by Amgen prior to the expiration date of the '895 patent was not an infringement of the '895 patent. Any manufacture and use of ABP 215 by Amgen prior to the expiration date of the '895 patent was solely for uses reasonably related to the development and submission of information under a

Federal law, for example to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k), which regulates biological products. These are not acts of infringement. 35 U.S.C. § 271(e)(1).

285. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether commercial marketing of the biological product that is the subject of Amgen's BLA for ABP 215 would infringe any valid and enforceable claim of the '895 patent.

286. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

287. Amgen is entitled to a judicial declaration that Amgen has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '895 patent.

COUNT XLIII

Declaratory Judgment of Invalidity of U.S. Patent No. 8,460,895

288. Amgen restates and incorporates by reference the allegations in paragraphs 1–287 above as if fully set forth herein.

289. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '895 patent is invalid. Among other reasons, the claims of the '895 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '895 patent.

290. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether the claims of the '895 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

291. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

292. Amgen is entitled to a judicial declaration that all claims of the '895 patent are invalid.

COUNT XLIV

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,512,983

293. Amgen restates and incorporates by reference the allegations in paragraphs 1–292 above as if fully set forth herein.

294. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '983 patent would not be infringed by the commercial marketing of ABP 215. For example, the claims of the '983 patent recite "a glutamine-free production culture medium containing asparagine, wherein the asparagine is added at a concentration in the range of 7.5 mM to 15 mM," or "[a] ready-to-use glutamine-free cell culture medium containing asparagine for the production of a polypeptide in a production phase, wherein the asparagine is at a concentration in the range of 7.5 mM to 15 mM," which Amgen's ABP 215 biological product and associated manufacturing processes do not satisfy. In addition, Amgen cannot infringe the '983 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 ("To say that an invalid patent cannot be infringed, or that someone cannot be induced to infringe an invalid patent, is in one sense a simple truth, both as a matter of logic and semantics . . . To be sure, if at the end of the day, an act that would have been an infringement or an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed."). To the extent there is an invention which is properly the subject of a United States patent, any manufacture, use, sale, offer for sale or import into the United States of ABP 215 by Amgen prior to the expiration date of the '983 patent was not an

infringement of the '983 patent. Any manufacture and use of ABP 215 by Amgen prior to the expiration date of the '983 patent was solely for uses reasonably related to the development and submission of information under a Federal law, for example to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k), which regulates biological products. These are not acts of infringement. 35 U.S.C. § 271(e)(1).

295. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether commercial marketing of the biological product that is the subject of Amgen's BLA for ABP 215 would infringe any valid and enforceable claim of the '983 patent.

296. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

297. Amgen is entitled to a judicial declaration that Amgen has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '983 patent.

COUNT XLV

Declaratory Judgment of Invalidity of U.S. Patent No. 8,512,983

298. Amgen restates and incorporates by reference the allegations in paragraphs 1–297 above as if fully set forth herein.

299. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '983 patent is invalid. Among other reasons, the claims of the '983 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '983 patent.

300. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether the claims of the '983 patent are invalid for

failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

301. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

302. Amgen is entitled to a judicial declaration that all claims of the '983 patent are invalid.

COUNT XLVI

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

303. Amgen restates and incorporates by reference the allegations in paragraphs 1–302 above as if fully set forth herein.

304. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '869 patent would not be infringed by the commercial marketing of ABP 215. For example, the claims of the '869 patent recite sparging pre-harvest or harvested cell culture fluid "following fermentation," which Amgen's ABP 215 biological product and associated manufacturing processes do not satisfy. In addition, Amgen cannot infringe the '869 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 ("To say that an invalid patent cannot be infringed, or that someone cannot be induced to infringe an invalid patent, is in one sense a simple truth, both as a matter of logic and semantics . . . To be sure, if at the end of the day, an act that would have been an infringement or an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed."). To the extent there is an invention which is properly the subject of a United States patent, any manufacture, use, sale, offer for sale or import into the United States of ABP 215 by Amgen prior to the expiration date of the '869 patent was not an infringement of the '869 patent. Any manufacture and use of

ABP 215 by Amgen prior to the expiration date of the '869 patent was solely for uses reasonably related to the development and submission of information under a Federal law, for example to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k), which regulates biological products. These are not acts of infringement. 35 U.S.C. § 271(e)(1).

305. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether commercial marketing of the biological product that is the subject of Amgen's BLA for ABP 215 would infringe any valid and enforceable claim of the '869 patent.

306. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

307. Amgen is entitled to a judicial declaration that Amgen has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '869 patent.

COUNT XLVII

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

308. Amgen restates and incorporates by reference the allegations in paragraphs 1–307 above as if fully set forth herein.

309. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '869 patent is invalid. Among other reasons, the claims of the '869 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '869 patent.

310. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether the claims of the '869 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code,

including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

311. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

312. Amgen is entitled to a judicial declaration that all claims of the '869 patent are invalid.

COUNT XLVIII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,633,302

313. Amgen restates and incorporates by reference the allegations in paragraphs 1–312 above as if fully set forth herein.

314. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '302 patent would not be infringed by the commercial marketing of ABP 215. For example, the claims of the '302 patent recite a method with "variable transmembrane pressure and cross-flow," or transmembrane pressures and cross-flows within recited ranges, which Amgen's ABP 215 biological product and associated manufacturing processes do not satisfy. In addition, Amgen cannot infringe the '302 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 ("To say that an invalid patent cannot be infringed, or that someone cannot be induced to infringe an invalid patent, is in one sense a simple truth, both as a matter of logic and semantics . . . To be sure, if at the end of the day, an act that would have been an infringement or an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed."). To the extent there is an invention which is properly the subject of a United States patent, any manufacture, use, sale, offer for sale or import into the United States of ABP 215 by Amgen prior to the expiration date of the '302 patent was not an infringement of the '302 patent. Any manufacture and use of ABP 215 by Amgen

prior to the expiration date of the '302 patent was solely for uses reasonably related to the development and submission of information under a Federal law, for example to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k), which regulates biological products. These are not acts of infringement. 35 U.S.C. § 271(e)(1).

315. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether commercial marketing of the biological product that is the subject of Amgen's BLA for ABP 215 would infringe any valid and enforceable claim of the '302 patent.

316. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

317. Amgen is entitled to a judicial declaration that Amgen has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '302 patent.

COUNT XLIX

Declaratory Judgment of Invalidity of U.S. Patent No. 8,633,302

318. Amgen restates and incorporates by reference the allegations in paragraphs 1–317 above as if fully set forth herein.

319. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '302 patent is invalid. Among other reasons, the claims of the '302 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '302 patent.

320. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether the claims of the '302 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code,

including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

321. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

322. Amgen is entitled to a judicial declaration that all claims of the '302 patent are invalid.

COUNT L

Declaratory Judgment of Non-Infringement of U.S. Patent No. 8,710,196

323. Amgen restates and incorporates by reference the allegations in paragraphs 1–322 above as if fully set forth herein.

324. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '196 patent would not be infringed by the commercial marketing of ABP 215. For example, the claims of the '196 patent recite the conductivity of a wash buffer that "increase[s] from a second conductivity that is higher than the first conductivity to a third conductivity during the washing," which Amgen's ABP 215 biological product and associated manufacturing processes do not satisfy. In addition, Amgen cannot infringe the '196 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 ("To say that an invalid patent cannot be infringed, or that someone cannot be induced to infringe an invalid patent, is in one sense a simple truth, both as a matter of logic and semantics . . . To be sure, if at the end of the day, an act that would have been an infringement or an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed."). To the extent there is an invention which is properly the subject of a United States patent, any manufacture, use, sale, offer for sale or import into the United States of ABP 215 by Amgen prior to the expiration date of the '196 patent was not an infringement of the '196 patent. Any manufacture and use of

ABP 215 by Amgen prior to the expiration date of the '196 patent was solely for uses reasonably related to the development and submission of information under a Federal law, for example to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k), which regulates biological products. These are not acts of infringement. 35 U.S.C. § 271(e)(1).

325. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether commercial marketing of the biological product that is the subject of Amgen's BLA for ABP 215 would infringe any valid and enforceable claim of the '196 patent.

326. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

327. Amgen is entitled to a judicial declaration that Amgen has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '196 patent.

COUNT LI

Declaratory Judgment of Invalidity of U.S. Patent No. 8,710,196

328. Amgen restates and incorporates by reference the allegations in paragraphs 1–327 above as if fully set forth herein.

329. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '196 patent is invalid. Among other reasons, the claims of the '196 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '196 patent.

330. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether the claims of the '196 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code,

including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

331. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

332. Amgen is entitled to a judicial declaration that all claims of the '196 patent are invalid.

COUNT LII

Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,441,035

333. Amgen restates and incorporates by reference the allegations in paragraphs 1–332 above as if fully set forth herein.

334. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '035 patent would not be infringed by the commercial marketing of ABP 215. For example, the claims of the '035 patent recite a "cell culture medium compris[ing] copper, insulin, and cysteine," or a cell culture medium where "the cysteine is at a concentration of form 1.25 mM to 2.5 mM," which Amgen's ABP 215 biological product and associated manufacturing processes do not satisfy. In addition, Amgen cannot infringe the '035 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 ("To say that an invalid patent cannot be infringed, or that someone cannot be induced to infringe an invalid patent, is in one sense a simple truth, both as a matter of logic and semantics . . . To be sure, if at the end of the day, an act that would have been an infringement or an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed."). To the extent there is an invention which is properly the subject of a United States patent, any manufacture, use, sale, offer for sale or import into the United States of ABP 215 by Amgen prior to the expiration date of the '035 patent was not an infringement of the '035 patent. Any manufacture and

use of ABP 215 by Amgen prior to the expiration date of the '035 patent was solely for uses reasonably related to the development and submission of information under a Federal law, for example to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k), which regulates biological products. These are not acts of infringement. 35 U.S.C. § 271(e)(1).

335. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether commercial marketing of the biological product that is the subject of Amgen's BLA for ABP 215 would infringe any valid and enforceable claim of the '035 patent.

336. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

337. Amgen is entitled to a judicial declaration that Amgen has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '035 patent.

COUNT LIII

Declaratory Judgment of Invalidity of U.S. Patent No. 9,441,035

338. Amgen restates and incorporates by reference the allegations in paragraphs 1–337 above as if fully set forth herein.

339. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '035 patent is invalid. Among other reasons, the claims of the '035 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '035 patent.

340. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether the claims of the '035 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code,

including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

341. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

342. Amgen is entitled to a judicial declaration that all claims of the '035 patent are invalid.

COUNT LIV

Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,478,809

343. Amgen restates and incorporates by reference the allegations in paragraphs 1–342 above as if fully set forth herein.

344. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '809 patent would not be infringed by the commercial marketing of ABP 215. For example, the claims of the '809 patent recite culturing cell comprising "a first heterologous nucleic acid sequence encoding a small interfering RNA (siRNA) specific for a lactate dehydrogenase," or cells comprising "a second heterologous nucleic acid sequence encoding an siRNA specific for a pyruvate dehydrogenase kinase (PDHK)," which Amgen's ABP 215 biological product and associated manufacturing processes do not satisfy. In addition, Amgen cannot infringe the '809 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 ("To say that an invalid patent cannot be infringed, or that someone cannot be induced to infringe an invalid patent, is in one sense a simple truth, both as a matter of logic and semantics . . . To be sure, if at the end of the day, an act that would have been an infringement or an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed."). To the extent there is an invention which is properly the subject of a United States patent, any manufacture, use, sale, offer for sale or import into the United States of ABP

215 by Amgen prior to the expiration date of the '809 patent was not an infringement of the '809 patent. Any manufacture and use of ABP 215 by Amgen prior to the expiration date of the '809 patent was solely for uses reasonably related to the development and submission of information under a Federal law, for example to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k), which regulates biological products. These are not acts of infringement. 35 U.S.C. § 271(e)(1).

345. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether commercial marketing of the biological product that is the subject of Amgen's BLA for ABP 215 would infringe any valid and enforceable claim of the '809 patent.

346. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

347. Amgen is entitled to a judicial declaration that Amgen has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '809 patent.

COUNT LV

Declaratory Judgment of Invalidity of U.S. Patent No. 9,478,809

348. Amgen restates and incorporates by reference the allegations in paragraphs 1–347 above as if fully set forth herein.

349. On May 23, 2017, Amgen provided Genentech with a detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B) describing the factual and legal bases for Amgen's opinion at the time that the '809 patent is invalid. Among other reasons, the claims of the '809 patent are invalid in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '809 patent.

350. There is a real, substantial, and justiciable controversy between Amgen and Genentech concerning whether the claims of the '809 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

351. The controversy between the parties is amenable to specific relief through a decree of a conclusive character.

352. Amgen is entitled to a judicial declaration that all claims of the '809 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Amgen respectfully requests that this Court enter judgment in its favor against Genentech and City of Hope and grant the following relief:

A. Declare that Amgen has not, does not, and will not infringe any valid and enforceable claim of the '297 patent.

B. Declare that all claims of the '297 patent are invalid.

C. Declare that Amgen has not, does not, and will not infringe any valid and enforceable claim of the '428 patent.

D. Declare that all claims of the '428 patent are invalid.

E. Declare that Amgen has not, does not, and will not infringe any valid and enforceable claim of the '177 patent.

F. Declare that all claims of the '177 patent are invalid.

G. Declare that Amgen has not, does not, and will not infringe any valid and enforceable claim of the '415 patent.

H. Declare that all claims of the '415 patent are invalid.

I. Declare that Amgen has not, does not, and will not infringe any valid and enforceable claim of the '213 patent.

J. Declare that all claims of the '213 patent are invalid.

K. Declare that all claims of the '213 patent are unenforceable due to Genentech's inequitable conduct before the Patent Office.

L. Declare that Amgen has not, does not, and will not infringe any valid and enforceable claim of the '335 patent.

M. Declare that all claims of the '335 patent are invalid.

N. Declare that Amgen has not, does not, and will not infringe any valid and enforceable claim of the '206 patent.

O. Declare that all claims of the '206 patent are invalid.

P. Declare that Amgen has not, does not, and will not infringe any valid and enforceable claim of the '516 patent.

Q. Declare that all claims of the '516 patent are invalid.

R. Declare that Amgen has not, does not, and will not infringe any valid and enforceable claim of the '918 patent.

S. Declare that all claims of the '918 patent are invalid.

T. Declare that Amgen has not, does not, and will not infringe any valid and enforceable claim of the '034 patent.

U. Declare that all claims of the '034 patent are invalid.

V. Declare that Amgen has not, does not, and will not infringe any valid and enforceable claim of the '879 patent.

W. Declare that all claims of the '879 patent are invalid.

X. Declare that Amgen has not, does not, and will not infringe any valid and enforceable claim of the '269 patent.

Y. Declare that all claims of the '269 patent are invalid.

Z. Declare that Amgen has not, does not, and will not infringe any valid and enforceable claim of the '901 patent.

AA. Declare that all claims of the '901 patent are invalid.

BB. Declare that Amgen has not, does not, and will not infringe any valid and enforceable claim of the ’334 patent.

CC. Declare that all claims of the ’334 patent are invalid.

DD. Declare that Amgen has not, does not, and will not infringe any valid and enforceable claim of the ’553 patent.

EE. Declare that all claims of the ’553 patent are invalid.

FF. Declare that Amgen has not, does not, and will not infringe any valid and enforceable claim of the ’193 patent.

GG. Declare that all claims of the ’193 patent are invalid.

HH. Declare that Amgen has not, does not, and will not infringe any valid and enforceable claim of the ’115 patent.

II. Declare that all claims of the ’115 patent are invalid.

JJ. Declare that Amgen has not, does not, and will not infringe any valid and enforceable claim of the ’799 patent.

KK. Declare that all claims of the ’799 patent are invalid.

LL. Declare that Amgen has not, does not, and will not infringe any valid and enforceable claim of the ’221 patent.

MM. Declare that all claims of the ’221 patent are invalid.

NN. Declare that Amgen has not, does not, and will not infringe any valid and enforceable claim of the ’017 patent.

OO. Declare that all claims of the ’017 patent are invalid.

PP. Declare that Amgen has not, does not, and will not infringe any valid and enforceable claim of the ’895 patent.

QQ. Declare that all claims of the ’895 patent are invalid.

RR. Declare that Amgen has not, does not, and will not infringe any valid and enforceable claim of the ’983 patent.

SS. Declare that all claims of the ’983 patent are invalid.

TT. Declare that Amgen has not, does not, and will not infringe any valid and enforceable claim of the '869 patent.

UU. Declare that all claims of the '869 patent are invalid.

VV. Declare that Amgen has not, does not, and will not infringe any valid and enforceable claim of the '302 patent.

WW. Declare that all claims of the '302 patent are invalid.

XX. Declare that Amgen has not, does not, and will not infringe any valid and enforceable claim of the '196 patent.

YY. Declare that all claims of the '196 patent are invalid.

ZZ. Declare that Amgen has not, does not, and will not infringe any valid and enforceable claim of the '035 patent.

AAA. Declare that all claims of the '035 patent are invalid.

BBB. Declare that Amgen has not, does not, and will not infringe any valid and enforceable claim of the '809 patent.

CCC. Declare that all claims of the '809 patent are invalid.

DDD. Declare that this is an exceptional case in favor of Amgen and award Amgen its reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

EEE. Award Amgen costs and expenses.

FFF. Award any and all such other relief as the Court determines to be just and proper, including pursuant to 28 U.S.C. § 2202.

Dated: October 6, 2017

PROSKAUER ROSE LLP

By: */s/ Siegmund Y. Gutman*

Attorneys for Plaintiff Amgen Inc.