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17 AMGEN INC.

18 UNITED STATES DISTRICT COURT
19 CENTRAL DISTRICT OF CALIFORNIA

20
21 AMGEN INC.,

22 Plaintiff,

23 v.

24 GENENTECH, INC. and CITY OF
25 HOPE,

26 Defendants.

Case No. 17-cv-7349

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

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

4 **NATURE OF THE CASE**

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

- 7 (i) U.S. Patent No. 6,054,297 (“the ’297 patent”);
8 (ii) U.S. Patent No. 6,121,428 (“the ’428 patent”);
9 (iii) U.S. Patent No. 6,242,177 (“the ’177 patent”);
10 (iv) U.S. Patent No. 6,331,415 (“the ’415 patent”);
11 (v) U.S. Patent No. 6,407,213 (“the ’213 patent”);
12 (vi) U.S. Patent No. 6,417,335 (“the ’335 patent”);
13 (vii) U.S. Patent No. 6,586,206 (“the ’206 patent”);
14 (viii) U.S. Patent No. 6,610,516 (“the ’516 patent”);
15 (ix) U.S. Patent No. 6,620,918 (“the ’918 patent”);
16 (x) U.S. Patent No. 6,870,034 (“the ’034 patent”);
17 (xi) U.S. Patent No. 6,884,879 (“the ’879 patent”);
18 (xii) U.S. Patent No. 7,060,269 (“the ’269 patent”);
19 (xiii) U.S. Patent No. 7,169,901 (“the ’901 patent”);
20 (xiv) U.S. Patent No. 7,297,334 (“the ’334 patent”);
21 (xv) U.S. Patent No. 7,323,553 (“the ’553 patent”);
22 (xvi) U.S. Patent No. 7,375,193 (“the ’193 patent”);
23 (xvii) U.S. Patent No. 7,622,115 (“the ’115 patent”);
24 (xviii) U.S. Patent No. 7,807,799 (“the ’799 patent”);
25 (xix) U.S. Patent No. 7,923,221 (“the ’221 patent”);
26 (xx) U.S. Patent No. 8,044,017 (“the ’017 patent”);
27 (xxi) U.S. Patent No. 8,460,895 (“the ’895 patent”);

1 (xxii) U.S. Patent No. 8,512,983 (“the ’983 patent”);
2 (xxiii) U.S. Patent No. 8,574,869 (“the ’869 patent”);
3 (xxiv) U.S. Patent No. 8,633,302 (“the ’302 patent”);
4 (xxv) U.S. Patent No. 8,710,196 (“the ’196 patent”);
5 (xxvi) U.S. Patent No. 9,441,035 (“the ’035 patent”); and
6 (xxvii) U.S. Patent No. 9,487,809 (“the ’809 patent”) (collectively, “the
7 patents-in-suit”).

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

12 3. A substantial controversy exists between Amgen, on the one hand, and
13 Genentech and City of Hope, on the other hand, in which the parties have adverse
14 legal interests of sufficient immediacy and reality to warrant the issuance of a
15 declaratory judgment. Amgen submitted an application to the FDA under 42 U.S.C.
16 § 262(k) for licensure of a bevacizumab biological product (hereinafter, “biosimilar
17 product,” “ABP 215,” or “Mvasi™”) that is highly similar to the Avastin® brand of
18 bevacizumab. Amgen provided Genentech with a copy of its application and in
19 response, Genentech identified the patents-in-suit, which Genentech alleges could
20 reasonably be asserted against Amgen if it were to manufacture, use, offer for sale,
21 or sell in the United States, or import into the United States, its biosimilar product.
22 In addition, Genentech provided Amgen with a statement purporting to contain the
23 factual and legal basis of Genentech’s opinion that the patents-in-suit would be
24 infringed by the commercial marketing of Amgen’s biosimilar product. Finally,
25 Genentech has asserted that patents-in-suit have been infringed by the manufacture
26 and/or use of Amgen’s bevacizumab biological product for uses that were not
27 reasonably related to the development and submission of information to the FDA.

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

6 **PARTIES**

7 4. Amgen Inc. is a corporation organized under the laws of the State of
8 Delaware, with its principal place of business at One Amgen Center Drive,
9 Thousand Oaks, CA 91320.

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

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

17 **JURISDICTION AND VENUE**

18 7. This Court has subject matter jurisdiction pursuant to 28 U.S.C.
19 §§ 1331, 1338(a), 2201, and 2202, as well as 35 U.S.C. § 271(e)(2). Amgen
20 provided to Genentech the application and information required under 42 U.S.C.
21 § 262(l)(2)(A). And in response, Genentech identified the patents-in-suit pursuant
22 to 42 U.S.C. § 262(l)(3)(A), which Genentech alleges could reasonably be asserted
23 against Amgen if it were to manufacture, use, offer for sale, or sell in the United
24 States, or import into the United States, its biosimilar product. On October 6, 2017,
25 Amgen provided notice of commercial marketing to Genentech pursuant to 42
26 U.S.C. § 262(l)(8)(A).

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

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

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

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

1 District relating to the enforcement of the patents-in-suit, including the transmission
2 of (i) notice letters, (ii) a list identifying the patents-in-suit among those patents that
3 Genentech believes could reasonably be asserted against Amgen following the
4 submission of its subsection (k) application, and (iii) a statement that purports to
5 describe Genentech’s opinions regarding the infringement, validity, and
6 enforceability of the patents-in-suit. Genentech also attended an in-person meeting
7 with Amgen in this District to determine which, if any, patents should be the subject
8 of an action for patent infringement. Both Genentech and City of Hope have
9 litigated in this District at least 11 separate actions relating to patents-in-suit,
10 including those having civil action numbers 2-16-cv-04992, 2-15-cv-09991, 2-15-
11 cv-05685, 2-13-cv-07248, 2-13-cv-05400, 2-11-cv-06594, 2-11-cv-03065, 2-11-cv-
12 06519, 2-10-cv-02764, 2-08-cv-03573, and 2-03-cv-02567. Furthermore, a
13 substantial part of the events giving rise to Genentech’s assertions that Amgen has
14 infringed the patents-in-suit occurred in this District. Amgen, a resident of this
15 District, prepared and filed its application for its biosimilar product pursuant to 42
16 U.S.C. § 262(k) (“subsection (k)” application) from within this District. Amgen
17 also has conducted substantial activities, including correspondence with the FDA, in
18 furtherance of its subsection (k) application from within this District. Amgen also
19 has performed substantial activities in this District relating to the development,
20 manufacture, and future commercial marketing of its biosimilar product.

21 **FACTUAL BACKGROUND**

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

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

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

18 14. In 2011, Amgen announced that it would develop and commercialize
19 several oncology antibody biosimilar drugs, including biosimilar versions of
20 Genentech’s Avastin®, Herceptin®, and Rituxan®. In the announcement, Amgen
21 recognized that “the development and commercialization of biosimilar products will
22 not follow a pure brand or generic model, and will require significant expertise,
23 infrastructure, and investment to ensure safe, reliably supplied therapies for
24 patients.” Amgen and Watson Announce Collaboration to Develop and
25 Commercialize Oncology Biosimilars, Media Release (Dec. 19, 2011),
26 <http://www.amgenbiosimilars.com/media/media-releases/2011/12/amgen-and->
27

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

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

17 **Congress Enacts Legislation Creating a Regulatory Pathway for**
18 **Biosimilar Biological Products**

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

24 17. “The BPCIA governs a type of drug called a biosimilar, which is a
25 biologic product that is highly similar to a biologic product that has already been
26 approved by the Food and Drug Administration (FDA).” *Sandoz Inc. v. Amgen Inc.*,
27 137 S. Ct. 1664, 1669 (2017).

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

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

17 20. The BPCIA describes a process whereby the reference product sponsor
18 and the biosimilar applicant exchange information in advance of a specific and
19 statutorily prescribed action for patent infringement. *First*, the process begins when
20 the applicant provides “a copy of the application submitted to the Secretary under
21 subsection (k), and such other information that describes the process or processes
22 used to manufacture the biological product that is the subject of such application.”
23 42 U.S.C. § 262(l)(2)(A). In addition, the applicant “may provide to the reference
24 product sponsor additional information requested by or on behalf of the reference
25 product sponsor.” 42 U.S.C. § 262(l)(2)(B). *Second*, the BPCIA states that the
26 reference product sponsor shall provide “a list of patents for which the reference
27 product sponsor believes a claim of patent infringement could reasonably be

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

20 21. Following the information exchange, the BPCIA requires the reference
21 product sponsor and the applicant to engage in “good faith negotiations to agree on
22 which, if any, patents listed under paragraph (3) by the subsection (k) applicant or
23 the reference product sponsor shall be the subject of an action for patent
24 infringement under paragraph (6) [of the statute].” 42 U.S.C. § 262(l)(4). If
25 agreement cannot be reached, the statute provides for a mechanism of further
26 exchanges to determine which patent(s) will be the subject of a paragraph (6) patent
27 litigation. 42 U.S.C. § 262(l)(4)(B)-(5). While the procedure and timing depend on
28

1 whether the reference product sponsor and the applicant can reach agreement, the
2 process may result in a statutorily defined action for patent infringement. 42 U.S.C.
3 § 262(l)(6).

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

12 **The Parties’ Exchanges Following the Filing of Amgen’s**

13 **Subsection (k) Application for Approval of Its Biosimilar Product**

14 23. According to the FDA’s “Purple Book,” Genentech’s Avastin® brand
15 of bevacizumab was first approved on February 26, 2004.

16 24. On November 14, 2016, Amgen filed its Biologics License Application
17 (“BLA”) for Mvasi™ pursuant to 42 U.S.C. § 262(k). Amgen’s BLA was filed after
18 the expiration of the 4 year and 12 year statutory periods provided by 42 U.S.C.
19 § 262(k)(7). Amgen received notification from the FDA that its BLA had been
20 accepted for review on January 4, 2017.

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

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

9 27. Together with Amgen’s § 262(l)(2)(A) disclosure, Amgen sent a letter
10 to Genentech communicating Amgen’s good-faith belief that its disclosure
11 contained sufficiently detailed information regarding its biosimilar product and
12 manufacturing processes, which “satisfie[d] Amgen’s production obligations under
13 42 U.S.C. § 262(l)(2)(A) and enable[d] Genentech to undertake its obligations under
14 42 U.S.C. § 262(l)(3)(A).”

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

20 29. Amgen communicated its willingness to reasonably cooperate with
21 Genentech in response to specific requests for non-cumulative information if
22 Genentech believed it needed additional information to assist it in fulfilling its
23 § 262(l)(3)(A) duties. Amgen wrote the following to Genentech in a letter dated
24 January, 25, 2017:

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

1 infringement pursuant to § 262(l)(3)(A). If, however, in
2 your evaluation of Amgen’s disclosure you believe that
3 additional targeted information not already provided in
4 Amgen’s § 262(l)(2)(A) disclosure would be helpful to
5 Genentech in making its determination under
6 § 262(l)(3)(A), we would be happy to discuss the
7 production of such information if it is reasonably
8 available to Amgen.

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

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

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

1 Genentech, however, failed to inform the Court that it had already provided Amgen
2 with its (3)(A) list. The Supreme Court subsequently issued its decision in the
3 *Amgen v. Sandoz* case on June 12, 2017. Following the decision, Genentech again
4 did not file a declaratory judgment action for patent infringement pursuant to 42
5 U.S.C. § 262(l)(9)(C), which, according to the Supreme Court, “excludes all other
6 federal remedies, including injunctive relief,” for any alleged noncompliance with
7 § 262(l)(2)(A).

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

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

1 to “justify” contentions that Amgen’s commercial marketing of Mvasi™ would
2 somehow infringe Genentech’s patents.

3 35. On September 6, 2017, Amgen wrote to Genentech regarding its non-
4 compliance with § 262(l)(3)(C). For example, Amgen explained that “Genentech’s
5 § 262(l)(3)(C) statement fails to provide the requisite detailed factual and legal basis
6 for its infringement contentions when . . . Genentech relies on Amgen’s alleged
7 § 262(l)(2)(A) violation.” Amgen also explained that, according to recent Supreme
8 Court precedent, any purported or perceived violation of § 262(l)(2)(A) is not an act
9 of patent infringement and, therefore, cannot serve as the basis for Genentech’s
10 continued assertion of 11 patents and 2 claims of a twelfth patent. *See Sandoz Inc.*
11 *v. Amgen Inc.*, 137 S.Ct. 1664, 1674 (2017) (“Failing to disclose the application and
12 manufacturing information under § 262(l)(2)(A) does not [constitute an act of
13 infringement under 35 U.S.C. § 271(e)(2)].”) In view of Genentech’s failure to
14 properly address the 13 patents and 3 claims described in Paragraph 34 above,
15 Amgen requested that Genentech confirm that it would remove them from its (3)(A)
16 list, or otherwise covenant that it would not assert them with respect to Mvasi™.

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

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

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

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

8 **THE PATENTS-IN-SUIT**

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

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

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

23 43. U.S. Patent No. 6,331,415, titled "Methods of Producing
24 Immunoglobulins, Vectors and Transformed Host Cells for Use Therein," issued on
25 December 18, 2001. Upon information and belief, Genentech and City of Hope co-
26 own the '415 patent. The earliest possible priority date for the '415 patent is April
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1 8, 1983. Upon information and belief, the '415 patent expires on December 18,
2 2018.

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

7 45. U.S. Patent No. 6,417,335, titled "Protein Purification," issued on July
8 9, 2002. Upon information and belief, Genentech owns the '335 patent. The
9 earliest possible priority date for the '335 patent is May 6, 1998. Upon information
10 and belief, the '213 patent expires on May 3, 2019.

11 46. U.S. Patent No. 6,586,206, titled "Methods for Making Recombinant
12 Proteins Using Apoptosis Inhibitors," issued on July 1, 2003. Upon information and
13 belief, Genentech owns the '206 patent. The earliest possible priority date for the
14 '206 patent is September 27, 1999. Upon information and belief, the '206 patent
15 expires on September 25, 2020.

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

20 48. U.S. Patent No. 6,620,918, titled "Separation of Polypeptide
21 Monomers," issued on September 16, 2003. Upon information and belief,
22 Genentech owns the '918 patent. The earliest possible priority date for the '918
23 patent is June 1, 1998. Upon information and belief, the '918 patent expires on May
24 26, 2019.

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

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

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

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

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

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

21 54. U.S. Patent No. 7,323,553, titled "Non-Affinity Purification of
22 Proteins," issued on January 29, 2008. Upon information and belief, Genentech
23 owns the '553 patent. The earliest possible priority date for the '553 patent is April
24 26, 2002. Upon information and belief, the '553 patent expires on April 25, 2023.

25 55. U.S. Patent No. 7,375,193, titled "Anti-VEGF Antibodies," issued on
26 May 20, 2008. Upon information and belief, Genentech owns the '193 patent. The
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1 earliest possible priority date of the '193 patent is August 7, 1997. Upon
2 information and belief, the '193 patent expired on August 7, 2017.

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

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

13 58. U.S. Patent No. 7,923,221, titled "Methods of Making Antibody Heavy
14 and Light Chains Having Specificity for a Desired Antigen," issued on April 12,
15 2011. Upon information and belief, Genentech and City of Hope co-own the '221
16 patent. The earliest possible priority date of the '221 patent is April 8, 1983. Upon
17 information and belief, the '221 patent expires on December 18, 2018.

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

22 60. U.S. Patent No. 8,460,895, titled "Method for Producing Recombinant
23 Proteins with a Constant Content of pCO₂ in the Medium," issued on June 11, 2013.
24 Upon information and belief, the '895 patent is owned by Hoffman-La Roche, Inc.
25 with all substantial rights exclusively licensed to Genentech. The earliest possible
26 priority date for the '895 patent is March 12, 2008. Upon information and belief,
27 the '895 patent expires on August 8, 2029.

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

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

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

17 64. U.S. Patent No. 8,710,196, titled “Protein Purification,” issued on April
18 29, 2014. Upon information and belief, Genentech owns the ’196 patent. The
19 earliest possible priority date for the ’196 patent is September 11, 2002. Upon
20 information and belief, the ’196 patent expires on September 10, 2023.

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

26 66. U.S. Patent No. 9,487,809, titled “Decreasing Lactate Level and
27 Increasing Polypeptide Production by Downregulating the Expression of Lactate
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1 Dehydrogenase and Pyruvate Dehydrogenase Kinase,” issued on November 8, 2016.
2 Upon information and belief, Genentech owns the ’809 patent. The earliest possible
3 priority date for the ’809 patent is May 28, 2010. Upon information and belief, the
4 ’809 patent expires on January 14, 2032.

5 **COUNT I**

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

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

9 68. To the extent there is an invention which is properly the subject of a
10 United States patent, any manufacture, use, sale, offer for sale or import into the
11 United States of ABP 215 by Amgen prior to the expiration date of the ’297 patent
12 was not an infringement of the ’297 patent. Any manufacture and use of ABP 215
13 by Amgen prior to the expiration date of the ’297 patent was solely for uses
14 reasonably related to the development and submission of information under a
15 Federal law, for example to the FDA under the Public Health Service Act including
16 42 U.S.C. § 262(k), which regulates biological products. These are not acts of
17 infringement. 35 U.S.C. § 271(e)(1). In addition, Amgen cannot infringe the ’297
18 patent because it is invalid. *See Commil USA, LLC v. Cisco Systems, Inc.*, 135 S. Ct.
19 1920, 1929 (2015) (“To say that an invalid patent cannot be infringed, or that
20 someone cannot be induced to infringe an invalid patent, is in one sense a simple
21 truth, both as a matter of logic and semantics . . . To be sure, if at the end of the day,
22 an act that would have been an infringement or an inducement to infringe pertains to
23 a patent that is shown to be invalid, there is no patent to be infringed.”).

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

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

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

6 **COUNT II**

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

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

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

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

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

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

22 **COUNT III**

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

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

26 78. To the extent there is an invention which is properly the subject of a
27 United States patent, any manufacture, use, sale, offer for sale or import into the
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1 United States of ABP 215 by Amgen prior to the expiration date of the '428 patent
2 was not an infringement of the '428 patent. Any manufacture and use of ABP 215
3 by Amgen prior to the expiration date of the '428 patent was solely for uses
4 reasonably related to the development and submission of information under a
5 Federal law, for example to the FDA under the Public Health Service Act including
6 42 U.S.C. § 262(k), which regulates biological products. These are not acts of
7 infringement. 35 U.S.C. § 271(e)(1). In addition, Amgen cannot infringe the '428
8 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 (“To say that an invalid
9 patent cannot be infringed, or that someone cannot be induced to infringe an invalid
10 patent, is in one sense a simple truth, both as a matter of logic and semantics . . . To
11 be sure, if at the end of the day, an act that would have been an infringement or an
12 inducement to infringe pertains to a patent that is shown to be invalid, there is no
13 patent to be infringed.”).

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

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

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

22 **COUNT IV**

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

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

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

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

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

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

13 **COUNT V**

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

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

17 88. To the extent there is an invention which is properly the subject of a
18 United States patent, any manufacture, use, sale, offer for sale or import into the
19 United States of ABP 215 by Amgen prior to the expiration date of the '177 patent
20 was not an infringement of the '177 patent. Any manufacture and use of ABP 215
21 by Amgen prior to the expiration date of the '177 patent was solely for uses
22 reasonably related to the development and submission of information under a
23 Federal law, for example to the FDA under the Public Health Service Act including
24 42 U.S.C. § 262(k), which regulates biological products. These are not acts of
25 infringement. 35 U.S.C. § 271(e)(1). In addition, Amgen cannot infringe the '177
26 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 (“To say that an invalid
27 patent cannot be infringed, or that someone cannot be induced to infringe an invalid
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1 patent, is in one sense a simple truth, both as a matter of logic and semantics . . . To
2 be sure, if at the end of the day, an act that would have been an infringement or an
3 inducement to infringe pertains to a patent that is shown to be invalid, there is no
4 patent to be infringed.”).

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

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

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

13 **COUNT VI**

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

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

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

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

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

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

3 **COUNT VII**

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

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

7 98. To the extent there is an invention which is properly the subject of a
8 United States patent, any manufacture, use, sale, offer for sale or import into the
9 United States of ABP 215 by Amgen prior to the expiration date of the '415 patent
10 was not an infringement of the '415 patent. Any manufacture and use of ABP 215
11 by Amgen prior to the expiration date of the '415 patent was solely for uses
12 reasonably related to the development and submission of information under a
13 Federal law, for example to the FDA under the Public Health Service Act including
14 42 U.S.C. § 262(k), which regulates biological products. These are not acts of
15 infringement. 35 U.S.C. § 271(e)(1). In addition, Amgen cannot infringe the '415
16 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 (“To say that an invalid
17 patent cannot be infringed, or that someone cannot be induced to infringe an invalid
18 patent, is in one sense a simple truth, both as a matter of logic and semantics . . . To
19 be sure, if at the end of the day, an act that would have been an infringement or an
20 inducement to infringe pertains to a patent that is shown to be invalid, there is no
21 patent to be infringed.”).

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

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

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

4 **COUNT VIII**

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

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

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

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

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

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

21 **COUNT IX**

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

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

25 108. On May 23, 2017, Amgen provided Genentech with a detailed
26 statement pursuant to 42 U.S.C. §§ 262(l)(3)(B) describing the factual and legal
27 bases for Amgen's opinion at the time that the '213 patent would not be infringed by
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1 the commercial marketing of ABP 215. For example, the claims of the '213 patent
2 recite amino acid substitutions at specific sites in the framework region(s) which
3 Amgen's ABP 215 biological product does not satisfy. In addition, Amgen cannot
4 infringe the '213 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 (“To
5 say that an invalid patent cannot be infringed, or that someone cannot be induced to
6 infringe an invalid patent, is in one sense a simple truth, both as a matter of logic
7 and semantics . . . To be sure, if at the end of the day, an act that would have been an
8 infringement or an inducement to infringe pertains to a patent that is shown to be
9 invalid, there is no patent to be infringed.”). To the extent there is an invention
10 which is properly the subject of a United States patent, any manufacture, use, sale,
11 offer for sale or import into the United States of ABP 215 by Amgen prior to the
12 expiration date of the '213 patent was not an infringement of the '213 patent. Any
13 manufacture and use of ABP 215 by Amgen prior to the expiration date of the '213
14 patent was solely for uses reasonably related to the development and submission of
15 information under a Federal law, for example to the FDA under the Public Health
16 Service Act including 42 U.S.C. § 262(k), which regulates biological products.
17 These are not acts of infringement. 35 U.S.C. § 271(e)(1).

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

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

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

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1 **COUNT X**

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

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

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

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

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

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

20 **COUNT XI**

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

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

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

1 119. Genentech deliberately misrepresented the teachings of U.S. Patent No.
2 5,530,101 (“’101 patent”) to the Patent Office in order to overcome a rejection
3 based on that reference. Specifically, Genentech told the Examiner that the ’101
4 patent does not use the Kabat numbering system, despite its repeated references to
5 “numbering according to Kabat” and “the Kabat system.”

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

13 121. On November 17, 1993, Genentech filed its patent application with
14 claims requiring substitutions at specific locations, including positions “62L” and
15 “93H.” On December 9, 1994, the Examiner issued a Non-Final Rejection, rejecting
16 the claims as obvious under § 103 over EP 0239400, Queen 1989, Riechmann 1988.

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

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

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

26 125. On October 7, 1997, Genentech argued in its remarks to the Patent
27 Office that Queen 1989 and the ’101 patent were distinguishable because they “use
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1 sequential numbering for the variable domain residues of the antibodies described in
2 these references, whereas the claims of the instant application use Kabat numbering
3 for the framework region residues.” Genentech repeated the same argument later in
4 the prosecution of the ’213 patent to distinguish Queen 1989 and the ’101 patent
5 with specific reference to residue “93H”:

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

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

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

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

1 to position 93 in the heavy chain. (*See id.* at 15:17–37.) Moreover, Table 5 of the
 2 '101 patent refers to residue “H93,” with explicit reference to numbering “according
 3 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 |
| <u>Fd79</u> | | |
| L49 | Lys | L50Y, L53N, L55E, H99D, H100Y |
| H93 | Leu | H35S, H37V, H100CF |
| <u>Fd138-80</u> | | |
| 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.

17 128. In order to overcome the § 102 rejection based on the '101 patent,
 18 Genentech falsely represented to the Patent Office that the '101 patent used
 19 sequential numbering, while arguing that the “claims of the instant application use
 20 Kabat numbering for the framework region residues.” Genentech misrepresented
 21 the teachings of the '101 patent, despite clear and repeated references in the '101
 22 patent to the Kabat numbering system. Absent Genentech’s false and misleading
 23 distinction, the Examiner had no reason to withdraw the § 102 rejection based on the
 24 '101 patent.

25 129. Genentech also made deliberate and material misrepresentations and
 26 omissions regarding Queen 1989 during the prosecution of the '213 patent.
 27 Genentech distinguished Queen 1989 on the ground that it used “sequential
 28

1 numbering,” as opposed to the Kabat numbering system. At the Examiner’s request,
2 Genentech submitted a comparison of the different numbering systems purportedly
3 utilized in Queen 1989 and the pending claims.¹ The alignments provided by
4 Genentech to the Examiner conspicuously omitted the “62L” residue in both
5 numbering systems. As noted above, residue “62L” was recited in then-pending
6 claims of the ’213 patent, and Queen 1989 expressly discloses “residues at positions
7 corresponding to . . . 47 and 62 of the light chain (Fig. 2).” (*See* Queen 1989 at
8 10032.) Importantly, Queen 1989 discloses residues in the Kabat numbering system
9 and, in particular, residue “62 of the light chain.”

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

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

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

17 **COUNT XII**

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

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

21 134. On May 23, 2017, Amgen provided Genentech with a detailed
22 statement pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases
23 for Amgen’s opinion at the time that the ’335 patent would not be infringed by the
24

25 ¹ *See* 10/7/97 Applicant Remarks at 6–10 (“As requested by the Examiner in the
26 interview, alignments of heavy chain variable domain (Exhibit A) and light chain
27 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.”).

1 commercial marketing of ABP 215. For example, the claims of the '335 patent
2 recite an “anti-HER2 antibody,” which Amgen’s ABP 215 biological product does
3 not satisfy. In addition, Amgen cannot infringe the '335 patent because it is invalid.
4 *See Commil*, 135 S. Ct. at 1929 (“To say that an invalid patent cannot be infringed,
5 or that someone cannot be induced to infringe an invalid patent, is in one sense a
6 simple truth, both as a matter of logic and semantics . . . To be sure, if at the end of
7 the day, an act that would have been an infringement or an inducement to infringe
8 pertains to a patent that is shown to be invalid, there is no patent to be infringed.”).
9 To the extent there is an invention which is properly the subject of a United States
10 patent, any manufacture, use, sale, offer for sale or import into the United States of
11 ABP 215 by Amgen prior to the expiration date of the '335 patent was not an
12 infringement of the '335 patent. Any manufacture and use of ABP 215 by Amgen
13 prior to the expiration date of the '335 patent was solely for uses reasonably related
14 to the development and submission of information under a Federal law, for example
15 to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k),
16 which regulates biological products. These are not acts of infringement. 35 U.S.C.
17 § 271(e)(1).

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

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

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

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1 **COUNT XIII**

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

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

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

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

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

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

20 **COUNT XIV**

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

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

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

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

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

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

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

4 **COUNT XV**

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

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

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

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

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

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

23 **COUNT XVI**

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

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

1 154. On May 23, 2017, Amgen provided Genentech with a detailed
2 statement pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases
3 for Amgen’s opinion at the time that the ’516 patent would not be infringed by the
4 commercial marketing of ABP 215. For example, the claims of the ’516 patent
5 recite a “process for producing a human glycoprotein having multiple glycoforms,”
6 and culturing cells “in the presence of about 0 to 2 mM of a butyrate salt,” which
7 Amgen’s ABP 215 biological product and associated manufacturing processes do
8 not satisfy. In addition, Amgen cannot infringe the ’516 patent because it is invalid.
9 *See Commil*, 135 S. Ct. at 1929 (“To say that an invalid patent cannot be infringed,
10 or that someone cannot be induced to infringe an invalid patent, is in one sense a
11 simple truth, both as a matter of logic and semantics To be sure, if at the end of
12 the day, an act that would have been an infringement or an inducement to infringe
13 pertains to a patent that is shown to be invalid, there is no patent to be infringed.”).
14 To the extent there is an invention which is properly the subject of a United States
15 patent, any manufacture, use, sale, offer for sale or import into the United States of
16 ABP 215 by Amgen prior to the expiration date of the ’516 patent was not an
17 infringement of the ’516 patent. Any manufacture and use of ABP 215 by Amgen
18 prior to the expiration date of the ’516 patent was solely for uses reasonably related
19 to the development and submission of information under a Federal law, for example
20 to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k),
21 which regulates biological products. These are not acts of infringement. 35 U.S.C.
22 § 271(e)(1).

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

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

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

6 **COUNT XVII**

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

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

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

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

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

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

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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),

1 which regulates biological products. These are not acts of infringement. 35 U.S.C.
2 § 271(e)(1).

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

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

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

12 **COUNT XIX**

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

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

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

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

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

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

5 **COUNT XX**

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

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

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

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

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

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

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

18 **COUNT XXI**

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

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

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

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

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

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

10 **COUNT XXII**

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

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

14 184. To the extent there is an invention which is properly the subject of a
15 United States patent, any manufacture, use, sale, offer for sale or import into the
16 United States of ABP 215 by Amgen prior to the expiration date of the '879 patent
17 was not an infringement of the '879 patent. Any manufacture and use of ABP 215
18 by Amgen prior to the expiration date of the '879 patent was solely for uses
19 reasonably related to the development and submission of information under a
20 Federal law, for example to the FDA under the Public Health Service Act including
21 42 U.S.C. § 262(k), which regulates biological products. These are not acts of
22 infringement. 35 U.S.C. § 271(e)(1). In addition, Amgen cannot infringe the '879
23 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 (“To say that an invalid
24 patent cannot be infringed, or that someone cannot be induced to infringe an invalid
25 patent, is in one sense a simple truth, both as a matter of logic and semantics . . . To
26 be sure, if at the end of the day, an act that would have been an infringement or an
27

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

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

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

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

11 **COUNT XXIII**

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

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

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

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

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

25 192. Amgen is entitled to a judicial declaration that all claims of the ’879
26 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

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

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

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

8 **COUNT XXV**

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

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

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

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

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

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

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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).

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

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

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

10 **COUNT XXVII**

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

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

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

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

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

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

3 **COUNT XXVIII**

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

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

7 214. To the extent there is an invention which is properly the subject of a
8 United States patent, any manufacture, use, sale, offer for sale or import into the
9 United States of ABP 215 by Amgen prior to the expiration date of the '334 patent
10 was not an infringement of the '334 patent. Any manufacture and use of ABP 215
11 by Amgen prior to the expiration date of the '334 patent was solely for uses
12 reasonably related to the development and submission of information under a
13 Federal law, for example to the FDA under the Public Health Service Act including
14 42 U.S.C. § 262(k), which regulates biological products. These are not acts of
15 infringement. 35 U.S.C. § 271(e)(1). In addition, Amgen cannot infringe the '334
16 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 (“To say that an invalid
17 patent cannot be infringed, or that someone cannot be induced to infringe an invalid
18 patent, is in one sense a simple truth, both as a matter of logic and semantics . . . To
19 be sure, if at the end of the day, an act that would have been an infringement or an
20 inducement to infringe pertains to a patent that is shown to be invalid, there is no
21 patent to be infringed.”).

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

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

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

4 **COUNT XXIX**

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

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

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

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

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

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

20 **COUNT XXX**

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

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

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

1 recite “wherein said method includes no affinity purification step,” which Amgen’s
2 ABP 215 biological product and associated manufacturing processes do not satisfy.
3 In addition, Amgen cannot infringe the ’553 patent because it is invalid. *See*
4 *Commil*, 135 S. Ct. at 1929 (“To say that an invalid patent cannot be infringed, or
5 that someone cannot be induced to infringe an invalid patent, is in one sense a
6 simple truth, both as a matter of logic and semantics To be sure, if at the end of
7 the day, an act that would have been an infringement or an inducement to infringe
8 pertains to a patent that is shown to be invalid, there is no patent to be infringed.”).
9 To the extent there is an invention which is properly the subject of a United States
10 patent, any manufacture, use, sale, offer for sale or import into the United States of
11 ABP 215 by Amgen prior to the expiration date of the ’553 patent was not an
12 infringement of the ’553 patent. Any manufacture and use of ABP 215 by Amgen
13 prior to the expiration date of the ’553 patent was solely for uses reasonably related
14 to the development and submission of information under a Federal law, for example
15 to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k),
16 which regulates biological products. These are not acts of infringement. 35 U.S.C.
17 § 271(e)(1).

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

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

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

1 **COUNT XXXI**

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

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

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

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

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

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

20 **COUNT XXXII**

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

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

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

1 by Amgen prior to the expiration date of the '193 patent was solely for uses
2 reasonably related to the development and submission of information under a
3 Federal law, for example to the FDA under the Public Health Service Act including
4 42 U.S.C. § 262(k), which regulates biological products. These are not acts of
5 infringement. 35 U.S.C. § 271(e)(1). In addition, Amgen cannot infringe the '193
6 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 (“To say that an invalid
7 patent cannot be infringed, or that someone cannot be induced to infringe an invalid
8 patent, is in one sense a simple truth, both as a matter of logic and semantics . . . To
9 be sure, if at the end of the day, an act that would have been an infringement or an
10 inducement to infringe pertains to a patent that is shown to be invalid, there is no
11 patent to be infringed.”).

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

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

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

20 **COUNT XXXIII**

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

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

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

1 Amgen prior to the expiration date of the '115 patent was not an infringement of the
2 '115 patent. Any manufacture and use of ABP 215 by Amgen prior to the
3 expiration date of the '115 patent was solely for uses reasonably related to the
4 development and submission of information under a Federal law, for example to the
5 FDA under the Public Health Service Act including 42 U.S.C. § 262(k), which
6 regulates biological products. These are not acts of infringement. 35 U.S.C.
7 § 271(e)(1).

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

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

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

17 **COUNT XXXV**

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

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

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

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

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

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

10 COUNT XXXVI

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

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

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

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

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

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

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

17 **COUNT XXXVII**

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

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

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

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

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

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

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

11 **COUNT XXXIX**

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

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

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

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

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

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

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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

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

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

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

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

12 **COUNT XLI**

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

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

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

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

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

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

5 **COUNT XLII**

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

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

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

1 Federal law, for example to the FDA under the Public Health Service Act including
2 42 U.S.C. § 262(k), which regulates biological products. These are not acts of
3 infringement. 35 U.S.C. § 271(e)(1).

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

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

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

13 **COUNT XLIII**

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

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

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

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

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

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

5 **COUNT XLIV**

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

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

9 294. On May 23, 2017, Amgen provided Genentech with a detailed
10 statement pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases
11 for Amgen's opinion at the time that the '983 patent would not be infringed by the
12 commercial marketing of ABP 215. For example, the claims of the '983 patent
13 recite "a glutamine-free production culture medium containing asparagine, wherein
14 the asparagine is added at a concentration in the range of 7.5 mM to 15 mM," or "[a]
15 ready-to-use glutamine-free cell culture medium containing asparagine for the
16 production of a polypeptide in a production phase, wherein the asparagine is at a
17 concentration in the range of 7.5 mM to 15 mM," which Amgen's ABP 215
18 biological product and associated manufacturing processes do not satisfy. In
19 addition, Amgen cannot infringe the '983 patent because it is invalid. *See Commil*,
20 135 S. Ct. at 1929 ("To say that an invalid patent cannot be infringed, or that
21 someone cannot be induced to infringe an invalid patent, is in one sense a simple
22 truth, both as a matter of logic and semantics . . . To be sure, if at the end of the day,
23 an act that would have been an infringement or an inducement to infringe pertains to
24 a patent that is shown to be invalid, there is no patent to be infringed."). To the
25 extent there is an invention which is properly the subject of a United States patent,
26 any manufacture, use, sale, offer for sale or import into the United States of ABP
27 215 by Amgen prior to the expiration date of the '983 patent was not an

1 infringement of the '983 patent. Any manufacture and use of ABP 215 by Amgen
2 prior to the expiration date of the '983 patent was solely for uses reasonably related
3 to the development and submission of information under a Federal law, for example
4 to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k),
5 which regulates biological products. These are not acts of infringement. 35 U.S.C.
6 § 271(e)(1).

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

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

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

16 **COUNT XLV**

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

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

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

26 300. There is a real, substantial, and justiciable controversy between Amgen
27 and Genentech concerning whether the claims of the '983 patent are invalid for
28

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

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

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

8 **COUNT XLVI**

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

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

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

1 ABP 215 by Amgen prior to the expiration date of the '869 patent was solely for
2 uses reasonably related to the development and submission of information under a
3 Federal law, for example to the FDA under the Public Health Service Act including
4 42 U.S.C. § 262(k), which regulates biological products. These are not acts of
5 infringement. 35 U.S.C. § 271(e)(1).

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

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

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

15 **COUNT XLVII**

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

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

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

25 310. There is a real, substantial, and justiciable controversy between Amgen
26 and Genentech concerning whether the claims of the '869 patent are invalid for
27 failure to comply with the requirements of Title 35 of the United States Code,
28

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

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

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

7 **COUNT XLVIII**

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

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

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

1 prior to the expiration date of the '302 patent was solely for uses reasonably related
2 to the development and submission of information under a Federal law, for example
3 to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k),
4 which regulates biological products. These are not acts of infringement. 35 U.S.C.
5 § 271(e)(1).

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

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

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

15 **COUNT XLIX**

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

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

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

25 320. There is a real, substantial, and justiciable controversy between Amgen
26 and Genentech concerning whether the claims of the '302 patent are invalid for
27 failure to comply with the requirements of Title 35 of the United States Code,
28

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

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

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

7 **COUNT L**

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

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

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

1 ABP 215 by Amgen prior to the expiration date of the '196 patent was solely for
2 uses reasonably related to the development and submission of information under a
3 Federal law, for example to the FDA under the Public Health Service Act including
4 42 U.S.C. § 262(k), which regulates biological products. These are not acts of
5 infringement. 35 U.S.C. § 271(e)(1).

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

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

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

15 **COUNT LI**

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

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

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

25 330. There is a real, substantial, and justiciable controversy between Amgen
26 and Genentech concerning whether the claims of the '196 patent are invalid for
27 failure to comply with the requirements of Title 35 of the United States Code,
28

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

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

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

7 **COUNT LII**

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

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

11 334. On May 23, 2017, Amgen provided Genentech with a detailed
12 statement pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases
13 for Amgen's opinion at the time that the '035 patent would not be infringed by the
14 commercial marketing of ABP 215. For example, the claims of the '035 patent
15 recite a "cell culture medium compris[ing] copper, insulin, and cysteine," or a cell
16 culture medium where "the cysteine is at a concentration of from 1.25 mM to
17 2.5 mM," which Amgen's ABP 215 biological product and associated
18 manufacturing processes do not satisfy. In addition, Amgen cannot infringe the
19 '035 patent because it is invalid. *See Commil*, 135 S. Ct. at 1929 ("To say that an
20 invalid patent cannot be infringed, or that someone cannot be induced to infringe an
21 invalid patent, is in one sense a simple truth, both as a matter of logic and semantics
22 . . . To be sure, if at the end of the day, an act that would have been an infringement
23 or an inducement to infringe pertains to a patent that is shown to be invalid, there is
24 no patent to be infringed."). To the extent there is an invention which is properly
25 the subject of a United States patent, any manufacture, use, sale, offer for sale or
26 import into the United States of ABP 215 by Amgen prior to the expiration date of
27 the '035 patent was not an infringement of the '035 patent. Any manufacture and
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1 use of ABP 215 by Amgen prior to the expiration date of the '035 patent was solely
2 for uses reasonably related to the development and submission of information under
3 a Federal law, for example to the FDA under the Public Health Service Act
4 including 42 U.S.C. § 262(k), which regulates biological products. These are not
5 acts of infringement. 35 U.S.C. § 271(e)(1).

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

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

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

15 **COUNT LIII**

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

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

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

25 340. There is a real, substantial, and justiciable controversy between Amgen
26 and Genentech concerning whether the claims of the '035 patent are invalid for
27 failure to comply with the requirements of Title 35 of the United States Code,
28

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

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

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

7 **COUNT LIV**

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

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

11 344. On May 23, 2017, Amgen provided Genentech with a detailed
12 statement pursuant to 42 U.S.C. § 262(l)(3)(B) describing the factual and legal bases
13 for Amgen's opinion at the time that the '809 patent would not be infringed by the
14 commercial marketing of ABP 215. For example, the claims of the '809 patent
15 recite culturing cell comprising “a first heterologous nucleic acid sequence encoding
16 a small interfering RNA (siRNA) specific for a lactate dehydrogenase,” or cells
17 comprising “a second heterologous nucleic acid sequence encoding an siRNA
18 specific for a pyruvate dehydrogenase kinase (PDHK),” which Amgen's ABP 215
19 biological product and associated manufacturing processes do not satisfy. In
20 addition, Amgen cannot infringe the '809 patent because it is invalid. *See Commil*,
21 135 S. Ct. at 1929 (“To say that an invalid patent cannot be infringed, or that
22 someone cannot be induced to infringe an invalid patent, is in one sense a simple
23 truth, both as a matter of logic and semantics . . . To be sure, if at the end of the day,
24 an act that would have been an infringement or an inducement to infringe pertains to
25 a patent that is shown to be invalid, there is no patent to be infringed.”). To the
26 extent there is an invention which is properly the subject of a United States patent,
27 any manufacture, use, sale, offer for sale or import into the United States of ABP

1 215 by Amgen prior to the expiration date of the '809 patent was not an
2 infringement of the '809 patent. Any manufacture and use of ABP 215 by Amgen
3 prior to the expiration date of the '809 patent was solely for uses reasonably related
4 to the development and submission of information under a Federal law, for example
5 to the FDA under the Public Health Service Act including 42 U.S.C. § 262(k),
6 which regulates biological products. These are not acts of infringement. 35 U.S.C.
7 § 271(e)(1).

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

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

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

17 **COUNT LV**

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

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

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

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

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

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

10 **PRAYER FOR RELIEF**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

18 EEE. Award Amgen costs and expenses.

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

21
22
23 Dated: October 6, 2017

PROSKAUER ROSE LLP

24
25 By: /s/ Siegmund Y. Gutman

26 Attorneys for Plaintiff Amgen Inc.
27
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