IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC. and ABBVIE BIOTECHNOLOGY LTD., Plaintiffs, v. AMGEN INC. and AMGEN MANUFACTURING LTD., Defendants.	Civil No. 16-666-SLR

COUNTERCLAIMS AND ANSWER OF DEFENDANTS-COUNTERCLAIM PLAINTIFFS AMGEN INC. AND AMGEN MANUFACTURING LTD.

Amgen Inc. ("Amgen") and Amgen Manufacturing Ltd. ("AML"), by their undersigned attorneys, state as follows:

COUNTERCLAIMS

Parties

1. Counterclaim-Plaintiff Amgen is a company organized and existing under the laws of the State of Delaware with its corporate headquarters at One Amgen Center Drive, Thousand Oaks, California 91320.

2. Counterclaim-Plaintiff AML is a corporation organized and existing under the laws of Bermuda with its principal place of business at Road 31, km 24.6, Juncos, Puerto Rico 00777.

3. Amgen is the world's largest independent biotechnology company and a pioneer in developing biologic medicines. As set forth in its Mission Statement, Amgen strives to serve patients by transforming the promise of science and biotechnology into therapies that have the power to restore health or save lives. AML is an Amgen subsidiary

that participates in the manufacture of medications marketed by Amgen and its subsidiaries.

4. Amgen has been manufacturing, distributing, and selling biological medicines in the US since 1989. Currently, Amgen has at least 12 biological medicines it manufactures, distributes, and sells in the US, and across the world, to help millions of patients deal with diseases that often have devastating consequences, such as cancer and arthritis.

5. Amgen's biosimilars business is committed to building on Amgen's experience in the development, manufacture, and distribution of biological medicines.

6. On information and belief, Counterclaim-Defendant AbbVie Inc. ("AbbVie") is a corporation organized and existing under the laws of Delaware with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064.

7. On information and belief, Counterclaim-Defendant AbbVie Biotechnology Ltd. ("ABL") is a corporation organized and existing under the laws of Bermuda, with a place of business at Clarendon House, 2 Church Street, Hamilton HM11, Bermuda. AbbVie owns ABL through intermediate organizations.

Jurisdiction and Venue

8. Amgen's Counterclaims arise under the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02. This Court has subject matter jurisdiction over Amgen's Counterclaims under at least 28 U.S.C. §§ 1331, 1338, and 2201.

9. Venue is proper in this District under 28 U.S.C. § 1391(b) because AbbVie is a Delaware corporation and because the assertion of patent infringement claims

by AbbVie against Amgen and AML in this District gave rise to these Counterclaims. AbbVie contends in its Complaint that venue is proper in this District.

10. AbbVie and ABL have consented to personal jurisdiction in the State of Delaware and in this District by bringing the present action against Amgen and AML.

The BPCIA

11. In 2010, Congress enacted the Biologics Price Competition and Innovation Act ("BPCIA"), which created a new, abbreviated pathway (42 U.S.C. § 262(k), often referred to as the "subsection (k) pathway") for FDA licensure of biological products that are determined to be highly similar to previously-licensed biological products (called "reference products"). The BPCIA defines a "biosimilar" to be a biological product that: (1) is "highly similar to the reference product notwithstanding minor differences in clinically inactive components," and (2) has "no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product." 42 U.S.C. §§ 262(*l*)(2)(A) and (B).

12. In addition to creating the abbreviated pathway for product licensure, the BPCIA created an intricate and carefully orchestrated set of procedures for the subsection (k) applicant ("biosimilar applicant") and the sponsor of the reference product ("the Reference Product Sponsor" or "RPS") to identify patents in dispute, to resolve or narrow those disputes, and to commence litigation, if appropriate. Generally, the process involves a private and confidential disclosure of information, exchange of contentions, conduct of negotiations, and notice of commercial marketing as set forth at 42 U.S.C. § 262(*l*).

Amgen's Compliance with the BPCIA and AbbVie's Non-Compliance

13. In its Complaint, AbbVie has described Amgen as a company that disregards the requirements of the BPCIA when it is in the position of a biosimilar

applicant. This is not true. As detailed below, Amgen has fully complied with its obligations under the BPCIA, while AbbVie has repeatedly violated the BPCIA or frustrated the goals of the BPCIA process.

14. On November 25, 2015, Amgen submitted its Biologics License Application (BLA No. 761024) to the FDA under the subsection (k) pathway seeking a license to market ABP 501 (adalimumab) in the United States. In its application, Amgen designated AbbVie's adalimumab biologic Humira as the reference product. On January 25, 2016, Amgen informed AbbVie that the FDA had accepted its BLA for review.

15. On February 10, 2016, Amgen provided AbbVie with a copy of its BLA under the confidentiality provisions set forth in 42 U.S.C. § 262(*l*)(1) of the BPCIA. . The BLA contains extensive information concerning ABP 501, including information that describes the processes used to manufacture ABP 501.

§ 262(*l*)(3) Information Exchange

16. On April 11, 2016, AbbVie sent Amgen its statement under 42 U.S.C. § 262(*l*)(3)(A) (the "3(A) List"), listing 66 issued or allowed patents for which AbbVie said it believed a claim for patent infringement could reasonably be asserted by AbbVie if Amgen engaged in the making, using, offering to sell, selling, or importing into the United States of ABP 501. AbbVie later added another patent to this list purportedly under the procedures set forth in 42 U.S.C. § 262(*l*)(7). Neither before nor at the time of providing its 3(A) List did AbbVie identify any information that it believed Amgen was required to disclose pursuant to Section 262(*l*)(2)(A) that had not been adequately described in Amgen's BLA.

17. On June 10, 2016, under 42 U.S.C. § 262(*l*)(3)(B), Amgen provided AbbVie with a detailed statement describing the factual and legal basis for Amgen's view that 65 of the patents on AbbVie's 3(A) List are invalid and/or would not be infringed by Amgen's commercial marketing of ABP 501 (the "3(B) Statement"). As to the remaining patent, Amgen certified that it does not intend to begin commercial marketing of ABP 501 before that patent expires on December 31, 2016.

18. Amgen's 3(B) Statement totaled over 2,750 pages. Amgen provided detailed non-infringement contentions and supported those contentions with citations to the BLA. Amgen also provided detailed invalidity contentions, explaining why each of AbbVie's patent claims is invalid because it is anticipated, obvious, indefinite, not enabled, or lacks written description. Amgen supported its invalidity contentions with extensive claim charts and citations to the specifications of AbbVie's patents and numerous prior-art references.

19. AbbVie now complains that Amgen did not provide additional non-infringement information or copies of the prior art references discussed in the 3(B) Statement, citing AbbVie's generic request for such materials when it served its 3(A) List. Yet, as noted above, Amgen provided detailed supporting information in the 3(B) Statement, including citations to specific information in the BLA, and clearly identified the publicly available invalidity references on which it relied. After receiving Amgen's 3(B) Statement, AbbVie did not complain about the adequacy of the 3(B) Statement. AbbVie only later raised complaints to try to justify the inadequacies in its response to the 3(B) Statement.

20. To comply with its obligations under 42 U.S.C. § 262(*l*)(3)(C), AbbVie was required to provide to Amgen a "detailed statement that describes, with respect to each patent . . . on a claim by claim basis, the factual and legal basis of [its] opinion . . . that such patent will be infringed . . . and a response to the statement concerning validity" provided by Amgen in its 3(B) Statement. The BPCIA gave AbbVie 60 days, until August 9, 2016, to provide a compliant 3(C) statement. On June 21, 2016—eleven days after receiving Amgen's 3(B) Statement—AbbVie provide to Amgen what purported to be a response under Section (*l*)(3)(C) (the "June Response").

21. AbbVie's June Response did not provide any response for six of the patents identified on AbbVie's 3(A) List and discussed in Amgen's 3(B) Statement, confirming that AbbVie had no factual basis or legal basis to believe that a claim for patent infringement could reasonably be asserted against Amgen when it included these patents on its 3(A) List. The June Response also failed to provide infringement contentions for all claims of the other 59 patents AbbVie had included on its 3(A) List. Despite these omissions, AbbVie said that it "reserves the right to assert [the omitted patents and claims] and seek any and all remedies, including lost profits and injunctive relief."

22. In its June Response AbbVie also failed to respond to many of the non-infringement contentions set forth in Amgen's 3(B) Statement. Instead, AbbVie repeatedly cited as an excuse that it supposedly did not have sufficient information from Amgen to formulate an infringement theory. Yet AbbVie, after receiving Amgen's 3(B) Statement, did not ask Amgen for any specific information regarding those aspects of Amgen's manufacturing process that AbbVie believed were implicated by the asserted patents and had not, in its view, been adequately described in the BLA.

23. AbbVie's June Response also ignored many of Amgen's invalidity contentions and failed to respond to Amgen's invalidity claim charts.

§ 262(*l*)(4) Negotiations and § 262(*l*)(5) Patent Resolution Exchange

24. After the (*l*)(3) exchange of information, the BPCIA requires that, under 42 U.S.C. § 262(*l*)(4), both parties engage in good-faith negotiations ("(*l*)(4) Negotiations") to identify which patents, if any, should be the subject of patent infringement litigation under section 262(*l*)(6) (the "(*l*)(6) Litigation").

25. The BPCIA states that the (*l*)(4) Negotiations begin "[a]fter receipt by the [biosimilar] applicant of the statement under paragraph (3)(C)." On June 24, 2016, July 1, 2016, and July 15, 2016, Amgen alerted AbbVie that AbbVie had not complied with paragraph (3)(C). Amgen provided AbbVie with detailed lists of deficiencies in AbbVie's June Response, including a list of the Amgen non-infringement and invalidity contentions to which AbbVie had provided no response. AbbVie repeatedly refused to supplement or otherwise correct its June Response. Instead, in an attempt to excuse the deficiencies in its June Response, AbbVie complained about Amgen's 3(B) Statement.

26. Despite the non-compliance of AbbVie's June Response, AbbVie declared on June 28, 2016 that the (*l*)(4) Negotiations had automatically begun when it served the June Response and had stated that it wished to assert 61 patents in the (*l*)(6) Litigation. Amgen promptly responded on July 1, 2016, that negotiations could not begin until AbbVie provided a response that complied with subparagraph (*l*)(3)(C) and Amgen had an opportunity to consider that response.

27. Confronted with AbbVie's failure to comply with its obligations under Section 262(*l*)(3)(C), Amgen reached an agreement with AbbVie on July 7, 2016, under

which (*l*)(4) Negotiations would begin on July 15, 2016. Amgen did so without waiving its objections to AbbVie's inadequate June Response.

28. Because of the impracticality of litigating the infringement and invalidity of 61 patents containing more than a thousand claims, Amgen repeatedly invited AbbVie to offer a proposal to make the litigation manageable for the court and the parties, such as by selecting patents and/or patent claims that present unique issues of invalidity and/or infringement. AbbVie refused to put forth any such proposals.

29. Under 42 U.S.C. § 262(*l*)(5)(A), if the parties do not reach agreement during the (*l*)(4) Negotiations, the biosimilar applicant must notify the RPS of the number of patents it believes should be the subject of the (*l*)(6) Litigation. According to the Federal Circuit, the BPCIA process "gives the applicant a scope-limiting ability, based on an exchange of lists of patents to be litigated" and gives the "applicant substantial authority to force such a limitation on the scope of the first-stage litigation." *Amgen Inc. v. Apotex Inc.*, No. 2016-1308, slip op. at 6, 18 (Fed. Cir. July 5, 2016).

30. Because AbbVie refused to offer any proposal to limit the scope of the (*l*)(6) Litigation, Amgen, at the end of the (*l*)(4) Negotiation period on July 30, 2016, exercised its right under (*l*)(5)(A) to limit the number of patents to be litigated in this action, by notifying AbbVie that Amgen believed six patents should be the subject of the (*l*)(6) Litigation, effectively limiting the (*l*)(6) Litigation to twelve patents at most.

31. 42 U.S.C. § 262(*l*)(5)(B) requires the RPS and the biosimilar applicant to simultaneously exchange lists of patents (the "5(B) Lists") that each "believes should be the subject of an action for patent infringement" in the (*l*)(6) Litigation. Unless certain exceptions are met, which do not apply here, each list can contain no more than the number

of patents, here six, specified by the biosimilar applicant in accordance with 42 U.S.C. 262(*l*)(5)(A). On August 4, 2016, Amgen and AbbVie exchanged their 5(B) Lists, each identifying six patents. Because in two instances Amgen and AbbVie had each put the same patent on their respective 5(B) Lists, a maximum of ten patents could be included in the (*l*)(6) Litigation. *See Amgen Inc. v. Apotex Inc.*, No. 2016-1308, slip op. at 6, 18 (Fed. Cir. July 5, 2016).

§ 262(*l*)(6) Litigation

32. That same evening, AbbVie filed a complaint against Amgen and AML in this Court asserting all ten patents and referencing hundreds of patent claims.

33. As set forth below, Amgen and AML seek a declaration that each of the ten patents asserted in the Complaint is not infringed and/or is invalid.

§ 262(*l*)(8)(A) Commercial Notice

34. In its Complaint, AbbVie alleges that Amgen will refuse to comply with 42 U.S.C. § 262(*l*)(8)(A). AbbVie's allegation is baseless. Under subparagraph (*l*)(8)(A), the "subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." To be clear, Amgen intends to fully comply with its obligations under 42 U.S.C. § 262(*l*)(8)(A).

35. On June 21, 2016, the same day that AbbVie served the June Response, which did not comply with subparagraph (*l*)(3)(C), AbbVie also asked that "[o]n or before June 28, 2016, please confirm that Amgen will provide AbbVie with . . . a notice of commercial marketing should it receive a license to sell ABP 501 from the FDA." AbbVie provided neither an explanation for its arbitrary deadline nor an explanation why it believed

that Amgen would not comply with its statutory obligations. Indeed, Amgen has publicly stated that "it fully intends to meet its obligations under the BPCIA both in the role of innovator and biosimilar applicant." *See, e.g.*, *From Hunted to Hunter: Amgen Seeks Approval of Biosimilar to Humira*, Pink Sheet, Nov. 25, 2015.

36. In two cases before the Federal Circuit, Amgen has argued that the notice provision of paragraph (8)(A) is mandatory, and in both the Federal Circuit has agreed. First, in *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1357 (Fed. Cir. 2015), the Federal Circuit held that "under paragraph (*l*)(8)(A), a subsection (k) applicant may only give effective notice of commercial marketing after the FDA has licensed its product." Second, and more recently, in *Amgen Inc. v. Apotex Inc.*, No. 2016-1308, slip op. at 3–4 (Fed. Cir. July 5, 2016), the Federal Circuit held that "the commercial marketing provision is mandatory, with the 180-day period beginning only upon post-licensure notice," even for an applicant that has complied with the information exchange procedures under paragraphs (*l*)(2) to (*l*)(6). Currently controlling precedent, therefore, requires Amgen as the biosimilar applicant to provide notice to AbbVie, the RPS, only after ABP 501 is licensed by FDA and then no later than 180 days before the date of the first commercial marketing of ABP 501.

37. Amgen's ABP 501 has not yet been licensed by FDA. Therefore, under the holding of *Amgen v. Sandoz* and *Amgen Inc. v. Apotex Inc.*, Amgen cannot provide effective notice of commercial marketing at this time. Once ABP 501 is a licensed product and then no later than 180 days before the date of the first commercial marketing of ABP 501, Amgen will comply with its obligations under (*l*)(8)(A) by providing notice to AbbVie.

COUNT I

Non-Infringement and Invalidity of U.S. Patent No. 8,663,945

38. Amgen and AML incorporate by reference the averments of paragraphs 1-37 as if fully set forth herein.

39. AbbVie has alleged that AbbVie Inc. is the owner by assignment of U.S. Patent No. 8,663,945 ("the '945 Patent"). AbbVie has alleged that ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods, that would infringe the '945 Patent in the United States.

40. A case or controversy exists because AbbVie has alleged that Amgen and AML have infringed and will infringe the '945 Patent, including at least claims 1-5, 7, 9-16, 18, 20-27, 29, and 31-39.

41. The claims of the '945 Patent, including claims 1-5, 7, 9-16, 18, 20-27, 29, and 31-39, are invalid under at least 35 U.S.C. §§ 102, 103, and/or 112, for at least the reasons set forth in Amgen's 3(B) Statement.

42. Amgen and AML have not directly or indirectly infringed, and will not directly or indirectly infringe, any valid claim of the '945 Patent.

43. Under 35 U.S.C. § 271(e)(1), Amgen and AML have not directly or indirectly infringed, and will not directly or indirectly infringe, the '945 Patent because particular activities related to ABP 501, such as the manufacture or testing of ABP 501 related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs.

COUNT II

Non-Infringement and Invalidity of U.S. Patent No. 8,911,964

44. Amgen and AML incorporate by reference the averments of paragraphs 1-43 as if fully set forth herein.

45. AbbVie has alleged that AbbVie Inc. is the owner by assignment of the U.S. Patent No. 8,911,964 ("the '964 Patent"). AbbVie has alleged that ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods, that would infringe the '964 Patent in the United States.

46. A case or controversy exists because AbbVie has alleged that Amgen and AML have infringed and will infringe the '964 Patent, including at least claims 1-5, 9-16, 20-21, 23-26, and 29-30.

47. The claims of the '964 Patent, including claims 1-5, 9-16, 20-21, 23-26, and 29-30, are invalid under at least 35 U.S.C. §§ 102, 103, and/or 112 for at least the reasons set forth in Amgen's 3(B) Statement.

48. Amgen and AML have not directly or indirectly infringed, and will not directly or indirectly infringe, any valid claim of the '964 Patent.

49. Under 35 U.S.C. § 271(e)(1), Amgen and AML have not directly or indirectly infringed, and will not directly or indirectly infringe, the '964 Patent because particular activities related to ABP 501, such as the manufacture or testing of ABP 501 related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs.

COUNT III

Non-Infringement and Invalidity of U.S. Patent No. 8,916,157

50. Amgen and AML incorporate by reference the averments of paragraphs 1-49 as if fully set forth herein.

51. AbbVie has alleged that ABL is the owner by assignment of U.S. Patent No. 8,916,157 ("the '157 Patent"). AbbVie has alleged that AbbVie Inc. is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods, that would infringe the '157 Patent in the United States.

52. A case or controversy exists because AbbVie has alleged that Amgen and AML have infringed and will infringe the '157 Patent, including at least claims 1-7, 10-11, 15-16, and 18-30.

53. The claims of the '157 Patent, including claims 1-7, 10-11, 15-16, and 18-30, and 29-30, are invalid under at least 35 U.S.C. §§ 102, 103, and/or 112 for at least the reasons set forth in Amgen's 3(B) Statement.

54. Amgen and AML have not directly or indirectly infringed, and will not directly or indirectly infringe, any valid claim of the '157 Patent.

55. Under 35 U.S.C. § 271(e)(1), Amgen and AML have not directly or indirectly infringed, and will not directly or indirectly infringe, the '157 Patent because particular activities related to ABP 501, such as the manufacture or testing of ABP 501 related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs.

COUNT IV

Non-Infringement and Invalidity of U.S. Patent No. 8,961,973

56. Amgen and AML incorporate by reference the averments of paragraphs 1-55 as if fully set forth herein.

57. AbbVie has alleged that ABL is the owner by assignment of U.S. Patent No. 8,961,973 (the "'973 Patent"). AbbVie has alleged that AbbVie Inc. is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods, that would infringe the '973 Patent in the United States.

58. A case or controversy exists because AbbVie has alleged that Amgen and AML have infringed and will infringe the '973 Patent, including at least claims 1-30.

59. The claims of the '973 Patent, including claims 1-30, are invalid under at least 35 U.S.C. §§ 102, 103, and/or 112, as well as the doctrine of obviousness-type double patenting, for at least the reasons set forth in Amgen's 3(B) Statement.

60. Amgen and AML have not directly or indirectly infringed, and will not directly or indirectly infringe, any valid claim of the '973 Patent.

61. Under 35 U.S.C. § 271(e)(1), Amgen and AML have not directly or indirectly infringed, and will not directly or indirectly infringe, the '973 Patent because particular activities related to ABP 501, such as the manufacture or testing of ABP 501 related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs.

COUNT V

Non-Infringement and Invalidity of U.S. Patent No. 8,986,693

62. Amgen and AML incorporate by reference the averments of paragraphs 1-61 as if fully set forth herein.

63. AbbVie has alleged that ABL is the owner by assignment of U.S. Patent No. 8,986,693 (the "'693 Patent"). AbbVie has alleged that AbbVie Inc. is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods, that would infringe the '693 Patent in the United States.

64. A case or controversy exists because AbbVie has alleged that Amgen and AML have infringed and will infringe the '693 Patent, including at least claims 1-8.

65. The claims of the '693 Patent, including claims 1-8, are invalid under at least 35 U.S.C. § 103 and/or the doctrine of obviousness-type double patenting for at least the reasons set forth in Amgen's 3(B) Statement.

66. Amgen and AML have not directly or indirectly infringed, and will not directly or indirectly infringe, any valid claim of the '693 Patent.

67. Under 35 U.S.C. § 271(e)(1), Amgen and AML have not directly or indirectly infringed, and will not directly or indirectly infringe, the '693 Patent because particular activities related to ABP 501, such as the manufacture or testing of ABP 501 related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs.

COUNT VI

Non-Infringement and Invalidity of U.S. Patent No. 9,096,666

68. Amgen and AML incorporate by reference the averments of paragraphs 1-67 as if fully set forth herein.

69. AbbVie has alleged that ABL is the owner by assignment of U.S. Patent No. 9,096,666 ("the '666 Patent"). AbbVie has alleged that AbbVie Inc. is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods, that would infringe the '666 Patent in the United States.

70. A case or controversy exists because AbbVie has alleged that Amgen and AML have infringed and will infringe the '666 Patent, including at least claims 1-30.

71. The claims of the '666 Patent, including claims 1-30, are invalid under at least 35 U.S.C. §§ 102, 103, and/or 112 for at least the reasons set forth in Amgen's 3(B) Statement.

72. Amgen and AML have not directly or indirectly infringed, and will not directly or indirectly infringe, any valid claim of the '666 Patent.

73. Under 35 U.S.C. § 271(e)(1), Amgen and AML have not directly or indirectly infringed, and will not directly or indirectly infringe, the '666 Patent because particular activities related to ABP 501, such as the manufacture or testing of ABP 501 related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs.

COUNT VII

Non-Infringement and Invalidity of U.S. Patent No. 9,220,781

74. Amgen and AML incorporate by reference the averments of paragraphs 1-73 as if fully set forth herein.

75. AbbVie has alleged that ABL is the owner by assignment of U.S. Patent No. 9,220,781 ("the '781 Patent"). AbbVie has alleged that AbbVie Inc. is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods, that would infringe the '781 Patent in the United States.

76. A case or controversy exists because AbbVie has alleged that Amgen and AML have infringed and will infringe the '781 Patent, including at least claims 1-2, 4-6, 15-18, 20-22, 27, and 29-30.

77. The claims of the '781 Patent, including claims 1-2, 4-6, 15-18, 20-22, 27, and 29-30, are invalid under at least 35 U.S.C. §§ 102, 103, and/or 112 for at least the reasons set forth in Amgen's 3(B) Statement.

78. Amgen and AML have not directly or indirectly infringed, and will not directly or indirectly infringe, any valid claim of the '781 Patent.

79. Under 35 U.S.C. § 271(e)(1), Amgen and AML have not directly or indirectly infringed, and will not directly or indirectly infringe, the '781 Patent because particular activities related to ABP 501, such as the manufacture or testing of ABP 501 related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs.

COUNT VIII

Non-Infringement and Invalidity of U.S. Patent No. 9,272,041

80. Amgen and AML incorporate by reference the averments of paragraphs 1-79 as if fully set forth herein.

81. AbbVie has alleged that ABL is the owner by assignment of U.S. Patent No. 9,272,041 ("the '041 Patent"). AbbVie has alleged that AbbVie Inc. is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods, that would infringe the '041 Patent in the United States.

82. A case or controversy exists because AbbVie has alleged that Amgen and AML have infringed and will infringe the '041 Patent, including at least claims 1-2, 4-7, 16-19, 21-23, and 28-30.

83. The claims of the '041 Patent, including claims 1-2, 4-7, 16-19, 21-23, and 28-30, are invalid under at least 35 U.S.C. §§ 102, 103, and/or 112 for at least the reasons set forth in Amgen's 3(B) Statement.

84. Amgen and AML have not directly or indirectly infringed, and will not directly or indirectly infringe, any valid claim of the '041 Patent.

85. Under 35 U.S.C. § 271(e)(1), Amgen and AML have not directly or indirectly infringed, and will not directly or indirectly infringe, the '041 Patent because particular activities related to ABP 501, such as the manufacture or testing of ABP 501 related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs.

COUNT IX

Non-Infringement and Invalidity of U.S. Patent No. 9,359,434

86. Amgen and AML incorporate by reference the averments of paragraphs 1-85 as if fully set forth herein.

87. AbbVie has alleged that AbbVie Inc. is the owner by assignment of U.S. Patent No. 9,359,434 ("the '434 Patent"). AbbVie has alleged that ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods, that would infringe the '434 Patent in the United States.

88. A case or controversy exists because AbbVie has alleged that Amgen and AML have infringed and will infringe the '434 Patent, including at least claims 1-5, 7-21, and 23-30.

89. The claims of the '434 Patent, including claims 1-5, 7-21, and 23-30, are invalid under at least 35 U.S.C. §§ 102, 103, and/or 112 for at least the reasons set forth in Amgen's 3(B) Statement.

90. Amgen and AML have not directly or indirectly infringed, and will not directly or indirectly infringe, any valid claim of the '434 Patent.

91. Under 35 U.S.C. § 271(e)(1), Amgen and AML have not directly or indirectly infringed, and will not directly or indirectly infringe, the '434 Patent because particular activities related to ABP 501, such as the manufacture or testing of ABP 501 related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs.

COUNT X

Non-Infringement and Invalidity of U.S. Patent No. 9,365,645

92. Amgen and AML incorporate by reference the averments of paragraphs 1-91 as if fully set forth herein.

93. AbbVie has alleged that AbbVie Inc. is the owner by assignment of U.S. Patent No. 9,365,645 ("the '645 Patent"). AbbVie has alleged that ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods, that would infringe the '645 Patent in the United States.

94. A case or controversy exists because AbbVie has alleged that Amgen and AML have infringed and will infringe the '645 Patent, including at least claims 1-7, 12-21, and 26-30.

95. The claims of the '645 Patent, including claims 1-7, 12-21, and 26-30, are invalid under at least 35 U.S.C. §§ 102, 103, and/or 112 for at least the reasons set forth in Amgen's 3(B) Statement.

96. Amgen and AML have not directly or indirectly infringed, and will not directly or indirectly infringe, any valid claim of the '645 Patent.

97. Under 35 U.S.C. § 271(e)(1), Amgen and AML have not directly or indirectly infringed, and will not directly or indirectly infringe, the '645 Patent because particular activities related to ABP 501, such as the manufacture or testing of ABP 501 related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs.

ANSWER AND DEFENSES

Each of the paragraphs below corresponds to the same-numbered paragraphs in the Complaint. Defendants deny all allegations in the Complaint, whether express or implied, that are not specifically admitted below. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications, or speculations that may arguably follow from the admitted facts. Defendants deny that Plaintiffs are entitled to the relief requested or any other relief.

In the Complaint, AbbVie and ABL define "Amgen" to include both Defendants Amgen and AML. Likewise, AbbVie and ABL define "AbbVie" to include both Plaintiffs AbbVie and ABL. These definitions create confusion and render some of Plaintiffs' allegations unintelligible or nonsensical. In their Answer and Defenses, Amgen and AML will refer to themselves collectively as "Defendants" and to AbbVie and ABL as "Plaintiffs." All references in this Answer and Defenses to "Amgen," "AML," "AbbVie" and "ABL" shall be to the individual defendant or plaintiff. To the extent the use of the collective terms "Amgen" and "AbbVie" in the Complaint introduces any ambiguity into the Answer and Defenses, Amgen denies the allegation in question.

1. Defendants deny the allegations of paragraph 1, except admit that this is a purported action for patent infringement, that AbbVie has identified 61 patents for which it says it believes a claim of patent infringement could reasonably be asserted against Amgen if Amgen were to market its adalimumab biosimilar, called ABP 501, that the BPCIA created an abbreviated regulatory pathway for approval of biosimilar versions of

approved biologic products, such as Humira, and that AbbVie seeks an injunction in this case.

2. Defendants deny the allegations of paragraph 2, except admit that Humira is in a category of drugs known as biologics, that biologics are proteins manufactured using living cells rather than by chemical synthesis, that some biologics are important medicines which are difficult to develop, manufacture, formulate, and administer, and that adalimumab was the first fully human antibody approved by the FDA.

3. Defendants deny the last sentence of paragraph 3, admit that Humira has been approved by the FDA to treat the listed indications, permitting AbbVie to market Humira for the treatment of the listed diseases in accordance with its FDA license, and lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 3.

4. Defendants deny the allegations of paragraph 4, except admit that Humira is a subcutaneous, high concentration, liquid formulation, that it may be convenient for certain patients to inject medicines using pre-filled syringes and to take fewer injections.

5. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in the first sentence of paragraph 5. Defendants deny the remaining allegations of paragraph 5, except admit that certain components of biologics, including Humira, are expressed in living organisms.

6. Defendants deny the allegations of paragraph 6.

7. Defendants deny the allegations of paragraph 7, except admit that AbbVie has identified 61 patents for which it says it believes a claim of patent infringement could reasonably be asserted against Amgen if Amgen were to market its adalimumab biosimilar

called ABP 501, that Amgen filed two petitions in 2015 seeking *inter partes* review of U.S. Patent Nos. 8,916,157 and 8,916,158, and that the Patent Trial and Appeal Board declined to institute those proceedings based on the limited record before it.

8. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations about AbbVie's intentions in the eighth and ninth sentences of paragraph 8. Defendants deny the remainder of the allegations of paragraph 8, except admit that 42 U.S.C. § 262(*l*) of the BPCIA sets forth steps for the disclosure of information, the exchange of contentions, the resolution or narrowing of patent disputes, and, if necessary, the commencement of litigation, all within specified times triggered initially by the biosimilar applicant's submission and the FDA's acceptance of a BLA under the § 262(k) pathway; that AbbVie has identified 61 patents for which it says it believes a claim of patent infringement could reasonably be asserted against Amgen if Amgen were to market its adalimumab biosimilar called ABP 501; that, under 42 U.S.C. § 262(*l*)(5)(A), Amgen provided AbbVie with notice of the number of patents (six) that Amgen believed should be the subject of an action for patent infringement under 42 U.S.C. § 262(*l*)(6); that, under 42 U.S.C. § 262(*l*)(5)(B), AbbVie and Amgen simultaneously exchanged lists of the six patents they each believed should be included in the (*l*)(6) Litigation; and that because two patents were selected by both Amgen and AbbVie, ten patents are the subject of this (*l*)(6) Litigation.

9. Defendants deny the allegations of paragraph 9, except admit that they filed a complaint in *Amgen Inc. v. Sandoz Inc.*, No. 3:16-cv-02581 (N.D. Cal.), and refer to that complaint for the complete contents thereof.

10. Defendants deny the allegations of the first sentence of paragraph 10, except admit that AbbVie seeks an injunction in this case. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of the second sentence of paragraph 10.

11. Defendants deny the allegations of paragraph 11, except admit that the Complaint purports to bring an action for alleged patent infringement under the patent laws of the United States and under the Declaratory Judgment Act to compel compliance with 42 U.S.C. 262(*l*)(8)(A).

12. Defendants deny the allegations of paragraph 12.

13. Defendants admit the allegations of paragraph 13.

14. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of the first sentence of paragraph 14. Defendants deny the allegations of the remainder of paragraph 14, except admit that adalimumab is a biologic and a fully human antibody with a high affinity for human TNF-α, a protein made by the human body as part of the body's immune response.

15. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of the third sentence of paragraph 15. Defendants deny the remaining allegations of paragraph 15, except admit that adalimumab was the first fully human antibody approved by the FDA and that REMICADE (infliximab) is a chimeric antibody that was approved for intravenous injection.

16. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 16.

17. Defendants deny the allegations of paragraph 17, except admit that, in 2007, Humira was one of the recipients of the Prix Galien USA.

18. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 18.

19. Defendants deny the allegations of paragraph 19, except admit that AbbVie has identified 61 patents for which it says it believes a claim of patent infringement could reasonably be asserted against Amgen if Amgen were to market its adalimumab biosimilar, ABP 501.

20. Defendants deny the allegations of paragraph 20, except admit that, as described in their response to paragraph 8, pursuant to the procedures set forth in the BPCIA, ten patents are the subject of this litigation, that the current law, as interpreted in *Amgen Inc. v. Apotex Inc.,* No. 2016-1308, slip op. at 3–4 (Fed. Cir. July 5, 2016) (citing *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1357 (Fed. Cir. 2015)), requires Amgen as the biosimilar applicant to provide notice to AbbVie, the RPS, only after ABP 501 is licensed by the FDA and then no later than 180 days before the date of the first commercial marketing of ABP 501, and that the 180 days' notice of commercial marketing enables the RPS to seek a preliminary injunction before the biosimilar applicant commences commercial marketing of the biosimilar product.

21. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of the last sentence of paragraph 21. Defendants deny the remaining allegations of paragraph 21, except admit that the BPCIA created a new, abbreviated pathway for the approval of biological products that are highly similar to

previously-licensed biological products, and that AbbVie is seeking an injunction on certain asserted claims of ten patents.

22. Upon information and belief, Defendants admit the allegations of paragraph 22.

23. Upon information and belief, Defendants admit the allegations of paragraph 23.

24. Defendants admit the allegations of paragraph 24.

25. Defendants admit the allegations of paragraph 25.

26. Defendants deny the allegations of paragraph 26, except admit that AML participates in the manufacture of biologic medicines for treating particular diseases in humans, that AML has manufactured lots of ABP 501 solely for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture, use, or sale of drugs (including biologics), and that Amgen has filed BLA No. 761024 with the FDA seeking approval of ABP 501 in the United States.

27. The allegations in paragraph 27 are legal conclusions that require no response from Defendants. To the extent that the allegations in paragraph 27 require a response, Defendants deny them.

28. Defendants deny the allegations of paragraph 28, except admit that this Court has subject matter jurisdiction over AbbVie's claims for patent infringement under 28 U.S.C. §§ 1331 and 1338(a).

29. Defendants admit the allegations of paragraph 29.

30. The allegations in paragraph 30 are legal conclusions that require no response from Defendants. To the extent that the allegations of paragraph 30 require a response, Defendants deny them.

31. The allegations in paragraph 31 are legal conclusions that require no response from Defendants. To the extent that the allegations of paragraph 31 require a response, Defendants deny them.

32. Defendants deny the allegations of paragraph 32, except admit that AML has manufactured lots of ABP 501 solely for uses reasonably related to the development and submission of information under a federal law which regulates the manufacture, use, or sale of drugs (including biologics), and that the results of the clinical trials conducted by Amgen that were included in BLA No. 761024 were presented to the FDA Arthritis Advisory Committee on July 12, 2016.

33. The allegations in paragraph 33 are legal conclusions that require no response from Defendants. To the extent that the allegations of paragraph 33 require a response, Defendants deny them.

34. The allegations in paragraph 34 are legal conclusions that require no response from Defendants. To the extent that the allegations of paragraph 34 require a response, Defendants deny them.

35. Defendants admit the allegations of paragraph 35.

36. Defendants admit the allegations of the second and third sentences of paragraph 36 and deny the remaining allegations, except admit that Amgen sought FDA licensure of ABP 501 in BLA No. 761024.

37. Defendants deny the allegations of paragraph 37, except admit that Congress enacted the BPCIA and refer to the BPCIA for its contents.

38. Defendants deny the allegations of paragraph 38, except admit that on January 26, 2016, AbbVie sent a letter to Amgen in which it requested that Amgen confirm that it "is planning to provide its aBLA and manufacturing information by February 11, in accordance with the BPCIA" and that in February 2016 the parties began exchanging information in accordance with the BPCIA.

39. Defendants deny the allegations of paragraph 39, except admit that on April 11, 2016, under 42 U.S.C. § 262(*l*)(3)(A), AbbVie provided Amgen with a letter that listed 61 patents and 5 allowed patent applications for which AbbVie stated that it believed a claim of patent infringement could reasonably be asserted against Amgen if Amgen were to market its adalimumab biosimilar called ABP 501 and in which AbbVie made certain other statements, and Amgen refers to that letter for the contents thereof.

40. Defendants admit the allegations of paragraph 40.

41. Defendants deny the allegations of paragraph 41, except admit that on June 10, 2016, under 42 U.S.C. § 262(*l*)(3)(B), Amgen provided AbbVie with more than 2,750 pages of detailed statements that describe, on a claim-by-claim basis, the factual and legal bases of Amgen's opinions that the 61 patents and 5 allowed applications are invalid and/or not infringed, including citations to the documentary evidence relied upon therein, and that Amgen did not provide any additional documents with its 3(B) Statement but specifically deny that Amgen had any obligation under the BPCIA or otherwise to do so.

42. Defendants deny the allegations of paragraph 42, except admit that on June 21, 2016, AbbVie provided a 1,441 page response (*i.e.*, AbbVie's June Response) to

some of the statements in Amgen's 3(B) Statement in which AbbVie referred to about 1,100 claims of 60 patents, but specifically deny that the June Response complied with the requirements of 42 U.S.C. § 262(*l*)(3)(C).

43. Defendants admit the allegations of paragraph 43.

44. Defendants admit the allegations of paragraph 44.

45. Defendants deny the allegations of paragraph 45, except admit that the parties agreed to begin negotiations pursuant to 42 U.S.C. § 262(*l*)(4) on July 15, 2016.

46. Defendants deny the allegations of paragraph 46, except admit that AbbVie has consistently expressed its intent to litigate all 61 patents identified in Exhibit 1 of the Complaint, a plan that Amgen rejected as unworkable, and that, when AbbVie refused to offer a proposal to limit this case to a reasonable set of patents and claims, Amgen exercised its right under 42 U.S.C. § 262(*l*)(5)(A) to limit the number of patents to be litigated in this action by notifying AbbVie that Amgen believed six patents should be the subject of an action for patent infringement under 42 U.S.C. § 262(*l*)(6), effectively limiting this litigation to, at most, twelve patents.

47. Defendants admit the allegations in paragraph 47.

48. Defendants deny the allegations of paragraph 48, except admit that under the BPCIA, AbbVie may assert ten patents in this litigation.

49. Defendants admit the allegations of paragraph 49.

50. Defendants deny the allegations of paragraph 50, except admit that Amgen submitted BLA No. 761024 to the FDA on November 25, 2015, and that the FDA has publicly stated that it is committed to reviewing and acting "on 70 percent of original biosimilar biological product application submissions within 10 months of receipt."

51. Defendants deny the allegations in paragraph 51, except admit that Amgen stated in the July 12, 2016, Arthritis Advisory Committee Meeting Briefing Document that "ABP 501 was developed as a biosimilar product to the United States (US)-licensed reference product, Humira (adalimumab [US])," and that Amgen Inc.'s BLA No. 761024 meets all of the requirements of 42 U.S.C. § 262(k)(2)(A)(i).

52. Defendants deny the allegations in paragraph 52, except admit that Amgen Inc. submitted the referenced documents to the FDA Arthritis Advisory Committee and refer to those documents for their contents.

53. Defendants deny the allegations of paragraph 53.

54. Defendants deny the allegations of paragraph 54, except admit that AbbVie is limited to asserting the cited patents in the present action..

55. Defendants admit that the PTO issued the '945 Patent, titled "Methods of Producing Anti-TNF-Alpha Antibodies in Mammalian Cell Culture," on March 4, 2014. Defendants also admit that Exhibit 5 to the Complaint appears to be a copy of the '945 Patent. Defendants deny that the '945 Patent was duly and legally issued.

56. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 56.

57. Defendants admit that the PTO issued the '964 Patent, titled "Fed-Batch Method of Making Human Anti-TNF-Alpha Antibody," on December 16, 2014. Defendants also admit that Exhibit 6 to the Complaint appears to be a copy of the '964 Patent. Defendants deny that the '964 Patent was duly and legally issued.

58. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 58.

59. Defendants admit that the PTO issued the '157 Patent, titled "Formulation of Human Antibodies for Treating TNF-α Associated Disorders," on December 23, 2014. Defendants also admit that Exhibit 7 to the Complaint appears to be a copy of the '157 Patent. Defendants deny that the '157 Patent was duly and legally issued.

60. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 60.

61. Defendants admit that the PTO issued the '973 Patent, titled "Multiple-Variable Dose Regimen for Treating TNFα-Related Disorders," on February 24, 2015. Defendants also admit that Exhibit 8 to the Complaint appears to be a copy of the '973 Patent. Defendants deny that the '973 Patent was duly and legally issued.

62. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 62.

63. Defendants admit that the PTO issued the '693 Patent, titled "Use of TNFα Inhibitor for Treatment of Psoriasis," on March 24, 2015. Defendants also admit that Exhibit 9 to the Complaint appears to be a copy of the '693 Patent. Defendants deny that the '693 Patent was duly and legally issued.

64. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 64.

65. Defendants admit that the PTO issued the '666 Patent, titled "Purified Antibody Composition," on August 4, 2015. Defendants also admit that Exhibit 10 to the Complaint appears to be a copy of the '666 Patent. Defendants deny that the '666 Patent was duly and legally issued.

66. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 66.

67. Defendants admit that the PTO issued the '781 Patent, titled "Formulation of Human Antibodies for Treating TNF-Alpha Associated Disorders," on December 29, 2015. Defendants also admit that Exhibit 11 to the Complaint appears to be a copy of the '781 Patent. Defendants deny that the '781 Patent was duly and legally issued.

68. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 68.

69. Defendants admit that the PTO issued the '041 Patent, titled "Formulation of Human Antibodies Treating TNF-Alpha Associated Disorders," on March 1, 2016. Defendants also admit that Exhibit 12 to the Complaint appears to be a copy of the '041 Patent. Defendants deny that the '041 Patent was duly and legally issued.

70. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 70.

71. Defendants admit that the PTO issued the '434 Patent, titled "Cell Culture Methods to Reduce Acidic Species," on June 7, 2016. Defendants also admit that Exhibit 13 to the Complaint appears to be a copy of the '434 Patent. Defendants deny that the '434 Patent was duly and legally issued.

72. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 72.

73. Defendants admit that the PTO issued the '645 Patent, titled "Methods for Controlling the Galactosylation Profile of Recombinantly-Expressed Proteins," on June 14,

2016. Defendants also admit that Exhibit 14 to the Complaint appears to be a copy of the '645 Patent. Defendants deny that the '645 Patent was duly and legally issued.

74. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 74.

75. Defendants repeat their responses to paragraphs 1-74.

76. Defendants deny the allegations of paragraph 76, except admit that Amgen Inc. filed BLA No. 761024 with the FDA on November 25, 2015, in which Amgen Inc. seeks approval of ABP 501, a biosimilar of adalimumab, in the United States under the BPCIA.

77. Defendants admit that the FDA accepted Amgen Inc.'s BLA No. 761024 on January 22, 2016.

78. Defendants admit the allegations of paragraph 78.

79. Defendants deny the allegations of paragraph 79, except state that the current law, as interpreted in *Amgen Inc. v. Apotex Inc.,* No. 2016-1308, slip op. at 3–4 (Fed. Cir. July 5, 2016) (citing *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1357 (Fed. Cir. 2015)), requires Amgen as the biosimilar applicant to provide notice to AbbVie, the RPS, only after ABP 501 is licensed by the FDA and then no later than 180 days before the date of the first commercial marketing of ABP 501.

80. Defendants deny the allegations of paragraph 80.

81. Defendants deny the allegations of paragraph 81.

82. Defendants deny the allegations of paragraph 82, except admit that AbbVie listed the '945 Patent on its 3(A) List and that AbbVie has asserted the '945 Patent against Amgen in this case.

83. Defendants deny the allegations of paragraph 83.

84. Defendants deny the allegations of paragraph 84.

85. Defendants deny the allegations of paragraph 85.

86. Defendants deny the allegations of paragraph 86.

87. Defendants deny the allegations of paragraph 87.

88. Defendants deny the allegations of paragraph 88.

89. Defendants repeat their responses to paragraphs 1-88.

90. Defendants deny the allegations of paragraph 90, except admit that Amgen Inc. filed BLA No. 761024 with the FDA on November 25, 2015, in which Amgen Inc. seeks approval of ABP 501, a biosimilar of adalimumab, in the United States pursuant to the BPCIA.

91. Defendants admit that the FDA accepted Amgen Inc.'s BLA No. 761024 on January 22, 2016.

92. Defendants admit the allegations of paragraph 92.

93. Defendants deny the allegations of paragraph 93, except state that the current law, as interpreted in *Amgen Inc. v. Apotex Inc.*, No. 2016-1308, slip op. at 3–4 (Fed. Cir. July 5, 2016) (citing *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1357 (Fed. Cir. 2015)), requires Amgen as the biosimilar applicant to provide notice to AbbVie, the RPS, only after ABP 501 is licensed by the FDA and then no later than 180 days before the date of the first commercial marketing of ABP 501.

94. Defendants deny the allegations of paragraph 94.

95. Defendants deny the allegations of paragraph 95.

96. Defendants deny the allegations of paragraph 96, except admit that AbbVie listed the '964 Patent on its 3(A) List and that AbbVie has asserted the '964 Patent against Defendants in this case.

97. Defendants deny the allegations of paragraph 97.

98. Defendants deny the allegations of paragraph 98.

99. Defendants deny the allegations of paragraph 99.

100. Defendants deny the allegations of paragraph 100.

101. Defendants deny the allegations of paragraph 101.

102. Defendants deny the allegations of paragraph 102.

103. Defendants repeat their responses to paragraphs 1-102.

104. Defendants deny the allegations of paragraph 104, except admit that Amgen Inc. filed BLA No. 761024 with the FDA on November 25, 2015, in which Amgen Inc. seeks approval of ABP 501, a biosimilar of adalimumab, in the United States pursuant to the BPCIA.

105. Defendants admit that the FDA accepted Amgen Inc.'s BLA No. 761024 on January 22, 2016.

106. Defendants admit the allegations of paragraph 106.

107. Defendants deny the allegations of paragraph 107, except state that the current law, as interpreted in *Amgen Inc. v. Apotex Inc.,* No. 2016-1308, slip op. at 3–4 (Fed. Cir. July 5, 2016) (citing *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1357 (Fed. Cir. 2015)), requires Amgen as the biosimilar applicant to provide notice to AbbVie, the RPS, only after ABP 501 is licensed by the FDA and then no later than 180 days before the date of the first commercial marketing of ABP 501.

108. Defendants deny the allegations of paragraph 108.

109. Defendants deny the allegations of paragraph 109.

110. Defendants deny the allegations of paragraph 110, except admit that AbbVie listed the '157 Patent on its 3(A) List and that AbbVie has asserted the '157 Patent against Defendants in this case.

111. Defendants deny the allegations of paragraph 111.

112. Defendants deny the allegations of paragraph 112.

113. Defendants deny the allegations of paragraph 113.

114. Defendants deny the allegations of paragraph 114.

115. Defendants deny the allegations of paragraph 115.

116. Defendants deny the allegations of paragraph 116.

117. Defendants repeat their responses to paragraphs 1-116.

118. Defendants deny the allegations of paragraph 118, except admit that Amgen Inc. filed BLA No. 761024 with the FDA on November 25, 2015, in which Amgen Inc. seeks approval of ABP 501, a biosimilar of adalimumab, in the United States pursuant to the BPCIA.

119. Defendants admit that the FDA accepted Amgen Inc.'s BLA No. 761024 on January 22, 2016.

120. Defendants admit the allegations of paragraph 120.

121. Defendants deny the allegations of paragraph 121, except state that the current law, as interpreted in *Amgen Inc. v. Apotex Inc.*, No. 2016-1308, slip op. at 3–4 (Fed. Cir. July 5, 2016) (citing *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1357 (Fed. Cir. 2015)), requires Amgen as the biosimilar applicant to provide notice to AbbVie, the RPS,

only after ABP 501 is licensed by the FDA and then no later than 180 days before the date of the first commercial marketing of ABP 501.

122. Defendants deny the allegations of paragraph 122.

123. Defendants deny the allegations of paragraph 123, except admit that AbbVie listed the '973 Patent on its 3(A) List and that AbbVie has asserted the '973 Patent against Defendants in this case.

124. Defendants deny the allegations of paragraph 124.

125. Defendants deny the allegations of paragraph 125.

126. Defendants deny the allegations of paragraph 126.

127. Defendants deny the allegations of paragraph 127.

128. Defendants deny the allegations of paragraph 128.

129. Defendants deny the allegations of paragraph 129.

130. Defendants repeat their responses to paragraphs 1-129.

131. Defendants deny the allegations of paragraph 131, except admit that Amgen Inc. filed BLA No. 761024 with the FDA on November 25, 2015, in which Amgen Inc. seeks approval of ABP 501, a biosimilar of adalimumab, in the United States pursuant to the BPCIA.

132. Defendants admit that the FDA accepted Amgen's BLA No. 761024 on January 22, 2016.

133. Defendants admit the allegations of paragraph 133.

134. Defendants deny the allegations of paragraph 134, except state that the current law, as interpreted in *Amgen Inc. v. Apotex Inc.,* No. 2016-1308, slip op. at 3–4 (Fed. Cir. July 5, 2016) (citing *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1357 (Fed. Cir.

2015)), requires Amgen as the biosimilar applicant to provide notice to AbbVie, the RPS, only after ABP 501 is licensed by the FDA and then no later than 180 days before the date of the first commercial marketing of ABP 501.

135. Defendants deny the allegations of paragraph 135.

136. Defendants deny the allegations of paragraph 136, except admit that AbbVie listed the '693 Patent on its 3(A) List and that AbbVie has asserted the '693 Patent against Amgen in this case.

137. Defendants deny the allegations of paragraph 124.

138. Defendants deny the allegations of paragraph 138.

139. Defendants deny the allegations of paragraph 139.

140. Defendants deny the allegations of paragraph 140.

141. Defendants deny the allegations of paragraph 141.

142. Defendants deny the allegations of paragraph 142.

143. Defendants repeat their responses to paragraphs 1-142.

144. Defendants deny the allegations of paragraph 144, except admit that Amgen Inc. filed BLA No. 761024 with the FDA on November 25, 2015, in which Amgen Inc. seeks approval of ABP 501, a biosimilar of adalimumab, in the United States pursuant to the BPCIA.

145. Defendants admit that the FDA accepted Amgen Inc.'s BLA No. 761024 on January 22, 2016.

146. Defendants admit the allegations of paragraph 146.

147. Defendants deny the allegations of paragraph 147, except state that the current law, as interpreted in *Amgen Inc. v. Apotex Inc.*, No. 2016-1308, slip op. at 3–4

(Fed. Cir. July 5, 2016) (citing *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1357 (Fed. Cir. 2015)), requires Amgen as the biosimilar applicant to provide notice to AbbVie, the RPS, only after ABP 501 is licensed by the FDA and then no later than 180 days before the date of the first commercial marketing of ABP 501.

148. Defendants deny the allegations of paragraph 148.

149. Defendants deny the allegations of paragraph 149.

150. Defendants deny the allegations of paragraph 150, except admit that AbbVie listed the '666 Patent on its 3(A) List and that AbbVie has asserted the '666 Patent against Defendants in this case.

151. Defendants deny the allegations of paragraph 151.

152. Defendants deny the allegations of paragraph 152.

153. Defendants deny the allegations of paragraph 153.

154. Defendants deny the allegations of paragraph 154.

155. Defendants deny the allegations of paragraph 155.

156. Defendants deny the allegations of paragraph 156.

157. Defendants repeat their responses to paragraphs 1-156.

158. Defendants deny the allegations of paragraph 158, except admit that Amgen Inc. filed BLA No. 761024 with the FDA on November 25, 2015, in which Amgen Inc. seeks approval of ABP 501, a biosimilar of adalimumab, in the United States pursuant to the BPCIA.

159. Defendants admit that the FDA accepted Amgen Inc.'s BLA No. 761024 on January 22, 2016.

160. Defendants admit the allegations of paragraph 160.

161. Defendants deny the allegations of paragraph 161, except state that the current law, as interpreted in *Amgen Inc. v. Apotex Inc.,* No. 2016-1308, slip op. at 3–4 (Fed. Cir. July 5, 2016) (citing *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1357 (Fed. Cir. 2015)), requires Amgen as the biosimilar applicant to provide notice to AbbVie, the RPS, only after ABP 501 is licensed by the FDA and then no later than 180 days before the date of the first commercial marketing of ABP 501.

162. Defendants deny the allegations of paragraph 162.

163. Defendants deny the allegations of paragraph 163.

164. Defendants deny the allegations of paragraph 164, except admit that AbbVie listed the '781 Patent on its 3(A) List and that AbbVie has asserted the '781 Patent against Defendants in this case.

165. Defendants deny the allegations of paragraph 165.

166. Defendants deny the allegations of paragraph 166.

167. Defendants deny the allegations of paragraph 167.

168. Defendants deny the allegations of paragraph 168.

169. Defendants deny the allegations of paragraph 169.

170. Defendants deny the allegations of paragraph 170.

171. Defendants repeat their responses to paragraphs 1-170.

172. Defendants deny the allegations of paragraph 172, except admit that Amgen Inc. filed BLA No. 761024 with the FDA on November 25, 2015, in which Amgen Inc. seeks approval of ABP 501, a biosimilar of adalimumab, in the United States pursuant to the BPCIA.

173. Defendants admit that the FDA accepted Amgen's BLA No. 761024 on January 22, 2016.

174. Defendants admit the allegations of paragraph 174.

175. Defendants deny the allegations of paragraph 175, except state that the current law, as interpreted in *Amgen Inc. v. Apotex Inc.*, No. 2016-1308, slip op. at 3–4 (Fed. Cir. July 5, 2016) (citing *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1357 (Fed. Cir. 2015)), requires Amgen as the biosimilar applicant to provide notice to AbbVie, the RPS, only after ABP 501 is licensed by the FDA and then no later than 180 days before the date of the first commercial marketing of ABP 501.

176. Defendants deny the allegations of paragraph 176.

177. Defendants deny the allegations of paragraph 177.

178. Defendants deny the allegations of paragraph 164, except admit that AbbVie listed the '041 Patent on its 3(A) List and that AbbVie has asserted the '041 Patent against Defendants in this case.

179. Defendants deny the allegations of paragraph 179.

180. Defendants deny the allegations of paragraph 180.

181. Defendants deny the allegations of paragraph 181.

182. Defendants deny the allegations of paragraph 182.

183. Defendants deny the allegations of paragraph 183.

184. Defendants deny the allegations of paragraph 184.

185. Defendants repeat their responses to paragraphs 1-184.

186. Defendants deny the allegations in paragraph 186, except admit that Amgen Inc. filed BLA No. 761024 with the FDA on November 25, 2015, in which Amgen

Inc. seeks approval of ABP 501, a biosimilar of adalimumab, in the United States pursuant to the BPCIA.

187. Defendants admit that the FDA accepted Amgen Inc.'s BLA No. 761024 on January 22, 2016.

188. Defendants admit the allegations in paragraph 188.

189. Defendants deny the allegations in paragraph 189, except state that the current law, as interpreted in *Amgen Inc. v. Apotex Inc.,* No. 2016-1308, slip op. at 3–4 (Fed. Cir. July 5, 2016) (citing *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1357 (Fed. Cir. 2015)), requires Amgen as the biosimilar applicant to provide notice to AbbVie, the RPS, only after ABP 501 is licensed by the FDA and then no later than 180 days before the date of the first commercial marketing of ABP 501.

190. Defendants deny the allegations of paragraph 190.

191. Defendants deny the allegations of paragraph 191.

192. Defendants deny the allegations of paragraph 192, except admit that AbbVie listed the '434 Patent on its 3(A) List and that AbbVie has asserted the '434 Patent against Defendants in this case.

193. Defendants deny the allegations of paragraph 193.

194. Defendants deny the allegations of paragraph 194.

195. Defendants deny the allegations of paragraph 195.

196. Defendants deny the allegations of paragraph 196.

197. Defendants deny the allegations of paragraph 197.

198. Defendants deny the allegations of paragraph 198.

199. Defendants repeat their responses to paragraphs 1-198.

200. Defendants deny the allegations of paragraph 200, except admit that Amgen Inc. filed BLA No. 761024 with the FDA on November 25, 2015, in which Amgen seeks approval of ABP 501, a biosimilar of adalimumab, in the United States pursuant to the BPCIA.

201. Defendants admit that the FDA accepted Amgen's BLA No. 761024 on January 22, 2016.

202. Defendants, deny the allegations of paragraph 202, except state that AbbVie supplemented its 3(A) list to include the '645 Patent pursuant to 42 U.S.C. § 262(*l*)(7).

203. Defendants deny the allegations of paragraph 203, except state that the current law, as interpreted in *Amgen Inc. v. Apotex Inc.,* No. 2016-1308, slip op. at 3–4 (Fed. Cir. July 5, 2016) (citing *Amgen Inc. v. Sandoz Inc.*, 794 F.3d 1347, 1357 (Fed. Cir. 2015)), requires Amgen as the biosimilar applicant to provide notice to AbbVie, the RPS, only after ABP 501 is licensed by the FDA and then no later than 180 days before the date of the first commercial marketing of ABP 501.

204. Defendants deny the allegations of paragraph 204.

205. Defendants deny the allegations of paragraph 205.

206. Defendants deny the allegations of paragraph 206, except admit that AbbVie supplemented its 3(A) List to include the '645 Patent and that AbbVie has asserted the '645 Patent against Defendants in this case.

207. Defendants deny the allegations of paragraph 207.

208. Defendants deny the allegations of paragraph 208.

209. Defendants deny the allegations of paragraph 209.

210. Defendants deny the allegations of paragraph 210.

211. Defendants deny the allegations of paragraph 211.

212. Defendants deny the allegations of paragraph 212.

213. Defendants repeat their responses to paragraphs 1-212.

214. Defendants deny the allegations of paragraph 214.

215. Defendants admit the allegations of paragraph 215 under the current law.

216. Defendants deny the allegations in paragraph 216, except admit that Amgen Inc. filed BLA No. 761024 with the FDA on November 25, 2015, in which Amgen Inc. seeks approval of ABP 501, a biosimilar of adalimumab, in the United States pursuant to the BPCIA.

217. Defendants admit that the FDA accepted Amgen Inc.'s BLA No. 761024 on January 22, 2016.

218. Defendants deny the allegations of paragraph 218, except admit that AbbVie made a similar request in a letter to Amgen dated June 21, 2016.

219. Defendants deny the allegations of paragraph 219, except admit that Amgen did not respond to AbbVie's request because it had no obligation to do so under the BPCIA or otherwise. Amgen states that it intends to comply with the notice requirements of the BPCIA.

220. Defendants deny the allegations of paragraph 220, and specifically deny that they intend to violate the BPCIA.

221. Defendants deny the allegations of paragraph 221.

FIRST AFFIRMATIVE DEFENSE

1. Plaintiffs' Complaint fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

2. The '945 Patent, the '964 Patent, the '157 Patent, the '973 Patent, the '693 Patent, the '666 Patent, the '781 Patent, the '041 Patent, the '434 Patent, and the '645 Patent, and each of the claims thereof, are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 102, 103, and/or 112, or under other judicially-created bases for invalidation.

THIRD AFFIRMATIVE DEFENSE

3. Defendants have not, do not, and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '945 Patent, the '964 Patent, the '157 Patent, the '973 Patent, the '693 Patent, the '666 Patent, the '781 Patent, the '041 Patent, the '434 Patent, or the '645 Patent.

FOURTH AFFIRMATIVE DEFENSE

4. Defendants have not, do not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the '945 Patent, the '964 Patent, the '157 Patent, the '973 Patent, the '693 Patent, the '666 Patent, the '781 Patent, the '041 Patent, the '434 Patent, or the '645 Patent.

FIFTH AFFIRMATIVE DEFENSE

5. To the extent Plaintiffs' claim that the manufacture and clinical use of ABP 501 is an act of infringement, Defendants are exempt from liability under the safe harbor of 35 U.S.C. § 271(e)(1).

SIXTH AFFIRMATIVE DEFENSE

6. Plaintiffs are barred by 35 U.S.C. § 288 from recovering any costs associated with this action.

SEVENTH AFFIRMATIVE DEFENSE

7. Defendants' actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

EIGHTH AFFIRMATIVE DEFENSE

8. Plaintiffs are not entitled to preliminary and/or permanent equitable relief.

NINTH AFFIRMATIVE DEFENSE

9. Plaintiffs lack standing to assert the patents-in-suit.

TENTH AFFIRMATIVE DEFENSE

10. Plaintiffs cannot maintain a cause of action for any of the asserted patents because they have not complied with the BPCIA.

ELEVENTH AFFIRMATIVE DEFENSE

11. Plaintiffs cannot obtain equitable relief, including injunctive relief, because of unclean hands.

OTHER AFFIRMATIVE DEFENSES RESERVED

Defendants reserve the right to assert any other defenses that discovery may reveal.

PRAYER FOR RELIEF

WHEREFORE, Defendants-Counterclaim-Plaintiffs Amgen and AML respectfully request that the Court enter judgment:

a. dismissing the Complaint in its entirety with prejudice;

b. declaring that the claims of the patents-in-suit have not been and will not be infringed by Amgen or AML;

c. declaring that the claims of the patents-in-suit are invalid;

d. finding that this is an exceptional case under 35 U.S.C. § 285;

e. awarding attorneys' fees, costs and disbursements to Amgen and AML; and

f. granting such other and further relief as this Court deems just and proper.

YOUNG CONAWAY STARGATT & TAYLOR, LLP

Melanie K. Sharp (No. 2501)
James L. Higgins (No. 5021)
1000 North King Street
Wilmington, DE 19801
(302) 571-6681
msharp@ycst.com
jhiggins@ycst.com

CRAVATH, SWAINE & MOORE LLP
Evan R. Chesler
Keith R. Hummel
David N. Greenwald
Worldwide Plaza
825 Eighth Avenue
New York, NY 10019-7475
(212) 474-1000

MARSHALL, GERSTEIN & BORUN LLP
Kevin M. Flowers
John R. Labbe
Mark H. Izraelewicz
6300 Willis Tower
233 South Wacker Drive
Chicago, IL 60606-6357
(312) 474-6300

Dated: September 13, 2016

Attorneys for Amgen Inc. and Amgen Manufacturing Ltd.