IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AbbVie Inc. and AbbVie Biotechnology Ltd, Plaintiffs/Counterclaim-Defendants, v. Boehringer Ingelheim International GmbH, Boehringer Ingelheim Fremont, Inc., and Boehringer Ingelheim Pharmaceuticals, Inc. Defendants/Counterclaim-Plaintiffs.	C.A. No. 17-1065-MSG-RL [redacted] [redacted] PUBLIC VERSION FILED 9/21/2018

BOEHRINGER INGELHEIM INTERNATIONAL GMBH, BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., AND BOEHRINGER INGELHEIM FREMONT, INC.'S MOTION FOR LEAVE TO FILE AN AMENDED ANSWER, DEFENSES, AND COUNTERCLAIMS

Pursuant to Federal Rule of Civil Procedure 15(a)(2), Boehringer Ingelheim Int'l GmbH et al. ("Boehringer"), for the reasons set forth below, respectfully moves this Court for leave to file an Amended Answer, Defenses, and Counterclaims in the form attached hereto as Exhibit 1. A comparison of the Answer, Defenses, and Counterclaims, and proposed amendments, is attached hereto as Exhibit 2. Boehringer seeks to update the allegations with respect to its unclean hands defense (D.I. 20, Boehringer's Ninth Defense), in view of information developed to date in the case. No other amendments are sought at this time.

On November 1, 2017, this Court entered a scheduling Order, which provided that "[a]ll motions to join other parties and/or amend pleadings shall be filed on or before Thursday, August 30, 2018." (D.I. 29, Section E.) The Court granted the parties' stipulation extending that deadline to September 14, 2018. (D.I. 188.) Boehringer is timely seeking amendment.

I. Background

Boehringer filed its Answer, Defenses, and Counterclaims on September 11, 2017. (D.I. 20.) Boehringer's Ninth Defense asserted "Unclean Hands," and its Answer and Counterclaims contained allegations with respect to the unclean hands defense. (*E.g*, D.I. 20 at 44-47, ¶¶ 21-34). Boehringer further elaborated the defense of unclean hands in its May 3, 2018 responses to AbbVie's contention interrogatory No. 20. (*See* D.I. 71, Ex. 2.)

During discovery, Boehringer moved to compel the production of documents and things concerning its unclean hands defense. (D.I. 71, citing Request Nos. 36-37 and 40-43 of Boehringer's Second Set of Requests for Production of Documents and Things.) AbbVie opposed Boehringer's Motion to Compel, arguing in part that Boehringer had failed to adequately plead or allege facts supporting such a defense and that unclean hands discovery was therefore irrelevant. (D.I. 79.) Judge Lloret granted Boehringer's Motion to Compel, and ordered that AbbVie promptly respond to Boehringer's Requests for Production. (D.I. 112 at 4.) The parties continue to dispute whether AbbVie has fully complied with that Order.

In compliance with the present deadline to amend pleadings, Boehringer seeks leave to Amend its Ninth Defense of unclean hands to provide a fuller statement in view of information developed thus far in the case.

II. Legal Standard

The Court has broad discretion to grant a motion to amend, *Foman v. Davis*, 371 U.S. 178, 182 (1962), and "[t]he court should freely give leave when justice so requires." Fed. R. Civ. P. 15(a)(2). The Third Circuit has adopted a liberal policy favoring the amendment of pleadings to ensure that claims are "decided on the merits rather than on technicalities." *Dole v. Arco Chem. Co.,* 921 F.2d 484, 487 (3d Cir. 1990) (citations omitted); *see also, Bechtel v. Robinson,* 886 F.2d 644, 652 (3d Cir. 1989) (stating that courts "have shown a strong liberality" in

considering whether to grant leave to amend) (quotations and citations omitted); *Heyl & Patterson Int'l., Inc. v. F.D. Rich Housing of Virgin Islands, Inc.*, 663 F.2d 419, 426 (3d. Cir. 1981) (explaining that, under the federal rules "the purpose of pleading is to facilitate a proper decision on the merits") (citations omitted). Amendment should ordinarily be permitted absent a showing of "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc." *Foman,* 371 U.S. at 182; *see also Arthur v. Maersk, Inc*., 434 F.3d 196, 204 (3d Cir. 2006) ("Leave to amend must generally be granted unless equitable considerations render it otherwise unjust.").

III. Argument

Justice permits Boehringer's proposed amendment. Boehringer has diligently sought discovery relating to its unclean hands defense, and now seeks to supplement its already adequately plead defense to reflect information learned about AbbVie's scheme. Discovery is ongoing; AbbVie has not finished producing unclean hands documents, and depositions have not yet begun.

Boehringer has not delayed. It is moving promptly and within the supplementation deadline set by the Court. (D.I. 29, 188.) To that end, the requested amendment will have no effect on the Court's schedule. Judicial economy and efficiency will not be infringed upon by the amendments, and will in fact be enhanced.

The amendment would cause no substantial or undue prejudice to AbbVie. Boehringer seeks to supplement a defense with additional facts to support its already adequately pled unclean hands defense. AbbVie has of course been on notice of a defense of unclean hands since September 2017, and Boehringer's desire to pursue discovery of that defense. Moreover, as can be seen in Exhibit 1, the allegations generally concern information in the possession, custody,

and control of AbbVie. *See e.g., ICU Medical, Inc. v. RyMed Tech., Inc.*, 674 F.Supp.2d 574 (D. Del. 2009) (permitting addition of inequitable conduct claim and finding no undue prejudice where key witness-alleged joint inventor had been deposed and plaintiff presumably possessed extensive pertinent information); *see also Betchel*, 886 F.2d at 652 ("[T]he non-moving party must do more than merely claim prejudice; it must show that it was unfairly disadvantaged or deprived of the opportunity to present facts or evidence which it would have offered . . .") (internal quotations and citations omitted).

Finally, the amendment sought is not frivolous or advancing a defense that is facially legally insufficient. *See, e.g., Agere Sys. Guardian Corp. v. Proxim, Inc.,* 190 F. Supp. 2d 726, 736-37 (D. Del. 2002); (D.I. 112, citing authorities). As noted above, AbbVie previously argued that Boehringer's unclean hands defense was not sufficiently pled (D.I. 79), and Judge Lloret did not accept that argument. (D.I. 112, at 4.) Accordingly, the parties are currently engaged in discovery with respect to the defense. Just as AbbVie's Opposition to Boehringer's Motion to Compel was not the proper "mechanism for litigating the substance of the defense" (D.I. 112, at 4), Rule 15(a)(2) "does not contemplate substantive motion practice on the merits of the claims." *High 5 Games, LLC v. Marks*, No. 13-7161, 2017 WL 349375, at *5 (D.N.J. Jan. 24, 2017) (internal citations omitted). Here, Boehringer's unclean hands defense is not a frivolous pursuit, nor is it a surprise to AbbVie; it is grounded in fact and law.

WHEREFORE, for the foregoing reasons, Boehringer respectfully requests that the Court grant it leave to file an Amended Answer, Defenses, and Counterclaims in the form attached hereto as Exhibit 1.

Dated: September 14, 2018

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, James D. Taylor, Jr., Esquire, hereby certify that on the 14th day of September, 2018, a copy of Defendants' Boehringer Ingelheim International GmbH, Boehringer Ingelheim Pharmaceuticals, Inc., and Boehringer Ingelheim Fremont, Inc.'s ***Motion for Leave to File an Amended Answer, Defenses and Counterclaims*** was caused to be served via e-mail on the following counsel of record:

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC. and ABBVIE BIOTECHNOLOGY LTD, Plaintiffs, -against- BOEHRINGER INGELHEIM INTERNATIONAL GMBH, BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., and BOEHRINGER INGELHEIM FREMONT, INC., Defendants.	Civil Action No. 17-cv-01065-MSG [redacted] PUBLIC VERSION

BOEHRINGER INGELHEIM INTERNATIONAL GMBH, BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., AND BOEHRINGER INGELHEIM FREMONT, INC.'S AMENDED ANSWER, DEFENSES, AND COUNTERCLAIMS

Defendants and Counterclaim-Plaintiffs Boehringer Ingelheim International GmbH ("BII"), Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI"), and Boehringer Ingelheim Fremont, Inc. ("BIFI") (collectively, "Defendants"), by their undersigned attorneys, hereby respond to the complaint of Plaintiffs and Counterclaim-Defendants AbbVie Inc. and AbbVie Biotechnology Ltd (collectively, "Plaintiffs") as follows.

Plaintiffs' complaint defines "Boehringer" to include BII, BIPI, and BIFI, and "AbbVie" to include AbbVie Inc. and AbbVie Biotechnology Ltd. The use of these definitions in the complaint creates ambiguity and confusion with respect to certain of Plaintiffs' allegations. In their Answer, Defenses, and Counterclaims, BII, BIPI, and BIFI refer to themselves collectively as "Defendants" and to AbbVie Inc. and AbbVie Biotechnology Ltd as "Plaintiffs." All references in Defendants' Answer, Defenses, and Counterclaims to BII, BIPI, BIFI, AbbVie Inc., and AbbVie Biotechnology Ltd mean the individual defendant or plaintiff.

ANSWER AND DEFENSES

Each of the paragraphs below corresponds to the same numbered paragraph in Plaintiffs' complaint. Defendants deny all allegations in the complaint, whether express or implied, that are not specifically admitted below. Defendants further deny that Plaintiffs are entitled to the relief requested or any other relief. Any factual allegation below is admitted only as to the specific admitted facts, and not as to any purported conclusions, characterizations, implications, or speculations that may arguably follow from the admitted facts. Many of Plaintiffs' allegations in the complaint are vague and/or ambiguous, including, *inter alia*, Plaintiffs' use of the collective terms "Boehringer" and "AbbVie." To the extent any allegation in Plaintiffs' complaint is vague and/or ambiguous, Defendants deny the allegation in question.

INTRODUCTION

1. Admitted in part; denied in part. Defendants admit only that this is a purported action for patent infringement; that Plaintiffs' complaint identifies 74 patents that they allege could reasonably be asserted with respect to the adalimumab product set forth in Biologics License Application No. 761058 ("the BLA Product"); that the Biosimilar Price Competition and Innovation Act ("BPCIA") created an abbreviated regulatory pathway for approval of biosimilar versions of approved biologic products, such as Humira®; and that Plaintiffs seek (but are not entitled to) an injunction in this case. Defendants deny the remaining allegations of paragraph 1.

2. Admitted in part; denied in part. Defendants admit only that the active ingredient in Humira®, adalimumab, is a biologic drug; that biologic drugs are manufactured in living cells rather than by chemical synthesis; and that adalimumab was the first fully human antibody approved by the Food and Drug Administration ("FDA"). Defendants deny the remaining allegations of paragraph 2.

3. Admitted in part; denied in part. Defendants admit only that the approved indications for Humira® include rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, psoriasis, Crohn's disease (adult and pediatric), ulcerative colitis, hidradenitis suppurativa, uveitis, and juvenile idiopathic arthritis. Defendants deny the allegations of the last sentence of paragraph 3. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 3, and therefore deny the same.

4. Admitted in part; denied in part. Defendants admit only that Humira® contains adalimumab in a liquid formulation for subcutaneous injection. Defendants deny the remaining allegations of paragraph 4.

5. Admitted in part; denied in part. Defendants admit only that Humira® contains adalimumab, a biologic drug created in living organisms. Defendants deny the remaining allegations of paragraph 5.

6. Denied.

7. Admitted in part; denied in part. Defendants admit only that the BPCIA describes a multi-step process for the disclosure of information, the resolution or narrowing of patent disputes, and, if necessary and appropriate, the commencement of patent litigation; that from March 13, 2017, until July 26, 2017, Plaintiffs identified 74 patents that they contended could reasonably be asserted with respect to the BLA Product; that on July 26, 2017, and pursuant to 42 U.S.C. § 262(*l*)(5)(A), counsel for Defendants provided counsel for Plaintiffs with notice of the number of patents (up to five) to be selected by each side for litigation filed under 42 U.S.C. § 262(*l*)(6)(B); that on July 31, 2017, at 5 pm Eastern Time, counsel for Plaintiffs and Defendants simultaneously exchanged their respective lists of five patents pursuant to 42 U.S.C. § 262(*l*)(5)(B); and that, because two patents were identified by counsel for both Plaintiffs and

Defendants, the eight patents asserted in this litigation include all of the patents identified by both sides. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in the sixth and seventh sentences of paragraph 7 concerning Plaintiffs' future plans, and therefore deny the same. Defendants deny the remaining allegations of paragraph 7.

8. Admitted in part; denied in part. Defendants admit only that Plaintiffs are seeking an injunction in this litigation, to which Plaintiffs are not entitled. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of the second sentence of paragraph 8 concerning Plaintiffs' future plans, and therefore deny the same. Defendants deny the remaining allegations of paragraph 8.

NATURE OF THE ACTION

9. Admitted in part; denied in part. Defendants admit only that paragraph 9 of the complaint identifies AbbVie Inc. and AbbVie Biotechnology Ltd as plaintiffs in this action. Defendants deny any other allegations in paragraph 9.

10. Admitted in part; denied in part. Defendants admit only that the complaint alleges that this action arises under the patent laws of the United States, 35 U.S.C. §§ 1, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202. Defendants deny the remaining allegations of paragraph 10.

11. Denied.

12. On information and belief, admitted.

13. Admitted in part; denied in part. Defendants admit only that adalimumab is a biologic drug; that adalimumab is a fully human, high-affinity, and neutralizing therapeutic antibody to human TNFα; and that TNFα is a protein made by the human body as part of the body's immune response. Defendants lack sufficient knowledge or information to form a belief

as to the allegations of the first sentence of paragraph 13, and therefore deny the same. Defendants deny the remaining allegations of paragraph 13.

14. Admitted in part; denied in part. Defendants admit only that adalimumab was the first fully human antibody approved by the FDA; that adalimumab, disclosed and claimed in U.S. Patent No. 6,090,382 ("the '382 patent"), was a significant scientific achievement; and that Remicade® (infliximab) is a chimeric antibody approved for intravenous injection. Defendants lack sufficient knowledge or information to form a belief as to the allegations of the third sentence of paragraph 14, and therefore deny the same. Defendants deny the remaining allegations of paragraph 14.

15. Denied. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 15, and therefore deny the same.

16. Admitted in part; denied in part. On information and belief, Defendants admit only that Humira® (adalimumab) was one of the recipients of the Prix Galien USA in 2007. Otherwise, denied.

17. Denied. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 17, and therefore deny the same.

18. Admitted in part, denied in part. Defendants admit only that Plaintiffs' complaint identifies 74 patents that Plaintiffs allege could reasonably be asserted with respect to the BLA Product. Defendants deny the remaining allegations of paragraph 18.

19. Admitted in part; denied in part. Defendants admit only that, pursuant to the procedures set forth in the BPCIA and the circumstances described in paragraph 7 above, there are eight patents at issue in this litigation. The last sentence of paragraph 19 states legal

conclusions to which no answer is required. Defendants deny the remaining allegations of paragraph 19.

20. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek an injunction, to which they are not entitled, relating to the eight patents in dispute in this case, and that the BPCIA created an abbreviated regulatory pathway for the approval of biosimilar drugs. Defendants lack sufficient knowledge or information to form a belief as to the truth of the last sentence of paragraph 20 concerning Plaintiffs' future plans, and therefore deny the same. Defendants deny the remaining allegations of paragraph 20.

PARTIES

21. On information and belief, admitted.

22. On information and belief, admitted.

23. Admitted.

24. Admitted in part; denied in part. Defendants admit only that the BLA Product will be distributed in the United States, including the State of Delaware, but not before any required notice to engage in such activities is provided. Defendants deny the remaining allegations of paragraph 24.

25. Admitted.

26. Admitted in part; denied in part. Defendants admit only that the BLA Product will be distributed in the United States, including the State of Delaware, but not before any required notice to engage in such activities is provided. Defendants deny the remaining allegations of paragraph 26.

27. Admitted.

28. Admitted in part; denied in part. Defendants admit only that the BLA Product will be distributed in the United States, including the State of Delaware, but not before any

required notice to engage in such activities is provided. Defendants deny the remaining allegations of paragraph 28.

29. Admitted.

30. Admitted in part; denied in part. Defendants admit only that the BLA Product will be distributed in the United States, including the State of Delaware, but not before any required notice to engage in such activities is provided, and that such activities will provide benefits, including to patients. Defendants deny the remaining allegations of paragraph 30.

JURISDICTION AND VENUE

31. Admitted in part; denied in part. Defendants admit only that the complaint alleges this action arises under the patent laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, and that a justiciable case or controversy exists. Defendants deny the remaining allegations of paragraph 31.

32. Without waiver of their right to challenge the propriety of jurisdiction in other cases, Defendants do not contest this Court's exercise of personal jurisdiction over them solely for the purposes of the above-captioned action. Otherwise, denied.

33. Without waiver of its right to challenge the propriety of jurisdiction in other cases, BIPI does not contest this Court's exercise of personal jurisdiction over it solely for the purposes of the above-captioned action. Otherwise, denied.

34. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured in the United States, and that the BLA Product will be marketed in the United States, including the State of Delaware, but not before any required notice to engage in such activities is provided. Otherwise, denied.

35. Without waiver of its right to challenge the propriety of jurisdiction in other cases, BIFI does not contest this Court's exercise of personal jurisdiction over it solely for the purposes of the above-captioned action. Otherwise, denied.

36. Admitted in part; denied in part. Defendants admit only that BIFI's facilities will be used for the manufacture of biologic products, and that the sources cited in paragraph 36 include the quoted language. Otherwise, denied.

37. Admitted in part; denied in part. Defendants admit only that BIFI's facilities will be used to manufacture the BLA Product. Otherwise, denied.

38. Without waiver of its right to challenge the propriety of jurisdiction in other cases, BII does not contest this Court's exercise of personal jurisdiction over it solely for the purposes of the above-captioned action. Otherwise, denied.

39. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured in the United States, and that the BLA Product will be marketed in the United States, including the State of Delaware, but not before any required notice to engage in such activities is provided. Otherwise, denied.

40. Admitted in part; denied in part. Defendants admit only that BII has been involved in clinical studies related to the BLA Product. Otherwise, denied.

41. Admitted in part; denied in part. Defendants admit only that the BLA Product will be distributed in the United States, including the State of Delaware, but not before any required notice to engage in such activities is provided. Otherwise, denied.

42. Denied.

43. Admitted in part; denied in part. Defendants admit only that the source cited in paragraph 43 includes the quoted language. Otherwise, denied.

44. Admitted.

45. Admitted in part; denied in part. Defendants admit only that counsel for Defendants communicated with counsel for Plaintiffs during the BPCIA exchanges. Otherwise, denied.

46. Admitted in part; denied in part. Defendants admit only that BII previously initiated certain patent infringement lawsuits in the District of Delaware that are not related to this action. Otherwise, denied.

47. Without waiver of its right to challenge the propriety of jurisdiction in other cases, BII does not contest this Court's exercise of personal jurisdiction over it solely for the purposes of the above-captioned action. Otherwise, denied.

48. Without waiver of their right to challenge the propriety of venue in other cases, Defendants do not contest venue in the District of Delaware solely for the purposes of the above-captioned action. Otherwise, denied.

THE PARTIES' EXCHANGES UNDER THE BPCIA

49. Admitted in part; denied in part. Defendants admit only the second sentence of paragraph 49 and that BIPI submitted Biologics License Application No. 761058 for the BLA Product ("BLA 761058") to the FDA on October 27, 2016. Defendants deny the remaining allegations of paragraph 49.

50. Admitted in part; denied in part. Defendants admit that Congress created an act of artificial infringement related to the submission of an application under subsection 262(k) for purposes of subject matter jurisdiction; that the BPCIA sets forth a series of pre-litigation exchanges outlined at 42 U.S.C. § 262(*l*); that 42 U.S.C. § 262(*l*)(8)(A) states, "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)"; and that 42 U.S.C. § 262(*l*)(8)(B) states that "the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement . . . ." Defendants deny the remaining allegations of paragraph 50.

51. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

52. Admitted in part; denied in part. Defendants admit only that counsel for Defendants contacted counsel for Plaintiffs on January 9, 2017, to inform Plaintiffs that BLA 761058 had been accepted by the FDA for review. Otherwise, denied.

53. Admitted in part; denied in part. Defendants admit only that the exchange of information in accordance with the procedures outlined in the BPCIA began in January 2017 and that, on January 13, 2017, Plaintiffs were provided with access to 93,750 pages relating to BLA 761058, which included, *inter alia*, information concerning the process or processes used to manufacture the BLA Product ("the 2A Disclosure"). Defendants deny the remaining allegations of paragraph 53.

54. Admitted in part; denied in part. Defendants admit only that, on March 13, 2017, pursuant to 42 U.S.C. § 262(*l*)(3)(A), counsel for Plaintiffs sent a letter to counsel for Defendants identifying the 72 patents of Plaintiffs' then-existing patents for which Plaintiffs alleged a claim of patent infringement could reasonably be asserted against the BLA Product ("the 3A List"), and that the letter included the quotation recited in paragraph 54 of the complaint. Defendants lack sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 54, and therefore deny the same.

55. Admitted in part; denied in part. Defendants admit only that, on April 18, 2017, June 6, 2017, and June 20, 2017, counsel for Plaintiffs provided supplemental lists to counsel for Defendants identifying certain issued patents.

56. Admitted in part; denied in part. Defendants admit only that, on May 12, 2017, pursuant to 42 U.S.C. § 262(*l*)(3)(B), counsel for Defendants provided counsel for Plaintiffs with 1,841 pages describing, in detail, bases for noninfringement and invalidity of the 72 patents identified on the 3A List ("the 3B Statement"); and that, on May 18, 2017, and July 6, 2017, pursuant to 42 U.S.C. § 262(*l*)(7), counsel for Defendants provided counsel for Plaintiffs with statements describing, in detail, bases for noninfringement and invalidity of the three patents identified in Plaintiffs' supplemental lists. Defendants deny the remaining allegations of paragraph 56.

57. Admitted in part; denied in part. Defendants admit only that, on July 11, 2017, Plaintiffs purported to respond to the 3B Statement ("the 3C Statement"), and that the 3C Statement provided by Plaintiffs purported to address the patents identified in the table included in paragraph 57 of the complaint (yet, in doing so, did not fulfill the requirements of 42 U.S.C. § 262(*l*)(3)(C)). Defendants deny the remaining allegations of paragraph 57.

58. Denied.

59. Admitted in part; denied in part. Defendants admit only that, after Plaintiffs provided the 3C Statement, Plaintiffs proposed litigating 71 patents; and that, pursuant to the procedures set forth in the BPCIA and the circumstances described in paragraph 7 above, counsel for Defendants notified counsel for Plaintiffs that each side could choose up to five patents (as opposed to the dozens of patents Plaintiffs proposed) to be litigated. Defendants deny the remaining allegations of paragraph 59.

60. Admitted.

61. Denied. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence of paragraph 61 concerning Plaintiffs' future plans, and therefore deny the same. Defendants deny the remaining allegations of paragraph 61.

THE BLA PRODUCT

62. Admitted in part; denied in part. Defendants admit only that the BLA Product is being developed for distribution in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

63. Admitted in part; denied in part. Defendants admit only that BIPI submitted BLA 761058 to the FDA seeking approval of the BLA Product. Otherwise, denied.

64. Admitted in part; denied in part. Defendants admit only that the document cited in paragraph 64 refers to the acceptance of BLA 761058 by the FDA and is dated January 18, 2017. Otherwise, denied.

65. Admitted in part; denied in part. Defendants admit only that the source cited in paragraph 65 includes the quoted language. Otherwise, denied.

66. Admitted in part; denied in part. Defendants admit only that clinical trials have been conducted with regard to the use of the BLA Product for treatment of moderate to severe rheumatoid arthritis; that data from those clinical trials were submitted in connection with BLA 761058; and that clinical trials with regard to the use of the BLA Product for treatment of plaque psoriasis and Crohn's disease are ongoing. Otherwise, denied.

67. Admitted in part; denied in part. Defendants admit only that the source cited in paragraph 67 includes the quoted language. Otherwise, denied.

68. Admitted in part; denied in part. Defendants admit that, as of the date of the filing of Plaintiffs' complaint, the FDA had not yet approved the BLA Product. Otherwise, denied.

69. Admitted in part; denied in part. Defendants admit that a justiciable case or controversy exists between the parties, but deny that any act of infringement has occurred.

THE ADALIMUMAB PATENTS

70. Denied. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 70, and therefore deny the same.

71. Admitted in part; denied in part. Defendants admit only that Plaintiffs are limited to asserting U.S. Patent Nos. 8,926,975 ("the '975 patent"), 9,018,361 ("the '361 patent"), 9,090,867 ("the '867 patent"), 9,096,666 ("the '666 patent"), 9,255,143 ("the '143 patent"), 9,266,949 ("the '949 patent"),9,272,041 ("the '041 patent"), and 9,546,212 ("the '212 patent") (collectively, the "Asserted Patents") in this lawsuit. Defendants deny the remaining allegations of paragraph 71.

72. Admitted.

73. Admitted in part; denied in part. Defendants admit only that, on January 6, 2015, the '975 patent, titled "Method of Treating Ankylosing Spondylitis," was issued by the United States Patent and Trademark Office ("USPTO"), and that Exhibit 8 appears to be a copy of the '975 patent. Otherwise, denied.

74. Admitted in part; denied in part. Defendants admit only that AbbVie Biotechnology Ltd is listed as the assignee on the face of the '975 patent. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations of paragraph 74, and therefore deny the same.

75. Admitted in part; denied in part. Defendants admit only that, on April 28, 2015, the '361 patent, titled "Isolation and Purification of Antibodies Using Protein A Affinity Chromatography," was issued by the USPTO, and that Exhibit 9 appears to be a copy of the '361 patent. Otherwise, denied.

76. Admitted in part; denied in part. Defendants admit only that AbbVie Inc. is listed as the assignee on the face of the '361 patent. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations of paragraph 76, and therefore deny the same.

77. Admitted in part; denied in part. Defendants admit only that, on July 28, 2015, the '867 patent, titled "Fed-Batch Method of Making Anti-TNF-Alpha Antibody," was issued by the USPTO, and that Exhibit 10 appears to be a copy of the '867 patent. Otherwise, denied.

78. Admitted in part; denied in part. Defendants admit only that AbbVie Inc. is listed as the assignee on the face of the '867 patent. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations of paragraph 78, and therefore deny the same.

79. Admitted in part; denied in part. Defendants admit only that, on August 4, 2015, the '666 patent, titled "Purified Antibody Composition," was issued by the USPTO, and that Exhibit 11 appears to be a copy of the '666 patent. Otherwise, denied.

80. Admitted in part; denied in part. Defendants admit only that AbbVie Biotechnology Ltd is listed as the assignee on the face of the '666 patent. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations of paragraph 80, and therefore deny the same.

81. Admitted in part; denied in part. Defendants admit only that, on February 9, 2016, the '143 patent, titled "Methods for Controlling the Galactosylation Profile of Recombinantly-Expressed Proteins," was issued by the USPTO, and that Exhibit 12 appears to be a copy of the '143 patent. Otherwise, denied.

82. Admitted in part; denied in part. Defendants admit only that AbbVie Inc. is listed as the assignee on the face of the '143 patent. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations of paragraph 82, and therefore deny the same.

83. Admitted in part; denied in part. Defendants admit only that, on February 23, 2016, the '949 patent, titled "Low Acidic Species Compositions and Methods for Producing and Using the Same," was issued by the USPTO, and that Exhibit 13 appears to be a copy of the '949 patent. Otherwise, denied.

84. Admitted in part; denied in part. Defendants admit only that AbbVie Inc. is listed as the assignee on the face of the '949 patent. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations of paragraph 84, and therefore deny the same.

85. Admitted in part; denied in part. Defendants admit only that, on March 1, 2016, the '041 patent, titled "Formulation of Human Antibodies for Treating TNF-Alpha Associated Disorders," was issued by the USPTO, and that Exhibit 14 appears to be a copy of the '041 patent. Otherwise, denied.

86. Admitted in part; denied in part. Defendants admit only that AbbVie Biotechnology Ltd is listed as the assignee on the face of the '041 patent. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations of paragraph 86, and therefore deny the same.

87. Admitted in part; denied in part. Defendants admit only that, on January 17, 2017, the '212 patent, titled "Methods of Administering Anti-TNFα Antibodies," was issued by the USPTO, and that Exhibit 15 appears to be a copy of the '212 patent. Otherwise, denied.

88. Admitted in part; denied in part. Defendants admit only that AbbVie Biotechnology Ltd is listed as the assignee on the face of the '212 patent. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations of paragraph 88, and therefore deny the same.

89. Admitted.

90. Admitted in part; denied in part. Defendants admit that Plaintiffs purported to provide responses pursuant to 42 U.S.C. § 262(*l*)(3)(C) for certain claims of the Asserted Patents, but deny that those responses fulfilled the requirements of the BPCIA.

ANSWER TO COUNT I
(Alleged Infringement of the '975 Patent)

91. Defendants repeat and restate their responses to paragraphs 1-90 of the complaint as if fully set forth herein.

92. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

93. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

94. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

95. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

96. Denied.

97. Admitted in part; denied in part. Defendants admit only that information relating to the proposed indications, dosage, and methods of use for the BLA Product was provided to Plaintiffs pursuant to 42 U.S.C. § 262(*l*)(2)(A). Defendants deny the remaining allegations of paragraph 97.

98. Admitted in part; denied in part. Defendants admit only that BLA 761058 includes information regarding the administration of the BLA Product. Defendants deny the remaining allegations of paragraph 98.

99. Denied.

100. Denied.

101. Admitted.

102. Denied.

103. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek an injunction, but deny that Plaintiffs are entitled to any such relief.

ANSWER TO COUNT II
(Alleged Infringement of the '361 Patent)

104. Defendants repeat and restate their responses to paragraphs 1-103 of the complaint as if fully set forth herein.

105. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

106. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

107. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

108. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

109. Denied.

110. Denied.

111. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

112. Denied.

113. Denied.

114. Denied.

115. Denied.

116. Admitted.

117. Denied.

118. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek an injunction, but deny that Plaintiffs are entitled to any such relief.

ANSWER TO COUNT III
(Alleged Infringement of the '867 Patent)

119. Defendants repeat and restate their responses to paragraphs 1-118 of the complaint as if fully set forth herein.

120. Defendants admit that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

121. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

122. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

123. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

124. Denied.

125. Denied.

126. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

127. Denied.

128. Denied.

129. Denied.

130. Denied.

131. Admitted.

132. Denied.

133. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek an injunction, but deny that Plaintiffs are entitled to any such relief.

ANSWER TO COUNT IV
(Alleged Infringement of the '666 Patent)

134. Defendants repeat and restate their responses to paragraphs 1-133 of the complaint as if fully set forth herein.

135. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

136. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

137. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

138. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

139. Denied.

140. Denied.

141. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

142. Denied.

143. Denied.

144. Denied.

145. Denied.

146. Admitted.

147. Denied.

148. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek an injunction, but deny that Plaintiffs are entitled to any such relief.

ANSWER TO COUNT V
(Alleged Infringement of the '143 Patent)

149. Defendants repeat and restate their responses to paragraphs 1-148 of the complaint as if fully set forth herein.

150. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

151. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

152. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

153. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

154. Denied.

155. Denied.

156. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

157. Denied.

158. Denied.

159. Denied.

160. Denied.

161. Admitted.

162. Denied.

163. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek an injunction, but deny that Plaintiffs are entitled to any such relief.

ANSWER TO COUNT VI
(Alleged Infringement of the '949 Patent)

164. Defendants repeat and restate their responses to paragraphs 1-163 of the complaint as if fully set forth herein.

165. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

166. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

167. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

168. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

169. Denied.

170. Denied.

171. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

172. Denied.

173. Denied.

174. Denied.

175. Denied.

176. Admitted.

177. Denied.

178. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek an injunction, but deny that Plaintiffs are entitled to any such relief.

ANSWER TO COUNT VII
(Alleged Infringement of the '041 Patent)

179. Defendants repeat and restate their responses to paragraphs 1-178 of the complaint as if fully set forth herein.

180. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

181. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

182. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

183. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

184. Denied.

185. Denied.

186. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

187. Denied.

188. Denied.

189. Denied.

190. Denied.

191. Admitted.

192. Denied.

193. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek an injunction, but deny that Plaintiffs are entitled to any such relief.

ANSWER TO COUNT VIII
(Alleged Infringement of the '212 Patent)

194. Defendants repeat and restate their responses to paragraphs 1-193 of the complaint as if fully set forth herein.

195. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

196. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

197. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

198. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

199. Denied.

200. Admitted in part; denied in part. Defendants admit only that information relating to the proposed indications, dosage, and methods of use for the BLA Product was provided to Plaintiffs pursuant to 42 U.S.C. § 262(*l*)(2)(A). Defendants deny the remaining allegations of paragraph 200.

201. Admitted in part; denied in part. Defendants deny the allegations of paragraph 201, except that Defendants admit that BLA 761058 includes information regarding the administration of the BLA Product.

202. Denied.

203. Denied.

204. Admitted.

205. Denied.

206. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek an injunction, but deny that Plaintiffs are entitled to any such relief.

ANSWER TO COUNT IX
(Declaratory Judgment for Alleged Infringement of the '975 Patent)

207. Defendants repeat and restate their responses to paragraphs 1-206 of the complaint as if fully set forth herein.

208. Admitted in part; denied in part. Defendants admit only that the complaint alleges that this action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Otherwise, denied.

209. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

210. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

211. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

212. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

213. Denied.

214. Denied.

215. Admitted in part; denied in part. Defendants admit only that information relating to the proposed indications, dosage, and methods of use for the BLA Product was provided to Plaintiffs pursuant to 42 U.S.C. § 262(*l*)(2)(A). Defendants deny the remaining allegations of paragraph 215.

216. Admitted in part; denied in part. Defendants admit only that BLA 761058 includes information regarding the administration of the BLA Product. Defendants deny the remaining allegations of paragraph 216.

217. Denied.

218. Denied.

219. Admitted.

220. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek a declaratory judgment, but deny that Plaintiffs are entitled to any such relief.

221. Denied.

ANSWER TO COUNT X
(Declaratory Judgment for Alleged Infringement of the '361 Patent)

222. Defendants repeat and restate their responses to paragraphs 1-221 of the complaint as if fully set forth herein.

223. Admitted in part; denied in part. Defendants admit only that the complaint alleges that this action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Otherwise, denied.

224. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

225. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

226. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

227. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

228. Denied.

229. Denied.

230. Denied.

231. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

232. Denied.

233. Denied.

234. Denied.

235. Denied.

236. Admitted.

237. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek a declaratory judgment, but deny that Plaintiffs are entitled to any such relief.

238. Denied.

ANSWER TO COUNT XI
(Declaratory Judgment for Alleged Infringement of the '867 Patent)

239. Defendants repeat and restate their responses to paragraphs 1-238 of the complaint as if fully set forth herein.

240. Admitted in part; denied in part. Defendants admit that the complaint alleges that this action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Otherwise, denied.

241. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

242. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

243. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

244. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

245. Denied.

246. Denied.

247. Denied.

248. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

249. Denied.

250. Denied.

251. Denied.

252. Denied.

253. Admitted.

254. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek a declaratory judgment, but deny that Plaintiffs are entitled to any such relief.

255. Denied.

ANSWER TO COUNT XII
(Declaratory Judgment for Alleged Infringement of the '666 Patent)

256. Defendants repeat and restate their responses to paragraphs 1-255 of the complaint as if fully set forth herein.

257. Admitted in part; denied in part. Defendants admit only that the complaint alleges that this action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Otherwise, denied.

258. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

259. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

260. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

261. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

262. Denied.

263. Denied.

264. Denied.

265. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

266. Denied.

267. Denied.

268. Denied.

269. Denied.

270. Admitted.

271. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek a declaratory judgment, but deny that Plaintiffs are entitled to any such relief.

272. Denied.

ANSWER TO COUNT XIII
(Declaratory Judgment for Alleged Infringement of the '143 Patent)

273. Defendants repeat and restate their responses to paragraphs 1-272 of the complaint as if fully set forth herein.

274. Admitted in part; denied in part. Defendants admit only that the complaint alleges that this action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Otherwise, denied.

275. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

276. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

277. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

278. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

279. Denied.

280. Denied.

281. Denied.

282. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

283. Denied.

284. Denied.

285. Denied.

286. Denied.

287. Admitted.

288. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek a declaratory judgment, but deny that Plaintiffs are entitled to any such relief.

289. Denied.

ANSWER TO COUNT XIV
(Declaratory Judgment for Alleged Infringement of the '949 Patent)

290. Defendants repeat and restate their responses to paragraphs 1-289 of the complaint as if fully set forth herein.

291. Admitted in part; denied in part. Defendants admit only that the complaint alleges this action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Otherwise, denied.

292. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

293. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

294. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

295. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

296. Denied.

297. Denied.

298. Denied.

299. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

300. Denied.

301. Denied.

302. Denied.

303. Denied.

304. Admitted.

305. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek a declaratory judgment, but deny that Plaintiffs are entitled to any such relief.

306. Denied.

ANSWER TO COUNT XV
(Declaratory Judgment for Alleged Infringement of the '041 Patent)

307. Defendants repeat and restate their responses to paragraphs 1-306 of the complaint as if fully set forth herein.

308. Admitted in part; denied in part. Defendants admit only that the complaint alleges this action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Otherwise denied.

309. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

310. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

311. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

312. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

313. Denied.

314. Denied.

315. Denied.

316. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

317. Denied.

318. Denied.

319. Denied.

320. Denied.

321. Admitted.

322. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek a declaratory judgment, but deny that Plaintiffs are entitled to any such relief.

323. Denied.

ANSWER TO COUNT XVI
(Declaratory Judgment for Alleged Infringement of the '212 Patent)

324. Defendants repeat and restate their responses to paragraphs 1-323 of the complaint as if fully set forth herein.

325. Admitted in part; denied in part. Defendants admit only that the complaint alleges this action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Otherwise, denied.

326. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

327. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

328. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

329. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

330. Denied.

331. Denied.

332. Admitted in part; denied in part. Defendants admit only that information relating to the proposed indications, dosage, and methods of use for the BLA Product was provided to Plaintiffs pursuant to 42 U.S.C. § 262(*l*)(2)(A). Defendants deny the remaining allegations of paragraph 332.

333. Admitted in part; denied in part. Defendants admit only that BLA 761058 includes information regarding the administration of the BLA Product. Defendants deny the remaining allegations of paragraph 333.

334. Denied.

335. Denied.

336. Admitted.

337. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek a declaratory judgment, but deny that Plaintiffs are entitled to any such relief.

338. Denied.

PRAYER FOR RELIEF

The remainder of Plaintiffs' complaint recites a prayer for relief to which no response is required. To the extent any response is required, Defendants deny that Plaintiffs are entitled to any remedy or relief.

WHEREFORE Defendants respectfully request that the Court enter judgment in their favor, and against Plaintiffs, along with attorney fees, costs of suit, and such other and further relief as the Court deems appropriate.

DEFENSES

Without prejudice to the denials set forth in their Answer, and without admitting any allegation of the complaint not expressly admitted herein, Defendants assert the following separate defenses to the complaint without assuming the burden of proof on any such defense

that would otherwise rest with Plaintiffs. Defendants expressly reserve their rights to assert additional defenses that discovery may reveal.

FIRST DEFENSE
(Failure to State a Claim)

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

SECOND DEFENSE
(Noninfringement of the Asserted Patents)

2. Defendants have not and will not, directly or indirectly, literally or under the doctrine of equivalents, infringe any valid and enforceable claim of the '975 patent.

3. Defendants have not and will not, directly or indirectly, literally or under the doctrine of equivalents, infringe any valid and enforceable claim of the '361 patent.

4. Defendants have not and will not, directly or indirectly, literally or under the doctrine of equivalents, infringe any valid and enforceable claim of the '867 patent.

5. Defendants have not and will not, directly or indirectly, literally or under the doctrine of equivalents, infringe any valid and enforceable claim of the '666 patent.

6. Defendants have not and will not, directly or indirectly, literally or under the doctrine of equivalents, infringe any valid and enforceable claim of the '143 patent.

7. Defendants have not and will not, directly or indirectly, literally or under the doctrine of equivalents, infringe any valid and enforceable claim of the '949 patent.

8. Defendants have not and will not, directly or indirectly, literally or under the doctrine of equivalents, infringe any valid and enforceable claim of the '041 patent.

9. Defendants have not and will not, directly or indirectly, literally or under the doctrine of equivalents, infringe any valid and enforceable claim of the '212 patent.

THIRD DEFENSE
(Invalidity of the Asserted Patents)

10. The claims of the '975 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

11. The claims of the '361 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

12. The claims of the '867 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

13. The claims of the '666 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

14. The claims of the '143 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

15. The claims of the '949 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

16. The claims of the '041 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

17. The claims of the '212 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

FOURTH DEFENSE
(§ 271(e) Safe Harbor)

18. To the extent Plaintiffs claim that the manufacture and clinical use of the BLA Product is an act of infringement, Defendants are exempt from liability under the safe harbor provision of 35 U.S.C. § 271(e).

FIFTH DEFENSE
(Prohibition of Costs)

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

SIXTH DEFENSE
(No Exceptional Case)

20. Defendants' actions related to this case do not give rise to an exceptional case finding under 35 U.S.C. § 285.

SEVENTH DEFENSE
(No Equitable Relief)

21. Plaintiffs are not entitled to preliminary or permanent equitable relief.

EIGHTH DEFENSE
(BPCIA Noncompliance)

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

NINTH DEFENSE
(Unclean Hands)

23. Plaintiffs cannot obtain relief, including injunctive relief, because of their unclean hands.

24. AbbVie has engaged in a multifaceted, illegal scheme to prevent the sale of adalimumab in competition against Humira®. AbbVie enjoyed exclusivity for Humira® for some 13 years under its patent claiming adalimumab and compositions and uses of that active ingredient. With the looming expiration of that patent, AbbVie set about to, and did, engage in a multifaceted scheme to inhibit the goal of the BPCIA to allow for biosimilar competition by, *inter alia*, generating a large quantity of dubious, overlapping patents and manipulating the patent system to obtain them and the judicial process using them.

25. AbbVie's intensive desire to create a patent thicket encouraged and fostered an unconscionable pattern of withholding and/or misrepresenting information to the U.S. Patent and Trademark Office during prosecution of its patents in a manner that subverted the integrity of the patent system and resulted in the issuance of patents that otherwise would not have been issued. AbbVie's documents, including documents believed to exist that continue to improperly be withheld from discovery, demonstrate a disregard for the duty of candor required for prosecution of patents at the U.S. Patent and Trademark Office. At least the individuals identified herein, and those acting in concert with them, possessed an intent to deceive the Patent Office examiner into granting patents so that the patents could be included in the AbbVie patent thicket.

26. AbbVie's program was successful in creating a thicket that AbbVie has exploited to delay competition of an FDA-approved adalimumab biosimilar. AbbVie's tactics have included withholding from discovery documents about the alleged misconduct itself, requiring, for example, a Court order compelling unclean hands discovery.

27. AbbVie's misconduct, individually and collectively, harms the public, including Defendants, and renders its assertion of its patents violative of principles of equity. The patents-in-suit are unenforceable because of Plaintiffs' unclean hands.

AbbVie's Plan to Create a Patent
Thicket to Prevent Adalimumab Competition

28. The '382 patent ("the adalimumab patent") allowed AbbVie to gain more than a decade of monopoly profits through its Humira® product. Until expiration in 2016, the '382 patent claimed adalimumab and formulations and uses thereof, including the disclosure of therapeutic uses for autoimmune diseases relating to anti-TNFα activity such as rheumatoid arthritis, rheumatoid spondylitis, and osteoarthritis. ('382 patent at 25:42-55.) A basic *quid pro quo* for AbbVie's ownership of this monopoly was that a person of ordinary skill in the art would be able to make and use adalimumab once the adalimumab patent expired in 2016. (*See, e.g.*, 35 U.S.C. § 112.) AbbVie's vast patent thicket is an attempt to effectively re-patent adalimumab, blocking efforts to make and use that active ingredient.

29. For many years after issuance, the adalimumab patent remained the only issued patent drawn to Humira®. Under the exclusivity of this patent, AbbVie reaped tens of billions of dollars in sales of adalimumab in the United States.

30. Unwilling to stomach biosimilar competition with the expiration of the adalimumab patent approaching, and dissatisfied with a small portfolio of applications, AbbVie set out to, and did, generate a vast portfolio of dubious, overlapping patents years after the launch of Humira®; these patents were designed to prevent an adalimumab biosimilar, including patents based on observations of routine aspects of the manufacture of adalimumab. AbbVie's focus has been to set landmines on the road to biosimilarity and approval. AbbVie has called the scheme "our biosimilar strategy." (*See, e.g.*, AbbVie Inc. at Bank of America Merrill Lynch Healthcare Conference (May 13, 2015) at 4.)

31. AbbVie's business strategy—widely disseminated and known throughout the company and among certain third parties—was aimed at protecting Humira® from legitimate

competition from an adalimumab biosimilar. [redacted] This scheme involved disclosures to numerous AbbVie employees, [redacted] By way of example, [redacted] Indeed, AbbVie's strategy to attack, among other things, [redacted]

32. The strategic initiative within AbbVie focused on [redacted] In furtherance of its scheme, [redacted] including an October 2010 internal conference [redacted] to brainstorm ideas to continue its monopoly on adalimumab. [redacted] Participants were specifically asked [redacted]) Similarly, at an internal meeting in [redacted], participants were asked to consider [redacted] Instead of innovation, AbbVie's illegal patenting scheme targeted [redacted] AbbVie's documents describe [redacted]

[redacted]

33. [redacted] developed at the October 2010 conference. [redacted]

34. [redacted] To do so, AbbVie asked itself: [redacted]

35. AbbVie's [redacted] has confirmed that, upon its formation in 2013, the company was well into the execution phase of its

scheme. Indeed, AbbVie set out to create "an absolute minefield of IP" for adalimumab competition. (*See* AbbVie Inc. Q3 2013 Earnings Call (Oct. 25, 2013) at 10.) Even before becoming [redacted] had been directly involved with [redacted]

36. In early 2014—more than a decade after the adalimumab patent issued, and within almost two years of its expiration—the company told investors it was in the process of filing hundreds of patent applications with the Patent Office and proclaimed that "[m]any of those [will] issue," which was just "one of the lines of defense that we have put in place." (AbbVie Inc. Q4 2013 Earnings Call (Jan. 31, 2014) at 9-10.) In so stating, AbbVie simultaneously admitted that (1) its shotgun approach would be a tactic to push patent applications through the Patent Office, and (2) building a patent portfolio to target biosimilarity was part of a larger scheme to thwart adalimumab competition.

37. AbbVie has explained that a central component of its Humira® scheme is to obfuscate the ability of competitors to meet biosimilarity requirements. As late-stage prosecution efforts for the Humira® scheme were hitting full stride—more than a decade after Humira®'s approval, and shortly before the adalimumab patent expired—AbbVie's [redacted] was asked to comment on "the thicket of patents for HUMIRA in the US." (AbbVie Inc. at Goldman Sachs Healthcare Conference (June 11, 2014) at 7.) His response revealed AbbVie's goal to force would-be competitors toward adalimumab products that did not meet basic FDA standards for safety and efficacy:

> [S]uffice to say that with a product as important and as attractive as HUMIRA, you do everything you can on the IP front to ensure that you've protected it to the best you can. The bulk of that IP strategy . . . is designed to make it more difficult for a biosimilar to follow behind you and come up with a very, very similar

> biosimilar . . . . [T]he less similar, the greater likelihood of a difference in efficacy or, very importantly, a difference in safety.

(*Id*.)

38. By 2015, AbbVie executives regularly touted that the newly formed company, which now had the rights to Humira®, had "developed [a] comprehensive strategy in anticipation of biosimilar entry," including efforts to further develop its "Broad U.S. Humira Patent Estate." (AbbVie Long-Term Strategy Presentation (Oct. 30, 2015) at 3, 14.)

39. While contemplating "biosimilar uncertainty around HUMIRA" in relation to the new company's valuation, AbbVie's [redacted] explained the plan: "[W]hat we have laid out for investors is a clear strategy that we put in place, starting back in 2013, of how we were going to ***deal with that***." (AbbVie Inc. Q2 2016 Earnings Call (July 29, 2016) at 11 (emphasis added).)

40. Recognizing the pending competition from Defendants and other companies that had commenced late-stage clinical trials to study biosimilar versions of adalimumab, AbbVie ramped up its scheme, filing at least 140 patent applications targeting competition in adalimumab since 2013.

41. To date, AbbVie has aggregated more than 170 patents and pending applications in its thicket. AbbVie thus continues its intended scheme to mitigate biosimilar competition through creation of "an absolute minefield of IP" for adalimumab competition. (AbbVie Inc. Q3 2013 Earnings Call (Oct. 25, 2013) at 10.)

42. Observers have recognized that the challenge for any adalimumab competition is the "seemingly impregnable fortress of patents AbbVie has methodically constructed around its prized moneymaker." (Cynthia Koons, *This Shield of Patents Protects the World's Best-Selling Drug*, BLOOMBERG (Sept. 7, 2017), https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patentsprotects-the-world-s-best-selling-drug.)

AbbVie's Thicket of Dubious and Overlapping Patents

43. As part of its scheme to prevent adalimumab competition, AbbVie created a thicket of patents for formulations of adalimumab, including formulations that were not used in Humira® and which AbbVie never created, but which would effectively extend the monopoly of its expired adalimumab patent that had claimed formulations. AbbVie admitted as such when bragging that its patents "cover not only our commercial formulation, but also other related formulations that biosimilar companies might employ." (AbbVie Inc. Q3 2015 Earnings Call (Oct. 30, 2015) at 9.)

44. At least nine of AbbVie's formulation patents in the Humira® patent scheme do not contain even one claim that reflects the Humira® formulation. U.S. Patent Nos. 8,795,670, 9,327,032, and 9,732,152, for example, sought to patent the use of ***histidine***, but the Humira® formulation does not include ***histidine***. U.S. Patent Nos. 8,802,101 and 9,272,041 sought to patent the use of ***acetate***, but the Humira® formulation does not include ***acetate***. U.S. Patent Nos. 8,802,102, 9,295,725, and 9,738,714 sought to patent the use of ***succinate***, but the Humira® formulation does not include ***succinate***. U.S. Patent No. 8,940,305 sought to patent ***gluconate***, but the Humira® formulation does not include ***gluconate***. AbbVie's goal of claiming as many different adalimumab products as possible to effectively prevent competition in the use of adalimumab provides no benefit to, and instead harms, American patients, doctors, and third-party payers.

45. In parallel, AbbVie has also engaged in a pattern of seeking to patent observations about adalimumab or its manufacture, and not invention. For example, AbbVie's late-stage prosecution of the cathepsin L patent family, which consists of at least 11 patents and pending patent applications, purports to be an observation about routine protein purification. The patents and applications assert that purifying the biologic of impurities resulted in an adalimumab

composition with low levels of an impurity referred to as "cathepsin L." AbbVie does not claim to have discovered, and did not discover, the idea of purifying proteins in the manufacture of biologics. AbbVie does not claim to have discovered that protein manufacture routinely includes purification of impurities, including proteases (*i.e.*, enzymes that break down proteins, including antibodies). As early as the issuance of the now-expired adalimumab patent, persons of ordinary skill in the art knew to use conventional purification methods, such as Protein A chromatography, to rid biologics of impurities. AbbVie's scheme of flooding the Patent Office with patents directed to adalimumab, with additional observations about the results of purification, is effectively a scheme to re-patent adalimumab by seeking to block routine manufacturing techniques for making that antibody.

46. AbbVie did not just aggressively pursue the creation of strategies for re-patenting adalimumab, but also aggressively pushed its applications through the Patent Office, including by making untrue and misleading statements and withholding material information. Publicly available information and AbbVie's own documents, including documents Defendants believe Plaintiffs have withheld from production despite Court orders compelling their production (*see, e.g.*, D.I. 112, 156), demonstrate that the aggressive scheme to generate a patent thicket included deceiving the Patent Office.

47. In prosecuting patents covering methods of treating rheumatoid arthritis with adalimumab, AbbVie submitted a false and misleading declaration regarding the purpose of one of AbbVie's Phase III clinical studies and made material omissions concerning key prior art.

48. The '212 patent that AbbVie asserted in this litigation claims priority to, and is a continuation of, U.S. Patent No. 8,889,135 ("the '135 patent"). Both patents recite "administering subcutaneously to a human subject having rheumatoid arthritis a total body dose

of 40 mg of a human anti-TNFα antibody once every 13-15 days." (*See* '135 patent at claims 1-4; '212 patent at claims 1-24.)

49. The '135 patent issued on November 18, 2014, from U.S. Application No. 10/163,657 ("the '657 application"), filed on June 5, 2002. During the more than 12-year prosecution of the '135 patent, the Examiner repeatedly rejected the pending claims as obvious. (*See, e.g.*, '135 patent prosecution history, 9/21/06 Non-Final Rejection at 7-9; '135 patent prosecution history, 6/18/07 Final Rejection at 10-12.)

50. By way of example, on December 1, 2009, the Examiner rejected the then-pending claims—a 20 to 80 mg biweekly dosing regimen ('135 patent prosecution history, 3/25/09 Claims at 2)—as obvious to one of ordinary skill in the art in view of the prior art. ('135 patent prosecution history, 12/1/09 Non-Final Rejection at 2-5.) The Examiner found that the prior art (L. B.A. van de Putte et al., *Efficacy of the Fully Human Anti-TNF Antibody D2E7 in Rheumatoid Arthritis*, 42(Supp.) Arthritis & Rheum. S400 (1999) ("van de Putte")) taught 20, 40, or 80 mg weekly doses of adalimumab. (*Id.* at 2-4.) The Examiner further found that the prior art (R. Rau et al., *Experience with D2E7*, 25 Akt. Rheumatol. 83 (2000) ("Rau")) taught every-other-week dosing, and reasoned that it would have been obvious to administer 40 mg every two weeks, rather than administering 20 mg every week. (*Id.* at 4.)

51. On July 20, 2010, AbbVie's prosecution attorney submitted a declaration by [redacted] to rebut this position. ('135 patent prosecution history, 7/20/10 Supplemental Response at 1; '135 patent prosecution history, [redacted] at ¶ 4.) In that declaration, [redacted] stated he was the [redacted] for the study disclosed in van de Putte (DE007). ('135 patent prosecution history, 7/20/10 [redacted] Declaration at ¶ 1.)

52. [redacted] acknowledged the Examiner's position that "van de Putte teaches near equal efficacy of treating Rheumatoid Arthritis using weekly injections of either 20, 40, or 80 mg of [adalimumab]." (*Id*. at ¶ 3.) [redacted] further acknowledged the Examiner's position that "it takes mere routine optimization for one to derive the presently claimed biweekly dosing regimens based on the van de Putte data." (*Id.*)

53. [redacted] asserted, however, that "the Examiner has not provided adequate reasons based on scientific and medical principles to support his positions." (*Id*. at ¶ 4.) [redacted] claimed instead that it would not have been routine or predictable to change from 20 mg weekly doses disclosed in the prior art to 40 mg every-other-week doses:

> Partly out of the ***concern for the lack of correlation between optimal dosing regimens*** and drug pharmacokinetics alone, one of the large scale, double bind, ***placebo-controlled Phase III clinical trials, DE019, was conducted to directly compare the efficacy of weekly 20 mg s.c. injection with biweekly 40 mg s.c. injection***. . . . Had the regimen change from weekly 20 mg to biweekly 40 mg been so routine or predictable, as the Examiner suggests, it is hardly justifiable to commit such an effort and financial resources to conduct such a large scale Phase III trial over so long a period of time.

(*Id.* at ¶ 21 (emphasis added).)

54. AbbVie amplified its assertion with remarks during prosecution of the '135 patent on February 7, 2014, that included declarations from three experts (*i.e.*, [redacted]) to argue that 20 mg weekly would have been viewed as an ineffective dose based on the results of the prior art DE007 study, and therefore 40 mg every-other-week was allegedly inventive:

- A skilled artisan "would have understood from the data in van de Putte that a dose of 20 mg, administered subcutaneously on a weekly schedule, would be too low" ('135 patent prosecution history, 2/7/14 Remarks at 21 (quoting '135 patent prosecution history, 2/7/14 [redacted] Declaration at ¶ 72));

- "[T]he weekly 20 mg sc dose in van de Putte would have been understood to be too low a dose" (*id.* at 22 (quoting '135 patent prosecution history, 2/7/14 [redacted] Declaration at ¶ 90));

- A skilled artisan "would have understood van de Putte and Rau S51 to teach that administering 20 mg D2E7 once a week is too low a dose" (*id.* at 19-20 (quoting '135 patent prosecution history, 2/7/14 [redacted] Declaration at ¶ 63)).

The declarations thus alleged that, because there is "no reason to expect that administering 40 mg biweekly should provide any better result than 20 mg weekly," a skilled artisan would have also "expected that 40 mg biweekly would likewise be too low a dose." (*See, e.g.*, '135 patent prosecution history, 2/7/14 Amendment Under 37 CFR § 1.114 at 19-20 (quoting '135 patent prosecution history, 2/7/14 [redacted] Declaration at ¶ 63), 22 (quoting '135 patent prosecution history, 2/7/14 [redacted] Declaration at ¶ 90).)

55. [redacted]

This is made clear by, for example, [redacted]

[redacted] AbbVie's documents show [redacted]

56. [redacted]

57. [redacted]

58. [redacted]

59. These AbbVie documents [redacted]

60. [redacted]

61. [redacted]

62. [redacted]

63. [redacted]

64. [redacted]

65. The '135 patent and its progeny, including the '212 patent, would not have issued but for those expert declarations and the failure to disclose evidence inconsistent with those declarations. The Examiner cited those declarations when granting the claims of the '135 patent, which recite: "administering subcutaneously to a human subject having rheumatoid arthritis a total body dose of 40 mg of a human anti-TNFα antibody once every 13-15 days." ('135 patent at claims 1-4; '135 patent prosecution history, 7/8/14 Notice of Allowance and Fees Due at 2-5.) This misconduct applies with equal weight to the '212 patent, whose claims also recite: "administering subcutaneously to a human subject having rheumatoid arthritis a total body dose of 40 mg of a human anti-TNFα antibody once every 13-15 days." ('212 patent at claims 1-24.)

66. AbbVie misled the Patent Office during prosecution of its process patents as well. Given that its patent thicket included patent filings made long after AbbVie began selling Humira®, AbbVie was forced to make material misrepresentations and/or conceal from the Patent Office material facts—including that AbbVie had already sold what it was trying to patent, which renders the claims unpatentable.

67. For example, during prosecution of the '867 patent, AbbVie withheld critical and material information from the Patent Office: [redacted] But for this nondisclosure, the '867 patent would not have issued.

68. AbbVie initially filed its BLA in 2002, 12 years before it filed the original application that ultimately led to the '867 patent. (*See* ABV-BI00466517 at 517 (original cover letter).) AbbVie's original BLA [redacted]

[redacted] The BLA also states [redacted] features are the same process features that appeared in the then-pending '867 patent claims.

69. Further, AbbVie's original BLA contained [redacted], that further illustrate the process features discussed above. [redacted]) For example, [redacted]

70. In 2006, AbbVie, for the first time, attempted to patent features of the process that it had implemented since 2002 to manufacture prior art Humira®. For example, claim 1 of the '867 patent claims methods for making adalimumab comprising culturing mammalian cells "wherein the pH of the cell culture production medium is adjusted such that the culturing begins at a starting pH and ends at a final pH that is less than the starting pH." Claim 13 of the '867

patent depends from claim 1 and further recites a method "wherein the mammalian cells are cultured at a first temperature, wherein said first temperature under which the mammalian cells are cultured is then reduced to a second temperature." Claim 15 of the '867 patent depends from claim 1 and further recites a method "wherein glucose concentration in said cell production medium is monitored, the glucose concentration in said medium decreases to below 2 g/L, and glucose is added to said medium when the glucose concentration in said medium decreases to below 2 g/L, or the glucose concentration in said medium is monitored and glucose is added to said medium to maintain the glucose concentration in said medium at a concentration of at least 2 g/L but no greater than 7 g/L."

71. Despite these claimed features having been part of AbbVie's commercial process for years, neither [redacted] nor others from AbbVie notified the Patent Office of this material information. It was apparent that such material information was relied upon by the Examiner. For example, during prosecution of the '867 patent, the Examiner cited a different named inventor's presentation materials ("Chang materials") and specifically asked AbbVie to provide "***any details*** they see as pertinent to the instant claims (e.g. 2 g/L antibody production, pH ramp, two different temperatures)." (*See* '867 patent prosecution history, 2/13/15 Non-Final Rejection at 8 (emphasis in original).) At least this specific request by the Examiner put AbbVie on notice of the materiality of AbbVie's prior work, and commercialization of that work. Even with that knowledge, AbbVie failed to fully inform the Examiner of its prior art processes. Instead, AbbVie simply stated to the Examiner that:

> [AbbVie] further respectfully submit[s] that none of the cited documents teach, suggest, or render obvious *inter alia* the use of a pH shift in a method of producing an antibody, let alone a fed batch method for making an anti-TNFα antibody comprising a light chain variable region (LCVR) comprising the sequence of SEQ ID NO: 1 and a heavy chain variable region

> (HCVR) comprising the sequence of SEQ ID NO: 2, said method comprising culturing mammalian cells comprising a nucleic acid encoding said anti-TNFα antibody in a cell culture production medium in large scale, wherein the pH of the cell culture production medium is adjusted according to a pH shift ramp comprising beginning at a starting pH and ending at a final pH that is less than the starting pH, such that said anti-TNFα antibody is produced at a titer of at least 2 g/L in said cell culture production medium, according to the pending claims.

('867 patent prosecution history, 5/28/15 Reply at 11.)

72. In sum, at least AbbVie's named inventors had a duty to disclose at least the above-identified information concerning AbbVie's prior art processes to the Examiner during prosecution of the '867 patent. They did not do so, even after the Examiner specifically asked AbbVie about its own work relating to the patent application. But for this omission, claims of the '867 patent would not have issued.

73. AbbVie's pattern of misbehavior in the prosecution of its process patents was not an isolated instance. Similar to the prosecution of the '867 patent, in other prosecutions AbbVie was forced to hide from the Patent Office the material fact that AbbVie had already sold what it was trying to patent. Indeed, AbbVie concealed the material fact of prior invalidating sales of the alleged inventions claimed in the '143 patent.

74. Claim 1 of the '143 patent, the only independent claim, recites "[a] composition comprising adalimumab, wherein more than 25% of the total N-linked oligosaccharides present on said adalimumab are of a galactose-containing fucosylated biantennary oligosaccharide form (sum of NA1F+NA2F)." NA1F and NA2F were said to be two kinds of fucosylated oligosaccharides present on adalimumab, and part of an oligosaccharide profile. Regulatory agencies require that the oligosaccharide profiles of therapeutic antibodies be characterized as part of the approval process. AbbVie did not purport to discover that adalimumab had an

oligosaccharide profile. But AbbVie did use this FDA requirement, like it did in many other instances, as a target for its landmine approach to patenting.

75. During prosecution of the '143 patent, the Examiner rejected the pending claims for obviousness because the claimed oligosaccharide profiles overlapped or fell within ranges taught in the prior art. ('143 patent prosecution history, 8/4/15 Amendment and Response at 8-12.) AbbVie overcame the rejection, in part, by arguing that the Examiner was mistakenly looking at all fucosylated forms, rather than the particular ones identified in its patent claims. (*Id.*) In its response, AbbVie represented that its prior-art Humira® did not meet the criteria of the claims, stating that "the adalimumab compositions disclosed in Salfeld and sold commercially as Humira do not comprise adalimumab in which more than 25% of the total N-linked oligosaccharides are ***NA1F and NA2F***." (*Id.* at 12 (emphasis added).)

76. In support of its assertion, AbbVie referred the examiner to an article published by AbbVie after the patent filing that discussed the "average" amount of NA1F and NA2F values for a period running from before until after the patent filing. (*Id.* at 10 (citing Tebbey *et al.*, *Consistency of Quality Attributes for the Glycosylated Monoclonal Antibody Humira® (Adalimumab)*, MAbs. 3:7(5), 805-11 (2015) ("Tebbey 2015").)

77. The Examiner, who lacked access to AbbVie's internal information that could have allowed cross-examination of these assertions, accepted the response, withdrew the rejection, and subsequently allowed the claims. ('143 patent prosecution history, 12/8/15 Notice of Allowance at 2 ("All objections and rejections of record are withdrawn in light of Applicant's Amendments and Remarks.").)

78. AbbVie did not disclose that these assertions were untrue: [redacted]

[redacted] For example, a [redacted] This information was not disclosed to the Patent Office.

79. Named inventor [redacted] was aware that AbbVie had [redacted] Documents found [redacted] If AbbVie had disclosed to the Patent Office that it [redacted] rather than arguing the opposite, the patent would not have issued.

80. AbbVie also engaged in misconduct in pursuing its cathepsin L patents, [redacted] which were material to the prosecution of the '666 patent application.

81. The '666 patent purports to claim an adalimumab composition expressed in a CHO cell expression system that, when assayed in a cathepsin L kinetic assay, has a level of activity which is less than 1.84 RFU/s/mg of adalimumab. (*See* '666 patent at claim 1.)

82. [redacted]

[redacted] In 2004, AbbVie [redacted]

83. An internal AbbVie report [redacted]

84. As the named inventors of the '666 patent, [redacted] and [redacted] had a duty to disclose the above-identified material information concerning these prior art batches to the Examiner during prosecution of the '666 patent and its priority applications. AbbVie, however, failed to disclose this important information to the Examiner, even after the Examiner specifically asked AbbVie about the existence of prior art adalimumab batches that had "cathepsin L activity of less than 1.84 RFU/s/mg of antibody, or a cathepsin L activity of no greater than 1.3 RFU/s/mg of antibody, when said activity was/is assayed by any technique other than the precise technique described in Example 4 of the instant specification" during the

prosecution of a priority application to the '666 patent. ('153 patent prosecution history, 6/24/14 Amendment and Response at 9-10.)[1]

85. In fact, despite the existence of the above-mentioned information known within AbbVie about its prior art product, AbbVie affirmatively represented to the Examiner that it "[did] not have or [could not] readily obtain data from assaying samples of adalimumab, produced prior to April 5, 2006, with a cathepsin L assay other than the precise technique described in Example 4 of the instant specification, where the cathepsin L activity is less than 1.84 RFU/s/mg of adalimumab or no greater than 1.3 RFU/s/mg of adalimumab." (*See id.*) By not disclosing the information regarding these prior art batches, AbbVie withheld material information from the Examiner during prosecution.

86. As yet another example of its misbehavior in the prosecution of its process patents, the '361 patent claims "[a] process for purifying adalimumab from a fermentation harvest of a Chinese Hamster Ovary (CHO) cell culture expressing said adalimumab, said process comprising: a) binding adalimumab from said fermentation harvest to a Protein A resin, b) eluting the bound adalimumab at an elution pH of 3.6-4, and c) incubating the eluted adalimumab for 1 to 3 hours." ('361 patent at claim 1.) During prosecution, AbbVie submitted a misleading declaration by its employee, [redacted] ([redacted] Declaration"). The [redacted] Declaration stated that, as of October 20, 2008, it was unexpected that adalimumab could be purified using Protein A chromatography without significant degradation. The [redacted] Declaration specifically stated:

[1] The '666 patent is a continuation of U.S. Patent No. 8,916,153 ("the '153 patent"), which is also directed to cathepsin activity levels like the '666 patent. (*See* '153 patent at claim 1.)

> Therefore, it is my opinion that it was unexpected that adalimumab could be successfully purified from CHO cells without significantly [sic] degradation, even with acidic elution of protein A resins followed by a substantial period of viral inactivation under low-pH conditions.

('361 patent prosecution history, 8/18/14 [redacted] Declaration at ¶ 9.)

87. The [redacted] Declaration, however, was inconsistent with AbbVie's statements regarding the use of Protein A in making adalimumab in its earlier prior art references, including the '382 patent, the patent application that issued as AbbVie's '867 patent, and the WO2007117490 publication ("the WO'490 publication")—which has one joint inventor with the '361 patent.

88. The '382 patent, which claimed adalimumab, disclosed that the antibodies of the invention "can be recovered from the culture medium using standard protein purification methods." ('382 patent at 17:29-30.) The WO'490 publication disclosed, *inter alia*, that "Protein A capture, in which an antibody-HCP mixture is applied to a protein A column such that the antibody binds to protein A and HCPs flow through, typically is used as an initial purification step in antibody purification procedures as a means to remove HCPs." (*See, e.g.*, WO'490 publication at 5.)

89. Further, AbbVie's prior art patent application, which issued as the '867 patent, made abundantly clear that "[i]t is also possible to utilize an affinity column comprising a polypeptide-binding polypeptide, such as a monoclonal antibody to the recombinant protein, to affinity-purify expressed polypeptides. Other types of affinity purification steps can be a Protein A or a Protein G column, which affinity agents bind to proteins that contain Fc domains." ('867 patent at 42:4-9.) Although AbbVie did not disclose this application during the prosecution of the '361 patent, this application as amended specifically claimed a method wherein the

"produced adalimumab is affinity purified using a Protein A resin" (*id*. at claim 30) and expires about two years earlier than the '361 patent.

90. AbbVie's above-identified prior art disclosures make clear that Protein A purification was a typical and straightforward technique that could be used to purify adalimumab. Therefore, it was a misrepresentation for AbbVie to claim through [redacted] declaration that "it was unexpected that adalimumab could be successfully purified from CHO cells without significantly [*sic*] degradation." ('361 patent prosecution history, 8/18/14 [redacted] Declaration at ¶ 9.) In fact, AbbVie's own teachings show that it was entirely expected that adalimumab could be purified from CHO cells, and nothing in those teachings suggests that degradation would be a problem. But for this misrepresentation, the '361 patent would not have issued.

AbbVie's Misuse of the Thicket in Proceedings under the BPCIA and in Judicial Enforcement

91. AbbVie's business strategy has been to leverage its thicket of dubious and overlapping patents to delay biosimilar competition. AbbVie has used the complexities and specific requirements of the BPCIA and the judicial process, as applied to its patent thicket, as a tool to delay competition, irrespective of the merits of its patent estate.

92. AbbVie executives have assuaged investors by pointing to the anticipated length of patent litigation proceedings involving its thicket: "I think that as you look at events play out in the legal space, you [have] got to keep your eye on the totality of the IP and the length of time that it's going to take to ultimately work." (AbbVie Inc. at Deutsche Bank Health Care Conference (May 3, 2017) at 6.) AbbVie reflected on how events were playing out in adalimumab biosimilar litigation as it had desired:

> [W]e have a court date on Amgen. It's November of 2019. And so that will give you some sense of even if Amgen were to prevail

> on every claim under 61 patents, the earliest we'll be getting a decision is 2020 . . . . So now what about the other biosimilar competitors? Well, nobody is as far along as Amgen. We have not been able to even go through the discovery process with the other competitors. But we certainly feel that there is a very strong likelihood that they are going to be in the same situation as Amgen. We know that Amgen is a very, very knowledgeable company around biologics. They obviously understand the proprietary pharma space very well. They understand the IP that often goes into those spaces, and we've seen what's happened to Amgen. . . . [W]hile the number may not be 61, I'm confident the number is not going to be 0 . . . .

(AbbVie Inc. at Goldman Sachs Global Healthcare Conference (June 13, 2017) at 2.)

93. AbbVie further stated that, even if Amgen had "prevail[ed] and knock[ed] down every claim under all of those 61 patents, we would then have obviously the right to appeal. That would take a year. And so that gets you into mid-2021. What's nice is you begin to see that the time line is starting to merge on that 2022 anyways, and I think the market is beginning to recognize that as well." (*Id*. at 3.) Likewise, [redacted] has boasted that the "litigation process" for a case involving multiple patents could take "4 to 5 years" and, thus, AbbVie's "biosimilar intellectual property and litigation [would] protect Humira biosimilar entry until 2022." (AbbVie, Inc. Long-Term Strategy Presentation (Oct. 30, 2015) at 16, 19.)

94. During the pre-litigation BPCIA process, AbbVie included expired and invalidated patents in its list provided under the statutory framework, which requires good-faith belief that a claim of infringement could reasonably be asserted. In its "3A List," AbbVie included the adalimumab patent, even though the patent had expired more than two months before on December 31, 2016. AbbVie proceeded through the dance on patents that had been invalided by the Patent Office in *inter partes* review (U.S. Patents Nos. 8,889,135 ("the '135 patent"), 9,017,680 ("the '680 patent"), and 9,073,987 ("the '987 patent")).

95. AbbVie's thicket forced a massive volume of work in responding to contentions for these patents. Defendants, for example, provided AbbVie with 1,841 pages describing bases for noninfringement and invalidity of all 72 patents identified on AbbVie's 3A List. Counsel for AbbVie responded on July 11, 2017, alleging infringement and validity for 71 out of the 72 patents ("3C Responses"), omitting only the expired adalimumab patent.

96. Those allegations included AbbVie patents for which it admits that it had no evidence of infringement. For example, with respect to all claims of U.S. Patent No. 9,096,666, AbbVie merely provided a boilerplate statement alleging that AbbVie possessed insufficient evidence to assert infringement. AbbVie's 3C Responses contained the '135, '680, and '987 patents, when those patents had been found invalid by the Patent Trial and Appeal Board.

97. On July 21, 2017, AbbVie was requested to remove at least 16 asserted patents for which AbbVie expressly admitted that it lacked evidence to allege infringement (*e.g.*, U.S. Patent Nos. 8,231,876, 8,883,156, 8,895,009, 8,906,372, 8,916,153, 9,096,666, 9,102,723, 9,273,132, 9,328,165, 9,085,618, 9,200,069, 9,200,070, 9,150,645, 9,359,434, 9,249,182, and 8,946,395). AbbVie declined. AbbVie's alleged excuse was that it lacked evidence of infringement, even while it had possession of Defendants' aBLA, because it needed more unspecified information. AbbVie did not articulate any theory of what information specifically it believed would show infringement of specific claims, or the identification of any information it currently possessed to make any such assertion.

98. In fact, between January 13, 2017, when Defendants provided AbbVie 93,750 pages relating to BLA 761058, until July 11, 2017, when AbbVie provided its 3C Responses, AbbVie never notified Defendants that any information necessary for AbbVie's assessment was missing.

99. In the present litigation, AbbVie improperly refused to produce, *inter alia*, relevant third-party discovery, supply, distribution, and manufacturing agreements, research and discovery documents, and BLA/IND documents and discovery relating to unclean hands, and has clawed back documents hours after their disclosure as relevant to Boehringer's unclean hands defense.

100. AbbVie has an ulterior motive for using the BPCIA process and patent litigation to delay Defendants' entry onto the market, and thus obtain an unfair advantage over competitors to maintain its "dominant position" in the marketplace. As AbbVie has explained, its delay tactics will ensure that, by the time adalimumab competition would otherwise occur, it will have established a commercial strategy to make it "difficult for a biosimilar competitor to actually challenge [AbbVie] within a payer environment ***purely on price***." (*See, e.g.*, AbbVie at UBS Global Healthcare Conference (May 20, 2015) at 4 (emphasis added); [redacted]

[redacted]

RESERVATION OF DEFENSES

101. Defendants reserve the right to assert any additional defenses or counterclaims, at law or equity, which may exist.

WHEREFORE Defendants respectfully request that the Court enter judgment in their favor, and against Plaintiffs, along with attorney fees, costs of suit, and such other and further relief as the Court deems appropriate.

COUNTERCLAIMS

Defendants hereby counterclaim against Plaintiffs as follows:

PARTIES

1. BII is a private limited liability company organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim am Rhein, Germany.

2. BIPI is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877.

3. BIFI is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 6701 Kaiser Drive, Fremont, California 94555.

4. On information and belief, AbbVie Inc. is a corporation organized and existing under the laws of Delaware with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064.

5. On information and belief, AbbVie Biotechnology Ltd 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.

JURISDICTION AND VENUE

6. Defendants' counterclaims for declaratory judgments of invalidity and noninfringement arise under the patent laws of the United States, 35 U.S.C. §§ 1, *et seq*. This Court has subject matter jurisdiction to hear Defendants' counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. This Court has personal jurisdiction over Plaintiffs because, among other reasons, they subjected themselves to the jurisdiction of this Court by filing the above-captioned action (C.A. No. 17-cv-01065-MSG) against Defendants in the District of Delaware.

8. Venue with respect to the counterclaims is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400. Plaintiffs allege that venue is proper in this District in their complaint.

9. An actual and justiciable controversy has arisen and now exists between the parties because, among other reasons, Plaintiffs have filed the above-captioned action against Defendants in the District of Delaware alleging infringement of the Asserted Patents. As explained in detail below, the present lawsuit stems from Plaintiffs' attempts to improperly extend their monopoly on adalimumab, the active ingredient of the drug Humira®.

BACKGROUND

The BLA Product

10. Defendants are part of one of the world's leading pharmaceutical groups. With a history dating back to 1885, there are now 143 global Boehringer affiliates employing more than 45,600 people. Boehringer companies have spent decades developing innovative therapies to improve the lives of patients. In 2016 alone, Boehringer companies invested more than $3.3 billion on the research and development of new medicines, including treatments for immunology and respiratory disorders, cardiovascular and metabolic diseases, cancer, and diseases of the central nervous system.

11. Boehringer companies have been pioneers in the field of biologic medicines, with over 35 years of experience and more than 25 drugs manufactured. Biologics produced by Boehringer companies include monoclonal antibodies in oncology and immunology, interferons, and other targeted medicines. AbbVie Inc. itself recently partnered with a Boehringer company to develop two therapeutic antibody candidates invented by Boehringer, BI 655066 and BI 655064, which included an initial payment of $595 million from AbbVie Inc. (*See* Ex. A, Press Release, AbbVie, AbbVie and Boehringer Ingelheim Announce Global Collaboration on Promising Immunology Compounds (Mar. 7, 2016) at *1, 4.)

12. The BLA Product is an injectable formulation containing adalimumab as the active ingredient. Adalimumab and a biologic drug product containing adalimumab were disclosed and claimed in a patent application filed in 1996 that issued as the now-expired '382 patent. The '382 patent conferred a statutory monopoly and attendant exclusivity in the United States to Plaintiffs for more than 16 years (from its issuance on July 18, 2000, to its expiration on December 31, 2016), excluding others from adalimumab, formulations containing adalimumab, and methods of making and using adalimumab. Plaintiffs further relied on clinical trials performed with adalimumab to gain an extension of the '382 patent term under 35 U.S.C. § 156.

Plaintiffs Purchase Adalimumab and Create a Patent Thicket

13. The antibody adalimumab was originally developed through a collaboration between BASF AG and Cambridge Antibody Technology. Adalimumab was disclosed in U.S. Application No. 08/599,226, filed on February 9, 1996, which later issued as the '382 patent. BASF AG was the original assignee for the '382 patent.

14. On information and belief, on December 14, 2000, Plaintiffs' predecessor, Abbott Laboratories ("Abbott") entered into an agreement to purchase BASF AG's pharmaceutical business, thus acquiring rights to the adalimumab antibody. On information and belief, the purchase was completed on March 2, 2001.

15. The adalimumab antibody was approved by the FDA for use in treating humans on December 31, 2002.

16. During the nearly 15 years since adalimumab's approval by the FDA, Abbott (and subsequently Plaintiffs) have marketed adalimumab under the trade name Humira®. At times during the period of exclusivity of the '382 patent, Humira® has cost nearly $50,000 per year. (Ex. B, Andrew Pollack, *Makers of Humira and Enbrel Using New Drug Patents to Delay Generic Versions*, N.Y. TIMES, (July 16, 2016),

https://www.nytimes.com/2016/07/16/business/makers-of-humira-and-enbrel-using-new-drug-patents-to-delay-generic-versions.html at *1 ("Pollack 2016").) In 2016, global sales of Humira® totaled $16.078 billion. (Ex. C, *AbbVie Reports Full-Year and Fourth-Quarter 2016 Financial Results*, ABBVIE PRESSROOM (Jan. 17, 2017), https://news.abbvie.com/news/abbvie-reports-full-year-and-fourth-quarter-2016-financial-results.htm at *1.)

17. During pre-suit BPCIA exchanges related to the BLA product, Plaintiffs identified a total of 75 patents pursuant to 42 U.S.C. §§ 262(*l*)(3)(A) and 262(*l*)(7).

18. As of the time of FDA approval of adalimumab in 2002, the only patent of the 75 patents identified by Plaintiffs in pre-suit exchanges pursuant to 42 U.S.C. §§ 262(*l*)(3)(A) and 262(*l*)(7) that had issued was the '382 patent. Plaintiffs have acknowledged that the '382 patent would not be infringed by the BLA Product.

19. As of the year 2011, nine years later, the only patent of the 75 patents identified by Plaintiffs in pre-suit exchanges pursuant to 42 U.S.C. §§ 262(*l*)(3)(A) and 262(*l*)(7) that had issued was the '382 patent.

20. As of 2001, when Abbott acquired rights to the adalimumab antibody, it was aware of the expiration of the '382 patent in December 2016, which had created exclusivity in, *inter alia*, adalimumab, formulations containing adalimumab, and methods of making and using adalimumab.

21. On information and belief, Plaintiffs engaged in a pattern of pursuing numerous overlapping and non-inventive patents for the purpose of developing a "patent thicket," using the patenting process itself as a means to seek to delay competition against its expensive and lucrative adalimumab product. That strategy has generated, according to paragraph 18 of Plaintiffs' complaint, more than 100 patents.

22. All 74 patents listed in paragraphs 57-58 of Plaintiffs' complaint, which Plaintiffs identified as the then-existing patents for which a claim of patent infringement could reasonably be asserted with respect to the BLA Product, were issued between 2012 and 2017.

23. All 74 patents identified in paragraphs 57-58 of the complaint stem from less than half as many patent families. Many of the patents identified by Plaintiffs share common specifications and have overlapping and nearly identical claims. (*See, e.g.*, U.S. Patent Nos. 8,802,100, 8,802,101, 8,916,157, 8,916,158, 9,114,166, 9,220,781, and 9,302,011, and the '041 patent.) Many of Plaintiffs' patents from different families also have substantially similar disclosures and claims, despite claiming priority to different applications. (*See, e.g.*, U.S. Patent Nos. 9,346,879 and 9,315,574.)

24. On information and belief, Plaintiffs have made public statements citing the existence of the patent thicket as a reason for delaying competition for adalimumab. (*See, e.g.*, Ex. B, Pollack 2016 at *3 (quoting AbbVie Inc. CEO Richard A Gonzalez, "Any company seeking to market a biosimilar version of Humira will have to contend with this extensive patent estate, which AbbVie intends to enforce vigorously."); Ex. D, Excerpt from Abbott Laboratories, Annual Report at 7 (Form 10-K) (Feb. 25, 2004) (describing the purpose of patents directed to formulations, uses, or manufacturing processes as potentially extending Abbott's drug product exclusivity).)

Plaintiffs' Asserted Patents Do Not Represent Innovation

25. As will be shown in this litigation, Plaintiffs' patents do not represent innovation, but rather are attempts to claim methods of treatment, methods of production, and formulations derived from the prior art for the purpose of creating a patent thicket or estate that competitors must, as AbbVie has publicly stated, "contend with" to sell the active ingredient previously disclosed and claimed in the now-expired '382 patent.

26. Humira®'s success is not due to the alleged inventions of the patents Plaintiffs now assert against Defendants, but rather is because of the properties of its active ingredient, adalimumab. Adalimumab was the first fully human monoclonal antibody approved by the FDA, and as such represented a true scientific achievement. The formulations, production processes, and dosing regimens claimed in Plaintiffs' patent estate are not.

27. During *inter partes* review ("IPR") proceedings against U.S. Patent No. 8,889,135 ("the '135 patent"), which is directed to certain methods of treating rheumatoid arthritis using adalimumab, AbbVie Biotechnology Ltd's commercial success expert acknowledged that adalimumab's status as the first fully human monoclonal antibody was a significant reason for Humira®'s commercial success. (*E.g.*, Ex. E, Excerpt from 1/4/17 Deposition Transcript of Jerry Hausman, Ph.D. at 49:23-50:4, IPR2016-00408.)

28. In its final decisions in connection with IPR2016-00408 and IPR2016-00409, the Patent Trial and Appeal Board ("PTAB") concluded that, *inter alia*, AbbVie Biotechnology Ltd had not shown that Humira®'s commercial success was due to the claimed method of treatment, as opposed to the already known and patented adalimumab antibody. (*See* Ex. F, IPR2016-00408 at 41 (P.T.A.B. July 6, 2017); Ex. G, IPR2016-00409 at 43 (P.T.A.B. July 6, 2017).) The PTAB further stated, "[I]t appears from the evidence that the driving force behind the satisfaction of a long-felt need and success where others had failed was the introduction of the first fully human anti-TNFα antibody, not the claimed dosing regimen." (Ex. F, IPR2016-00408 at 42; Ex. G, IPR2016-00409 at 44.)

29. The claims of the '135 patent were found unpatentable in decisions by the PTAB on May 16, 2017, and July 6, 2017.

30. The claims of U.S. Patent Nos. 9,017,680 ("the '680 patent") and 9,073,987 ("the '987 patent"), which are also directed to methods of treating rheumatoid arthritis using adalimumab, were found unpatentable by the PTAB on June 9, 2017.

31. Plaintiffs allege in their complaint that the '135, '680, and '987 patents could reasonably be asserted with respect to the BLA Product, even though these patents were found unpatentable by the PTAB.

32. On March 3, 2017, the United Kingdom High Court found methods of treating rheumatoid arthritis, psoriatic arthritis, and psoriasis claimed in European Patents EP 1,406,656, EP 1,944,322, and EP 2,940,044 to be obvious and/or anticipated in light of the prior art. (*See* Ex. H, *Fujifilm Kyowa Kirin Biologics Co. v. AbbVie Biotech. Ltd* ("the *Fujifilm* Action") [2017] EWHC (Pat) 395 [3]-[4], [415] (Eng.) (granting declarations that petitioner's biosimilar products to be administered using claimed methods were obvious and/or anticipated as of priority dates for subject patents).)

33. The United Kingdom High Court reached a final ruling on invalidity in the *Fujifilm* Action despite the fact that AbbVie Biotechnology Ltd revoked or de-designated its patents with respect to the United Kingdom during the proceedings, noting that AbbVie Biotechnology Ltd's gamesmanship warranted a decision on the merits. The United Kingdom High Court stated:

> The Claimants allege that the object and cumulative consequence of AbbVie's conduct is intended to delay the entry of competing biosimilars, and AbbVie has sought to achieve this by prolonging commercial uncertainty by a series of acts of abandonment of protection, whilst re-filing divisionals for essentially the same subject matter. This puts into issue AbbVie's intentions, which I do not accept are irrelevant, on the basis of the pleaded issues. However, even if I were to consider only the objective effect of AbbVie's conduct, my conclusions would be no different. I consider that the intention and the objective effect is to shield its patent portfolio from examination of validity whilst continuing to file further

> divisionals and to threaten infringement proceedings against biosimilars, wherever they may be launched.

(*Id*. at [388].)

34. Plaintiffs' efforts to create a patent thicket or estate in the United States are part of a global effort to improperly delay competition with respect to adalimumab.

Defendants' Compliance with the BPCIA and
Plaintiffs' Failure to Provide Evidence of Infringement

35. The BPCIA created an abbreviated approval pathway for biosimilar therapies. The statute balances incentives for reference product sponsors to develop new active ingredients with the critical importance of promoting competition and ensuring patients' access to biologic medicines at efficient prices within the United States.

36. To incentivize the development of new biologics, the BPCIA permits 12 years of exclusivity for a reference product before a biosimilar may be licensed. *See* 42 U.S.C. § 262(k)(7)(A). The BPCIA also sets forth specific steps regarding pre-suit disclosures and exchanges for patent litigation in connection with a biosimilar application.

37. BIPI submitted BLA 761058 to the FDA on October 27, 2016. On January 9, 2017, counsel for Defendants notified counsel for Plaintiffs that BLA 761058 had been accepted for review.

38. Pursuant to 42 U.S.C. § 262(*l*)(2)(A), on January 13, 2017, counsel for Defendants provided Plaintiffs with access to 93,750 pages relating to BLA 761058, which included, *inter alia*, information concerning "the process or processes used to manufacture" the BLA Product.

39. From January 13, 2017, when Plaintiffs were provided with the 2A Disclosure, through March 13, 2017, when Plaintiffs proceeded to identify the patents for which Plaintiffs

alleged a claim of infringement could reasonably be asserted against the BLA Product, Plaintiffs made no assertion that Defendants did not comply with the BPCIA.

40. From January 13, 2017, when Plaintiffs were provided with the 2A Disclosure, through March 13, 2017, when Plaintiffs proceeded to identify the patents for which Plaintiffs alleged a claim of infringement could reasonably be asserted against the BLA Product, Plaintiffs did not notify Defendants that any manufacturing information necessary for Plaintiffs' assessment was missing from the 2A Disclosure.

41. From January 13, 2017, when Plaintiffs were provided with the 2A Disclosure, through March 13, 2017, when Plaintiffs proceeded to identify the patents for which Plaintiffs alleged a claim of infringement could reasonably be asserted against the BLA Product, Plaintiffs did not request permission for any outside experts to view the 2A Disclosure or express any issue with any alleged limitation on access for outside experts.

42. Pursuant to 42 U.S.C. § 262(*l*)(3)(A), on March 13, 2017, counsel for Plaintiffs sent a letter to counsel for Defendants identifying the 72 patents of Plaintiffs' then-existing patents for which Plaintiffs alleged a claim of infringement could reasonably be asserted against the BLA Product.

43. The 3A List included the '382 patent, even though that patent had expired on December 31, 2016.

44. Plaintiffs' inclusion of the '382 patent on the 3A List was consistent with an attempt to improperly extend a statutory monopoly based on that patent and to impede competition.

45. The 3A List also included the '135, '680, and '987 patents. Paragraph 57 of Plaintiffs' complaint continues to allege these patents could reasonably be asserted with respect

to the BLA Product, even though these patents were found unpatentable by the PTAB before the filing of Plaintiffs' complaint.

46. On April 18, 2017, counsel for Plaintiffs notified counsel for Defendants that Plaintiffs were supplementing the 3A List with U.S. Patent No. 9,624,295 ("the '295 patent") pursuant to 42 U.S.C. § 262(*l*)(7).

47. Pursuant to 42 U.S.C. § 262(*l*)(3)(B), on May 12, 2017, counsel for Defendants provided Plaintiffs with 1,841 pages describing in detail bases for noninfringement and invalidity of all 72 patents identified on the 3A List.

48. Pursuant to 42 U.S.C. § 262(*l*)(7), on May 18, 2017, counsel for Defendants provided Plaintiffs with a statement describing in detail bases for noninfringement and invalidity of the '295 patent.

49. On June 6, 2017, counsel for Plaintiffs notified counsel for Defendants that Plaintiffs were supplementing their 3A List with U.S. Patent No. 9,669,093 ("the '093 patent") pursuant to 42 U.S.C. § 262(*l*)(7).

50. On June 20, 2017, counsel for Plaintiffs notified counsel for Defendants that Plaintiffs were supplementing their 3A List with U.S. Patent No. 9,683,033 ("the '033 patent") pursuant to 42 U.S.C. § 262(*l*)(7).

51. On July 6, 2017, counsel for Defendants provided Plaintiffs with statements describing in detail bases for noninfringement and invalidity of the '093 and '033 patents pursuant to 42 U.S.C. § 262(*l*)(7).

52. From January 13, 2017, when Plaintiffs were provided with the 2A Disclosure, until July 11, 2017, when Plaintiffs provided the 3C Statement, Plaintiffs made no assertion that Defendants did not comply with the BPCIA.

53. From January 13, 2017, when Plaintiffs were provided with the 2A Disclosure, until July 11, 2017, when Plaintiffs provided the 3C Statement, Plaintiffs did not notify Defendants that any manufacturing information necessary for Plaintiffs' assessment was missing from the 2A Disclosure.

54. From January 13, 2017, when Plaintiffs were provided with the 2A Disclosure, until July 11, 2017, when Plaintiffs provided the 3C Statement, Plaintiffs did not request permission for any outside experts to view the 2A Disclosure or express any issue with any alleged limitation on access for outside experts.

55. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), on July 11, 2017, counsel for Plaintiffs provided responses alleging infringement and validity for 71 of the 72 patents addressed in the 3B Statement. In the 3C Statement, Plaintiffs acknowledged that the BLA Product would not infringe the '382 patent.

56. In the 3C Statement, Plaintiffs did not withdraw infringement allegations for the '135, '680, and '987 patents, despite the fact that these patents had previously been found unpatentable by the PTAB.

57. Among other deficiencies, the 3C Statement failed to provide evidence for many claims that Plaintiffs alleged, and continue to allege, would be infringed by the BLA Product. Plaintiffs omitted claims entirely from claim charts they provided purporting to set forth bases for infringement, including, for example, claims 3, 8-15, 20, and 24-27 of the '041 patent. For many other claims (*e.g.*, all claims of the '666 patent), Plaintiffs provided a boilerplate statement alleging that they possessed insufficient evidence relating to the BLA Product, and also (incorrectly) contended that Plaintiffs were "not permitted under their confidentiality agreements with BI to consult with independent experts regarding BI confidential information."

58. In their 3C Statement, Plaintiffs, for the first time, alleged that information allegedly needed for their infringement analyses was not included in the 2A Disclosure.

59. In their 3C Statement, Plaintiffs, for the first time, alleged that they were not permitted to consult with outside experts based on the parties' confidentiality undertaking.

60. The language of the parties' confidentiality undertaking, which was agreed to on January 15, 2017, after careful negotiation, expressly contemplates outside experts reviewing the 2A Disclosure with written permission. (*See* Ex. I, E-mail from Arianna Evers to Hassen A. Sayeed (Jan. 15, 2017).) AbbVie attorneys signed the undertaking, which states in paragraph 4, "For the avoidance of doubt, I understand and agree that I may not disclose any confidential information in Boehringer's 2A Disclosure to . . . any outside scientific consultants . . . without the prior written consent of Boehringer." This language tracks the language of the BPCIA itself. *See* 42 U.S.C. § 262(*l*)(1)(C) ("No person that receives confidential information pursuant to subparagraph (B) shall disclose any confidential information to any other person or entity, including . . . scientific consultants retained by the reference product sponsor, without the prior written consent of the subsection (k) applicant, which shall not be unreasonably withheld.").

61. Plaintiffs did not raise any issue with the confidentiality undertaking's expert provisions during the parties' negotiations regarding that document from January 12, 2017, to January 15, 2017.

62. Plaintiffs did not identify any outside experts for which confidential access was sought pursuant to the undertaking.

63. Between January 13, 2017, and July 11, 2017, Plaintiffs sought, and were granted, permission for 43 outside attorneys and law firm technical advisors (including at least 14 attorneys with Ph.D. degrees) to view the 2A Disclosure. On May 25, 2017, and June 27, 2017,

Plaintiffs sought permission for in-house attorneys to view confidential information in excess of the number permitted by statute under 42 U.S.C. § 262(*l*)(1)(B)(ii)(II). Although Plaintiffs sought permission for outside and in-house counsel to review confidential information, Plaintiffs did not seek permission for any outside scientific consultants, or raise this as an issue before submitting the 3C Statement.

64. On July 13, 2017, in a teleconference with Defendants' counsel, Plaintiffs' counsel proposed litigating 71 of the patents identified on the 3A List (all except the '382 patent) in a single litigation. Plaintiffs' proposal included the '135, '680, and '987 patents, whose claims have been found unpatentable by the PTAB.

65. On July 21, 2017, in response to Plaintiffs' deficient 3C Statement and Plaintiffs' proposal to litigate 71 patents — many of which, as explained in paragraph 22 of Defendants' counterclaims above, have common or similar specifications and overlapping, nearly identical claims — in a single litigation, counsel for Defendants sent Plaintiffs a letter seeking removal of at least 16 patents for which Plaintiffs expressly admitted in their 3C Statement that they lacked sufficient evidence to allege infringement ("the July 21, 2017 Letter"). Plaintiffs declined to remove any of the 16 patents.

66. On July 26, 2017, within the time period expressly contemplated by the BPCIA under 42 U.S.C. § 262(*l*)(4)(b) and pursuant to 42 U.S.C. § 262(*l*)(5)(A), counsel for Defendants notified Plaintiffs that each side could select up to five patents to litigate in the present action.

67. On July 31, 2017, pursuant to 42 U.S.C. § 262(*l*)(5)(B), the lists of patents to be litigated in the present action were exchanged. Counsel for Plaintiffs identified the '975 patent, the '361 patent, the '949 patent, the '041 patent, and the '212 patent. Counsel for Defendants

identified the ’867 patent, the ’666 patent, and the ’143 patent, as well as the ’975 patent and the ’041 patent.

68. On August 2, 2017, Plaintiffs filed the present action alleging infringement of the eight non-overlapping patents.

69. Because, *inter alia*, Plaintiffs are aware that they expressed no factual basis for asserting infringement in the 3C Statement (and thus did not comply with the BPCIA) for at least the 16 patents identified in the July 21, 2017 Letter, Plaintiffs’ complaint miscites 35 U.S.C. § 295 for the erroneous premise that it is Defendants’ burden to prove noninfringement. 35 U.S.C. § 295, *inter alia*, does not address the standards for pre-suit investigation and is not applicable here.

70. As of July 11, 2017, when the 3C Statement was served, Plaintiffs acknowledged that they lacked a good-faith basis to assert infringement of at least the ’666 patent and the ’143 patent, among many others.

71. In their complaint, Plaintiffs allege that the BLA Product would infringe patents that Plaintiffs admitted they lack a reasonable basis to assert in the 3C Statement.

72. In their complaint, Plaintiffs allege that the BLA Product would infringe patents that have been found unpatentable by the PTAB.

73. Plaintiffs’ continued assertion of patents that Plaintiffs have no basis to assert, including patents found unpatentable by the PTAB, is part of a pattern of anticompetitive behavior designed to delay Defendants’ entrance into the market and improperly extend Plaintiffs’ monopoly over adalimumab.

74. Defendants reserve the right to pursue in this action any and all defenses and remedies based upon Plaintiffs’ improper behavior.

COUNT I
(Declaration of Noninfringement and Invalidity of the '975 Patent)

75. The averments of paragraphs 1-74 of Defendants' counterclaims are repeated, re-alleged, and incorporated by reference as if fully set forth herein.

76. At the time of the filing of Plaintiffs' complaint in the above-captioned action, AbbVie Biotechnology Ltd was listed as the assignee of the '975 patent. Plaintiffs have alleged that AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the '975 patent in the United States.

77. A case or controversy exists between Plaintiffs and Defendants because Plaintiffs have alleged that Defendants have infringed and will infringe the '975 patent.

78. Defendants have not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '975 patent under 35 U.S.C. § 271.

79. The claims of the '975 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

80. This case is an exceptional one, and Defendants are entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT II
(Declaration of Noninfringement and Invalidity of the '361 Patent)

81. The averments of paragraphs 1-80 of Defendants' counterclaims are repeated, re-alleged, and incorporated by reference as if fully set forth herein.

82. At the time of the filing of Plaintiffs' complaint in the above-captioned action, AbbVie Inc. was listed as the assignee of the '361 patent. Plaintiffs have alleged that AbbVie Biotechnology Ltd is exclusively licensed to import, have imported, manufacture, or have

manufactured products, and to use methods that would infringe the ’361 patent in the United States.

83. A case or controversy exists between Plaintiffs and Defendants because Plaintiffs have alleged that Defendants have infringed and will infringe the ’361 patent.

84. Defendants have not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the ’361 patent under 35 U.S.C. § 271.

85. The claims of the ’361 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

86. This case is an exceptional one, and Defendants are entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT III
(Declaration of Noninfringement and Invalidity of the ’867 Patent)

87. The averments of paragraphs 1-86 of Defendants’ counterclaims are repeated, re-alleged, and incorporated by reference as if fully set forth herein.

88. At the time of the filing of Plaintiffs’ complaint in the above-captioned action, AbbVie Inc. was listed as the assignee of the ’867 patent. Plaintiffs have alleged that AbbVie Biotechnology Ltd is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the ’867 patent in the United States.

89. A case or controversy exists between Plaintiffs and Defendants because Plaintiffs have alleged that Defendants have infringed and will infringe the ’867 patent.

90. Defendants have not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '867 patent under 35 U.S.C. § 271.

91. The claims of the '867 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

92. This case is an exceptional one, and Defendants are entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT IV
(Declaration of Noninfringement and Invalidity of the '666 Patent)

93. The averments of paragraphs 1-92 of Defendants' counterclaims are repeated, re-alleged, and incorporated by reference as if fully set forth herein.

94. At the time of the filing of Plaintiffs' complaint in the above-captioned action, AbbVie Biotechnology Ltd was listed as the assignee of the '666 patent. Plaintiffs have 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.

95. A case or controversy exists between Plaintiffs and Defendants because Plaintiffs have alleged that Defendants have infringed and will infringe the '666 patent.

96. Defendants have not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '666 patent under 35 U.S.C. § 271.

97. The claims of the '666 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

98. This case is an exceptional one, and Defendants are entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT V
(Declaration of Noninfringement and Invalidity of the '143 Patent)

99. The averments of paragraphs 1-98 of Defendants' counterclaims are repeated, re-alleged, and incorporated by reference as if fully set forth herein.

100. At the time of the filing of Plaintiffs' complaint in the above-captioned action, AbbVie Inc. was listed as the assignee of the '143 patent. Plaintiffs have alleged that AbbVie Biotechnology Ltd is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the '143 patent in the United States.

101. A case or controversy exists between Plaintiffs and Defendants because Plaintiffs have alleged that Defendants have infringed and will infringe the '143 patent.

102. Defendants have not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '143 patent under 35 U.S.C. § 271.

103. The claims of the '143 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

104. This case is an exceptional one, and Defendants are entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT VI
(Declaration of Noninfringement and Invalidity of the '949 Patent)

105. The averments of paragraphs 1-104 of Defendants' counterclaims are repeated, re-alleged, and incorporated by reference as if fully set forth herein.

106. At the time of the filing of Plaintiffs' complaint in the above-captioned action, AbbVie Inc. was listed as the assignee of the '949 patent. Plaintiffs have alleged that AbbVie Biotechnology Ltd is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the '949 patent in the United States.

107. A case or controversy exists between Plaintiffs and Defendants because Plaintiffs have alleged that Defendants have infringed and will infringe the '949 patent.

108. Defendants have not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '949 patent under 35 U.S.C. § 271.

109. The claims of the '949 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

110. This case is an exceptional one, and Defendants are entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT VII
(Declaration of Noninfringement and Invalidity of the '041 Patent)

111. The averments of paragraphs 1-110 of Defendants' counterclaims are repeated, re-alleged, and incorporated by reference as if fully set forth herein.

112. At the time of the filing of Plaintiffs' complaint in the above-captioned action, AbbVie Biotechnology Ltd was listed as the assignee of the '041 patent. Plaintiffs have alleged

that AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the ’041 patent in the United States.

113. A case or controversy exists between Plaintiffs and Defendants because Plaintiffs have alleged that Defendants have infringed and will infringe the ’041 patent.

114. Defendants have not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the ’041 patent under 35 U.S.C. § 271.

115. The claims of the ’041 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

116. This case is an exceptional one, and Defendants are entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT VIII
(Declaration of Noninfringement and Invalidity of the ’212 Patent)

117. The averments of paragraphs 1-116 of Defendants’ counterclaims are repeated, re-alleged, and incorporated by reference as if fully set forth herein.

118. At the time of the filing of Plaintiffs’ complaint in the above-captioned action, AbbVie Biotechnology Ltd was listed as the assignee of the ’212 patent. Plaintiffs have alleged that AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the ’212 patent in the United States.

119. A case or controversy exists between Plaintiffs and Defendants because Plaintiffs have alleged that Defendants have infringed and will infringe the ’212 patent.

120. Defendants have not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '212 patent under 35 U.S.C. § 271.

121. The claims of the '212 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

122. This case is an exceptional one, and Defendants are entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Defendants respectfully request that the Court enter:

A. An entry of judgment on Plaintiffs' complaint in favor of Defendants, and against Plaintiffs, with Plaintiffs not being awarded any relief thereon;

B. A declaratory judgment that Defendants have not infringed and will not infringe any valid and enforceable claim of the Asserted Patents under 35 U.S.C. § 271;

C. A declaratory judgment that the Asserted Patents are invalid;

D. An Order enjoining and restraining Plaintiffs and their officers, agents, servants, employees, attorneys, and those persons in active concert or participation with them from pursuing further charges of infringement or acts of enforcement based on the Asserted Patents against Defendants or their actual and prospective business partners, customers, suppliers, clinical investigators, and anyone in privity with Defendants;

E. A judgment that this case is exceptional and that Defendants are entitled to an award of attorney fees pursuant to 35 U.S.C. § 285;

F. An award of costs, expenses, and attorney fees pursuant to 28 U.S.C. § 1927;

G. An award of taxable costs;

H. An award of interest;

I. An Order for such other and further relief as the Court deems just and proper.

Dated: September 14, 2018

Respectfully submitted,

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Counsel for Defendants

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC. and ABBVIE BIOTECHNOLOGY LTD, Plaintiffs, -against- BOEHRINGER INGELHEIM INTERNATIONAL GMBH, BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., and BOEHRINGER INGELHEIM FREMONT, INC., Defendants.	Civil Action No. 17-cv-01065-MSG [redacted] PUBLIC VERSION

BOEHRINGER INGELHEIM INTERNATIONAL GMBH, BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., AND BOEHRINGER INGELHEIM FREMONT, INC.'S AMENDED ANSWER, DEFENSES, AND COUNTERCLAIMS

Defendants and Counterclaim-Plaintiffs Boehringer Ingelheim International GmbH ("BII"), Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI"), and Boehringer Ingelheim Fremont, Inc. ("BIFI") (collectively, "Defendants"), by their undersigned attorneys, hereby respond to the complaint of Plaintiffs and Counterclaim-Defendants AbbVie Inc. and AbbVie Biotechnology Ltd (collectively, "Plaintiffs") as follows.

Plaintiffs' complaint defines "Boehringer" to include BII, BIPI, and BIFI, and "AbbVie" to include AbbVie Inc. and AbbVie Biotechnology Ltd. The use of these definitions in the complaint creates ambiguity and confusion with respect to certain of Plaintiffs' allegations. In their Answer, Defenses, and Counterclaims, BII, BIPI, and BIFI refer to themselves collectively as "Defendants" and to AbbVie Inc. and AbbVie Biotechnology Ltd as "Plaintiffs." All references in Defendants' Answer, Defenses, and Counterclaims to BII, BIPI, BIFI, AbbVie Inc., and AbbVie Biotechnology Ltd mean the individual defendant or plaintiff.

ANSWER AND DEFENSES

Each of the paragraphs below corresponds to the same numbered paragraph in Plaintiffs' complaint. Defendants deny all allegations in the complaint, whether express or implied, that are not specifically admitted below. Defendants further deny that Plaintiffs are entitled to the relief requested or any other relief. Any factual allegation below is admitted only as to the specific admitted facts, and not as to any purported conclusions, characterizations, implications, or speculations that may arguably follow from the admitted facts. Many of Plaintiffs' allegations in the complaint are vague and/or ambiguous, including, *inter alia*, Plaintiffs' use of the collective terms "Boehringer" and "AbbVie." To the extent any allegation in Plaintiffs' complaint is vague and/or ambiguous, Defendants deny the allegation in question.

INTRODUCTION

1. Admitted in part; denied in part. Defendants admit only that this is a purported action for patent infringement; that Plaintiffs' complaint identifies 74 patents that they allege could reasonably be asserted with respect to the adalimumab product set forth in Biologics License Application No. 761058 ("the BLA Product"); that the Biosimilar Price Competition and Innovation Act ("BPCIA") created an abbreviated regulatory pathway for approval of biosimilar versions of approved biologic products, such as Humira®; and that Plaintiffs seek (but are not entitled to) an injunction in this case. Defendants deny the remaining allegations of paragraph 1.

2. Admitted in part; denied in part. Defendants admit only that the active ingredient in Humira®, adalimumab, is a biologic drug; that biologic drugs are manufactured in living cells rather than by chemical synthesis; and that adalimumab was the first fully human antibody approved by the Food and Drug Administration ("FDA"). Defendants deny the remaining allegations of paragraph 2.

3. Admitted in part; denied in part. Defendants admit only that the approved indications for Humira® include rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, psoriasis, Crohn's disease (adult and pediatric), ulcerative colitis, hidradenitis suppurativa, uveitis, and juvenile idiopathic arthritis. Defendants deny the allegations of the last sentence of paragraph 3. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 3, and therefore deny the same.

4. Admitted in part; denied in part. Defendants admit only that Humira® contains adalimumab in a liquid formulation for subcutaneous injection. Defendants deny the remaining allegations of paragraph 4.

5. Admitted in part; denied in part. Defendants admit only that Humira® contains adalimumab, a biologic drug created in living organisms. Defendants deny the remaining allegations of paragraph 5.

6. Denied.

7. Admitted in part; denied in part. Defendants admit only that the BPCIA describes a multi-step process for the disclosure of information, the resolution or narrowing of patent disputes, and, if necessary and appropriate, the commencement of patent litigation; that from March 13, 2017, until July 26, 2017, Plaintiffs identified 74 patents that they contended could reasonably be asserted with respect to the BLA Product; that on July 26, 2017, and pursuant to 42 U.S.C. § 262(*l*)(5)(A), counsel for Defendants provided counsel for Plaintiffs with notice of the number of patents (up to five) to be selected by each side for litigation filed under 42 U.S.C. § 262(*l*)(6)(B); that on July 31, 2017, at 5 pm Eastern Time, counsel for Plaintiffs and Defendants simultaneously exchanged their respective lists of five patents pursuant to 42 U.S.C. § 262(*l*)(5)(B); and that, because two patents were identified by counsel for both Plaintiffs and Defendants, the eight

patents asserted in this litigation include all of the patents identified by both sides. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in the sixth and seventh sentences of paragraph 7 concerning Plaintiffs' future plans, and therefore deny the same. Defendants deny the remaining allegations of paragraph 7.

8. Admitted in part; denied in part. Defendants admit only that Plaintiffs are seeking an injunction in this litigation, to which Plaintiffs are not entitled. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of the second sentence of paragraph 8 concerning Plaintiffs' future plans, and therefore deny the same. Defendants deny the remaining allegations of paragraph 8.

NATURE OF THE ACTION

9. Admitted in part; denied in part. Defendants admit only that paragraph 9 of the complaint identifies AbbVie Inc. and AbbVie Biotechnology Ltd as plaintiffs in this action. Defendants deny any other allegations in paragraph 9.

10. Admitted in part; denied in part. Defendants admit only that the complaint alleges that this action arises under the patent laws of the United States, 35 U.S.C. §§ 1, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202. Defendants deny the remaining allegations of paragraph 10.

11. Denied.

12. On information and belief, admitted.

13. Admitted in part; denied in part. Defendants admit only that adalimumab is a biologic drug; that adalimumab is a fully human, high-affinity, and neutralizing therapeutic antibody to human ~~TNF α~~TNFα; and that ~~TNF α~~TNFα is a protein made by the human body as part of the body's immune response. Defendants lack sufficient knowledge or information to form

a belief as to the allegations of the first sentence of paragraph 13, and therefore deny the same. Defendants deny the remaining allegations of paragraph 13.

14. Admitted in part; denied in part. Defendants admit only that adalimumab was the first fully human antibody approved by the FDA; that adalimumab, disclosed and claimed in U.S. Patent No. 6,090,382 ("the '382 patent"), was a significant scientific achievement; and that Remicade® (infliximab) is a chimeric antibody approved for intravenous injection. Defendants lack sufficient knowledge or information to form a belief as to the allegations of the third sentence of paragraph 14, and therefore deny the same. Defendants deny the remaining allegations of paragraph 14.

15. Denied. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 15, and therefore deny the same.

16. Admitted in part; denied in part. On information and belief, Defendants admit only that Humira® (adalimumab) was one of the recipients of the Prix Galien USA in 2007. Otherwise, denied.

17. Denied. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 17, and therefore deny the same.

18. Admitted in part, denied in part. Defendants admit only that Plaintiffs' complaint identifies 74 patents that Plaintiffs allege could reasonably be asserted with respect to the BLA Product. Defendants deny the remaining allegations of paragraph 18.

19. Admitted in part; denied in part. Defendants admit only that, pursuant to the procedures set forth in the BPCIA and the circumstances described in paragraph 7 above, there are eight patents at issue in this litigation. The last sentence of paragraph 19 states legal conclusions to which no answer is required. Defendants deny the remaining allegations of paragraph 19.

20. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek an injunction, to which they are not entitled, relating to the eight patents in dispute in this case, and that the BPCIA created an abbreviated regulatory pathway for the approval of biosimilar drugs. Defendants lack sufficient knowledge or information to form a belief as to the truth of the last sentence of paragraph 20 concerning Plaintiffs' future plans, and therefore deny the same. Defendants deny the remaining allegations of paragraph 20.

PARTIES

21. On information and belief, admitted.

22. On information and belief, admitted.

23. Admitted.

24. Admitted in part; denied in part. Defendants admit only that the BLA Product will be distributed in the United States, including the State of Delaware, but not before any required notice to engage in such activities is provided. Defendants deny the remaining allegations of paragraph 24.

25. Admitted.

26. Admitted in part; denied in part. Defendants admit only that the BLA Product will be distributed in the United States, including the State of Delaware, but not before any required notice to engage in such activities is provided. Defendants deny the remaining allegations of paragraph 26.

27. Admitted.

28. Admitted in part; denied in part. Defendants admit only that the BLA Product will be distributed in the United States, including the State of Delaware, but not before any required notice to engage in such activities is provided. Defendants deny the remaining allegations of paragraph 28.

29. Admitted.

30. Admitted in part; denied in part. Defendants admit only that the BLA Product will be distributed in the United States, including the State of Delaware, but not before any required notice to engage in such activities is provided, and that such activities will provide benefits, including to patients. Defendants deny the remaining allegations of paragraph 30.

JURISDICTION AND VENUE

31. Admitted in part; denied in part. Defendants admit only that the complaint alleges this action arises under the patent laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, and that a justiciable case or controversy exists. Defendants deny the remaining allegations of paragraph 31.

32. Without waiver of their right to challenge the propriety of jurisdiction in other cases, Defendants do not contest this Court's exercise of personal jurisdiction over them solely for the purposes of the above-captioned action. Otherwise, denied.

33. Without waiver of its right to challenge the propriety of jurisdiction in other cases, BIPI does not contest this Court's exercise of personal jurisdiction over it solely for the purposes of the above-captioned action. Otherwise, denied.

34. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured in the United States, and that the BLA Product will be marketed in the United States, including the State of Delaware, but not before any required notice to engage in such activities is provided. Otherwise, denied.

35. Without waiver of its right to challenge the propriety of jurisdiction in other cases, BIFI does not contest this Court's exercise of personal jurisdiction over it solely for the purposes of the above-captioned action. Otherwise, denied.

36. Admitted in part; denied in part. Defendants admit only that BIFI's facilities will be used for the manufacture of biologic products, and that the sources cited in paragraph 36 include the quoted language. Otherwise, denied.

37. Admitted in part; denied in part. Defendants admit only that BIFI's facilities will be used to manufacture the BLA Product. Otherwise, denied.

38. Without waiver of its right to challenge the propriety of jurisdiction in other cases, BII does not contest this Court's exercise of personal jurisdiction over it solely for the purposes of the above-captioned action. Otherwise, denied.

39. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured in the United States, and that the BLA Product will be marketed in the United States, including the State of Delaware, but not before any required notice to engage in such activities is provided. Otherwise, denied.

40. Admitted in part; denied in part. Defendants admit only that BII has been involved in clinical studies related to the BLA Product. Otherwise, denied.

41. Admitted in part; denied in part. Defendants admit only that the BLA Product will be distributed in the United States, including the State of Delaware, but not before any required notice to engage in such activities is provided. Otherwise, denied.

42. Denied.

43. Admitted in part; denied in part. Defendants admit only that the source cited in paragraph 43 includes the quoted language. Otherwise, denied.

44. Admitted.

45. Admitted in part; denied in part. Defendants admit only that counsel for Defendants communicated with counsel for Plaintiffs during the BPCIA exchanges. Otherwise, denied.

46. Admitted in part; denied in part. Defendants admit only that BII previously initiated certain patent infringement lawsuits in the District of Delaware that are not related to this action. Otherwise, denied.

47. Without waiver of its right to challenge the propriety of jurisdiction in other cases, BII does not contest this Court's exercise of personal jurisdiction over it solely for the purposes of the above-captioned action. Otherwise, denied.

48. Without waiver of their right to challenge the propriety of venue in other cases, Defendants do not contest venue in the District of Delaware solely for the purposes of the above-captioned action. Otherwise, denied.

THE PARTIES' EXCHANGES UNDER THE BPCIA

49. Admitted in part; denied in part. Defendants admit only the second sentence of paragraph 49 and that BIPI submitted Biologics License Application No. 761058 for the BLA Product ("BLA 761058") to the FDA on October 27, 2016. Defendants deny the remaining allegations of paragraph 49.

50. Admitted in part; denied in part. Defendants admit that Congress created an act of artificial infringement related to the submission of an application under subsection 262(k) for purposes of subject matter jurisdiction; that the BPCIA sets forth a series of pre-litigation exchanges outlined at 42 U.S.C. § 262(*l*); that 42 U.S.C. § 262(*l*)(8)(A) states, "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)"; and that 42 U.S.C. § 262(*l*)(8)(B) states that "the reference product sponsor may seek a preliminary

injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement . . . ." Defendants deny the remaining allegations of paragraph 50.

51. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

52. Admitted in part; denied in part. Defendants admit only that counsel for Defendants contacted counsel for Plaintiffs on January 9, 2017, to inform Plaintiffs that BLA 761058 had been accepted by the FDA for review. Otherwise, denied.

53. Admitted in part; denied in part. Defendants admit only that the exchange of information in accordance with the procedures outlined in the BPCIA began in January 2017 and that, on January 13, 2017, Plaintiffs were provided with access to 93,750 pages relating to BLA 761058, which included, *inter alia*, information concerning the process or processes used to manufacture the BLA Product ("the 2A Disclosure"). Defendants deny the remaining allegations of paragraph 53.

54. Admitted in part; denied in part. Defendants admit only that, on March 13, 2017, pursuant to 42 U.S.C. § 262(*l*)(3)(A), counsel for Plaintiffs sent a letter to counsel for Defendants identifying the 72 patents of Plaintiffs' then-existing patents for which Plaintiffs alleged a claim of patent infringement could reasonably be asserted against the BLA Product ("the 3A List"), and that the letter included the quotation recited in paragraph 54 of the complaint. Defendants lack sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 54, and therefore deny the same.

55. Admitted in part; denied in part. Defendants admit only that, on April 18, 2017, June 6, 2017, and June 20, 2017, counsel for Plaintiffs provided supplemental lists to counsel for Defendants identifying certain issued patents.

56. Admitted in part; denied in part. Defendants admit only that, on May 12, 2017, pursuant to 42 U.S.C. § 262(*l*)(3)(B), counsel for Defendants provided counsel for Plaintiffs with 1,841 pages describing, in detail, bases for noninfringement and invalidity of the 72 patents identified on the 3A List ("the 3B Statement"); and that, on May 18, 2017, and July 6, 2017, pursuant to 42 U.S.C. § 262(*l*)(7), counsel for Defendants provided counsel for Plaintiffs with statements describing, in detail, bases for noninfringement and invalidity of the three patents identified in Plaintiffs' supplemental lists. Defendants deny the remaining allegations of paragraph 56.

57. Admitted in part; denied in part. Defendants admit only that, on July 11, 2017, Plaintiffs purported to respond to the 3B Statement ("the 3C Statement"), and that the 3C Statement provided by Plaintiffs purported to address the patents identified in the table included in paragraph 57 of the complaint (yet, in doing so, did not fulfill the requirements of 42 U.S.C. § 262(*l*)(3)(C)). Defendants deny the remaining allegations of paragraph 57.

58. Denied.

59. Admitted in part; denied in part. Defendants admit only that, after Plaintiffs provided the 3C Statement, Plaintiffs proposed litigating 71 patents; and that, pursuant to the procedures set forth in the BPCIA and the circumstances described in paragraph 7 above, counsel for Defendants notified counsel for Plaintiffs that each side could choose up to five patents (as opposed to the dozens of patents Plaintiffs proposed) to be litigated. Defendants deny the remaining allegations of paragraph 59.

60. Admitted.

61. Denied. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in the second sentence of paragraph 61 concerning Plaintiffs' future plans, and therefore deny the same. Defendants deny the remaining allegations of paragraph 61.

THE BLA PRODUCT

62. Admitted in part; denied in part. Defendants admit only that the BLA Product is being developed for distribution in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

63. Admitted in part; denied in part. Defendants admit only that BIPI submitted BLA 761058 to the FDA seeking approval of the BLA Product. Otherwise, denied.

64. Admitted in part; denied in part. Defendants admit only that the document cited in paragraph 64 refers to the acceptance of BLA 761058 by the FDA and is dated January 18, 2017. Otherwise, denied.

65. Admitted in part; denied in part. Defendants admit only that the source cited in paragraph 65 includes the quoted language. Otherwise, denied.

66. Admitted in part; denied in part. Defendants admit only that clinical trials have been conducted with regard to the use of the BLA Product for treatment of moderate to severe rheumatoid arthritis; that data from those clinical trials were submitted in connection with BLA 761058; and that clinical trials with regard to the use of the BLA Product for treatment of plaque psoriasis and Crohn's disease are ongoing. Otherwise, denied.

67. Admitted in part; denied in part. Defendants admit only that the source cited in paragraph 67 includes the quoted language. Otherwise, denied.

68. Admitted in part; denied in part. Defendants admit that, as of the date of the filing of Plaintiffs' complaint, the FDA had not yet approved the BLA Product. Otherwise, denied.

69. Admitted in part; denied in part. Defendants admit that a justiciable case or controversy exists between the parties, but deny that any act of infringement has occurred.

THE ADALIMUMAB PATENTS

70. Denied. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 70, and therefore deny the same.

71. Admitted in part; denied in part. Defendants admit only that Plaintiffs are limited to asserting U.S. Patent Nos. 8,926,975 ("the '975 patent"), 9,018,361 ("the '361 patent"), 9,090,867 ("the '867 patent"), 9,096,666 ("the '666 patent"), 9,255,143 ("the '143 patent"), 9,266,949 ("the '949 patent"),9,272,041 ("the '041 patent"), and 9,546,212 ("the '212 patent") (collectively, the "Asserted Patents") in this lawsuit. Defendants deny the remaining allegations of paragraph 71.

72. Admitted.

73. Admitted in part; denied in part. Defendants admit only that, on January 6, 2015, the '975 patent, titled "Method of Treating Ankylosing Spondylitis," was issued by the United States Patent and Trademark Office ("USPTO"), and that Exhibit 8 appears to be a copy of the '975 patent. Otherwise, denied.

74. Admitted in part; denied in part. Defendants admit only that AbbVie Biotechnology Ltd is listed as the assignee on the face of the '975 patent. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations of paragraph 74, and therefore deny the same.

75. Admitted in part; denied in part. Defendants admit only that, on April 28, 2015, the '361 patent, titled "Isolation and Purification of Antibodies Using Protein A Affinity Chromatography," was issued by the USPTO, and that Exhibit 9 appears to be a copy of the '361 patent. Otherwise, denied.

76. Admitted in part; denied in part. Defendants admit only that AbbVie Inc. is listed as the assignee on the face of the '361 patent. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations of paragraph 76, and therefore deny the same.

77. Admitted in part; denied in part. Defendants admit only that, on July 28, 2015, the '867 patent, titled "Fed-Batch Method of Making Anti-TNF-Alpha Antibody," was issued by the USPTO, and that Exhibit 10 appears to be a copy of the '867 patent. Otherwise, denied.

78. Admitted in part; denied in part. Defendants admit only that AbbVie Inc. is listed as the assignee on the face of the '867 patent. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations of paragraph 78, and therefore deny the same.

79. Admitted in part; denied in part. Defendants admit only that, on August 4, 2015, the '666 patent, titled "Purified Antibody Composition," was issued by the USPTO, and that Exhibit 11 appears to be a copy of the '666 patent. Otherwise, denied.

80. Admitted in part; denied in part. Defendants admit only that AbbVie Biotechnology Ltd is listed as the assignee on the face of the '666 patent. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations of paragraph 80, and therefore deny the same.

81. Admitted in part; denied in part. Defendants admit only that, on February 9, 2016, the '143 patent, titled "Methods for Controlling the Galactosylation Profile of Recombinantly-Expressed Proteins," was issued by the USPTO, and that Exhibit 12 appears to be a copy of the '143 patent. Otherwise, denied.

82. Admitted in part; denied in part. Defendants admit only that AbbVie Inc. is listed as the assignee on the face of the '143 patent. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations of paragraph 82, and therefore deny the same.

83. Admitted in part; denied in part. Defendants admit only that, on February 23, 2016, the '949 patent, titled "Low Acidic Species Compositions and Methods for Producing and Using the Same," was issued by the USPTO, and that Exhibit 13 appears to be a copy of the '949 patent. Otherwise, denied.

84. Admitted in part; denied in part. Defendants admit only that AbbVie Inc. is listed as the assignee on the face of the '949 patent. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations of paragraph 84, and therefore deny the same.

85. Admitted in part; denied in part. Defendants admit only that, on March 1, 2016, the '041 patent, titled "Formulation of Human Antibodies for Treating TNF-Alpha Associated Disorders," was issued by the USPTO, and that Exhibit 14 appears to be a copy of the '041 patent. Otherwise, denied.

86. Admitted in part; denied in part. Defendants admit only that AbbVie Biotechnology Ltd is listed as the assignee on the face of the '041 patent. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations of paragraph 86, and therefore deny the same.

87. Admitted in part; denied in part. Defendants admit only that, on January 17, 2017, the '212 patent, titled "Methods of Administering Anti-TNFα Antibodies," was issued by the USPTO, and that Exhibit 15 appears to be a copy of the '212 patent. Otherwise, denied.

88. Admitted in part; denied in part. Defendants admit only that AbbVie Biotechnology Ltd is listed as the assignee on the face of the '212 patent. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations of paragraph 88, and therefore deny the same.

89. Admitted.

90. Admitted in part; denied in part. Defendants admit that Plaintiffs purported to provide responses pursuant to 42 U.S.C. § 262(*l*)(3)(C) for certain claims of the Asserted Patents, but deny that those responses fulfilled the requirements of the BPCIA.

ANSWER TO COUNT I
(Alleged Infringement of the '975 Patent)

91. Defendants repeat and restate their responses to paragraphs 1-90 of the complaint as if fully set forth herein.

92. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

93. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

94. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

95. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

96. Denied.

97. Admitted in part; denied in part. Defendants admit only that information relating to the proposed indications, dosage, and methods of use for the BLA Product was provided to Plaintiffs pursuant to 42 U.S.C. § 262(*l*)(2)(A). Defendants deny the remaining allegations of paragraph 97.

98. Admitted in part; denied in part. Defendants admit only that BLA 761058 includes information regarding the administration of the BLA Product. Defendants deny the remaining allegations of paragraph 98.

99. Denied.

100. Denied.

101. Admitted.

102. Denied.

103. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek an injunction, but deny that Plaintiffs are entitled to any such relief.

ANSWER TO COUNT II
(Alleged Infringement of the '361 Patent)

104. Defendants repeat and restate their responses to paragraphs 1-103 of the complaint as if fully set forth herein.

105. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

106. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

107. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

108. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

109. Denied.

110. Denied.

111. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

112. Denied.

113. Denied.

114. Denied.

115. Denied.

116. Admitted.

117. Denied.

118. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek an injunction, but deny that Plaintiffs are entitled to any such relief.

ANSWER TO COUNT III
(Alleged Infringement of the '867 Patent)

119. Defendants repeat and restate their responses to paragraphs 1-118 of the complaint as if fully set forth herein.

120. Defendants admit that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

121. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

122. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

123. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

124. Denied.

125. Denied.

126. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

127. Denied.

128. Denied.

129. Denied.

130. Denied.

131. Admitted.

132. Denied.

133. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek an injunction, but deny that Plaintiffs are entitled to any such relief.

ANSWER TO COUNT IV
(Alleged Infringement of the '666 Patent)

134. Defendants repeat and restate their responses to paragraphs 1-133 of the complaint as if fully set forth herein.

135. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

136. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

137. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

138. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

139. Denied.

140. Denied.

141. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

142. Denied.

143. Denied.

144. Denied.

145. Denied.

146. Admitted.

147. Denied.

148. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek an injunction, but deny that Plaintiffs are entitled to any such relief.

ANSWER TO COUNT V
(Alleged Infringement of the '143 Patent)

149. Defendants repeat and restate their responses to paragraphs 1-148 of the complaint as if fully set forth herein.

150. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

151. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

152. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

153. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

154. Denied.

155. Denied.

156. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

157. Denied.

158. Denied.

159. Denied.

160. Denied.

161. Admitted.

162. Denied.

163. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek an injunction, but deny that Plaintiffs are entitled to any such relief.

ANSWER TO COUNT VI
(Alleged Infringement of the '949 Patent)

164. Defendants repeat and restate their responses to paragraphs 1-163 of the complaint as if fully set forth herein.

165. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

166. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

167. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

168. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

169. Denied.

170. Denied.

171. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

172. Denied.

173. Denied.

174. Denied.

175. Denied.

176. Admitted.

177. Denied.

178. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek an injunction, but deny that Plaintiffs are entitled to any such relief.

ANSWER TO COUNT VII
(Alleged Infringement of the '041 Patent)

179. Defendants repeat and restate their responses to paragraphs 1-178 of the complaint as if fully set forth herein.

180. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

181. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

182. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

183. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

184. Denied.

185. Denied.

186. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

187. Denied.

188. Denied.

189. Denied.

190. Denied.

191. Admitted.

192. Denied.

193. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek an injunction, but deny that Plaintiffs are entitled to any such relief.

ANSWER TO COUNT VIII
(Alleged Infringement of the '212 Patent)

194. Defendants repeat and restate their responses to paragraphs 1-193 of the complaint as if fully set forth herein.

195. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

196. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

197. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

198. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

199. Denied.

200. Admitted in part; denied in part. Defendants admit only that information relating to the proposed indications, dosage, and methods of use for the BLA Product was provided to Plaintiffs pursuant to 42 U.S.C. § 262(*l*)(2)(A). Defendants deny the remaining allegations of paragraph 200.

201. Admitted in part; denied in part. Defendants deny the allegations of paragraph 201, except that Defendants admit that BLA 761058 includes information regarding the administration of the BLA Product.

202. Denied.

203. Denied.

204. Admitted.

205. Denied.

206. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek an injunction, but deny that Plaintiffs are entitled to any such relief.

ANSWER TO COUNT IX
(Declaratory Judgment for Alleged Infringement of the '975 Patent)

207. Defendants repeat and restate their responses to paragraphs 1-206 of the complaint as if fully set forth herein.

208. Admitted in part; denied in part. Defendants admit only that the complaint alleges that this action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Otherwise, denied.

209. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

210. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

211. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

212. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

213. Denied.

214. Denied.

215. Admitted in part; denied in part. Defendants admit only that information relating to the proposed indications, dosage, and methods of use for the BLA Product was provided to Plaintiffs pursuant to 42 U.S.C. § 262(*l*)(2)(A). Defendants deny the remaining allegations of paragraph 215.

216. Admitted in part; denied in part. Defendants admit only that BLA 761058 includes information regarding the administration of the BLA Product. Defendants deny the remaining allegations of paragraph 216.

217. Denied.

218. Denied.

219. Admitted.

220. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek a declaratory judgment, but deny that Plaintiffs are entitled to any such relief.

221. Denied.

ANSWER TO COUNT X
(Declaratory Judgment for Alleged Infringement of the '361 Patent)

222. Defendants repeat and restate their responses to paragraphs 1-221 of the complaint as if fully set forth herein.

223. Admitted in part; denied in part. Defendants admit only that the complaint alleges that this action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Otherwise, denied.

224. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

225. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

226. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

227. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

228. Denied.

229. Denied.

230. Denied.

231. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

232. Denied.

233. Denied.

234. Denied.

235. Denied.

236. Admitted.

237. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek a declaratory judgment, but deny that Plaintiffs are entitled to any such relief.

238. Denied.

ANSWER TO COUNT XI
(Declaratory Judgment for Alleged Infringement of the '867 Patent)

239. Defendants repeat and restate their responses to paragraphs 1-238 of the complaint as if fully set forth herein.

240. Admitted in part; denied in part. Defendants admit that the complaint alleges that this action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Otherwise, denied.

241. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

242. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

243. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

244. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

245. Denied.

246. Denied.

247. Denied.

248. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

249. Denied.

250. Denied.

251. Denied.

252. Denied.

253. Admitted.

254. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek a declaratory judgment, but deny that Plaintiffs are entitled to any such relief.

255. Denied.

ANSWER TO COUNT XII
(Declaratory Judgment for Alleged Infringement of the '666 Patent)

256. Defendants repeat and restate their responses to paragraphs 1-255 of the complaint as if fully set forth herein.

257. Admitted in part; denied in part. Defendants admit only that the complaint alleges that this action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Otherwise, denied.

258. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

259. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

260. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

261. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

262. Denied.

263. Denied.

264. Denied.

265. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

266. Denied.

267. Denied.

268. Denied.

269. Denied.

270. Admitted.

271. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek a declaratory judgment, but deny that Plaintiffs are entitled to any such relief.

272. Denied.

ANSWER TO COUNT XIII
(Declaratory Judgment for Alleged Infringement of the '143 Patent)

273. Defendants repeat and restate their responses to paragraphs 1-272 of the complaint as if fully set forth herein.

274. Admitted in part; denied in part. Defendants admit only that the complaint alleges that this action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Otherwise, denied.

275. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

276. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

277. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

278. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

279. Denied.

280. Denied.

281. Denied.

282. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

283. Denied.

284. Denied.

285. Denied.

286. Denied.

287. Admitted.

288. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek a declaratory judgment, but deny that Plaintiffs are entitled to any such relief.

289. Denied.

ANSWER TO COUNT XIV
(Declaratory Judgment for Alleged Infringement of the '949 Patent)

290. Defendants repeat and restate their responses to paragraphs 1-289 of the complaint as if fully set forth herein.

291. Admitted in part; denied in part. Defendants admit only that the complaint alleges this action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Otherwise, denied.

292. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

293. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

294. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

295. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

296. Denied.

297. Denied.

298. Denied.

299. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

300. Denied.

301. Denied.

302. Denied.

303. Denied.

304. Admitted.

305. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek a declaratory judgment, but deny that Plaintiffs are entitled to any such relief.

306. Denied.

ANSWER TO COUNT XV
(Declaratory Judgment for Alleged Infringement of the '041 Patent)

307. Defendants repeat and restate their responses to paragraphs 1-306 of the complaint as if fully set forth herein.

308. Admitted in part; denied in part. Defendants admit only that the complaint alleges this action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Otherwise denied.

309. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

310. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

311. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

312. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

313. Denied.

314. Denied.

315. Denied.

316. Admitted in part; denied in part. Defendants admit only that BIFI will manufacture the BLA Product. Otherwise, denied.

317. Denied.

318. Denied.

319. Denied.

320. Denied.

321. Admitted.

322. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek a declaratory judgment, but deny that Plaintiffs are entitled to any such relief.

323. Denied.

ANSWER TO COUNT XVI
(Declaratory Judgment for Alleged Infringement of the '212 Patent)

324. Defendants repeat and restate their responses to paragraphs 1-323 of the complaint as if fully set forth herein.

325. Admitted in part; denied in part. Defendants admit only that the complaint alleges this action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Otherwise, denied.

326. Admitted in part; denied in part. Defendants admit only that, on October 27, 2016, BIPI submitted BLA 761058 to the FDA, and that adalimumab is the subject of BLA No. 125057. Otherwise, denied.

327. Admitted in part; denied in part. Defendants admit only that the FDA accepted BLA 761058, submitted by BIPI, before January 9, 2017. Otherwise, denied.

328. Admitted in part; denied in part. Defendants admit only that the information required by 42 U.S.C. § 262(*l*)(2)(A) was provided to Plaintiffs on January 13, 2017. Otherwise, denied.

329. Admitted in part; denied in part. Defendants admit only that the BLA Product will be manufactured, used, sold, offered for sale, and/or imported in the United States, but not before any required notice to engage in such activities is provided. Otherwise, denied.

330. Denied.

331. Denied.

332. Admitted in part; denied in part. Defendants admit only that information relating to the proposed indications, dosage, and methods of use for the BLA Product was provided to Plaintiffs pursuant to 42 U.S.C. § 262(*l*)(2)(A). Defendants deny the remaining allegations of paragraph 332.

333. Admitted in part; denied in part. Defendants admit only that BLA 761058 includes information regarding the administration of the BLA Product. Defendants deny the remaining allegations of paragraph 333.

334. Denied.

335. Denied.

336. Admitted.

337. Admitted in part; denied in part. Defendants admit only that Plaintiffs seek a declaratory judgment, but deny that Plaintiffs are entitled to any such relief.

338. Denied.

PRAYER FOR RELIEF

The remainder of Plaintiffs' complaint recites a prayer for relief to which no response is required. To the extent any response is required, Defendants deny that Plaintiffs are entitled to any remedy or relief.

WHEREFORE Defendants respectfully request that the Court enter judgment in their favor, and against Plaintiffs, along with attorney fees, costs of suit, and such other and further relief as the Court deems appropriate.

DEFENSES

Without prejudice to the denials set forth in their Answer, and without admitting any allegation of the complaint not expressly admitted herein, Defendants assert the following separate defenses to the complaint without assuming the burden of proof on any such defense that would

otherwise rest with Plaintiffs. Defendants expressly reserve their rights to assert additional defenses that discovery may reveal.

FIRST DEFENSE
(Failure to State a Claim)

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

SECOND DEFENSE
(Noninfringement of the Asserted Patents)

2. Defendants have not and will not, directly or indirectly, literally or under the doctrine of equivalents, infringe any valid and enforceable claim of the '975 patent.

3. Defendants have not and will not, directly or indirectly, literally or under the doctrine of equivalents, infringe any valid and enforceable claim of the '361 patent.

4. Defendants have not and will not, directly or indirectly, literally or under the doctrine of equivalents, infringe any valid and enforceable claim of the '867 patent.

5. Defendants have not and will not, directly or indirectly, literally or under the doctrine of equivalents, infringe any valid and enforceable claim of the '666 patent.

6. Defendants have not and will not, directly or indirectly, literally or under the doctrine of equivalents, infringe any valid and enforceable claim of the '143 patent.

7. Defendants have not and will not, directly or indirectly, literally or under the doctrine of equivalents, infringe any valid and enforceable claim of the '949 patent.

8. Defendants have not and will not, directly or indirectly, literally or under the doctrine of equivalents, infringe any valid and enforceable claim of the '041 patent.

9. Defendants have not and will not, directly or indirectly, literally or under the doctrine of equivalents, infringe any valid and enforceable claim of the '212 patent.

THIRD DEFENSE
(Invalidity of the Asserted Patents)

10. The claims of the '975 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

11. The claims of the '361 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

12. The claims of the '867 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

13. The claims of the '666 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

14. The claims of the '143 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

15. The claims of the '949 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

16. The claims of the '041 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

17. The claims of the '212 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

FOURTH DEFENSE
(§ 271(e) Safe Harbor)

18. To the extent Plaintiffs claim that the manufacture and clinical use of the BLA Product is an act of infringement, Defendants are exempt from liability under the safe harbor provision of 35 U.S.C. § 271(e).

FIFTH DEFENSE
(Prohibition of Costs)

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

SIXTH DEFENSE
(No Exceptional Case)

20. Defendants' actions related to this case do not give rise to an exceptional case finding under 35 U.S.C. § 285.

SEVENTH DEFENSE
(No Equitable Relief)

21. Plaintiffs are not entitled to preliminary or permanent equitable relief.

EIGHTH DEFENSE
(BPCIA Noncompliance)

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

NINTH DEFENSE
(Unclean Hands)

23. Plaintiffs cannot obtain relief, including injunctive relief, because of their unclean hands.

24. AbbVie has engaged in a multifaceted, illegal scheme to prevent the sale of adalimumab in competition against Humira®. AbbVie enjoyed exclusivity for Humira® for some 13 years under its patent claiming adalimumab and compositions and uses of that active ingredient. With the looming expiration of that patent, AbbVie set about to, and did, engage in a multifaceted scheme to inhibit the goal of the BPCIA to allow for biosimilar competition by, *inter alia*, generating a large quantity of dubious, overlapping patents and manipulating the patent system to obtain them and the judicial process using them.

25. AbbVie's intensive desire to create a patent thicket encouraged and fostered an unconscionable pattern of withholding and/or misrepresenting information to the U.S. Patent and Trademark Office during prosecution of its patents in a manner that subverted the integrity of the patent system and resulted in the issuance of patents that otherwise would not have been issued. AbbVie's documents, including documents believed to exist that continue to improperly be withheld from discovery, demonstrate a disregard for the duty of candor required for prosecution of patents at the U.S. Patent and Trademark Office. At least the individuals identified herein, and those acting in concert with them, possessed an intent to deceive the Patent Office examiner into granting patents so that the patents could be included in the AbbVie patent thicket.

26. AbbVie's program was successful in creating a thicket that AbbVie has exploited to delay competition of an FDA-approved adalimumab biosimilar. AbbVie's tactics have included withholding from discovery documents about the alleged misconduct itself, requiring, for example, a Court order compelling unclean hands discovery.

27. AbbVie's misconduct, individually and collectively, harms the public, including Defendants, and renders its assertion of its patents violative of principles of equity. The patents-in-suit are unenforceable because of Plaintiffs' unclean hands.

AbbVie's Plan to Create a Patent Thicket to Prevent Adalimumab Competition

28. The '382 patent ("the adalimumab patent") allowed AbbVie to gain more than a decade of monopoly profits through its Humira® product. Until expiration in 2016, the '382 patent claimed adalimumab and formulations and uses thereof, including the disclosure of therapeutic uses for autoimmune diseases relating to anti-TNFα activity such as rheumatoid arthritis, rheumatoid spondylitis, and osteoarthritis. ('382 patent at 25:42-55.) A basic *quid pro quo* for AbbVie's ownership of this monopoly was that a person of ordinary skill in the art would be able to make and use adalimumab once the adalimumab patent expired in 2016. (*See, e.g.*, 35 U.S.C. § 112.) AbbVie's vast patent thicket is an attempt to effectively re-patent adalimumab, blocking efforts to make and use that active ingredient.

29. For many years after issuance, the adalimumab patent remained the only issued patent drawn to Humira®. Under the exclusivity of this patent, AbbVie reaped tens of billions of dollars in sales of adalimumab in the United States.

30. Unwilling to stomach biosimilar competition with the expiration of the adalimumab patent approaching, and dissatisfied with a small portfolio of applications, AbbVie set out to, and did, generate a vast portfolio of dubious, overlapping patents years after the launch of Humira®; these patents were designed to prevent an adalimumab biosimilar, including patents based on observations of routine aspects of the manufacture of adalimumab. AbbVie's focus has been to set landmines on the road to biosimilarity and approval. AbbVie has called the scheme "our biosimilar strategy." (*See, e.g.*, AbbVie Inc. at Bank of America Merrill Lynch Healthcare Conference (May 13, 2015) at 4.)

31. AbbVie's business strategy—widely disseminated and known throughout the company and among certain third parties—was aimed at protecting Humira® from legitimate

competition from an adalimumab biosimilar. [redacted] This scheme involved disclosures to numerous AbbVie employees, [redacted] By way of example, [redacted] Indeed, AbbVie's strategy to attack, among other things, [redacted]

32. The strategic initiative within AbbVie focused on [redacted] In furtherance of its scheme, [redacted], including an October 2010 internal conference [redacted], to brainstorm ideas to continue its monopoly on adalimumab. [redacted] Participants were specifically asked [redacted] Similarly, at an internal meeting in [redacted] participants were asked to consider [redacted] Instead of innovation, AbbVie's illegal patenting scheme targeted [redacted]) AbbVie's documents describe [redacted]

[redacted]

33. [redacted] developed at the October 2010 conference. [redacted]

[redacted]

34. [redacted] To do so, AbbVie asked itself:

[redacted]

35. AbbVie's [redacted], has confirmed that, upon its formation in 2013, the company was well into the execution phase of its

scheme. Indeed, AbbVie set out to create "an absolute minefield of IP" for adalimumab competition. (*See* AbbVie Inc. Q3 2013 Earnings Call (Oct. 25, 2013) at 10.) Even before becoming [redacted] had been directly involved with t[redacted] [redacted] (*See id.*; [redacted]

36. In early 2014—more than a decade after the adalimumab patent issued, and within almost two years of its expiration—the company told investors it was in the process of filing hundreds of patent applications with the Patent Office and proclaimed that "[m]any of those [will] issue," which was just "one of the lines of defense that we have put in place." (AbbVie Inc. Q4 2013 Earnings Call (Jan. 31, 2014) at 9-10.) In so stating, AbbVie simultaneously admitted that (1) its shotgun approach would be a tactic to push patent applications through the Patent Office, and (2) building a patent portfolio to target biosimilarity was part of a larger scheme to thwart adalimumab competition.

37. AbbVie has explained that a central component of its Humira® scheme is to obfuscate the ability of competitors to meet biosimilarity requirements. As late-stage prosecution efforts for the Humira® scheme were hitting full stride—more than a decade after Humira®'s approval, and shortly before the adalimumab patent expired—AbbVie's [redacted] [redacted] was asked to comment on "the thicket of patents for HUMIRA in the US." (AbbVie Inc. at Goldman Sachs Healthcare Conference (June 11, 2014) at 7.) His response revealed AbbVie's goal to force would-be competitors toward adalimumab products that did not meet basic FDA standards for safety and efficacy:

> [S]uffice to say that with a product as important and as attractive as HUMIRA, you do everything you can on the IP front to ensure that you've protected it to the best you can. The bulk of that IP strategy . . . is designed to make it more difficult for a biosimilar to follow behind you and come up with a very, very similar biosimilar . . . .

> [T]he less similar, the greater likelihood of a difference in efficacy or, very importantly, a difference in safety.

(*Id.*)

38. By 2015, AbbVie executives regularly touted that the newly formed company, which now had the rights to Humira®, had "developed [a] comprehensive strategy in anticipation of biosimilar entry," including efforts to further develop its "Broad U.S. Humira Patent Estate." (AbbVie Long-Term Strategy Presentation (Oct. 30, 2015) at 3, 14.)

39. While contemplating "biosimilar uncertainty around HUMIRA" in relation to the new company's valuation, AbbVie's [redacted] explained the plan: "[W]hat we have laid out for investors is a clear strategy that we put in place, starting back in 2013, of how we were going to ***deal with that***." (AbbVie Inc. Q2 2016 Earnings Call (July 29, 2016) at 11 (emphasis added).)

40. Recognizing the pending competition from Defendants and other companies that had commenced late-stage clinical trials to study biosimilar versions of adalimumab, AbbVie ramped up its scheme, filing at least 140 patent applications targeting competition in adalimumab since 2013.

41. To date, AbbVie has aggregated more than 170 patents and pending applications in its thicket. AbbVie thus continues its intended scheme to mitigate biosimilar competition through creation of "an absolute minefield of IP" for adalimumab competition. (AbbVie Inc. Q3 2013 Earnings Call (Oct. 25, 2013) at 10.)

42. Observers have recognized that the challenge for any adalimumab competition is the "seemingly impregnable fortress of patents AbbVie has methodically constructed around its prized moneymaker." (Cynthia Koons, *This Shield of Patents Protects the World's Best-Selling Drug*, BLOOMBERG (Sept. 7, 2017),

https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patentsprotects-the-world-s-best-selling-drug.)

AbbVie's Thicket of Dubious and Overlapping Patents

43. As part of its scheme to prevent adalimumab competition, AbbVie created a thicket of patents for formulations of adalimumab, including formulations that were not used in Humira® and which AbbVie never created, but which would effectively extend the monopoly of its expired adalimumab patent that had claimed formulations. AbbVie admitted as such when bragging that its patents "cover not only our commercial formulation, but also other related formulations that biosimilar companies might employ." (AbbVie Inc. Q3 2015 Earnings Call (Oct. 30, 2015) at 9.)

44. At least nine of AbbVie's formulation patents in the Humira® patent scheme do not contain even one claim that reflects the Humira® formulation. U.S. Patent Nos. 8,795,670, 9,327,032, and 9,732,152, for example, sought to patent the use of ***histidine***, but the Humira® formulation does not include ***histidine***. U.S. Patent Nos. 8,802,101 and 9,272,041 sought to patent the use of ***acetate***, but the Humira® formulation does not include ***acetate***. U.S. Patent Nos. 8,802,102, 9,295,725, and 9,738,714 sought to patent the use of ***succinate***, but the Humira® formulation does not include ***succinate***. U.S. Patent No. 8,940,305 sought to patent ***gluconate***, but the Humira® formulation does not include ***gluconate***. AbbVie's goal of claiming as many different adalimumab products as possible to effectively prevent competition in the use of adalimumab provides no benefit to, and instead harms, American patients, doctors, and third-party payers.

45. In parallel, AbbVie has also engaged in a pattern of seeking to patent observations about adalimumab or its manufacture, and not invention. For example, AbbVie's late-stage prosecution of the cathepsin L patent family, which consists of at least 11 patents and pending patent applications, purports to be an observation about routine protein purification. The patents

and applications assert that purifying the biologic of impurities resulted in an adalimumab composition with low levels of an impurity referred to as "cathepsin L." AbbVie does not claim to have discovered, and did not discover, the idea of purifying proteins in the manufacture of biologics. AbbVie does not claim to have discovered that protein manufacture routinely includes purification of impurities, including proteases (*i.e.*, enzymes that break down proteins, including antibodies). As early as the issuance of the now-expired adalimumab patent, persons of ordinary skill in the art knew to use conventional purification methods, such as Protein A chromatography, to rid biologics of impurities. AbbVie's scheme of flooding the Patent Office with patents directed to adalimumab, with additional observations about the results of purification, is effectively a scheme to re-patent adalimumab by seeking to block routine manufacturing techniques for making that antibody.

46. AbbVie did not just aggressively pursue the creation of strategies for re-patenting adalimumab, but also aggressively pushed its applications through the Patent Office, including by making untrue and misleading statements and withholding material information. Publicly available information and AbbVie's own documents, including documents Defendants believe Plaintiffs have withheld from production despite Court orders compelling their production (*see, e.g.*, D.I. 112, 156), demonstrate that the aggressive scheme to generate a patent thicket included deceiving the Patent Office.

47. In prosecuting patents covering methods of treating rheumatoid arthritis with adalimumab, AbbVie submitted a false and misleading declaration regarding the purpose of one of AbbVie's Phase III clinical studies and made material omissions concerning key prior art.

48. The '212 patent that AbbVie asserted in this litigation claims priority to, and is a continuation of, U.S. Patent No. 8,889,135 ("the '135 patent"). Both patents recite "administering

subcutaneously to a human subject having rheumatoid arthritis a total body dose of 40 mg of a human anti-TNFα antibody once every 13-15 days." (*See* '135 patent at claims 1-4; '212 patent at claims 1-24.)

49. The '135 patent issued on November 18, 2014, from U.S. Application No. 10/163,657 ("the '657 application"), filed on June 5, 2002. During the more than 12-year prosecution of the '135 patent, the Examiner repeatedly rejected the pending claims as obvious. (*See, e.g.*, '135 patent prosecution history, 9/21/06 Non-Final Rejection at 7-9; '135 patent prosecution history, 6/18/07 Final Rejection at 10-12.)

50. By way of example, on December 1, 2009, the Examiner rejected the then-pending claims—a 20 to 80 mg biweekly dosing regimen ('135 patent prosecution history, 3/25/09 Claims at 2)—as obvious to one of ordinary skill in the art in view of the prior art. ('135 patent prosecution history, 12/1/09 Non-Final Rejection at 2-5.) The Examiner found that the prior art (L. B.A. van de Putte et al., *Efficacy of the Fully Human Anti-TNF Antibody D2E7 in Rheumatoid Arthritis*, 42(Supp.) Arthritis & Rheum. S400 (1999) ("van de Putte")) taught 20, 40, or 80 mg weekly doses of adalimumab. (*Id*. at 2-4.) The Examiner further found that the prior art (R. Rau et al., *Experience with D2E7*, 25 Akt. Rheumatol. 83 (2000) ("Rau")) taught every-other-week dosing, and reasoned that it would have been obvious to administer 40 mg every two weeks, rather than administering 20 mg every week. (*Id*. at 4.)

51. On July 20, 2010, AbbVie's prosecution attorney submitted a declaration by [redacted] to rebut this position. ('135 patent prosecution history, 7/20/10 Supplemental Response at 1; '135 patent prosecution history, [redacted] at ¶ 4.) In that declaration, [redacted] stated he was the [redacted]

[redacted] for the study disclosed in van de Putte (DE007). ('135 patent prosecution history, 7/20/10 [redacted] Declaration at ¶ 1.)

52. [redacted] acknowledged the Examiner's position that "van de Putte teaches near equal efficacy of treating Rheumatoid Arthritis using weekly injections of either 20, 40, or 80 mg of [adalimumab]." (*Id.* at ¶ 3.) [redacted] further acknowledged the Examiner's position that "it takes mere routine optimization for one to derive the presently claimed biweekly dosing regimens based on the van de Putte data." (*Id.*)

53. [redacted] asserted, however, that "the Examiner has not provided adequate reasons based on scientific and medical principles to support his positions." (*Id.* at ¶ 4.) [redacted] [redacted] claimed instead that it would not have been routine or predictable to change from 20 mg weekly doses disclosed in the prior art to 40 mg every-other-week doses:

> Partly out of the ***concern for the lack of correlation between optimal dosing regimens*** and drug pharmacokinetics alone, one of the large scale, double bind, ***placebo-controlled Phase III clinical trials, DE019, was conducted to directly compare the efficacy of weekly 20 mg s.c. injection with biweekly 40 mg s.c. injection***. . . . Had the regimen change from weekly 20 mg to biweekly 40 mg been so routine or predictable, as the Examiner suggests, it is hardly justifiable to commit such an effort and financial resources to conduct such a large scale Phase III trial over so long a period of time.

(*Id.* at ¶ 21 (emphasis added).)

54. AbbVie amplified its assertion with remarks during prosecution of the '135 patent on February 7, 2014, that included declarations from three experts (*i.e.*, [redacted]) to argue that 20 mg weekly would have been viewed as an ineffective dose based on the results of the prior art DE007 study, and therefore 40 mg every-other-week was allegedly inventive:

- A skilled artisan "would have understood from the data in van de Putte that a dose of 20 mg, administered subcutaneously on a weekly schedule, would be too low" ('135 patent

prosecution history, 2/7/14 Remarks at 21 (quoting '135 patent prosecution history, 2/7/14 [redacted] Declaration at ¶ 72));

- "[T]he weekly 20 mg sc dose in van de Putte would have been understood to be too low a dose" (*id.* at 22 (quoting '135 patent prosecution history, 2/7/14 [redacted] Declaration at ¶ 90));

- A skilled artisan "would have understood van de Putte and Rau S51 to teach that administering 20 mg D2E7 once a week is too low a dose" (*id.* at 19-20 (quoting '135 patent prosecution history, 2/7/14 [redacted] Declaration at ¶ 63)).

The declarations thus alleged that, because there is "no reason to expect that administering 40 mg biweekly should provide any better result than 20 mg weekly," a skilled artisan would have also "expected that 40 mg biweekly would likewise be too low a dose." (*See, e.g.*, '135 patent prosecution history, 2/7/14 Amendment Under 37 CFR § 1.114 at 19-20 (quoting '135 patent prosecution history, 2/7/14 [redacted] Declaration at ¶ 63), 22 (quoting '135 patent prosecution history, 2/7/14 [redacted] Declaration at ¶ 90).)

55. [redacted] This is made clear by, for example, [redacted]

[redacted]

AbbVie's documents show [redacted]

[redacted]

56. [redacted]

[redacted]

57. [redacted]

[redacted]

58. [redacted]

[redacted]

59. These AbbVie documents [redacted]

60. [redacted]

61. [redacted]

62. [redacted]

63. [redacted]

64. [redacted]

65. The '135 patent and its progeny, including the '212 patent, would not have issued but for those expert declarations and the failure to disclose evidence inconsistent with those declarations. The Examiner cited those declarations when granting the claims of the '135 patent, which recite: "administering subcutaneously to a human subject having rheumatoid arthritis a total body dose of 40 mg of a human anti-TNFα antibody once every 13-15 days." ('135 patent at claims 1-4; '135 patent prosecution history, 7/8/14 Notice of Allowance and Fees Due at 2-5.) This misconduct applies with equal weight to the '212 patent, whose claims also recite: "administering subcutaneously to a human subject having rheumatoid arthritis a total body dose of 40 mg of a human anti-TNFα antibody once every 13-15 days." ('212 patent at claims 1-24.)

66. AbbVie misled the Patent Office during prosecution of its process patents as well. Given that its patent thicket included patent filings made long after AbbVie began selling Humira®, AbbVie was forced to make material misrepresentations and/or conceal from the Patent Office material facts—including that AbbVie had already sold what it was trying to patent, which renders the claims unpatentable.

67. For example, during prosecution of the '867 patent, AbbVie withheld critical and material information from the Patent Office: [redacted] But for this nondisclosure, the '867 patent would not have issued.

68. AbbVie initially filed its BLA in 2002, 12 years before it filed the original application that ultimately led to the '867 patent. (*See* ABV-BI00466517 at 517 (original cover letter).) AbbVie's original BLA [redacted]

[redacted]

features are the same process features that appeared in the then-pending '867 patent claims.

69. Further, AbbVie's original BLA contained [redacted] t, that further illustrate the process features discussed above. [redacted]

70. In 2006, AbbVie, for the first time, attempted to patent features of the process that it had implemented since 2002 to manufacture prior art Humira®. For example, claim 1 of the '867 patent claims methods for making adalimumab comprising culturing mammalian cells "wherein the pH of the cell culture production medium is adjusted such that the culturing begins at a starting pH and ends at a final pH that is less than the starting pH." Claim 13 of the '867 patent depends from claim 1 and further recites a method "wherein the mammalian cells are cultured at a first temperature, wherein said first temperature under which the mammalian cells are cultured is then

reduced to a second temperature." Claim 15 of the '867 patent depends from claim 1 and further recites a method "wherein glucose concentration in said cell production medium is monitored, the glucose concentration in said medium decreases to below 2 g/L, and glucose is added to said medium when the glucose concentration in said medium decreases to below 2 g/L, or the glucose concentration in said medium is monitored and glucose is added to said medium to maintain the glucose concentration in said medium at a concentration of at least 2 g/L but no greater than 7 g/L."

71. Despite these claimed features having been part of AbbVie's commercial process for years, neither [redacted] nor others from AbbVie notified the Patent Office of this material information. It was apparent that such material information was relied upon by the Examiner. For example, during prosecution of the '867 patent, the Examiner cited a different named inventor's presentation materials ("Chang materials") and specifically asked AbbVie to provide "***any details*** they see as pertinent to the instant claims (e.g. 2 g/L antibody production, pH ramp, two different temperatures)." (*See* '867 patent prosecution history, 2/13/15 Non-Final Rejection at 8 (emphasis in original).) At least this specific request by the Examiner put AbbVie on notice of the materiality of AbbVie's prior work, and commercialization of that work. Even with that knowledge, AbbVie failed to fully inform the Examiner of its prior art processes. Instead, AbbVie simply stated to the Examiner that:

> [AbbVie] further respectfully submit[s] that none of the cited documents teach, suggest, or render obvious *inter alia* the use of a pH shift in a method of producing an antibody, let alone a fed batch method for making an anti-TNFα antibody comprising a light chain variable region (LCVR) comprising the sequence of SEQ ID NO: 1 and a heavy chain variable region (HCVR) comprising the sequence of SEQ ID NO: 2, said method comprising culturing mammalian cells comprising a nucleic acid encoding said anti-TNFα antibody in a cell culture production medium in large scale, wherein the pH of the cell culture production medium is adjusted according to a pH

> shift ramp comprising beginning at a starting pH and ending at a final pH that is less than the starting pH, such that said anti-TNFα antibody is produced at a titer of at least 2 g/L in said cell culture production medium, according to the pending claims.

('867 patent prosecution history, 5/28/15 Reply at 11.)

72. In sum, at least AbbVie's named inventors had a duty to disclose at least the above-identified information concerning AbbVie's prior art processes to the Examiner during prosecution of the '867 patent. They did not do so, even after the Examiner specifically asked AbbVie about its own work relating to the patent application. But for this omission, claims of the '867 patent would not have issued.

73. AbbVie's pattern of misbehavior in the prosecution of its process patents was not an isolated instance. Similar to the prosecution of the '867 patent, in other prosecutions AbbVie was forced to hide from the Patent Office the material fact that AbbVie had already sold what it was trying to patent. Indeed, AbbVie concealed the material fact of prior invalidating sales of the alleged inventions claimed in the '143 patent.

74. Claim 1 of the '143 patent, the only independent claim, recites "[a] composition comprising adalimumab, wherein more than 25% of the total N-linked oligosaccharides present on said adalimumab are of a galactose-containing fucosylated biantennary oligosaccharide form (sum of NA1F+NA2F)." NA1F and NA2F were said to be two kinds of fucosylated oligosaccharides present on adalimumab, and part of an oligosaccharide profile. Regulatory agencies require that the oligosaccharide profiles of therapeutic antibodies be characterized as part of the approval process. AbbVie did not purport to discover that adalimumab had an oligosaccharide profile. But AbbVie did use this FDA requirement, like it did in many other instances, as a target for its landmine approach to patenting.

75. During prosecution of the '143 patent, the Examiner rejected the pending claims for obviousness because the claimed oligosaccharide profiles overlapped or fell within ranges taught in the prior art. ('143 patent prosecution history, 8/4/15 Amendment and Response at 8-12.) AbbVie overcame the rejection, in part, by arguing that the Examiner was mistakenly looking at all fucosylated forms, rather than the particular ones identified in its patent claims. (*Id.*) In its response, AbbVie represented that its prior-art Humira® did not meet the criteria of the claims, stating that "the adalimumab compositions disclosed in Salfeld and sold commercially as Humira do not comprise adalimumab in which more than 25% of the total N-linked oligosaccharides are ***NA1F and NA2F***." (*Id.* at 12 (emphasis added).)

76. In support of its assertion, AbbVie referred the examiner to an article published by AbbVie after the patent filing that discussed the "average" amount of NA1F and NA2F values for a period running from before until after the patent filing. (*Id.* at 10 (citing Tebbey *et al.*, *Consistency of Quality Attributes for the Glycosylated Monoclonal Antibody Humira® (Adalimumab)*, MAbs. 3:7(5), 805-11 (2015) ("Tebbey 2015").)

77. The Examiner, who lacked access to AbbVie's internal information that could have allowed cross-examination of these assertions, accepted the response, withdrew the rejection, and subsequently allowed the claims. ('143 patent prosecution history, 12/8/15 Notice of Allowance at 2 ("All objections and rejections of record are withdrawn in light of Applicant's Amendments and Remarks.").)

78. AbbVie did not disclose that these assertions were untrue: [redacted]. For example, [redacted]

[redacted] This information was not disclosed to the Patent Office.

79. Named inventor [redacted] was aware that AbbVie had [redacted]. Documents found [redacted] If AbbVie had disclosed to the Patent Office that it [redacted], rather than arguing the opposite, the patent would not have issued.

80. AbbVie also engaged in misconduct in pursuing its cathepsin L patents, [redacted] which were material to the prosecution of the '666 patent application.

81. The '666 patent purports to claim an adalimumab composition expressed in a CHO cell expression system that, when assayed in a cathepsin L kinetic assay, has a level of activity which is less than 1.84 RFU/s/mg of adalimumab. (*See* '666 patent at claim 1.)

82. [redacted] In 2004, AbbVie [redacted]

[redacted]

83. An internal AbbVie report [redacted]

84. As the named inventors of the '666 patent, [redacted] and [redacted] had a duty to disclose the above-identified material information concerning these prior art batches to the Examiner during prosecution of the '666 patent and its priority applications. AbbVie, however, failed to disclose this important information to the Examiner, even after the Examiner specifically asked AbbVie about the existence of prior art adalimumab batches that had "cathepsin L activity of less than 1.84 RFU/s/mg of antibody, or a cathepsin L activity of no greater than 1.3 RFU/s/mg of antibody, when said activity was/is assayed by any technique other than the precise technique described in Example 4 of the instant specification" during the prosecution of a priority application to the '666 patent. ('153 patent prosecution history, 6/24/14 Amendment and Response at 9-10.)[1]

85. In fact, despite the existence of the above-mentioned information known within AbbVie about its prior art product, AbbVie affirmatively represented to the Examiner that it "[did]

[1] The '666 patent is a continuation of U.S. Patent No. 8,916,153 ("the '153 patent"), which is also directed to cathepsin activity levels like the '666 patent. (*See* '153 patent at claim 1.)

not have or [could not] readily obtain data from assaying samples of adalimumab, produced prior to April 5, 2006, with a cathepsin L assay other than the precise technique described in Example 4 of the instant specification, where the cathepsin L activity is less than 1.84 RFU/s/mg of adalimumab or no greater than 1.3 RFU/s/mg of adalimumab." (*See id.*) By not disclosing the information regarding these prior art batches, AbbVie withheld material information from the Examiner during prosecution.

86. As yet another example of its misbehavior in the prosecution of its process patents, the '361 patent claims "[a] process for purifying adalimumab from a fermentation harvest of a Chinese Hamster Ovary (CHO) cell culture expressing said adalimumab, said process comprising: a) binding adalimumab from said fermentation harvest to a Protein A resin, b) eluting the bound adalimumab at an elution pH of 3.6-4, and c) incubating the eluted adalimumab for 1 to 3 hours." ('361 patent at claim 1.) During prosecution, AbbVie submitted a misleading declaration by its employee, [redacted] Declaration"). The [redacted] Declaration stated that, as of October 20, 2008, it was unexpected that adalimumab could be purified using Protein A chromatography without significant degradation. The [redacted] Declaration specifically stated:

> Therefore, it is my opinion that it was unexpected that adalimumab could be successfully purified from CHO cells without significantly [sic] degradation, even with acidic elution of protein A resins followed by a substantial period of viral inactivation under low-pH conditions.

('361 patent prosecution history, 8/18/14 [redacted] Declaration at ¶ 9.)

87. The [redacted] Declaration, however, was inconsistent with AbbVie's statements regarding the use of Protein A in making adalimumab in its earlier prior art references, including the '382 patent, the patent application that issued as AbbVie's '867 patent, and the WO2007117490 publication ("the WO'490 publication")—which has one joint inventor with the '361 patent.

88. The '382 patent, which claimed adalimumab, disclosed that the antibodies of the invention "can be recovered from the culture medium using standard protein purification methods." ('382 patent at 17:29-30.) The WO'490 publication disclosed, *inter alia*, that "Protein A capture, in which an antibody-HCP mixture is applied to a protein A column such that the antibody binds to protein A and HCPs flow through, typically is used as an initial purification step in antibody purification procedures as a means to remove HCPs." (*See, e.g.*, WO'490 publication at 5.)

89. Further, AbbVie's prior art patent application, which issued as the '867 patent, made abundantly clear that "[i]t is also possible to utilize an affinity column comprising a polypeptide-binding polypeptide, such as a monoclonal antibody to the recombinant protein, to affinity-purify expressed polypeptides. Other types of affinity purification steps can be a Protein A or a Protein G column, which affinity agents bind to proteins that contain Fc domains." ('867 patent at 42:4-9.) Although AbbVie did not disclose this application during the prosecution of the '361 patent, this application as amended specifically claimed a method wherein the "produced adalimumab is affinity purified using a Protein A resin" (*id.* at claim 30) and expires about two years earlier than the '361 patent.

90. AbbVie's above-identified prior art disclosures make clear that Protein A purification was a typical and straightforward technique that could be used to purify adalimumab. Therefore, it was a misrepresentation for AbbVie to claim through [redacted] declaration that "it was unexpected that adalimumab could be successfully purified from CHO cells without significantly [*sic*] degradation." ('361 patent prosecution history, 8/18/14 [redacted] Declaration at ¶ 9.) In fact, AbbVie's own teachings show that it was entirely expected that adalimumab could be

purified from CHO cells, and nothing in those teachings suggests that degradation would be a problem. But for this misrepresentation, the '361 patent would not have issued.

AbbVie's Misuse of the Thicket in Proceedings under the BPCIA and in Judicial Enforcement

91. AbbVie's business strategy has been to leverage its thicket of dubious and overlapping patents to delay biosimilar competition. AbbVie has used the complexities and specific requirements of the BPCIA and the judicial process, as applied to its patent thicket, as a tool to delay competition, irrespective of the merits of its patent estate.

92. AbbVie executives have assuaged investors by pointing to the anticipated length of patent litigation proceedings involving its thicket: "I think that as you look at events play out in the legal space, you [have] got to keep your eye on the totality of the IP and the length of time that it's going to take to ultimately work." (AbbVie Inc. at Deutsche Bank Health Care Conference (May 3, 2017) at 6.) AbbVie reflected on how events were playing out in adalimumab biosimilar litigation as it had desired:

> [W]e have a court date on Amgen. It's November of 2019. And so that will give you some sense of even if Amgen were to prevail on every claim under 61 patents, the earliest we'll be getting a decision is 2020 . . . . So now what about the other biosimilar competitors? Well, nobody is as far along as Amgen. We have not been able to even go through the discovery process with the other competitors. But we certainly feel that there is a very strong likelihood that they are going to be in the same situation as Amgen. We know that Amgen is a very, very knowledgeable company around biologics. They obviously understand the proprietary pharma space very well. They understand the IP that often goes into those spaces, and we've seen what's happened to Amgen. . . . [W]hile the number may not be 61, I'm confident the number is not going to be 0 . . . .

(AbbVie Inc. at Goldman Sachs Global Healthcare Conference (June 13, 2017) at 2.)

93. AbbVie further stated that, even if Amgen had "prevail[ed] and knock[ed] down every claim under all of those 61 patents, we would then have obviously the right to appeal. That

would take a year. And so that gets you into mid-2021. What's nice is you begin to see that the time line is starting to merge on that 2022 anyways, and I think the market is beginning to recognize that as well." (*Id.* at 3.) Likewise, [redacted] has boasted that the "litigation process" for a case involving multiple patents could take "4 to 5 years" and, thus, AbbVie's "biosimilar intellectual property and litigation [would] protect Humira biosimilar entry until 2022." (AbbVie, Inc. Long-Term Strategy Presentation (Oct. 30, 2015) at 16, 19.)

94. During the pre-litigation BPCIA process, AbbVie included expired and invalidated patents in its list provided under the statutory framework, which requires good-faith belief that a claim of infringement could reasonably be asserted. In its "3A List," AbbVie included the adalimumab patent, even though the patent had expired more than two months before on December 31, 2016. AbbVie proceeded through the dance on patents that had been invalided by the Patent Office in *inter partes* review (U.S. Patents Nos. 8,889,135 ("the '135 patent"), 9,017,680 ("the '680 patent"), and 9,073,987 ("the '987 patent")).

95. AbbVie's thicket forced a massive volume of work in responding to contentions for these patents. Defendants, for example, provided AbbVie with 1,841 pages describing bases for noninfringement and invalidity of all 72 patents identified on AbbVie's 3A List. Counsel for AbbVie responded on July 11, 2017, alleging infringement and validity for 71 out of the 72 patents ("3C Responses"), omitting only the expired adalimumab patent.

96. Those allegations included AbbVie patents for which it admits that it had no evidence of infringement. For example, with respect to all claims of U.S. Patent No. 9,096,666, AbbVie merely provided a boilerplate statement alleging that AbbVie possessed insufficient evidence to assert infringement. AbbVie's 3C Responses contained the '135, '680, and '987 patents, when those patents had been found invalid by the Patent Trial and Appeal Board.

97. On July 21, 2017, AbbVie was requested to remove at least 16 asserted patents for which AbbVie expressly admitted that it lacked evidence to allege infringement (*e.g.*, U.S. Patent Nos. 8,231,876, 8,883,156, 8,895,009, 8,906,372, 8,916,153, 9,096,666, 9,102,723, 9,273,132, 9,328,165, 9,085,618, 9,200,069, 9,200,070, 9,150,645, 9,359,434, 9,249,182, and 8,946,395). AbbVie declined. AbbVie's alleged excuse was that it lacked evidence of infringement, even while it had possession of Defendants' aBLA, because it needed more unspecified information. AbbVie did not articulate any theory of what information specifically it believed would show infringement of specific claims, or the identification of any information it currently possessed to make any such assertion.

98. In fact, between January 13, 2017, when Defendants provided AbbVie 93,750 pages relating to BLA 761058, until July 11, 2017, when AbbVie provided its 3C Responses, AbbVie never notified Defendants that any information necessary for AbbVie's assessment was missing.

99. In the present litigation, AbbVie improperly refused to produce, *inter alia*, relevant third-party discovery, supply, distribution, and manufacturing agreements, research and discovery documents, and BLA/IND documents and discovery relating to unclean hands, and has clawed back documents hours after their disclosure as relevant to Boehringer's unclean hands defense.

100. AbbVie has an ulterior motive for using the BPCIA process and patent litigation to delay Defendants' entry onto the market, and thus obtain an unfair advantage over competitors to maintain its "dominant position" in the marketplace. As AbbVie has explained, its delay tactics will ensure that, by the time adalimumab competition would otherwise occur, it will have established a commercial strategy to make it "difficult for a biosimilar competitor to actually challenge [AbbVie] within a payer environment ***purely on price***." (*See, e.g.*, AbbVie at UBS

Global Healthcare Conference (May 20, 2015) at 4 (emphasis added); [redacted]

[redacted]

RESERVATION OF DEFENSES

101. ~~24.~~ Defendants reserve the right to assert any additional defenses or counterclaims, at law or equity, which may exist.

WHEREFORE Defendants respectfully request that the Court enter judgment in their favor, and against Plaintiffs, along with attorney fees, costs of suit, and such other and further relief as the Court deems appropriate.

COUNTERCLAIMS

Defendants hereby counterclaim against Plaintiffs as follows:

PARTIES

1. BII is a private limited liability company organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim am Rhein, Germany.

2. BIPI is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877.

3. BIFI is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 6701 Kaiser Drive, Fremont, California 94555.

4. On information and belief, AbbVie Inc. is a corporation organized and existing under the laws of Delaware with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064.

5. On information and belief, AbbVie Biotechnology Ltd 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.

JURISDICTION AND VENUE

6. Defendants' counterclaims for declaratory judgments of invalidity and noninfringement arise under the patent laws of the United States, 35 U.S.C. §§ 1, *et seq*. This Court has subject matter jurisdiction to hear Defendants' counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. This Court has personal jurisdiction over Plaintiffs because, among other reasons, they subjected themselves to the jurisdiction of this Court by filing the above-captioned action (C.A. No. 17-cv-01065-MSG) against Defendants in the District of Delaware.

8. Venue with respect to the counterclaims is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400. Plaintiffs allege that venue is proper in this District in their complaint.

9. An actual and justiciable controversy has arisen and now exists between the parties because, among other reasons, Plaintiffs have filed the above-captioned action against Defendants in the District of Delaware alleging infringement of the Asserted Patents. As explained in detail below, the present lawsuit stems from Plaintiffs' attempts to improperly extend their monopoly on adalimumab, the active ingredient of the drug Humira®.

BACKGROUND

The BLA Product

10. Defendants are part of one of the world's leading pharmaceutical groups. With a history dating back to 1885, there are now 143 global Boehringer affiliates employing more than 45,600 people. Boehringer companies have spent decades developing innovative therapies to improve the lives of patients. In 2016 alone, Boehringer companies invested more than $3.3

billion on the research and development of new medicines, including treatments for immunology and respiratory disorders, cardiovascular and metabolic diseases, cancer, and diseases of the central nervous system.

11. Boehringer companies have been pioneers in the field of biologic medicines, with over 35 years of experience and more than 25 drugs manufactured. Biologics produced by Boehringer companies include monoclonal antibodies in oncology and immunology, interferons, and other targeted medicines. AbbVie Inc. itself recently partnered with a Boehringer company to develop two therapeutic antibody candidates invented by Boehringer, BI 655066 and BI 655064, which included an initial payment of $595 million from AbbVie Inc. (*See* Ex. A, Press Release, AbbVie, AbbVie and Boehringer Ingelheim Announce Global Collaboration on Promising Immunology Compounds (Mar. 7, 2016) at *1, 4.)

12. The BLA Product is an injectable formulation containing adalimumab as the active ingredient. Adalimumab and a biologic drug product containing adalimumab were disclosed and claimed in a patent application filed in 1996 that issued as the now-expired ’382 patent. The ’382 patent conferred a statutory monopoly and attendant exclusivity in the United States to Plaintiffs for more than 16 years (from its issuance on July 18, 2000, to its expiration on December 31, 2016), excluding others from adalimumab, formulations containing adalimumab, and methods of making and using adalimumab. Plaintiffs further relied on clinical trials performed with adalimumab to gain an extension of the ’382 patent term under 35 U.S.C. § 156.

Plaintiffs Purchase Adalimumab and Create a Patent Thicket

13. The antibody adalimumab was originally developed through a collaboration between BASF AG and Cambridge Antibody Technology. Adalimumab was disclosed in U.S. Application No. 08/599,226, filed on February 9, 1996, which later issued as the ’382 patent. BASF AG was the original assignee for the ’382 patent.

14. On information and belief, on December 14, 2000, Plaintiffs' predecessor, Abbott Laboratories ("Abbott"), entered into an agreement to purchase BASF AG's pharmaceutical business, thus acquiring rights to the adalimumab antibody. On information and belief, the purchase was completed on March 2, 2001.

15. The adalimumab antibody was approved by the FDA for use in treating humans on December 31, 2002.

16. During the nearly 15 years since adalimumab's approval by the FDA, Abbott (and subsequently Plaintiffs) have marketed adalimumab under the trade name Humira®. At times during the period of exclusivity of the '382 patent, Humira® has cost nearly $50,000 per year. (Ex. B, Andrew Pollack, *Makers of Humira and Enbrel Using New Drug Patents to Delay Generic Versions*, N.Y. TIMES, (July 16, 2016), https://www.nytimes.com/2016/07/16/business/makers-of-humira-and-enbrel-using-new-drug-patents-to-delay-generic-versions.html at *1 ("Pollack 2016").) In 2016, global sales of Humira® totaled $16.078 billion. (Ex. C, *AbbVie Reports Full-Year and Fourth-Quarter 2016 Financial Results*, ABBVIE PRESSROOM (Jan. 17, 2017), https://news.abbvie.com/news/abbvie-reports-full-year-and-fourth-quarter-2016-financial-results.htm at *1.)

17. During pre-suit BPCIA exchanges related to the BLA product, Plaintiffs identified a total of 75 patents pursuant to 42 U.S.C. §§ 262(*l*)(3)(A) and 262(*l*)(7).

18. As of the time of FDA approval of adalimumab in 2002, the only patent of the 75 patents identified by Plaintiffs in pre-suit exchanges pursuant to 42 U.S.C. §§ 262(*l*)(3)(A) and 262(*l*)(7) that had issued was the '382 patent. Plaintiffs have acknowledged that the '382 patent would not be infringed by the BLA Product.

19. As of the year 2011, nine years later, the only patent of the 75 patents identified by Plaintiffs in pre-suit exchanges pursuant to 42 U.S.C. §§ 262(*l*)(3)(A) and 262(*l*)(7) that had issued was the ’382 patent.

20. As of 2001, when Abbott acquired rights to the adalimumab antibody, it was aware of the expiration of the ’382 patent in December 2016, which had created exclusivity in, *inter alia*, adalimumab, formulations containing adalimumab, and methods of making and using adalimumab.

21. On information and belief, Plaintiffs engaged in a pattern of pursuing numerous overlapping and non-inventive patents for the purpose of developing a “patent thicket,” using the patenting process itself as a means to seek to delay competition against its expensive and lucrative adalimumab product. That strategy has generated, according to paragraph 18 of Plaintiffs’ complaint, more than 100 patents.

22. All 74 patents listed in paragraphs 57-58 of Plaintiffs’ complaint, which Plaintiffs identified as the then-existing patents for which a claim of patent infringement could reasonably be asserted with respect to the BLA Product, were issued between 2012 and 2017.

23. All 74 patents identified in paragraphs 57-58 of the complaint stem from less than half as many patent families. Many of the patents identified by Plaintiffs share common specifications and have overlapping and nearly identical claims. (*See, e.g.*, U.S. Patent Nos. 8,802,100, 8,802,101, 8,916,157, 8,916,158, 9,114,166, 9,220,781, and 9,302,011, and the ’041 patent.) Many of Plaintiffs’ patents from different families also have substantially similar disclosures and claims, despite claiming priority to different applications. (*See, e.g.*, U.S. Patent Nos. 9,346,879 and 9,315,574.)

24. On information and belief, Plaintiffs have made public statements citing the existence of the patent thicket as a reason for delaying competition for adalimumab. (*See, e.g.*, Ex. B, Pollack 2016 at *3 (quoting AbbVie Inc. CEO Richard A Gonzalez, "Any company seeking to market a biosimilar version of Humira will have to contend with this extensive patent estate, which AbbVie intends to enforce vigorously."); Ex. D, Excerpt from Abbott Laboratories, Annual Report at 7 (Form 10-K) (Feb. 25, 2004) (describing the purpose of patents directed to formulations, uses, or manufacturing processes as potentially extending Abbott's drug product exclusivity).)

Plaintiffs' Asserted Patents Do Not Represent Innovation

25. As will be shown in this litigation, Plaintiffs' patents do not represent innovation, but rather are attempts to claim methods of treatment, methods of production, and formulations derived from the prior art for the purpose of creating a patent thicket or estate that competitors must, as AbbVie has publicly stated, "contend with" to sell the active ingredient previously disclosed and claimed in the now-expired '382 patent.

26. Humira®'s success is not due to the alleged inventions of the patents Plaintiffs now assert against Defendants, but rather is because of the properties of its active ingredient, adalimumab. Adalimumab was the first fully human monoclonal antibody approved by the FDA, and as such represented a true scientific achievement. The formulations, production processes, and dosing regimens claimed in Plaintiffs' patent estate are not.

27. During *inter partes* review ("IPR") proceedings against U.S. Patent No. 8,889,135 ("the '135 patent"), which is directed to certain methods of treating rheumatoid arthritis using adalimumab, AbbVie Biotechnology Ltd's commercial success expert acknowledged that adalimumab's status as the first fully human monoclonal antibody was a significant reason for Humira®'s commercial success. (*E.g.*, Ex. E, Excerpt from 1/4/17 Deposition Transcript of Jerry Hausman, Ph.D. at 49:23-50:4, IPR2016-00408.)

28. In its final decisions in connection with IPR2016-00408 and IPR2016-00409, the Patent Trial and Appeal Board ("PTAB") concluded that, *inter alia*, AbbVie Biotechnology Ltd had not shown that Humira®'s commercial success was due to the claimed method of treatment, as opposed to the already known and patented adalimumab antibody. (*See* Ex. F, IPR2016-00408 at 41 (P.T.A.B. July 6, 2017); Ex. G, IPR2016-00409 at 43 (P.T.A.B. July 6, 2017).) The PTAB further stated, "[I]t appears from the evidence that the driving force behind the satisfaction of a long-felt need and success where others had failed was the introduction of the first fully human anti-TNFα antibody, not the claimed dosing regimen." (Ex. F, IPR2016-00408 at 42; Ex. G, IPR2016-00409 at 44.)

29. The claims of the '135 patent were found unpatentable in decisions by the PTAB on May 16, 2017, and July 6, 2017.

30. The claims of U.S. Patent Nos. 9,017,680 ("the '680 patent") and 9,073,987 ("the '987 patent"), which are also directed to methods of treating rheumatoid arthritis using adalimumab, were found unpatentable by the PTAB on June 9, 2017.

31. Plaintiffs allege in their complaint that the '135, '680, and '987 patents could reasonably be asserted with respect to the BLA Product, even though these patents were found unpatentable by the PTAB.

32. On March 3, 2017, the United Kingdom High Court found methods of treating rheumatoid arthritis, psoriatic arthritis, and psoriasis claimed in European Patents EP 1,406,656, EP 1,944,322, and EP 2,940,044 to be obvious and/or anticipated in light of the prior art. (*See* Ex. H, *Fujifilm Kyowa Kirin Biologics Co. v. AbbVie Biotech. Ltd* ("the *Fujifilm* Action") [2017] EWHC (Pat) 395 [3]-[4], [415] (Eng.) (granting declarations that petitioner's biosimilar products

to be administered using claimed methods were obvious and/or anticipated as of priority dates for subject patents).)

33. The United Kingdom High Court reached a final ruling on invalidity in the *Fujifilm* Action despite the fact that AbbVie Biotechnology Ltd revoked or de-designated its patents with respect to the United Kingdom during the proceedings, noting that AbbVie Biotechnology Ltd's gamesmanship warranted a decision on the merits. The United Kingdom High Court stated:

> The Claimants allege that the object and cumulative consequence of AbbVie's conduct is intended to delay the entry of competing biosimilars, and AbbVie has sought to achieve this by prolonging commercial uncertainty by a series of acts of abandonment of protection, whilst re-filing divisionals for essentially the same subject matter. This puts into issue AbbVie's intentions, which I do not accept are irrelevant, on the basis of the pleaded issues. However, even if I were to consider only the objective effect of AbbVie's conduct, my conclusions would be no different. I consider that the intention and the objective effect is to shield its patent portfolio from examination of validity whilst continuing to file further divisionals and to threaten infringement proceedings against biosimilars, wherever they may be launched.

(*Id*. at [388].)

34. Plaintiffs' efforts to create a patent thicket or estate in the United States are part of a global effort to improperly delay competition with respect to adalimumab.

Defendants' Compliance with the BPCIA and
Plaintiffs' Failure to Provide Evidence of Infringement

35. The BPCIA created an abbreviated approval pathway for biosimilar therapies. The statute balances incentives for reference product sponsors to develop new active ingredients with the critical importance of promoting competition and ensuring patients' access to biologic medicines at efficient prices within the United States.

36. To incentivize the development of new biologics, the BPCIA permits 12 years of exclusivity for a reference product before a biosimilar may be licensed. *See* 42 U.S.C. §

262(k)(7)(A). The BPCIA also sets forth specific steps regarding pre-suit disclosures and exchanges for patent litigation in connection with a biosimilar application.

37. BIPI submitted BLA 761058 to the FDA on October 27, 2016. On January 9, 2017, counsel for Defendants notified counsel for Plaintiffs that BLA 761058 had been accepted for review.

38. Pursuant to 42 U.S.C. § 262(*l*)(2)(A), on January 13, 2017, counsel for Defendants provided Plaintiffs with access to 93,750 pages relating to BLA 761058, which included, *inter alia*, information concerning "the process or processes used to manufacture" the BLA Product.

39. From January 13, 2017, when Plaintiffs were provided with the 2A Disclosure, through March 13, 2017, when Plaintiffs proceeded to identify the patents for which Plaintiffs alleged a claim of infringement could reasonably be asserted against the BLA Product, Plaintiffs made no assertion that Defendants did not comply with the BPCIA.

40. From January 13, 2017, when Plaintiffs were provided with the 2A Disclosure, through March 13, 2017, when Plaintiffs proceeded to identify the patents for which Plaintiffs alleged a claim of infringement could reasonably be asserted against the BLA Product, Plaintiffs did not notify Defendants that any manufacturing information necessary for Plaintiffs' assessment was missing from the 2A Disclosure.

41. From January 13, 2017, when Plaintiffs were provided with the 2A Disclosure, through March 13, 2017, when Plaintiffs proceeded to identify the patents for which Plaintiffs alleged a claim of infringement could reasonably be asserted against the BLA Product, Plaintiffs did not request permission for any outside experts to view the 2A Disclosure or express any issue with any alleged limitation on access for outside experts.

42. Pursuant to 42 U.S.C. § 262(*l*)(3)(A), on March 13, 2017, counsel for Plaintiffs sent a letter to counsel for Defendants identifying the 72 patents of Plaintiffs' then-existing patents for which Plaintiffs alleged a claim of infringement could reasonably be asserted against the BLA Product.

43. The 3A List included the '382 patent, even though that patent had expired on December 31, 2016.

44. Plaintiffs' inclusion of the '382 patent on the 3A List was consistent with an attempt to improperly extend a statutory monopoly based on that patent and to impede competition.

45. The 3A List also included the '135, '680, and '987 patents. Paragraph 57 of Plaintiffs' complaint continues to allege these patents could reasonably be asserted with respect to the BLA Product, even though these patents were found unpatentable by the PTAB before the filing of Plaintiffs' complaint.

46. On April 18, 2017, counsel for Plaintiffs notified counsel for Defendants that Plaintiffs were supplementing the 3A List with U.S. Patent No. 9,624,295 ("the '295 patent") pursuant to 42 U.S.C. § 262(*l*)(7).

47. Pursuant to 42 U.S.C. § 262(*l*)(3)(B), on May 12, 2017, counsel for Defendants provided Plaintiffs with 1,841 pages describing in detail bases for noninfringement and invalidity of all 72 patents identified on the 3A List.

48. Pursuant to 42 U.S.C. § 262(*l*)(7), on May 18, 2017, counsel for Defendants provided Plaintiffs with a statement describing in detail bases for noninfringement and invalidity of the '295 patent.

49. On June 6, 2017, counsel for Plaintiffs notified counsel for Defendants that Plaintiffs were supplementing their 3A List with U.S. Patent No. 9,669,093 ("the '093 patent") pursuant to 42 U.S.C. § 262(*l*)(7).

50. On June 20, 2017, counsel for Plaintiffs notified counsel for Defendants that Plaintiffs were supplementing their 3A List with U.S. Patent No. 9,683,033 ("the '033 patent") pursuant to 42 U.S.C. § 262(*l*)(7).

51. On July 6, 2017, counsel for Defendants provided Plaintiffs with statements describing in detail bases for noninfringement and invalidity of the '093 and '033 patents pursuant to 42 U.S.C. § 262(*l*)(7).

52. From January 13, 2017, when Plaintiffs were provided with the 2A Disclosure, until July 11, 2017, when Plaintiffs provided the 3C Statement, Plaintiffs made no assertion that Defendants did not comply with the BPCIA.

53. From January 13, 2017, when Plaintiffs were provided with the 2A Disclosure, until July 11, 2017, when Plaintiffs provided the 3C Statement, Plaintiffs did not notify Defendants that any manufacturing information necessary for Plaintiffs' assessment was missing from the 2A Disclosure.

54. From January 13, 2017, when Plaintiffs were provided with the 2A Disclosure, until July 11, 2017, when Plaintiffs provided the 3C Statement, Plaintiffs did not request permission for any outside experts to view the 2A Disclosure or express any issue with any alleged limitation on access for outside experts.

55. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), on July 11, 2017, counsel for Plaintiffs provided responses alleging infringement and validity for 71 of the 72 patents addressed in the 3B

Statement. In the 3C Statement, Plaintiffs acknowledged that the BLA Product would not infringe the '382 patent.

56. In the 3C Statement, Plaintiffs did not withdraw infringement allegations for the '135, '680, and '987 patents, despite the fact that these patents had previously been found unpatentable by the PTAB.

57. Among other deficiencies, the 3C Statement failed to provide evidence for many claims that Plaintiffs alleged, and continue to allege, would be infringed by the BLA Product. Plaintiffs omitted claims entirely from claim charts they provided purporting to set forth bases for infringement, including, for example, claims 3, 8-15, 20, and 24-27 of the '041 patent. For many other claims (*e.g.*, all claims of the '666 patent), Plaintiffs provided a boilerplate statement alleging that they possessed insufficient evidence relating to the BLA Product, and also (incorrectly) contended that Plaintiffs were "not permitted under their confidentiality agreements with BI to consult with independent experts regarding BI confidential information."

58. In their 3C Statement, Plaintiffs, for the first time, alleged that information allegedly needed for their infringement analyses was not included in the 2A Disclosure.

59. In their 3C Statement, Plaintiffs, for the first time, alleged that they were not permitted to consult with outside experts based on the parties' confidentiality undertaking.

60. The language of the parties' confidentiality undertaking, which was agreed to on January 15, 2017, after careful negotiation, expressly contemplates outside experts reviewing the 2A Disclosure with written permission. (*See* Ex. I, E-mail from Arianna Evers to Hassen A. Sayeed (Jan. 15, 2017).) AbbVie attorneys signed the undertaking, which states in paragraph 4, "For the avoidance of doubt, I understand and agree that I may not disclose any confidential information in Boehringer's 2A Disclosure to . . . any outside scientific consultants . . . without the

prior written consent of Boehringer." This language tracks the language of the BPCIA itself. *See* 42 U.S.C. § 262(*l*)(1)(C) ("No person that receives confidential information pursuant to subparagraph (B) shall disclose any confidential information to any other person or entity, including . . . scientific consultants retained by the reference product sponsor, without the prior written consent of the subsection (k) applicant, which shall not be unreasonably withheld.").

61. Plaintiffs did not raise any issue with the confidentiality undertaking's expert provisions during the parties' negotiations regarding that document from January 12, 2017, to January 15, 2017.

62. Plaintiffs did not identify any outside experts for which confidential access was sought pursuant to the undertaking.

63. Between January 13, 2017, and July 11, 2017, Plaintiffs sought, and were granted, permission for 43 outside attorneys and law firm technical advisors (including at least 14 attorneys with Ph.D. degrees) to view the 2A Disclosure. On May 25, 2017, and June 27, 2017, Plaintiffs sought permission for in-house attorneys to view confidential information in excess of the number permitted by statute under 42 U.S.C. § 262(*l*)(1)(B)(ii)(II). Although Plaintiffs sought permission for outside and in-house counsel to review confidential information, Plaintiffs did not seek permission for any outside scientific consultants, or raise this as an issue before submitting the 3C Statement.

64. On July 13, 2017, in a teleconference with Defendants' counsel, Plaintiffs' counsel proposed litigating 71 of the patents identified on the 3A List (all except the '382 patent) in a single litigation. Plaintiffs' proposal included the '135, '680, and '987 patents, whose claims have been found unpatentable by the PTAB.

65. On July 21, 2017, in response to Plaintiffs' deficient 3C Statement and Plaintiffs' proposal to litigate 71 patents — many of which, as explained in paragraph 22 of Defendants' counterclaims above, have common or similar specifications and overlapping, nearly identical claims — in a single litigation, counsel for Defendants sent Plaintiffs a letter seeking removal of at least 16 patents for which Plaintiffs expressly admitted in their 3C Statement that they lacked sufficient evidence to allege infringement ("the July 21, 2017 Letter"). Plaintiffs declined to remove any of the 16 patents.

66. On July 26, 2017, within the time period expressly contemplated by the BPCIA under 42 U.S.C. § 262(*l*)(4)(b) and pursuant to 42 U.S.C. § 262(*l*)(5)(A), counsel for Defendants notified Plaintiffs that each side could select up to five patents to litigate in the present action.

67. On July 31, 2017, pursuant to 42 U.S.C. § 262(*l*)(5)(B), the lists of patents to be litigated in the present action were exchanged. Counsel for Plaintiffs identified the '975 patent, the '361 patent, the '949 patent, the '041 patent, and the '212 patent. Counsel for Defendants identified the '867 patent, the '666 patent, and the '143 patent, as well as the '975 patent and the '041 patent.

68. On August 2, 2017, Plaintiffs filed the present action alleging infringement of the eight non-overlapping patents.

69. Because, *inter alia*, Plaintiffs are aware that they expressed no factual basis for asserting infringement in the 3C Statement (and thus did not comply with the BPCIA) for at least the 16 patents identified in the July 21, 2017 Letter, Plaintiffs' complaint miscites 35 U.S.C. § 295 for the erroneous premise that it is Defendants' burden to prove noninfringement. 35 U.S.C. § 295, *inter alia*, does not address the standards for pre-suit investigation and is not applicable here.

70. As of July 11, 2017, when the 3C Statement was served, Plaintiffs acknowledged that they lacked a good-faith basis to assert infringement of at least the ’666 patent and the ’143 patent, among many others.

71. In their complaint, Plaintiffs allege that the BLA Product would infringe patents that Plaintiffs admitted they lack a reasonable basis to assert in the 3C Statement.

72. In their complaint, Plaintiffs allege that the BLA Product would infringe patents that have been found unpatentable by the PTAB.

73. Plaintiffs’ continued assertion of patents that Plaintiffs have no basis to assert, including patents found unpatentable by the PTAB, is part of a pattern of anticompetitive behavior designed to delay Defendants’ entrance into the market and improperly extend Plaintiffs’ monopoly over adalimumab.

74. Defendants reserve the right to pursue in this action any and all defenses and remedies based upon Plaintiffs’ improper behavior.

COUNT I
(Declaration of Noninfringement and Invalidity of the ’975 Patent)

75. The averments of paragraphs 1-74 of Defendants’ counterclaims are repeated, re-alleged, and incorporated by reference as if fully set forth herein.

76. At the time of the filing of Plaintiffs’ complaint in the above-captioned action, AbbVie Biotechnology Ltd was listed as the assignee of the ’975 patent. Plaintiffs have alleged that AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the ’975 patent in the United States.

77. A case or controversy exists between Plaintiffs and Defendants because Plaintiffs have alleged that Defendants have infringed and will infringe the ’975 patent.

78. Defendants have not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the ’975 patent under 35 U.S.C. § 271.

79. The claims of the ’975 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

80. This case is an exceptional one, and Defendants are entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT II
(Declaration of Noninfringement and Invalidity of the ’361 Patent)

81. The averments of paragraphs 1-80 of Defendants’ counterclaims are repeated, re-alleged, and incorporated by reference as if fully set forth herein.

82. At the time of the filing of Plaintiffs’ complaint in the above-captioned action, AbbVie Inc. was listed as the assignee of the ’361 patent. Plaintiffs have alleged that AbbVie Biotechnology Ltd is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the ’361 patent in the United States.

83. A case or controversy exists between Plaintiffs and Defendants because Plaintiffs have alleged that Defendants have infringed and will infringe the ’361 patent.

84. Defendants have not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the ’361 patent under 35 U.S.C. § 271.

85. The claims of the '361 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

86. This case is an exceptional one, and Defendants are entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT III
(Declaration of Noninfringement and Invalidity of the '867 Patent)

87. The averments of paragraphs 1-86 of Defendants' counterclaims are repeated, re-alleged, and incorporated by reference as if fully set forth herein.

88. At the time of the filing of Plaintiffs' complaint in the above-captioned action, AbbVie Inc. was listed as the assignee of the '867 patent. Plaintiffs have alleged that AbbVie Biotechnology Ltd is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the '867 patent in the United States.

89. A case or controversy exists between Plaintiffs and Defendants because Plaintiffs have alleged that Defendants have infringed and will infringe the '867 patent.

90. Defendants have not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '867 patent under 35 U.S.C. § 271.

91. The claims of the '867 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

92. This case is an exceptional one, and Defendants are entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT IV
(Declaration of Noninfringement and Invalidity of the '666 Patent)

93. The averments of paragraphs 1-92 of Defendants' counterclaims are repeated, re-alleged, and incorporated by reference as if fully set forth herein.

94. At the time of the filing of Plaintiffs' complaint in the above-captioned action, AbbVie Biotechnology Ltd was listed as the assignee of the '666 patent. Plaintiffs have 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.

95. A case or controversy exists between Plaintiffs and Defendants because Plaintiffs have alleged that Defendants have infringed and will infringe the '666 patent.

96. Defendants have not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '666 patent under 35 U.S.C. § 271.

97. The claims of the '666 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

98. This case is an exceptional one, and Defendants are entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT V
(Declaration of Noninfringement and Invalidity of the '143 Patent)

99. The averments of paragraphs 1-98 of Defendants' counterclaims are repeated, re-alleged, and incorporated by reference as if fully set forth herein.

100. At the time of the filing of Plaintiffs' complaint in the above-captioned action, AbbVie Inc. was listed as the assignee of the '143 patent. Plaintiffs have alleged that AbbVie

Biotechnology Ltd is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the '143 patent in the United States.

101. A case or controversy exists between Plaintiffs and Defendants because Plaintiffs have alleged that Defendants have infringed and will infringe the '143 patent.

102. Defendants have not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '143 patent under 35 U.S.C. § 271.

103. The claims of the '143 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

104. This case is an exceptional one, and Defendants are entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT VI
(Declaration of Noninfringement and Invalidity of the '949 Patent)

105. The averments of paragraphs 1-104 of Defendants' counterclaims are repeated, re-alleged, and incorporated by reference as if fully set forth herein.

106. At the time of the filing of Plaintiffs' complaint in the above-captioned action, AbbVie Inc. was listed as the assignee of the '949 patent. Plaintiffs have alleged that AbbVie Biotechnology Ltd is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the '949 patent in the United States.

107. A case or controversy exists between Plaintiffs and Defendants because Plaintiffs have alleged that Defendants have infringed and will infringe the '949 patent.

108. Defendants have not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the ’949 patent under 35 U.S.C. § 271.

109. The claims of the ’949 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

110. This case is an exceptional one, and Defendants are entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT VII
(Declaration of Noninfringement and Invalidity of the ’041 Patent)

111. The averments of paragraphs 1-110 of Defendants’ counterclaims are repeated, re-alleged, and incorporated by reference as if fully set forth herein.

112. At the time of the filing of Plaintiffs’ complaint in the above-captioned action, AbbVie Biotechnology Ltd was listed as the assignee of the ’041 patent. Plaintiffs have alleged that AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the ’041 patent in the United States.

113. A case or controversy exists between Plaintiffs and Defendants because Plaintiffs have alleged that Defendants have infringed and will infringe the ’041 patent.

114. Defendants have not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the ’041 patent under 35 U.S.C. § 271.

115. The claims of the ’041 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

116. This case is an exceptional one, and Defendants are entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

COUNT VIII
(Declaration of Noninfringement and Invalidity of the '212 Patent)

117. The averments of paragraphs 1-116 of Defendants' counterclaims are repeated, re-alleged, and incorporated by reference as if fully set forth herein.

118. At the time of the filing of Plaintiffs' complaint in the above-captioned action, AbbVie Biotechnology Ltd was listed as the assignee of the '212 patent. Plaintiffs have alleged that AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the '212 patent in the United States.

119. A case or controversy exists between Plaintiffs and Defendants because Plaintiffs have alleged that Defendants have infringed and will infringe the '212 patent.

120. Defendants have not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '212 patent under 35 U.S.C. § 271.

121. The claims of the '212 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or under judicially created doctrines of invalidity.

122. This case is an exceptional one, and Defendants are entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Defendants respectfully request that the Court enter:

A. An entry of judgment on Plaintiffs' complaint in favor of Defendants, and against Plaintiffs, with Plaintiffs not being awarded any relief thereon;

B. A declaratory judgment that Defendants have not infringed and will not infringe any valid and enforceable claim of the Asserted Patents under 35 U.S.C. § 271;

C. A declaratory judgment that the Asserted Patents are invalid;

D. An Order enjoining and restraining Plaintiffs and their officers, agents, servants, employees, attorneys, and those persons in active concert or participation with them from pursuing further charges of infringement or acts of enforcement based on the Asserted Patents against Defendants or their actual and prospective business partners, customers, suppliers, clinical investigators, and anyone in privity with Defendants;

E. A judgment that this case is exceptional and that Defendants are entitled to an award of attorney fees pursuant to 35 U.S.C. § 285;

F. An award of costs, expenses, and attorney fees pursuant to 28 U.S.C. § 1927;

G. An award of taxable costs;

H. An award of interest;

I. An Order for such other and further relief as the Court deems just and proper.

Dated: September ~~11,~~14, ~~2017~~2018

Respectfully submitted,

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