IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JANSSEN BIOTECH, INC. and JANSSEN SCIENCES IRELAND UC, Plaintiffs, v. ACCORD BIOPHARMA, INC. and BIO-THERA SOLUTIONS, LTD., Defendants.	C.A. No. _____ [redacted]

COMPLAINT FOR PATENT INFRINGEMENT

Janssen Biotech, Inc. ("JBI") and Janssen Sciences Ireland UC ("JSI") (JBI and JSI collectively, "Janssen"), for their Complaint against Accord BioPharma, Inc. ("Accord") and Bio-Thera Solutions, Ltd. ("Bio-Thera") (Accord and Bio-Thera collectively, "Defendants"), allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement and declaratory judgment under 35 U.S.C. § 271(e)(2)(C), 28 U.S.C. § 2201, and 42 U.S.C. §§ 262(*l*)(8)(B) and 262(*l*)(9).

2. Janssen developed and sells SIMPONI® and SIMPONI ARIA®, biologic drugs that treat chronic inflammation. The active ingredient in both SIMPONI® and SIMPONI ARIA®, golimumab, is an antibody that blocks the inflammatory molecule called tumor necrosis factor alpha (TNFα). SIMPONI® is administered subcutaneously and is approved to treat rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and ulcerative colitis. SIMPONI ARIA® is administered intravenously and is approved to treat rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and polyarticular juvenile idiopathic arthritis. SIMPONI® and SIMPONI

ARIA® provide an exceptional advancement in patient care, significantly improving the quality of life for patients suffering from these debilitating inflammatory conditions.

3. Janssen holds numerous patents related to SIMPONI®, SIMPONI ARIA®, and the manufacture and delivery of biologic products like golimumab.

4. Defendants plan to sell BAT2506, their biosimilar copy of SIMPONI® and SIMPONI ARIA®. Defendants submitted abbreviated Biologics License Application ("aBLA")

[redacted]

5. Defendants did not independently develop BAT2506. Rather, Defendants are seeking regulatory approval based on Janssen's clinical studies and research data for SIMPONI® and SIMPONI ARIA®. By submitting their aBLA for BAT2506 and taking concrete steps to commercially market those products, Defendants have infringed, and threaten to infringe, Janssen's patents.

THE PARTIES

6. JBI is a Pennsylvania corporation with its principal place of business at 800 Ridgeview Drive, Horsham, Pennsylvania 19044.

7. JSI is an Irish company with its principal place of business at Airton Road, Dublin 24, Ireland, D24WR89.

8. Accord is a Delaware corporation with its principal place of business at 8041 Arco Corporate Drive, Suite 200, Raleigh, North Carolina 27617.

9. Bio-Thera is a Chinese company with its principal place of business at No.18 Luoxuan 2nd Road, International Bio-Island, Guangzhou, Guangdong, China.

JURISDICTION AND VENUE

10. Janssen's claims arise under the laws of the United States, including the Patent Act, Title 35, United States Code; the Declaratory Judgment Act, Title 28, United States Code, Chapter 151; and the Biologics Price Competition and Innovation Act, Title 42, United States Code, Section 262. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201(a), and 2202.

11. Defendants are subject to personal jurisdiction in Delaware because they have purposefully availed themselves of the benefits and protections of Delaware laws such that each should reasonably anticipate being sued in this Court.

12. In the alternative, on information and belief, this Court has personal jurisdiction over Bio-Thera under Federal Rule of Civil Procedure 4(k)(2) because it is not subject to jurisdiction in any other state's courts of general jurisdiction, and exercising jurisdiction is consistent with the United States Constitution and laws.

13. On information and belief, Defendants plan to market BAT2506 in Delaware.

14. Defendants seek regulatory approval to sell BAT2506 throughout the United States, including in Delaware. On information and belief, Accord intends to commercialize BAT2506 in the United States and Delaware, and Bio-Thera plans to direct sales of BAT2506 into the United States and Delaware through its partnership with Accord. Accord and Bio-Thera currently direct sales of other biosimilar products, including HERCESSI®, IMULDOSA®, STARJEMZA®, TOFIDENCE®, UDENYCA®, into Delaware.

15. On information and belief, Defendants developed and will manufacture BAT2506 for the entire United States market, including Delaware. On information and belief, Defendants will import BAT2506 into the United States and Delaware.

16. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400. Accord resides in Delaware, its state of incorporation. Bio-Thera is a foreign entity and thus is subject to suit in any judicial district in the United States, including the District of Delaware.

BACKGROUND

Janssen's SIMPONI® and SIMPONI ARIA® Products

17. SIMPONI® and SIMPONI ARIA® are advanced biologic therapies designed to provide powerful, targeted treatment for chronic inflammatory conditions. SIMPONI® offers the convenience of subcutaneous self-injection, making it a patient-friendly option for managing disease at home. SIMPONI ARIA® delivers proven efficacy through periodic in-clinic intravenous infusions.

18. Together, SIMPONI® and SIMPONI ARIA® offer patients complementary options at home and in a clinical setting to reduce inflammation, achieve sustained relief, and improve quality of life.

19. SIMPONI® and SIMPONI ARIA® have achieved tremendous market success. In 2024, sales of SIMPONI® and SIMPONI ARIA® in the United States exceeded $1 billion.

Janssen's Patents

20. Janssen developed SIMPONI® and SIMPONI ARIA®, and pioneered the use of SIMPONI® and SIMPONI ARIA® as therapies to treat debilitating autoimmune diseases of the spine and joints, including active ankylosing spondylitis and active psoriatic arthritis. These treatment options provide significant advancements in patient care.

21. Golimumab, the active ingredient in SIMPONI® and SIMPONI ARIA®, is an antibody—a molecule so large and complex that it cannot be synthesized in the laboratory. Instead, it must be grown in and purified from living cell cultures. As a result, there are substantial challenges to manufacturing golimumab on a commercial scale.

22. Janssen holds patents that protect its innovative work relating to golimumab, including treating ankylosing spondylitis and psoriatic arthritis patients, and manufacturing techniques applicable to biologic drugs such as golimumab. These innovations are protected by numerous patents, including:

U.S. Patent No. 8,017,325,

U.S. Patent No. 8,586,356,

U.S. Patent No. 8,852,889,

U.S. Patent No. 8,956,830,

U.S. Patent No. 9,170,249,

U.S. Patent No. 9,217,168,

U.S. Patent No. 9,475,858,

U.S. Patent No. 9,487,810,

U.S. Patent No. 9,663,810,

U.S. Patent No. 9,890,410,

U.S. Patent No. 11,014,982,

U.S. Patent No. 11,041,020,

U.S. Patent No. 12,122,824,

U.S. Patent No. 12,129,292,

U.S. Patent No. 12,139,735,

U.S. Patent No. 12,180,271, and

U.S. Patent No. 12,291,566,

(collectively, the "Janssen Patents").

23. JSI is the exclusive licensee of Janssen Patents that [redacted]

The Biosimilar Price Competition and Innovation Act

24. Defendants applied for regulatory approval of BAT2506 under the Biosimilar Price Competition and Innovation Act of 2009 ("BPCIA"), which established an abbreviated regulatory pathway for certain biosimilar products. But the BPCIA does not give Defendants license to infringe Janssen's patents. Defendants remain liable for patent infringement as long as Janssen's patents remain in force. Defendants' submission of their aBLA for BAT2506 infringes Janssen's patents under 35 U.S.C. § 271(e)(2)(C).

25. The BPCIA sets forth a process, colloquially called the "patent dance," by which the parties seek to resolve patent disputes before a biosimilar product is commercially launched, beginning with a series of information exchanges.

26. Although Accord provided Defendants' aBLA for BAT2506 [redacted], it failed to fully provide "such other information that describes the process or processes used to manufacture the biological product that is the subject of such application," as required by 42 U.S.C. § 262(*l*)(2)(A). For example, Defendants failed to provide complete documentation about [redacted] of BAT2506.

27. On [redacted] Janssen wrote to Defendants' counsel, requesting the missing information and specifically identifying the requested materials including by reference to, for example, [redacted]

[redacted] Defendants refused to provide that information, claiming they needed more information about Janssen's patent. Janssen sent follow-up correspondence on [redacted], pointing out that "Accord has failed to comply with Section (*l*)(2)(A)," which Defendants did not dispute.

28. Nevertheless, [redacted], Janssen voluntarily provided to Defendants a list of patents under 42 U.S.C. § 262(*l*)(3)(A) for which it believed a claim of patent infringement could reasonably be asserted. Yet even after receiving Janssen's patent list, Defendants still refused to provide complete information to Janssen. Because Defendants failed to meet their obligation to provide all the information required under 42 U.S.C. § 262(*l*)(2)(A), Janssen was not obligated to provide that list of patents nor is it subject to the limitations of 35 U.S.C. § 271(e)(6)(C).

29. [redacted] Accord provided disclosures pursuant to 42 U.S.C. § 262(l)(3)(B), along with a production of associated documents, purporting to include information showing the non-infringement and/or invalidity of the Janssen Patents. Despite providing limited additional information, Accord's § 262(l)(3)(B) disclosures failed to show that Defendants' manufacture or sale of BAT2506 will not infringe the Janssen Patents.

30. Defendants' failure to comply with their obligations under the BPCIA provides a proper basis for Janssen to assert patent infringement. *See, e.g.*, *Amgen Inc. v. Hospira, Inc.*, 866 F. 3d 1355, 1362 (Fed. Cir. 2017). Janssen is entitled to utilize the judicial process and the aid of discovery to confirm its belief and to present evidence that Defendants infringe the Janssen Patents. *See, e.g., Hoffmann-La Roche Inc. v. Invamed Inc.*, 213 F.3d 1359, 1364 (Fed. Cir. 2000).

31. Despite its failure to comply with the requirements of the BPCIA, [redacted]

[redacted]

32. Janssen brings this Complaint for preliminary and permanent injunctive relief and judgment of patent infringement against Defendants, based on the Janssen Patents.

Defendants Submitted their aBLA for BAT2506

33. [redacted] The reference products for BAT2506 are Janssen's SIMPONI® and SIMPONI ARIA® products. [redacted]

34. [redacted]

35. Bio-Thera is a submitter of the aBLA for BAT2506 because it [redacted] intends to directly benefit from the aBLA through the sale of BAT2506 in the United States upon regulatory approval.

36. Bio-Thera [redacted] Bio-Thera is responsible for the "development, manufacturing, and supply of BAT2506" and [redacted] *See, e.g.*, https://www.bio-thera.com/col_62/1130.html; [redacted]

[redacted]

[redacted]

37. Bio-Thera will financially benefit in a significant manner from regulatory approval of BAT2506. For example, Bio-Thera has entered into contracts under which it has received and will receive revenues and other financial compensation for the sale of BAT2506 in the United States. *See, e.g.*, https://www.bio-thera.com/col_62/1130.html.

38. BAT2506 will be offered for sale and sold by Accord within the United States. *See, e.g.*, https://www.bio-thera.com/col_62/1130.html. On information and belief, BAT2506 will be imported by Defendants into the United States. Bio-Thera will actively induce Accord to import, offer to sell, and sell BAT2506 by developing, supplying, soliciting purchase orders for, and licensing BAT2506 for Accord to import into, and offer to sell and sell within, the United States. *See, e.g.*, https://www.bio-thera.com/col_62/1130.html; [redacted]

COUNT I

Infringement of U.S. Patent No. 8,017,325 Under 35 U.S.C. § 271(e)(2)(C)

39. Janssen incorporates by reference the allegations set forth in paragraphs 1-38 above as if fully set forth herein.

40. U.S. Patent No. 8,017,325 ("the '325 patent") is titled "Selection of high-producing cell lines." The '325 patent was duly and legally issued on September 13, 2011. A true and correct copy of the '325 patent is attached hereto as Exhibit B. JBI is the owner by assignment of the '325 patent.

41. The ’325 patent is directed to methods for selecting a cell line for production of antibodies. The ’325 patent includes 11 claims, one of which is independent. Claim 1 is representative and recites:

> 1. A method for selecting a cell line for production of antibodies comprising the steps of:
>
> a. transfecting an antibody encoding gene, comprising at least a heavy chain gene and, optionally, a light chain gene, into two or more suitable mammalian host cells;
>
> b. culturing the transfected host cells;
>
> c. quantitating the mRNA encoded by the antibody heavy chain gene in the host cells; and
>
> d. selecting the host cell with highest heavy chain gene mRNA quantity.

42. On information and belief, the manufacture of BAT2506 is covered by one or more claims of the ’325 patent, literally or under the doctrine of equivalents.

43. [redacted]

44. [redacted]

47. On information and belief, Defendants quantitate the mRNA encoded by the antibody heavy chain gene in the host cells to select the cell line with highest heavy chain gene mRNA quantity. [redacted]

48. Janssen also attempted to ascertain details of Defendants' cell line selection process by examining materials that Defendants were obligated to provide under 42 U.S.C. § 262(*l*)(2)(A). Janssen sent a letter to Defendants' counsel on [redacted] requesting more information on Defendants' [redacted]. [redacted] Janssen is entitled to utilize the judicial process and the aid of discovery to obtain such information as is required to confirm its belief that Defendants quantitate the mRNA encoded by the antibody heavy chain gene in the host cells to select the cell line with highest heavy chain gene mRNA quantity.

49. Defendants' submission of their aBLA for BAT2506 infringed the '325 patent under 35 U.S.C. § 271(e)(2)(C).

50. Defendants have knowledge of the '325 patent, due to at least Janssen's disclosure of the '325 patent under 42 U.S.C. § 262(*l*)(3)(A) on [redacted], and through the filing

of this Complaint. On information and belief, Defendants have been aware of the ’325 patent and its relevance to BAT2506 even before Janssen identified it on [redacted]

51. On information and belief, Defendants acted with deliberate and intentional disregard of Janssen’s rights under the ’325 patent.

52. Janssen has no adequate remedy at law to redress the infringement by Defendants.

53. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the ’325 patent.

COUNT II

Declaratory Judgment of Infringement of U.S. Patent No. 8,017,325

54. Janssen incorporates by reference the allegations set forth in paragraphs 1-53 above as if fully set forth herein.

55. As set forth in Count I, Defendants would infringe the ’325 patent, literally or under the doctrine of equivalents, if BAT2506 is commercially made, used, offered for sale, sold, or imported in the United States.

56. Because Defendants would only have regulatory approval to sell BAT2506 as described in their aBLA, any imported BAT2506 made by the patented process will not be materially changed by subsequent processes nor be a trivial or nonessential component of another product.

57. Defendants have knowledge of and/or are willfully blind to the fact that the commercial manufacture, use, sale, offer for sale, and/or importation of BAT2506 will directly infringe one or more claims of the ’325 patent, literally or under the doctrine of equivalents.

58. Defendants will knowingly or with willful blindness induce or contribute to another's direct infringement of one or more claims of the '325 patent, literally or under the doctrine of equivalents.

59. By filing the aBLA for BAT2506, [redacted]

60. [redacted] presents a controversy of sufficient immediacy and reality to support declaratory judgment of patent infringement under 35 U.S.C. §§ 271(b) and/or 271(g). The BPCIA authorizes a declaratory judgment action for patent infringement due to Defendants' [redacted] failure to comply with their obligations under 42 U.S.C. § 262(*l*)(2)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

61. Janssen therefore seeks declaratory judgment that Defendants will infringe the '325 patent, literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(b) and/or 271(g).

62. Janssen has no adequate remedy at law to redress the infringement by Defendants.

63. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the '325 patent.

COUNT III

Infringement of U.S. Patent No. 8,586,356 Under 35 U.S.C. § 271(e)(2)(C)

64. Janssen incorporates by reference the allegations set forth in paragraphs 1-63 above as if fully set forth herein.

65. U.S. Patent No. 8,586,356 ("the '356 patent") is titled "Gal α1-3gal-containing N-glycans in glycoprotein products derived from CHO cells." The '356 patent was duly and legally issued on November 19, 2013. A true and correct copy of the '356 patent is attached hereto as Exhibit C. JBI is the owner by assignment of the '356 patent.

66. The '356 patent is directed to methods for evaluating CHO cells. The '356 patent includes 18 claims, one of which is independent. Claim 1 is representative and recites:

> 1. A method for screening Chinese Hamster Ovary (CHO) cells for the ability to produce a target recombinant glycoprotein comprising glycans containing a target level of terminal galactose-alpha-1-3-galactose epitopes, the method comprising:
>
> (a) producing a target recombinant glycoprotein comprising one or more glycans by culturing CHO cells under conditions suitable for expression of the target recombinant glycoprotein by the CHO cells, wherein the CHO cells have not been genetically engineered to produce terminal alpha-galactosyl residues on glycans;
>
> (b) treating the one or more glycans of the target recombinant glycoprotein with one or more exoglycosidases;
>
> (c) detecting digested terminal galactose-alpha-1-3-galactose residues to thereby measure glycans containing terminal galactose-alpha-1-3-galactose residues produced by the CHO cells, and
>
> (d) selecting the CHO cells if a target level of terminal galactose-alpha-1-3-galactose residues is measured.

67. On information and belief, the manufacture of BAT2506 is covered by one or more claims of the '356 patent, literally or under the doctrine of equivalents.

68. [redacted]

69. [redacted]

70. On information and belief, Defendants treat one or more glycans of the produced golimumab with one or more exoglycosidases. Janssen has a reasonable basis for this belief at least because Defendants failed to comply with their obligation under 42 U.S.C. § 262(*l*)(2)(A) to provide such other information that describes the process or processes used to manufacture the BAT2506, despite repeated follow up requests for this information on [redacted] and [redacted] On information and belief, Defendants withheld this information because they know or have reason to believe that they treat one or more glycans of the produced golimumab with one or more exoglycosidases.

71. Janssen also attempted to ascertain Defendants' [redacted] by examining materials that Defendants were obligated to provide under 42 U.S.C. § 262(*l*)(2)(A). Janssen sent a letter to Defendants' counsel on [redacted]. However, Defendants failed to provide complete information that describes the manufacturing of BAT2506. Janssen is entitled to utilize the judicial process and the aid of discovery to obtain such information as is required to confirm its belief that

Defendants treat one or more glycans of the produced golimumab with one or more exoglycosidases.

72. [redacted]

73. On information and belief, Defendants select CHO cells if a target level of terminal galactose-alpha-1-3-galactose residues is measured. Janssen has a reasonable basis for this belief at least because Defendants failed to comply with their obligation under 42 U.S.C. § 262(*l*)(2)(A) to provide such other information that describes the process or processes used to manufacture the BAT2506, despite repeated follow up requests for this information on [redacted], and [redacted] On information and belief, Defendants withheld this information because they know or have reason to believe that they select [redacted]

74. Janssen also attempted to ascertain details of Defendants' cell selection process by examining materials that Defendants were obligated to provide under 42 U.S.C. § 262(*l*)(2)(A). Janssen sent a letter to Defendants' counsel on [redacted], requesting more information on Defendants' [redacted]. [redacted] However, Defendants failed to provide complete information that describes the process used to select their cell line for production of BAT2506. Janssen is entitled to utilize the judicial process and the aid of discovery to obtain such information as is required to confirm its belief that Defendants select CHO cells if a target level of terminal galactose-alpha-1-3-galactose residues is measured.

75. Defendants' submission of their aBLA for BAT2506 infringed the '356 patent under 35 U.S.C. § 271(e)(2)(C).

76. Defendants have knowledge of the '356 patent, due to at least Janssen's disclosure of the '356 patent under 42 U.S.C. § 262(*l*)(3)(A) on [redacted] and through the filing of this Complaint. On information and belief, Defendants have been aware of the '356 patent and its relevance to BAT2506 even before Janssen identified it on [redacted]

77. On information and belief, Defendants acted with deliberate and intentional disregard of Janssen's rights under the '356 patent.

78. Janssen has no adequate remedy at law to redress the infringement by Defendants.

79. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the '356 patent.

COUNT IV

Declaratory Judgment of Infringement of U.S. Patent No. 8,586,356

80. Janssen incorporates by reference the allegations set forth in paragraphs 1-79 above as if fully set forth herein.

81. As set forth in Count III, Defendants would infringe the '356 patent, literally or under the doctrine of equivalents, if BAT2506 is commercially made, used, offered for sale, sold, or imported in the United States.

82. Because Defendants would only have regulatory approval to sell BAT2506 as described in their aBLAs, any imported BAT2506 made by the patented process will not be materially changed by subsequent processes nor be a trivial or nonessential component of another product.

83. Defendants have knowledge of and/or are willfully blind to the fact that the commercial manufacture, use, sale, offer for sale, and/or importation of BAT2506 will directly infringe one or more claims of the ’356 patent, literally or under the doctrine of equivalents.

84. Defendants will knowingly or with willful blindness induce or contribute to another’s direct infringement of one or more claims of the ’356 patent, literally or under the doctrine of equivalents.

85. [redacted]

86. [redacted] presents a controversy of sufficient immediacy and reality to support declaratory judgment of patent infringement under 35 U.S.C. §§ 271(b) and/or 271(g). The BPCIA authorizes a declaratory judgment action for patent infringement due to Defendants’ [redacted] failure to comply with their obligations under 42 U.S.C. § 262(*l*)(2)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

87. Janssen therefore seeks declaratory judgment that Defendants will infringe the ’356 patent, literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(b) and/or 271(g).

88. Janssen has no adequate remedy at law to redress the infringement by Defendants.

89. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the ’356 patent.

COUNT V

Infringement of U.S. Patent No. 8,852,889 Under 35 U.S.C. § 271(e)(2)(C)

90. Janssen incorporates by reference the allegations set forth in paragraphs 1-89 above as if fully set forth herein.

91. U.S. Patent No. 8,852,889 ("the '889 patent") is titled "Cell culture process." The '889 patent was duly and legally issued on October 7, 2014. A true and correct copy of the '889 patent is attached hereto as Exhibit D. JBI is the owner by assignment of the '889 patent.

92. The '889 patent is directed to and claims methods of manufacturing a preparation of a recombinant antibody. The '889 patent includes 30 claims, three of which are independent. Claims 6 and 16 are representative. Claim 6 (which depends from claim 1) recites:

> 1. A method of producing a preparation of a recombinant antibody, comprising:
>
> culturing a cell in a medium under conditions in which the cell expresses a recombinant antibody, wherein the medium comprises 1.5 g/L lysine to less than 20 g/L lysine; and
>
> isolating the recombinant antibody, thereby producing a preparation of the recombinant antibody.
>
> 6. The method of claim 1, wherein the culturing produces C-terminal variants of the recombinant antibody that differ in amino acid sequence only by the presence or absence of a lysine at their carboxyl termini, and the method further comprises measuring a level of one or more C-terminal variants of the recombinant antibody in the preparation.

Claim 16 recites:

> 16. A method of producing a preparation of a recombinant antibody, comprising:
>
> culturing a cell in a medium under conditions in which the cell expresses a recombinant antibody, wherein the medium comprises 1.5 g/L arginine to less than 20 g/L arginine, and wherein the culturing produces C-terminal variants of the recombinant antibody

that differ in amino acid sequence only by the presence or absence of a lysine at their carboxyl termini;

isolating the recombinant antibody, thereby producing a preparation of the recombinant antibody; and

measuring a level of one or more C-terminal variants of the recombinant antibody in the preparation.

93. On information and belief, the manufacture of BAT2506 is covered by one or more claims of the '889 patent, literally or under the doctrine of equivalents.

94. [redacted]

95. [redacted] On information and belief, Defendants' cell culture media, comprising basal culture media and feed, has 1.5 g/L lysine to 20 g/L lysine and 1.5 g/L arginine to 20 g/L arginine. Janssen has a reasonable basis for this belief at least because Defendants failed to comply with their obligation under 42 U.S.C. § 262(*l*)(2)(A) to provide such other information that describes the process or processes used to manufacture the BAT2506, despite repeated follow-up requests for this information on [redacted], and [redacted] On information and belief, Defendants withheld this information because they know or have reason to believe that the cell culture media comprises 1.5 g/L lysine to 20 g/L lysine and 1.5 g/L arginine to 20 g/L arginine.

96. Janssen also attempted to ascertain the full composition of the cell culture media by examining materials that Defendants were obligated to provide under 42 U.S.C. § 262(*l*)(2)(A) and 42 U.S.C. § 262(l)(3)(B). Janssen sent a letter to Defendants' counsel on [redacted], requesting more information on the composition of Defendant's cell culture media, specifically identifying [redacted] However, in disclosures pursuant to 42 U.S.C. §§ 262(*l*)(2)(A) and 262(l)(3)(B), Defendants failed to provide complete information that describes [redacted]. Janssen is entitled to utilize the judicial process and the aid of discovery to obtain such information as is required to confirm its belief that the cell culture media comprises 1.5 g/L lysine to 20 g/L lysine and 1.5 g/L arginine to 20 g/L arginine.

97. [redacted]

98. [redacted]

99. Defendants' commercial manufacturing of BAT2506 is intended to [redacted]

[redacted] Thus, [redacted]

100. Defendants are also seeking [redacted].

101. [redacted]

102. Defendants' submission of their aBLA for BAT2506 infringed the '889 patent under 35 U.S.C. § 271(e)(2)(C).

103. Defendants had knowledge of the '889 patent, due to at least Janssen's disclosure of the '889 patent under 42 U.S.C. § 262(*l*)(3)(A) on [redacted] and through the filing of this Complaint. On information and belief, Defendants had been aware of the '889 patent and its relevance to BAT2506 even before Janssen identified it on [redacted]

104. On information and belief, Defendants acted with deliberate and intentional disregard of Janssen's rights under the '889 patent.

105. Janssen has no adequate remedy at law to redress the infringement by Defendants.

106. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the ’889 patent.

COUNT VI

Declaratory Judgment of Infringement of U.S. Patent No. 8,852,889

107. Janssen incorporates by reference the allegations set forth in paragraphs 1-106 above as if fully set forth herein.

108. As set forth in Count V, Defendants would infringe the ’889 patent, literally or under the doctrine of equivalents, if BAT2506 is commercially made, used, offered for sale, sold, or imported in the United States.

109. Because Defendants would only have regulatory approval to sell BAT2506 as described in their aBLA, any imported BAT2506 made by the patented process will not be materially changed by subsequent processes nor be a trivial or nonessential component of another product.

110. Defendants have knowledge of and/or are willfully blind to the fact that the commercial manufacture, use, sale, offer for sale, and/or importation of BAT2506 will directly infringe one or more claims of the ’889 patent, literally or under the doctrine of equivalents.

111. Defendants will knowingly or with willful blindness induce or contribute to another’s direct infringement of one or more claims of the ’889 patent, literally or under the doctrine of equivalents.

112. By filing the aBLA for BAT2506, [redacted]

[redacted]

113. [redacted] presents a controversy of sufficient immediacy and reality to support declaratory judgment of patent infringement under 35 U.S.C. §§ 271(b) and/or 271(g). The BPCIA authorizes a declaratory judgment action for patent infringement due to Defendants' [redacted] failure to comply with their obligations under 42 U.S.C. § 262(*l*)(2)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

114. Janssen therefore seeks declaratory judgment that Defendants will infringe the '889 patent, literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(b) and/or 271(g).

115. Janssen has no adequate remedy at law to redress the infringement by Defendants.

116. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the '889 patent.

COUNT VII

Infringement of U.S. Patent No. 8,956,830 Under 35 U.S.C. § 271(e)(2)(C)

117. Janssen incorporates by reference the allegations set forth in paragraphs 1-116 above as if fully set forth herein.

118. U.S. Patent No. 8,956,830 ("the '830 patent") is titled "Methods of cell culture." The '830 patent was duly and legally issued on February 17, 2015. A true and correct copy of the '830 patent is attached hereto as Exhibit E. JBI is the owner by assignment of the '830 patent.

119. The ’830 patent is directed to and claims methods of manufacturing a preparation of a recombinant antibody. The ’830 patent includes 57 claims, seven of which are independent. Claims 15 and 37 are representative. Claim 15 recites:

> 15. A method of decreasing a level of one or more fucosylated glycans in a recombinant protein preparation, the method comprising:
>
> (a) providing a cell genetically engineered to express a recombinant protein;
>
> (b) culturing the cell in a culture medium comprising DMSO under conditions in which the cell expresses the recombinant protein; and
>
> (c) harvesting a preparation of the recombinant protein produced by the cell, wherein the preparation has a decreased level of at least 10% of one or more fucosylated glycans relative to a level of one or more fucosylated glycans in a preparation of the recombinant protein produced by culturing the cell in the medium not comprising DMSO.

Claim 37 recites:

> 37. A method of producing a recombinant protein preparation, the method comprising:
>
> (a) providing a mammalian cell genetically engineered to express a recombinant protein;
>
> (b) culturing the cell in a culture medium comprising DMSO under conditions in which the cell expresses the recombinant protein;
>
> (c) harvesting a preparation of the recombinant protein produced by the cell; and
>
> (d) formulating the preparation into a drug product if the preparation comprises a level of high mannose glycans at least 20% higher than a level of high mannose glycans in a preparation produced by culturing the cell in the medium not comprising DMSO.

120. On information and belief, the manufacture of BAT2506 is covered by one or more claims of the ’830 patent, literally or under the doctrine of equivalents.

121. [redacted]

122. Defendants use a method to produce BAT2506 that includes [redacted].

[redacted]

124. On information and belief, the cell culture media comprise DMSO. Janssen has a reasonable basis for this belief at least because Defendants failed to comply with their obligation under 42 U.S.C. § 262(*l*)(2)(A) to provide such other information that describes the process or processes used to manufacture the BAT2506, despite repeated follow-up requests for this information on [redacted], and [redacted]. On information and belief, Defendants withheld this information because they know or have reason to believe that the cell culture media comprise DMSO.

125. Janssen also attempted to ascertain the full composition of the cell culture media by examining materials that Defendants were obligated to provide under 42 U.S.C. § 262(*l*)(2)(A) and 42 U.S.C. § 262(l)(3)(B). Janssen sent a letter to Defendants' counsel on [redacted] requesting more information on the composition of Defendant's cell culture media, specifically identifying [redacted]

[redacted]

However, in disclosures pursuant to 42 U.S.C. §§ 262(*l*)(2)(A) and 262(l)(3)(B), Defendants failed to provide complete information that describes the cell culture media used for manufacturing of the BAT2506, including for instance the composition of [redacted] Janssen is entitled to utilize the judicial process and the aid of discovery to obtain such information as is required to confirm its belief that the cell culture media comprise DMSO.

126. [redacted]

127. On information and belief, BAT2506 has a decreased level of at least 10% of one or more fucosylated glycans relative to a level of one or more fucosylated glycans in a preparation produced by culturing the cell in the medium not comprising DMSO. Janssen has a reasonable basis for this belief at least because Defendants failed to comply with their obligation under 42 U.S.C. § 262(*l*)(2)(A) to provide such other information that describes the process or processes used to manufacture the BAT2506, despite repeated follow-up requests for this information on [redacted], and [redacted] On information and belief, Defendants withheld this information because they know or have reason to believe that BAT2506 has a decreased level of at least 10% of one or more fucosylated glycans relative to a level of one or more fucosylated glycans in a preparation produced by culturing the cell in the medium not comprising DMSO.

128. Janssen also attempted to ascertain that Defendants have a decreased level of at least 10% of one or more fucosylated glycans relative to a level of one or more fucosylated glycans in a preparation produced by culturing the cell in the medium not comprising DMSO, by examining materials that Defendants were obligated to provide under 42 U.S.C. § 262(*l*)(2)(A). Janssen sent a letter to Defendants' counsel on [redacted] requesting more information on their

[redacted] In its letter, Janssen requested information on the [redacted] Further, [redacted] However, Defendants failed to provide complete information that describes their process used to manufacture BAT2506 and [redacted]. Janssen is entitled to utilize the judicial process and the aid of discovery to obtain such information as is required to confirm its belief that that BAT2506 has a decreased level of at least 10% of one or more fucosylated glycans relative to a level of one or more fucosylated glycans in a preparation produced by culturing the cell in the medium not comprising DMSO.

129. Defendants' commercial manufacturing of BAT2506 is intended to produce [redacted]

130. Defendants are also seeking [redacted].

[redacted]

131. [redacted]

[redacted]

132. On information and belief, Defendants formulate BAT2506 if the preparation comprises a level of high mannose glycans at least 20% higher than a level of high mannose glycans in a preparation produced by culturing the cell in the medium not comprising DMSO. Janssen has a reasonable basis for this belief at least because Defendants failed to comply with their obligation under 42 U.S.C. § 262(*l*)(2)(A) to provide such other information that describes the process or processes used to manufacture the BAT2506, despite repeated follow-up requests for this information on [redacted] and [redacted]. On information and belief, Defendants withheld this information because they know or have reason to believe that it formulates BAT2506 if the preparation comprises a level of high mannose glycans at least 20%

higher than a level of high mannose glycans in a preparation produced by culturing the cell in the medium not comprising DMSO.

133. Janssen also attempted to ascertain that Defendants formulate BAT2506 if the preparation comprises a level of high mannose glycans at least 20% higher than a level of high mannose glycans in a preparation produced by culturing the cell in the medium not comprising DMSO, by examining materials that Defendants were obligated to provide under 42 U.S.C. § 262(*l*)(2)(A). Janssen sent a letter to Defendants' counsel on [redacted], requesting more information on their [redacted] In its letter, Janssen requested information on [redacted] Further, Janssen requested information regarding [redacted] However, Defendants failed to provide complete information that describes their process used to manufacture BAT2506 [redacted]. Janssen is entitled to utilize the judicial process and the aid of discovery to obtain such information as is required to confirm its belief that Defendants formulate BAT2506 if the preparation comprises a level of high mannose glycans at least 20% higher than a level of high mannose glycans in a preparation produced by culturing the cell in the medium not comprising DMSO.

134. Defendants' submission of their aBLA for BAT2506 infringed the '830 patent under 35 U.S.C. § 271(e)(2)(C).

135. Defendants have knowledge of the '830 patent, due to at least Janssen's disclosure of the '830 patent under 42 U.S.C. § 262(*l*)(3)(A) on [redacted] and through the filing of this Complaint. On information and belief, Defendants had been aware of the '830 patent and its relevance to BAT2506 even before Janssen identified it on [redacted]

136. On information and belief, Defendants acted with deliberate and intentional disregard of Janssen's rights under the '830 patent.

137. Janssen has no adequate remedy at law to redress the infringement by Defendants.

138. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the '830 patent.

COUNT VIII

Declaratory Judgment of Infringement of U.S. Patent No. 8,956,830

139. Janssen incorporates by reference the allegations set forth in paragraphs 1-138 above as if fully set forth herein.

140. As set forth in Count VII, Defendants would infringe the '830 patent, literally or under the doctrine of equivalents, if BAT2506 is commercially made, used, offered for sale, sold, or imported in the United States.

141. Because Defendants would only have regulatory approval to sell BAT2506 as described in their aBLA, any imported BAT2506 made by the patented process will not be materially changed by subsequent processes nor be a trivial or nonessential component of another product.

142. Defendants have knowledge of and/or are willfully blind to the fact that the commercial manufacture, use, sale, offer for sale, and/or importation of BAT2506 will directly infringe one or more claims of the ’830 patent, literally or under the doctrine of equivalents.

143. Defendants will knowingly or with willful blindness induce or contribute to another’s direct infringement of one or more claims of the ’830 patent, literally or under the doctrine of equivalents.

144. By filing the aBLA for BAT2506, [redacted]

145. [redacted] presents a controversy of sufficient immediacy and reality to support declaratory judgment of patent infringement under 35 U.S.C. §§ 271(b) and/or 271(g). The BPCIA authorizes a declaratory judgment action for patent infringement due to Defendants’ [redacted] failure to comply with their obligations under 42 U.S.C. § 262(*l*)(2)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

146. Janssen therefore seeks declaratory judgment that Defendants will infringe the ’830 patent, literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(b) and/or 271(g).

147. Janssen has no adequate remedy at law to redress the infringement by Defendants.

148. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the ’830 patent.

COUNT IX

Infringement of U.S. Patent No. 9,170,249 Under 35 U.S.C. § 271(e)(2)(C)

149. Janssen incorporates by reference the allegations set forth in paragraphs 1-148 above as if fully set forth herein.

150. U.S. Patent No. 9,170,249 ("the '249 patent") is titled "N-acetylhexosamine-containing N-glycans in glycoprotein products." The '249 patent was duly and legally issued on October 27, 2015. A true and correct copy of the '249 patent is attached hereto as Exhibit F. JBI is the exclusive licensee with the right to enforce the '249 patent.

151. The '249 patent is directed to and claims methods for manufacturing glycoprotein preparations as pharmaceutical products. The '249 patent includes 26 claims, one of which is independent. Claim 1 is representative and recites:

> 1. A method for manufacturing a glycoprotein preparation, the method comprising:
>
> culturing cells to produce a recombinant glycoprotein preparation;
>
> determining the absence, presence or amount of an N-linked glycan consisting of a single N-acetylhexosamine residue in the produced preparation; and
>
> processing the glycoprotein preparation as a pharmaceutical product based upon the determination.

152. On information and belief, the manufacture of BAT2506 is covered by one or more claims of the '249 patent, literally or under the doctrine of equivalents.

153. [redacted]

154. [redacted]

155. On information and belief, Defendants determine the absence, presence, or amount of an N-linked glycan consisting of a single N-acetylhexosamine residue in the produced preparation and process the glycoprotein preparation as a pharmaceutical product based upon the determination. Janssen has a reasonable basis for this belief at least because Defendants failed to comply with their obligation under 42 U.S.C. § 262(*l*)(2)(A) to provide such other information that describes the process or processes used to manufacture the BAT2506, despite repeated follow-up requests for this information on [redacted], and [redacted]. On information and belief, Defendants withheld this information because they know or have reason to believe that Defendants perform the claimed steps.

156. Janssen also attempted to ascertain details of Defendants' glycoprotein preparations by examining materials that Defendants were obligated to provide under 42 U.S.C. § 262(*l*)(2)(A). Janssen sent a letter to Defendants' counsel on [redacted], requesting more information on [redacted],

[redacted]. Janssen is entitled to utilize the judicial process and the aid of discovery to obtain such information as is required to confirm its belief that Defendants perform the claimed steps.

157. Defendants' submission of their aBLA for BAT2506 infringed the '249 patent under 35 U.S.C. § 271(e)(2)(C).

158. Defendants have knowledge of the '249 patent, due to at least Janssen's disclosure of the '249 patent under 42 U.S.C. § 262(*l*)(3)(A) on [redacted] and through the filing of this Complaint. On information and belief, Defendants have been aware of the '249 patent and its relevance to BAT2506 even before Janssen identified it on [redacted]

159. On information and belief, Defendants acted with deliberate and intentional disregard of Janssen's rights under the '249 patent.

160. Janssen has no adequate remedy at law to redress the infringement by Defendants.

161. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the '249 patent.

COUNT X

Declaratory Judgment of Infringement of U.S. Patent No. 9,170,249

162. Janssen incorporates by reference the allegations set forth in paragraphs 1-161 above as if fully set forth herein.

163. As set forth in Count IX, Defendants would infringe the '249 patent, literally or under the doctrine of equivalents, if BAT2506 is commercially made, used, offered for sale, sold, or imported in the United States.

164. Because Defendants would only have regulatory approval to sell BAT2506 as described in their aBLA, any imported BAT2506 made by the patented process will not be

materially changed by subsequent processes nor be a trivial or nonessential component of another product.

165. Defendants have knowledge of and/or are willfully blind to the fact that the commercial manufacture, use, sale, offer for sale, and/or importation of BAT2506 will directly infringe one or more claims of the '249 patent, literally or under the doctrine of equivalents.

166. Defendants will knowingly or with willful blindness induce or contribute to another's direct infringement of one or more claims of the '249 patent, literally or under the doctrine of equivalents.

167. By filing the aBLA for BAT2506, [redacted]

168. [redacted] presents a controversy of sufficient immediacy and reality to support declaratory judgment of patent infringement under 35 U.S.C. §§ 271(b) and/or 271(g). The BPCIA authorizes a declaratory judgment action for patent infringement due to Defendants' [redacted] failure to comply with their obligations under 42 U.S.C. § 262(*l*)(2)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

169. Janssen therefore seeks declaratory judgment that Defendants will infringe the '249 patent, literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(b) and/or 271(g).

170. Janssen has no adequate remedy at law to redress the infringement by Defendants.

171. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the ’249 patent.

COUNT XI

Infringement of U.S. Patent No. 9,217,168 Under 35 U.S.C. § 271(e)(2)(C)

172. Janssen incorporates by reference the allegations set forth in paragraphs 1-171 above as if fully set forth herein.

173. U.S. Patent No. 9,217,168 (“the ’168 patent”) is titled “Methods of cell culture.” The ’168 patent was duly and legally issued on December 22, 2015. A true and correct copy of the ’168 patent is attached hereto as Exhibit G. JBI is the owner by assignment of the ’168 patent.

174. The ’168 patent is directed to and claims methods of producing a recombinant protein preparation. The ’168 patent includes 28 claims, four of which are independent. Claims 13 and 16 are representative. Claim 13 recites:

> 13. A method of increasing a level of one or more of galactosylated glycans, and sialylated glycans in a recombinant protein preparation, the method comprising:
>
> (a) providing a cell genetically engineered to express a recombinant protein;
>
> (b) culturing the cell in a culture medium comprising 0.1 mg/L to 10 mg/L putrescine under conditions in which the cell expresses the recombinant protein; and
>
> (c) harvesting a preparation of the recombinant protein produced by the cell, wherein the preparation has a level of one or more of galactosylated glycans, and sialylated glycans that is at least 10% higher than a level of one or more of galactosylated glycans and sialylated glycans in a preparation of the recombinant protein produced by culturing the cell in the medium not comprising 0.1 mg/L to 10 mg/L putrescine.

Claim 16 recites:

> 16. A method of decreasing a level of one or more high mannose glycans in a recombinant protein preparation, the method comprising:
>
> (a) providing a cell genetically engineered to express a recombinant protein;
>
> (b) culturing the cell in a culture medium comprising 0.1 mg/L to 10 mg/L putrescine under conditions in which the cell expresses the recombinant protein; and
>
> (c) harvesting a preparation of the recombinant protein produced by the cell, wherein the preparation has a level of high mannose glycans that is at least 10% lower than a level of high mannose glycans in a preparation of the recombinant protein produced by culturing the cell in the medium not comprising 0.1 mg/L to 10 mg/L putrescine.

175. The manufacture of BAT2506 is covered by one or more claims of the ’168 patent, literally or under the doctrine of equivalents.

176. [redacted]

177. [redacted]

178. [redacted]

[redacted] Janssen also has a reasonable basis for this conclusion at least because Defendants failed to comply with their obligation under 42 U.S.C. § 262(*l*)(2)(A) to provide such other information that describes the process or processes used to manufacture the BAT2506, despite repeated follow-up requests for this information on [redacted], and [redacted]. On information and belief, Defendants withheld this information because they know or have reason to believe that the [redacted]. Further, [redacted]

179. Janssen also attempted to ascertain the full composition of the cell culture media by examining materials that Defendants were obligated to provide under 42 U.S.C. § 262(*l*)(2)(A) and 42 U.S.C. § 262(l)(3)(B). Janssen sent a letter to Defendants' counsel on [redacted], requesting more information on the composition of Defendant's cell culture media, specifically identifying [redacted]. However, in disclosures pursuant to 42 U.S.C. §§ 262(*l*)(2)(A) and 262(l)(3)(B), Defendants failed to provide complete information that describes the cell culture media used for manufacturing of the BAT2506, including for instance the composition of [redacted]. Janssen is entitled to utilize the judicial process and the aid of discovery to obtain such information as is required to further confirm that the cell culture media comprise 0.1 mg/L to 10 mg/L putrescine.

180. [redacted]

181. BAT2506 has a level of galactosylated glycans that is at least 10% higher than a level of galactosylated glycans in a preparation produced by culturing the cell in the medium not

comprising 0.1 mg/L to 10 mg/L putrescine, and a level of sialylated glycans that is at least 10% higher than a level of sialylated glycans in a preparation produced by culturing the cell in the medium not comprising 0.1 mg/L to 10 mg/L putrescine. *See, e.g.*, Ex. G, at col. 4:40-48; 6:17-25; 11:51-56. Janssen also has a reasonable basis for this conclusion at least because Defendants failed to comply with their obligation under 42 U.S.C. § 262(*l*)(2)(A) to provide such other information that describes the process or processes used to manufacture the BAT2506, despite repeated follow-up requests for this information on [redacted], and [redacted]. On information and belief, Defendants withheld this information because they know or have reason to believe that BAT2506 has a level of galactosylated glycans that is at least 10% higher than a level of galactosylated glycans in a preparation produced by culturing the cell in the medium not comprising 0.1 mg/L to 10 mg/L putrescine, and a level of sialylated glycans that is at least 10% higher than a level of sialylated glycans in a preparation produced by culturing the cell in the medium not comprising 0.1 mg/L to 10 mg/L putrescine.

182. Janssen also attempted to ascertain that BAT2506 has a level of galactosylated glycans that is at least 10% higher than a level of galactosylated glycans in a preparation produced by culturing the cell in the medium not comprising 0.1 mg/L to 10 mg/L putrescine, and a level of sialylated glycans that is at least 10% higher than a level of sialylated glycans in a preparation produced by culturing the cell in the medium not comprising 0.1 mg/L to 10 mg/L putrescine, by examining materials that Defendants were obligated to provide under 42 U.S.C. § 262(*l*)(2)(A). Janssen sent a letter to Defendants' counsel on [redacted], requesting more information on [redacted]. Defendants conducted a [redacted]

[redacted] In its letter, Janssen requested information on [redacted] Further, Janssen requested information regarding [redacted] However, Defendants failed to provide complete information that describes [redacted] process used to manufacture BAT2506. Janssen is entitled to utilize the judicial process and the aid of discovery to obtain such information as is required to further confirm that BAT2506 has a level of galactosylated glycans that is at least 10% higher than a level of galactosylated glycans in a preparation produced by culturing the cell in the medium not comprising 0.1 mg/L to 10 mg/L putrescine, and a level of sialylated glycans that is at least 10% higher than a level of sialylated glycans in a preparation produced by culturing the cell in the medium not comprising 0.1 mg/L to 10 mg/L putrescine.

183. BAT2506 has a level of high mannose glycans that is at least 10% lower than a level of high mannose glycans in a preparation produced by culturing the cell in the medium not comprising 0.1 mg/L to 10 mg/L putrescine. *See, e.g.*, Ex. G, at col. 4:49-55; 6:26-32; 11:51-56. Janssen has a reasonable basis for this conclusion at least because Defendants failed to comply with their obligation under 42 U.S.C. § 262(*l*)(2)(A) to provide such other information that describes the process or processes used to manufacture the BAT2506, despite repeated follow-up requests for this information on [redacted], and [redacted]. On information and belief, Defendants withheld this information because they know or have reason to believe that

BAT2506 has a level of high mannose glycans that is at least 10% lower than a level of high mannose glycans in a preparation produced by culturing the cell in the medium not comprising 0.1 mg/L to 10 mg/L putrescine.

184. Janssen also attempted to ascertain that BAT2506 has a level of high mannose glycans that is at least 10% lower than a level of high mannose glycans in a preparation produced by culturing the cell in the medium not comprising 0.1 mg/L to 10 mg/L putrescine, by examining materials that Defendants were obligated to provide under 42 U.S.C. § 262(*l*)(2)(A). Janssen sent a letter to Defendants' counsel on [redacted], requesting more information on [redacted]. Defendants conducted a [redacted] In its letter, Janssen requested information on the [redacted] Further, Janssen requested information regarding [redacted] However, Defendants failed to provide complete information that describes the media components tested, the results achieved, and their process used to manufacture BAT2506. Janssen is entitled to utilize the judicial process and the aid of discovery to obtain such information as is required to further confirm that BAT2506 has a level of high mannose glycans that is at least 10% lower than a level of high mannose glycans in a preparation produced by culturing the cell in the medium not comprising 0.1 mg/L to 10 mg/L putrescine.

185. Defendants' submission of their aBLA for BAT2506 infringed the '168 patent under 35 U.S.C. § 271(e)(2)(C).

186. Defendants had knowledge of the '168 patent, due to at least Janssen's disclosure of the '168 patent under 42 U.S.C. § 262(*l*)(3)(A) on [redacted] and through the filing of this Complaint. On information and belief, Defendants have been aware of the '168 patent and its relevance to BAT2506 even before Janssen identified it on [redacted]

187. On information and belief, Defendants acted with deliberate and intentional disregard of Janssen's rights under the '168 patent.

188. Janssen has no adequate remedy at law to redress the infringement by Defendants.

189. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the '168 patent.

COUNT XII

Declaratory Judgment of Infringement of U.S. Patent No. 9,217,168

190. Janssen incorporates by reference the allegations set forth in paragraphs 1-189 above as if fully set forth herein.

191. As set forth in Count XI, Defendants would infringe the '168 patent, literally or under the doctrine of equivalents, if BAT2506 is commercially made, used, offered for sale, sold, or imported in the United States.

192. Because Defendants would only have regulatory approval to sell BAT2506 as described in their aBLA, any imported BAT2506 made by the patented process will not be materially changed by subsequent processes nor be a trivial or nonessential component of another product.

193. Defendants have knowledge of and/or are willfully blind to the fact that the commercial manufacture, use, sale, offer for sale, and/or importation of BAT2506 will directly infringe one or more claims of the '168 patent, literally or under the doctrine of equivalents.

194. Defendants will knowingly or with willful blindness induce or contribute to another's direct infringement of one or more claims of the '168 patent, literally or under the doctrine of equivalents.

195. By filing the aBLA for BAT2506, [redacted]

196. [redacted] presents a controversy of sufficient immediacy and reality to support declaratory judgment of patent infringement under 35 U.S.C. §§ 271(b) and/or 271(g). The BPCIA authorizes a declaratory judgment action for patent infringement due to Defendants' [redacted] failure to comply with their obligations under 42 U.S.C. § 262(*l*)(2)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

197. Janssen therefore seeks declaratory judgment that Defendants will infringe the '168 patent, literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(b) and/or 271(g).

198. Janssen has no adequate remedy at law to redress the infringement by Defendants.

199. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the '168 patent.

COUNT XIII

Infringement of U.S. Patent No. 9,475,858 Under 35 U.S.C. § 271(e)(2)(C)

200. Janssen incorporates by reference the allegations set forth in paragraphs 1-199 above as if fully set forth herein.

201. U.S. Patent No. 9,475,858 ("the '858 patent") is titled "Cell culture process." The '858 patent was duly and legally issued on October 25, 2016. A true and correct copy of the '858 patent is attached hereto as Exhibit H. JBI is the owner by assignment of the '858 patent.

202. The '858 patent is directed to and claims methods of manufacturing a preparation of a recombinant antibody. The '858 patent includes 38 claims, two of which are independent. Claims 1 and 20 are representative. Claim 1 recites:

> 1. A method of manufacturing a preparation of a recombinant antibody, comprising:
>
> culturing a cell in a medium comprising 2 g/L lysine to 8 g/L lysine under conditions in which the cell expresses a recombinant antibody;
>
> isolating the recombinant antibody, thereby producing a preparation of the recombinant antibody; and
>
> formulating the preparation into a drug product if the preparation meets a target value of C-terminal variants of the recombinant antibody, wherein the C-terminal variants differ in amino acid sequence only by the presence or absence of a lysine at their carboxyl termini.

Claim 20 recites:

> 20. A method of manufacturing a preparation of a recombinant antibody, comprising:
>
> culturing a cell in a medium comprising 2 g/L arginine to 8 g/L arginine under conditions in which the cell expresses a recombinant antibody;
>
> isolating the recombinant antibody, thereby producing a preparation of the recombinant antibody;

> and formulating the preparation into a drug product if the preparation meets a target value of C-terminal variants of the recombinant antibody, wherein the C-terminal variants differ in amino acid sequence only by the presence or absence of a lysine at their carboxyl termini.

203. On information and belief, the manufacture of BAT2506 is covered by one or more claims of the '858 patent, literally or under the doctrine of equivalents.

204. [redacted]

205. [redacted] On information and belief, Defendants' cell culture media, comprising basal culture media and feed, has 2 g/L lysine to 8 g/L lysine and 2 g/L arginine to 8 g/L arginine. Janssen has a reasonable basis for this belief at least because Defendants failed to comply with their obligation under 42 U.S.C. § 262(*l*)(2)(A) to provide such other information that describes the process or processes used to manufacture the BAT2506, despite repeated follow-up requests for this information on [redacted], and [redacted] On information and belief, Defendants withheld this information because they know or have reason to believe that the cell culture media comprise 2 g/L lysine to 8 g/L lysine and 2 g/L arginine to 8 g/L arginine.

206. Janssen also attempted to ascertain the full composition of the cell culture media by examining materials that Defendants were obligated to provide under 42 U.S.C. § 262(*l*)(2)(A)

and 42 U.S.C. § 262(l)(3)(B). Janssen sent a letter to Defendants' counsel on [redacted], requesting more information on the composition of Defendant's cell culture media, specifically identifying [redacted] However, in disclosures pursuant to 42 U.S.C. §§ 262(*l*)(2)(A) and 262(l)(3)(B), Defendants failed to provide complete information that describes the cell culture media used for manufacturing of the BAT2506, including for instance the composition of [redacted]. Janssen is entitled to utilize the judicial process and the aid of discovery to obtain such information as is required to confirm its belief that the cell culture media comprise 2 g/L lysine to 8 g/L lysine and 2 g/L arginine to 8 g/L arginine.

207. [redacted]

208. Defendants' commercial manufacturing of BAT2506 is intended to produce [redacted]. Thus, [redacted]

209. Defendants are also seeking [redacted].

[redacted]

210. [redacted]

211. [redacted] On information and belief, Defendants [redacted]

212. Defendants' submission of their aBLA for BAT2506 infringed the '858 patent under 35 U.S.C. § 271(e)(2)(C).

213. Defendants have knowledge of the '858 patent, due to at least Janssen's disclosure of the '858 patent under 42 U.S.C. § 262(*l*)(3)(A) on [redacted] and through the filing of this Complaint. On information and belief, Defendants have been aware of the '858 patent and its relevance to BAT2506 even before Janssen identified it on [redacted]

214. On information and belief, Defendants acted with deliberate and intentional disregard of Janssen's rights under the '858 patent.

215. Janssen has no adequate remedy at law to redress the infringement by Defendants.

216. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the '858 patent.

COUNT XIV

Declaratory Judgment of Infringement of U.S. Patent No. 9,475,858

217. Janssen incorporates by reference the allegations set forth in paragraphs 1-216 above as if fully set forth herein.

218. As set forth in Count XIII, Defendants would infringe the '858 patent, literally or under the doctrine of equivalents, if BAT2506 is commercially made, used, offered for sale, sold, or imported in the United States.

219. Because Defendants would only have regulatory approval to sell BAT2506 as described in their aBLA, any imported BAT2506 made by the patented process will not be materially changed by subsequent processes nor be a trivial or nonessential component of another product.

220. Defendants have knowledge of and/or are willfully blind to the fact that the commercial manufacture, use, sale, offer for sale, and/or importation of BAT2506 will directly infringe one or more claims of the '858 patent, literally or under the doctrine of equivalents.

221. Defendants will knowingly or with willful blindness induce or contribute to another's direct infringement of one or more claims of the '858 patent, literally or under the doctrine of equivalents.

222. By filing the aBLA for BAT2506, [redacted]

223. [redacted] presents a controversy of sufficient immediacy and reality to support declaratory judgment of patent infringement under 35 U.S.C. §§ 271(b) and/or 271(g). The BPCIA authorizes a declaratory judgment action for patent infringement due to Defendants' [redacted] failure to comply with their obligations under 42 U.S.C. § 262(*l*)(2)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

224. Janssen therefore seeks declaratory judgment that Defendants will infringe the '858 patent, literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(b) and/or 271(g).

225. Janssen has no adequate remedy at law to redress the infringement by Defendants.

226. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the '858 patent.

COUNT XV

Infringement of U.S. Patent No. 9,487,810 Under 35 U.S.C. § 271(e)(2)(C)

227. Janssen incorporates by reference the allegations set forth in paragraphs 1-226 above as if fully set forth herein.

228. U.S. Patent No. 9,487,810 ("the '7810 patent") is titled "Methods of cell culture." The '7810 patent was duly and legally issued on November 8, 2016. A true and correct copy of the '7810 patent is attached hereto as Exhibit I. JBI is the owner by assignment of the '7810 patent.

229. The '7810 patent is directed to and claims methods of producing a recombinant protein preparation. The '7810 patent includes 69 claims, seven of which are independent. Claim 1 is representative and recites:

> 1. A method of producing a recombinant protein preparation having a target value of high mannose glycans, the method comprising:
>
> (a) providing a mammalian cell genetically engineered to express a recombinant protein;
>
> (b) culturing the cell in a culture medium comprising dimethylsulfoxide (DMSO) under conditions in which the cell expresses the recombinant protein; and
>
> (c) harvesting a preparation of the recombinant protein produced by the cell that meets the target value, wherein the target value is 0.1% to 20% high mannose glycans.

230. On information and belief, the manufacture of BAT2506 is covered by one or more claims of the '7810 patent, literally or under the doctrine of equivalents.

231. [redacted]

232. [redacted].

233. Defendants [redacted]

[redacted]

234. On information and belief, the cell culture media comprise DMSO. Janssen has a reasonable basis for this belief at least because Defendants failed to comply with their obligation under 42 U.S.C. § 262(*l*)(2)(A) to provide such other information that describes the process or processes used to manufacture the BAT2506, despite repeated follow-up requests for this information on [redacted], and [redacted]. On information and belief, Defendants withheld this information because they know or have reason to believe that the cell culture media comprise DMSO.

235. Janssen also attempted to ascertain the full composition of the cell culture media by examining materials that Defendants were obligated to provide under 42 U.S.C. § 262(*l*)(2)(A) and 42 U.S.C. § 262(l)(3)(B). Janssen sent a letter to Defendants' counsel on [redacted], requesting more information on the composition of Defendant's cell culture media, specifically identifying [redacted] However, in disclosures pursuant to 42 U.S.C. §§ 262(*l*)(2)(A) and 262(l)(3)(B), Defendants failed to provide complete information that describes the cell culture media used for manufacturing of the BAT2506, including for instance the composition of [redacted]. Janssen is entitled to utilize the judicial process and the aid of discovery to obtain such information as is required to confirm its belief that the cell culture media comprise DMSO.

236. [redacted]

237. Defendants' commercial manufacturing of BAT2506 is intended to produce [redacted]®. [redacted]

238. Defendants are also seeking i[redacted]

239. [redacted]

240. Defendants' submission of their aBLA for BAT2506 infringed the '7810 patent under 35 U.S.C. § 271(e)(2)(C).

241. Defendants have knowledge of the '7810 patent, due to at least Janssen's disclosure of the '7810 patent under 42 U.S.C. § 262(*l*)(3)(A) on [redacted] and through the filing of this Complaint. On information and belief, Defendants had been aware of the '7810 patent and its relevance to BAT2506 even before Janssen identified it on [redacted]

242. On information and belief, Defendants acted with deliberate and intentional disregard of Janssen's rights under the '7810 patent.

243. Janssen has no adequate remedy at law to redress the infringement by Defendants.

244. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the '7810 patent.

COUNT XVI

Declaratory Judgment of Infringement of U.S. Patent No. 9,487,810

245. Janssen incorporates by reference the allegations set forth in paragraphs 1-244 above as if fully set forth herein.

246. As set forth in Count XV, Defendants would infringe the '7810 patent, literally or under the doctrine of equivalents, if BAT2506 is commercially made, used, offered for sale, sold, or imported in the United States.

247. Because Defendants would only have regulatory approval to sell BAT2506 as described in their aBLA, any imported BAT2506 made by the patented process will not be materially changed by subsequent processes nor be a trivial or nonessential component of another product.

248. Defendants have knowledge of and/or are willfully blind to the fact that the commercial manufacture, use, sale, offer for sale, and/or importation of BAT2506 will directly infringe one or more claims of the ’7810 patent, literally or under the doctrine of equivalents.

249. Defendants will knowingly or with willful blindness induce or contribute to another’s direct infringement of one or more claims of the ’7810 patent, literally or under the doctrine of equivalents.

250. By filing the aBLA for BAT2506, [redacted]

251. [redacted] presents a controversy of sufficient immediacy and reality to support declaratory judgment of patent infringement under 35 U.S.C. §§ 271(b) and/or 271(g). The BPCIA authorizes a declaratory judgment action for patent infringement due to Defendants’ [redacted] failure to comply with their obligations under 42 U.S.C. § 262(*l*)(2)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

252. Janssen therefore seeks declaratory judgment that Defendants will infringe the ’7810 patent, literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(b) and/or 271(g).

253. Janssen has no adequate remedy at law to redress the infringement by Defendants.

254. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the ’7810 patent.

COUNT XVII

Infringement of U.S. Patent No. 9,663,810 Under 35 U.S.C. § 271(e)(2)(C)

255. Janssen incorporates by reference the allegations set forth in paragraphs 1-254 above as if fully set forth herein.

256. U.S. Patent No. 9,663,810 (“the ’3810 patent”) is titled “Methods of cell culture.” The ’3810 patent was duly and legally issued on May 30, 2017. A true and correct copy of the ’3810 patent is attached hereto as Exhibit J. JBI is the owner by assignment of the ’3810 patent.

257. The ’3810 patent is directed to and claims methods of producing a recombinant protein preparation. The ’3810 patent includes 24 claims, three of which are independent. Claim 14 is representative and recites:

> 14. A method of increasing a level of fucosylated glycans in a recombinant protein preparation, the method comprising:
>
> (a) providing a cell genetically engineered to express a recombinant protein;
>
> (b) culturing the cell in a culture medium comprising 0.1 mg/L to 10 mg/L putrescine under conditions in which the cell expresses the recombinant protein; and
>
> (c) harvesting a preparation of the recombinant protein produced by the cell, wherein the preparation has a level of fucosylated glycans, that is at least 10% higher than a level of fucosylated glycans in a preparation of the recombinant protein produced by culturing the cell in the medium not comprising 0.1 mg/L to 10 mg/L putrescine.

258. The manufacture of BAT2506 is covered by one or more claims of the ’3810 patent, literally or under the doctrine of equivalents.

259. [redacted]

[redacted].

[redacted]

261. [redacted]

262. Janssen also has a reasonable basis for this conclusion at least because Defendants failed to comply with their obligation under 42 U.S.C. § 262(*l*)(2)(A) to provide such other information that describes the process or processes used to manufacture the BAT2506, despite repeated follow-up requests for this information on [redacted] and [redacted] On information and belief, Defendants withheld this information because they know or have reason to believe that the cell culture media comprise 0.1 mg/L to 10 mg/L putrescine. Further, Defendants did not deny [redacted].

263. Janssen also attempted to ascertain the composition of the cell culture media by examining materials that Defendants were obligated to provide under 42 U.S.C. § 262(*l*)(2)(A) and 42 U.S.C. § 262(l)(3)(B). Janssen sent a letter to Defendants' counsel on [redacted] requesting more information on the composition of Defendant's cell culture media, specifically identifying [redacted]

[redacted]

However, in disclosures pursuant to 42 U.S.C. §§ 262(*l*)(2)(A) and 262(l)(3)(B), Defendants failed to provide complete information that describes the cell culture media used for manufacturing of the BAT2506, including for instance the composition of [redacted]. Janssen is entitled to utilize the judicial process and the aid of discovery to obtain such information as is required to further confirm that the cell culture media comprise 0.1 mg/L to 10 mg/L putrescine.

264. [redacted]

[redacted]

265. BAT2506's level of fucosylated glycans is at least 10% higher than a level of fucosylated glycans in a preparation produced by culturing the cell in the medium not comprising 0.1 mg/L to 10 mg/L putrescine. *See, e.g.*, Ex. J, at col. 4:43-51; 6:20-28; 11:63:12-1. Janssen has a reasonable basis for this conclusion at least because Defendants failed to comply with their obligation under 42 U.S.C. § 262(*l*)(2)(A) to provide such other information that describes the process or processes used to manufacture the BAT2506, despite repeated follow-up requests for this information on [redacted], and [redacted] On information and belief, Defendants withheld this information because they know or have reason to believe that BAT2506's level of fucosylated glycans is at least 10% higher than a level of fucosylated glycans in a preparation produced by culturing the cell in the medium not comprising 0.1 mg/L to 10 mg/L putrescine.

266. Janssen also attempted to ascertain that BAT2506 has a level of fucosylated glycans is at least 10% higher than a level of fucosylated glycans in a preparation produced by culturing the cell in the medium not comprising 0.1 mg/L to 10 mg/L putrescine, by examining materials that Defendants were obligated to provide under 42 U.S.C. § 262(*l*)(2)(A). Janssen sent a letter to

Defendants' counsel on [redacted], requesting more information on [redacted]. Defendants conducted [redacted] In its letter, Janssen requested information [redacted] Further, Janssen requested information regarding the [redacted] However, Defendants failed to provide complete information that describes their process used to manufacture BAT2506 and [redacted] Janssen is entitled to utilize the judicial process and the aid of discovery to obtain such information as is required to further confirm that BAT2506 has a level of fucosylated glycans is at least 10% higher than a level of fucosylated glycans in a preparation produced by culturing the cell in the medium not comprising 0.1 mg/L to 10 mg/L putrescine.

267. Defendants' submission of their aBLA for BAT2506 infringed the '3810 patent under 35 U.S.C. § 271(e)(2)(C).

268. Defendants had knowledge of the '3810 patent, due to at least Janssen's disclosure of the '3810 patent under 42 U.S.C. § 262(*l*)(3)(A) on [redacted] and through the filing of this Complaint. On information and belief, Defendants have been aware of the '3810 patent and its relevance to BAT2506 even before Janssen identified it on [redacted]

269. On information and belief, Defendants acted with deliberate and intentional disregard of Janssen's rights under the '3810 patent.

270. Janssen has no adequate remedy at law to redress the infringement by Defendants.

271. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the ’3810 patent.

COUNT XVIII

Declaratory Judgment of Infringement of U.S. Patent No. 9,663,810

272. Janssen incorporates by reference the allegations set forth in paragraphs 1-271 above as if fully set forth herein.

273. As set forth Count XVII, Defendants would infringe the ’3810 patent, literally or under the doctrine of equivalents, if BAT2506 is commercially made, used, offered for sale, sold, or imported in the United States.

274. Because Defendants would only have regulatory approval to sell BAT2506 as described in their aBLA, any imported BAT2506 made by the patented process will not be materially changed by subsequent processes nor be a trivial or nonessential component of another product.

275. Defendants have knowledge of and/or are willfully blind to the fact that the commercial manufacture, use, sale, offer for sale, and/or importation of BAT2506 will directly infringe one or more claims of the ’3810 patent, literally or under the doctrine of equivalents.

276. Defendants will knowingly or with willful blindness induce or contribute to another’s direct infringement of one or more claims of the ’3810 patent, literally or under the doctrine of equivalents.

277. By filing the aBLA for BAT2506, and [redacted]

[redacted]

278. [redacted] presents a controversy of sufficient immediacy and reality to support declaratory judgment of patent infringement under 35 U.S.C. §§ 271(b) and/or 271(g). The BPCIA authorizes a declaratory judgment action for patent infringement due to Defendants' [redacted] failure to comply with their obligations under 42 U.S.C. § 262(*l*)(2)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

279. Janssen therefore seeks declaratory judgment that Defendants will infringe the '3810 patent, literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(b) and/or 271(g).

280. Janssen has no adequate remedy at law to redress the infringement by Defendants.

281. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the '3810 patent.

COUNT XIX

Infringement of U.S. Patent No. 9,890,410 Under 35 U.S.C. § 271(e)(2)(C)

282. Janssen incorporates by reference the allegations set forth in paragraphs 1-281 above as if fully set forth herein.

283. U.S. Patent No. 9,890,410 ("the '410 patent") is titled "N-acetylhexosamine-containing N-glycans in glycoprotein products." The '410 patent was duly and legally issued on February 13, 2018. A true and correct copy of the '410 patent is attached hereto as Exhibit K. JBI is the exclusive licensee with the right to enforce the '410 patent.

284. The ’410 patent is directed to and claims methods for manufacturing glycoprotein preparations as pharmaceutical products. The ’410 patent includes 34 claims, two of which are independent. Claim 1 is representative and recites:

> 1. A method for manufacturing an antibody preparation, the method comprising:
>
> culturing mammalian cells to produce a recombinant antibody preparation;
>
> determining a level of an N-linked glycan consisting of a single N-acetylglucosamine residue in the produced preparation; and
>
> processing the antibody preparation as a pharmaceutical product based upon the determination.

285. On information and belief, the manufacture of BAT2506 is covered by one or more claims of the ’410 patent, literally or under the doctrine of equivalents.

286. [redacted]

287. [redacted]

288. On information and belief, Defendants determine a level of N-linked glycan consisting of a single N-acetylglucosamine residue in the produced preparation and process the antibody preparation as a pharmaceutical product based upon the determination. Janssen has a reasonable basis for this belief at least because Defendants failed to comply with their obligation under 42 U.S.C. § 262(*l*)(2)(A) to provide such other information that describes the process or processes used to manufacture the BAT2506, despite repeated follow-up requests for this

information on [redacted], and [redacted]. On information and belief, Defendants withheld this information because they know or have reason to believe that Defendants perform the claimed steps.

289. Janssen also attempted to ascertain details of Defendants antibody preparations by examining materials that Defendants were obligated to provide under 42 U.S.C. § 262(*l*)(2)(A). Janssen sent a letter to Defendants' counsel on [redacted] requesting more information on their [redacted] For example, [redacted]. However, Defendants failed to provide complete information that describes [redacted]. Janssen is entitled to utilize the judicial process and the aid of discovery to obtain such information as is required to confirm its belief that Defendants perform the claimed steps.

290. Defendants' submission of their aBLA for BAT2506 infringed the '410 patent under 35 U.S.C. § 271(e)(2)(C).

291. Defendants have knowledge of the '410 patent, due to at least Janssen's disclosure of the '410 patent under 42 U.S.C. § 262(*l*)(3)(A) on [redacted] and through the filing of this Complaint. On information and belief, Defendants have been aware of the '410 patent and its relevance to BAT2506 even before Janssen identified it on [redacted]

292. On information and belief, Defendants acted with deliberate and intentional disregard of Janssen's rights under the '410 patent.

293. Janssen has no adequate remedy at law to redress the infringement by Defendants.

294. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the '410 patent.

COUNT XX

Declaratory Judgment of Infringement of U.S. Patent No. 9,890,410

295. Janssen incorporates by reference the allegations set forth in paragraphs 1-294 above as if fully set forth herein.

296. As set forth in Count XIX, Defendants would infringe the '410 patent, literally or under the doctrine of equivalents, if BAT2506 is commercially made, used, offered for sale, sold, or imported in the United States.

297. Because Defendants would only have regulatory approval to sell BAT2506 as described in their aBLA, any imported BAT2506 made by the patented process will not be materially changed by subsequent processes nor be a trivial or nonessential component of another product.

298. Defendants have knowledge of and/or are willfully blind to the fact that the commercial manufacture, use, sale, offer for sale, and/or importation of BAT2506 will directly infringe one or more claims of the '410 patent, literally or under the doctrine of equivalents.

299. Defendants will knowingly or with willful blindness induce or contribute to another's direct infringement of one or more claims of the '410 patent, literally or under the doctrine of equivalents.

300. By filing the aBLA for BAT2506, [redacted]

301. [redacted] presents a controversy of sufficient immediacy and reality to support declaratory judgment of patent infringement under 35 U.S.C. §§ 271(b) and/or 271(g). The BPCIA authorizes a declaratory judgment action for patent infringement due to Defendants' [redacted] failure to comply with their obligations under 42 U.S.C. § 262(*l*)(2)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

302. Janssen therefore seeks declaratory judgment that Defendants will infringe the '410 patent, literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(b) and/or 271(g).

303. Janssen has no adequate remedy at law to redress the infringement by Defendants.

304. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the '410 patent.

COUNT XXI

Infringement of U.S. Patent No. 11,014,982 Under 35 U.S.C. § 271(e)(2)(C)

305. Janssen incorporates by reference the allegations set forth in paragraphs 1-304 above as if fully set forth herein.

306. U.S. Patent No. 11,014,982 ("the '982 patent") is titled "Anti-TNF antibodies, compositions, and methods for the treatment of active ankylosing spondylitis." The '982 patent

was duly and legally issued on May 25, 2021. A true and correct copy of the ’982 patent is attached hereto as Exhibit L. JBI is the owner by assignment of the ’982 patent.

307. The ’982 patent is directed to methods for treating active ankylosing spondylitis with intravenous administration of golimumab. The ’982 patent includes 10 claims, three of which are independent. Claim 4 recites:

> 4. A method for treating a TNF related condition, wherein the TNF related condition is active ankylosing spondylitis, the method comprising:
>
> administering a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF antibody having a heavy chain (HC) comprising the amino acid sequence set forth in SEQ ID NO:36 and a light chain (LC) comprising the amino acid sequence set forth in SEQ ID NO:37, and
>
> at least one pharmaceutically acceptable carrier or diluent, wherein said composition is administered via IV infusion, and
>
> wherein at week 16 of treatment patients treated with the anti-TNF antibody achieve a mean change from baseline in one or more criteria selected from the group consisting of: Bath Ankylosing Spondylitis Functional Index (BASFI)=−2.4±2.1 Standard Deviation (SD), Bath Ankylosing Spondylitis Metrology Index (BASMI)=−0.4±0.6 SD, 36-item Short-Form Health Survey Physical Component Summary (SF-36 PCS)=8.5±7.5 SD, 36-item Short-Form Health Survey Mental Component Summary (SF-36 MCS)=6.5±9.1 SD, and Ankylosing Spondylitis Qualify of Life questionnaire (ASQoL)=−5.4±5.0 SD.

Claim 7 recites:

> 7. A method for treating a TNF related condition, wherein the TNF related condition is active ankylosing spondylitis, the method comprising:
>
> administering a safe and effective amount of at least one isolated mammalian anti-TNF antibody having a heavy chain (HC) comprising the amino acid sequence set forth in SEQ ID NO:36 and a light chain (LC) comprising the amino acid sequence set forth in SEQ ID NO:37,

wherein said anti-TNF antibody is administered via intravenous (IV) infusion, and wherein ≥65% of patients receiving the treatment achieve Assessment in Ankylosing Spondylitis 20 (ASAS20) at week 16 of treatment.

308. [redacted]

309. [redacted]

310. [redacted]

311. [redacted]

312. [redacted]

313. .

314. Defendants' submission of their aBLA for BAT2506 infringed the '982 patent under 35 U.S.C. § 271(e)(2)(C).

315. Defendants have knowledge of the '982 patent, due to at least Janssen's disclosure of the '982 patent under 42 U.S.C. § 262(*l*)(3)(A) on and through the filing of this Complaint. On information and belief, Defendants have been aware of the '982 patent and its relevance to BAT2506 even before Janssen identified it on

316. On information and belief, Defendants acted with deliberate and intentional disregard of Janssen's rights under the '982 patent.

317. Janssen has no adequate remedy at law to redress the infringement by Defendants.

318. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the '982 patent.

COUNT XXII

Declaratory Judgment of Infringement of U.S. Patent No. 11,014,982

319. Janssen incorporates by reference the allegations set forth in paragraphs 1-318 above as if fully set forth herein.

320. As set forth in Count XXI, Defendants would infringe the ’982 patent, either literally or under the doctrine of equivalents, if BAT2506 is commercially made, used, offered for sale, sold, or imported in the United States. On information and belief, Defendants have an affirmative intent to contribute to and actively induce physicians and patients that use BAT2506 to infringe the ’982 patent.

321. Defendants have knowledge of and/or are willfully blind to the fact that the use of BAT2506 to treat active ankylosing spondylitis in accordance with Defendants’ label will directly infringe one or more claims of the ’982 patent, literally or under the doctrine of equivalents.

322. Defendants will knowingly or with willful blindness induce or contribute to another’s direct infringement of one or more claims of the ’982 patent, literally or under the doctrine of equivalents.

323. By filing the aBLA for BAT2506, [redacted]

324. [redacted] presents a controversy of sufficient immediacy and reality to support declaratory judgment of patent infringement under 35 U.S.C. §§ 271(b)-(c). The BPCIA authorizes a declaratory judgment action for patent infringement due to Defendants’ [redacted] failure to comply with their obligations under 42 U.S.C. § 262(*l*)(2)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

325. Janssen therefore seeks declaratory judgment that Defendants will infringe the '982 patent, literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(b)-(c).

326. Janssen has no adequate remedy at law to redress the infringement by Defendants.

327. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the '982 patent.

COUNT XXIII

Infringement of U.S. Patent No. 11,041,020 Under 35 U.S.C. § 271(e)(2)(C)

328. Janssen incorporates by reference the allegations set forth in paragraphs 1-327 above as if fully set forth herein.

329. U.S. Patent No. 11,041,020 ("the '020 patent") is titled "Methods for the treatment of active psoriatic arthritis." The '020 patent was duly and legally issued on June 22, 2021. A true and correct copy of the '020 patent is attached hereto as Exhibit M. JBI is the owner by assignment of the '020 patent.

330. The '020 patent is directed to and claims methods of treating active psoriatic arthritis with intravenous administration of golimumab. The '020 patent includes 10 claims, three of which are independent. Claim 4 recites:

> 4. A method for treating a TNF-α related condition, wherein the TNF-α related condition is active psoriatic arthritis, the method comprising:
>
> administering to a subject having active psoriatic arthritis a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF-α antibody having a heavy chain (HC) comprising SEQ ID NO:36 and a light chain (LC) comprising SEQ ID NO:37, and
>
> at least one pharmaceutically acceptable carrier or diluent, wherein said composition is administered via IV infusion, and

wherein at week 24 of treatment patients treated with the anti-TNF-α antibody achieve a mean change from baseline in van der Heijde-Sharp score (vdH-S)=−0.36±0.144 SE.

Claim 7 recites:

> 7. A method for treating a TNF-α related condition, wherein the TNF-α related condition is active psoriatic arthritis, the method comprising:
>
> administering to a subject having active psoriatic arthritis a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF-α antibody having a heavy chain (HC) comprising SEQ ID NO:36 and a light chain (LC) comprising SEQ ID NO:37,
>
> wherein said anti-TNF-α antibody is administered via intravenous (IV) infusion, and wherein ≥65% of patients receiving the treatment achieve ACR20 at week 14 of treatment.

331. [redacted].

332. [redacted]

334. [redacted]

337. Defendants' submission of their aBLA for BAT2506 infringed the '020 patent under 35 U.S.C. § 271(e)(2)(C).

338. Defendants have knowledge of the '020 patent, due to at least Janssen's disclosure of the '020 patent under 42 U.S.C. § 262(*l*)(3)(A) on [redacted] and through the filing of this Complaint. On information and belief, Defendants have been aware of the ' 020 patent and its relevance to BAT2506 even before Janssen identified it on [redacted]

339. On information and belief, Defendants acted with deliberate and intentional disregard of Janssen's rights under the '020 patent.

340. Janssen has no adequate remedy at law to redress the infringement by Defendants.

341. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the '020 patent.

COUNT XXIV

Declaratory Judgment of Infringement of U.S. Patent No. 11,041,020

342. Janssen incorporates by reference the allegations set forth in paragraphs 1-341 above as if fully set forth herein.

343. As set forth in Count XXIII, Defendants would infringe the ’020 patent, either literally or under the doctrine of equivalents, if BAT2506 is commercially made, used, offered for sale, sold, or imported in the United States. On information and belief, Defendants have an affirmative intent to contribute to and actively induce physicians and patients that use BAT2506 to infringe the ’020 patent.

344. Defendants have knowledge of and/or are willfully blind to the fact that the use of BAT2506 to treat active psoriatic arthritis in accordance with Defendants’ label will directly infringe one or more claims of the ’020 patent, literally or under the doctrine of equivalents.

345. Defendants will knowingly or with willful blindness induce or contribute to another’s direct infringement of one or more claims of the ’020 patent, literally or under the doctrine of equivalents.

346. By filing the aBLA for BAT2506, [redacted]

347. [redacted] presents a controversy of sufficient immediacy and reality to support declaratory judgment of patent infringement under 35 U.S.C. §§ 271(b)-(c). The BPCIA

authorizes a declaratory judgment action for patent infringement due to Defendants' [redacted] failure to comply with their obligations under 42 U.S.C. § 262(*l*)(2)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

348. Janssen therefore seeks declaratory judgment that Defendants will infringe the '020 patent, literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(b)-(c).

349. Janssen has no adequate remedy at law to redress the infringement by Defendants.

350. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the '020 patent.

COUNT XXV

Infringement of U.S. Patent No. 12,122,824 Under 35 U.S.C. § 271(e)(2)(C)

351. Janssen incorporates by reference the allegations set forth in paragraphs 1-350 above as if fully set forth herein.

352. U.S. Patent No. 12,122,824 ("the '824 patent") is titled "Anti-TNF antibodies, compositions, and methods for the treatment of active ankylosing spondylitis." The '824 patent was duly and legally issued on October 22, 2024. A true and correct copy of the '824 patent is attached hereto as Exhibit N. JBI is the owner by assignment of the '824 patent.

353. The '824 patent is directed to and claims methods of treating psoriatic arthritis with intravenous administration of golimumab. The '824 patent includes seven claims, three of which are independent. Claim 3 recites:

> 3. A method for treating a TNF-α related condition, wherein the TNF-α related condition is active psoriatic arthritis, the method comprising: administering to a subject having active psoriatic arthritis a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF-α antibody comprising:

a. a heavy chain (HC) complementary determining region (CDR) 1 comprising an amino acid sequence of SEQ ID NO: 1;

b. a HC CDR2 comprising an amino acid sequence of SEQ ID NO: 2; wherein position 1 of SEQ ID NO: 2 is phenylalanine, position 2 of SEQ ID NO: 2 is methionine, position 3 of SEQ ID NO: 2 is serine, position 4 of SEQ ID NO: 2 is tyrosine, position 10 of SEQ ID NO: 2 is lysine, position 11 of SEQ ID NO: 2 is tyrosine, and position 17 of SEQ ID NO: 2 is glycine;

c. a HC CDR3 comprising an amino acid sequence of SEQ ID NO: 3; wherein position 4 of SEQ ID NO: 3 is isoleucine, position 5 of SEQ ID NO: 3 is alanine, and position 9 of SEQ ID NO: 3 is asparagine;

d. a light chain (LC) CDR1 comprising an amino acid sequence of SEQ ID NO: 4; wherein position 7 of SEQ ID NO: 4 is tyrosine;

e. a LC CDR2 comprising an amino acid sequence of SEQ ID NO: 5; and

f. a LC CDR3 comprising an amino acid sequence of SEQ ID NO: 6, and

at least one pharmaceutically acceptable carrier or diluent, wherein said composition is administered via IV infusion, wherein said anti-TNF-α antibody is administered at a dose of 2 mg/kg, over 30±10 minutes, at Weeks 0 and 4, then every 8 weeks (q8w) thereafter, and

wherein at week 24 of treatment patients treated with the anti-TNF-α antibody achieve a mean change from baseline in total modified van der Heijde-Sharp score (vdH-S)=−0.36±0.144 SE.

Claim 5 recites:

5. A method for treating a TNF-α related condition, wherein the TNF-α related condition is active psoriatic arthritis, the method comprising: administering to a subject having active psoriatic arthritis a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF-α antibody comprising:

a. a heavy chain (HC) complementary determining region (CDR) 1 comprising an amino acid sequence of SEQ ID NO: 1;

b. a HC CDR2 comprising an amino acid sequence of SEQ ID NO: 2; wherein position 1 of SEQ ID NO: 2 is phenylalanine, position 2 of SEQ ID NO: 2 is methionine, position 3 of SEQ ID NO: 2 is

serine, position 4 of SEQ ID NO: 2 is tyrosine, position 10 of SEQ ID NO: 2 is lysine, position 11 of SEQ ID NO: 2 is tyrosine, and position 17 of SEQ ID NO: 2 is glycine;

c. a HC CDR3 comprising an amino acid sequence of SEQ ID NO: 3; wherein position 4 of SEQ ID NO: 3 is isoleucine, position 5 of SEQ ID NO: 3 is alanine, and position 9 of SEQ ID NO: 3 is asparagine;

d. a light chain (LC) CDR1 comprising an amino acid sequence of SEQ ID NO: 4; wherein position 7 of SEQ ID NO: 4 is tyrosine;

e. a LC CDR2 comprising an amino acid sequence of SEQ ID NO: 5; and

f. a LC CDR3 comprising an amino acid sequence of SEQ ID NO: 6,

wherein said anti-TNF-α antibody is administered via intravenous (IV) infusion, wherein said antibody is administered at a dose of 2 mg/kg, over 30±10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter, and

wherein ≥65% of patients receiving the treatment achieve ACR20 at week 14 of treatment.

354. [redacted]

355. [redacted]

[redacted]

360. Defendants' submission of their aBLA for BAT2506 infringed the '824 patent under 35 U.S.C. § 271(e)(2)(C).

361. Defendants have knowledge of the '824 patent, due to at least Janssen's disclosure of the '824 patent under 42 U.S.C. § 262(*l*)(3)(A) on [redacted] and through the filing of this Complaint. On information and belief, Defendants have been aware of the '824 patent and its relevance to BAT2506 even before Janssen identified it on [redacted]

362. On information and belief, Defendants acted with deliberate and intentional disregard of Janssen's rights under the '824 patent.

363. Janssen has no adequate remedy at law to redress the infringement by Defendants.

364. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the ’824 patent.

COUNT XXVI

Declaratory Judgment of Infringement of U.S. Patent No. 12,122,824

365. Janssen incorporates by reference the allegations set forth in paragraphs 1-364 above as if fully set forth herein.

366. As set forth in Count XXV, Defendants would infringe the ’824 patent, either literally or under the doctrine of equivalents, if BAT2506 is commercially made, used, offered for sale, sold, or imported in the United States. On information and belief, Defendants have an affirmative intent to contribute to and actively induce physicians and patients that use BAT2506 to infringe the ’824 patent.

367. Defendants have knowledge of and/or are willfully blind to the fact that the use of BAT2506 to treat active psoriatic arthritis in accordance with Defendants’ label will directly infringe one or more claims of the ’824 patent, literally or under the doctrine of equivalents.

368. Defendants will knowingly or with willful blindness induce or contribute to another’s direct infringement of one or more claims of the ’824 patent, literally or under the doctrine of equivalents.

369. By filing the aBLA for BAT2506, [redacted]

370. [redacted] presents a controversy of sufficient immediacy and reality to support declaratory judgment of patent infringement under 35 U.S.C. §§ 271(b)-(c). The BPCIA authorizes a declaratory judgment action for patent infringement due to Defendants' [redacted] failure to comply with their obligations under 42 U.S.C. § 262(*l*)(2)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

371. Janssen therefore seeks declaratory judgment that Defendants will infringe the '824 patent, literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(b)-(c).

372. Janssen has no adequate remedy at law to redress the infringement by Defendants.

373. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the '824 patent.

COUNT XXVII

Infringement of U.S. Patent No. 12,129,292 Under 35 U.S.C. § 271(e)(2)(C)

374. Janssen incorporates by reference the allegations set forth in paragraphs 1-373 above as if fully set forth herein.

375. U.S. Patent No. 12,129,292 ("the '292 patent") is titled "Anti-tumor necrosis factor (TNF) antibodies and compositions thereof." The '292 patent was duly and legally issued on October 29, 2024. A true and correct copy of the '292 patent is attached hereto as Exhibit O. JBI is the owner by assignment of the '292 patent.

376. The '292 patent is directed to Anti-TNF antibodies comprising specific amino acid sequences and oligosaccharide profiles and method of manufacturing. The '292 patent includes 17 claims, three of which are independent. Claim 1 is representative and recites:

1. Anti-TNF antibodies comprising:

(i) a heavy chain comprising an amino acid sequence of SEQ ID NO:38; and

(ii) a light chain comprising an amino acid sequence of SEQ ID NO:37,

wherein the oligosaccharide profile of the anti-TNF antibodies comprises total neutral oligosaccharide species>99.0% and total charged oligosaccharide species<1.0%.

377. On information and belief, BAT2506 is covered by one or more claims of the '292 patent, literally or under the doctrine of equivalents.

378. [redacted]

380. On information and belief, the oligosaccharide profile of BAT2506 comprises total neutral oligosaccharide species >99.0% and total charged oligosaccharide species<1.0% [redacted]

[redacted] Therefore, on information and belief, BAT2506 comprises total neutral oligosaccharide species >99.0% and total charged oligosaccharide species <1.0% [redacted] either literally or under the doctrine of equivalents.

381. Janssen also attempted to ascertain details of Defendants' quantification of oligosaccharide species by examining materials that Defendants were obligated to provide under 42 U.S.C. § 262(*l*)(2)(A). Janssen sent a letter to Defendants' counsel on [redacted], requesting [redacted]. However, Defendants failed to provide complete information [redacted] Janssen is entitled to utilize the judicial process and the aid of discovery to obtain such information as is required to confirm its belief that BAT2506 comprises total neutral oligosaccharide species >99.0% and total charged oligosaccharide species<1.0%.

382. Defendants' submission of their aBLAs for BAT2506 infringed the '292 patent under 35 U.S.C. § 271(e)(2)(C).

383. Defendants have knowledge of the '292 patent, due to at least Janssen's disclosure of the '292 patent under 42 U.S.C. § 262(*l*)(3)(A) on [redacted], and through the filing

of this Complaint. On information and belief, Defendants have been aware of the ’292 patent and its relevance to BAT2506 even before Janssen identified it on [redacted]

384. On information and belief, Defendants acted with deliberate and intentional disregard of Janssen’s rights under the ’292 patent.

385. Janssen has no adequate remedy at law to redress the infringement by Defendants.

386. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the ’292 patent.

COUNT XXVIII

Declaratory Judgment of Infringement of U.S. Patent No. 12,129,292

387. Janssen incorporates by reference the allegations set forth in paragraphs 1-386 above as if fully set forth herein.

388. As set forth in Count XXVII, Defendants would infringe the ’292 patent, literally or under the doctrine of equivalents, if BAT2506 is commercially made, used, offered for sale, sold, or imported in the United States.

389. Defendants have knowledge of and/or are willfully blind to the fact that the commercial manufacture, use, sale, offer for sale, and/or importation of BAT2506 will directly infringe one or more claims of the ’292 patent, literally or under the doctrine of equivalents.

390. Defendants will knowingly or with willful blindness induce or contribute to another’s direct infringement of one or more claims of the ’292 patent, literally or under the doctrine of equivalents.

391. By filing the aBLA for BAT2506, [redacted]

[redacted]

392. [redacted] presents a controversy of sufficient immediacy and reality to support declaratory judgment of patent infringement under 35 U.S.C. §§ 271(a)-(c) and (g). The BPCIA authorizes a declaratory judgment action for patent infringement due to Defendants' [redacted] failure to comply with their obligations under 42 U.S.C. § 262(*l*)(2)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

393. Janssen therefore seeks declaratory judgment that Defendants will infringe the '292 patent, literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g).

394. Janssen has no adequate remedy at law to redress the infringement by Defendants.

395. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the '292 patent.

COUNT XXIX

Infringement of U.S. Patent No. 12,139,735 Under 35 U.S.C. § 271(e)(2)(C)

396. Janssen incorporates by reference the allegations set forth in paragraphs 1-395 above as if fully set forth herein.

397. U.S. Patent No. 12,139,735 ("the '735 patent") is titled "Cell culture process." The '735 patent was duly and legally issued on November 12, 2024. A true and correct copy of the '735 patent is attached hereto as Exhibit P. JBI is the owner by assignment of the '735 patent.

398. The '735 patent is directed to and claims preparations of recombinant antibody. The '735 patent includes 20 claims, two of which are independent. Claim 1 is representative and recites:

> 1. A preparation of recombinant antibody having a target level of C-terminal variants, wherein the C-terminal variants comprise one or more of a K1 lysine variant of the recombinant antibody and a K2 lysine variant of the recombinant antibody,
>
> wherein the K1 lysine variant has a lysine residue at one heavy chain C-terminus,
>
> wherein the K2 lysine variant has a lysine residue at each heavy chain C-terminus,
>
> wherein the target level of C-terminal variants comprises (i) 12% to 25% K1 lysine variants, relative to total recombinant antibody in the preparation or (ii) 2% to 10% K2 lysine variants, relative to total recombinant antibody in the preparation or both (i) and (ii), and
>
> wherein the preparation of recombinant antibody is produced by expressing the recombinant antibody in a cell cultured in a medium comprising 2 g/L lysine to 20 g/L lysine.

399. On information and belief, BAT2506 is covered by one or more claims of the '735 patent, literally or under the doctrine of equivalents.

400. Defendants manufacture BAT2506, a preparation with the [redacted]

401. Defendants' commercial manufacturing of BAT2506 is intended to [redacted]

402. Defendants are also seeking [redacted]

[redacted]

403. [redacted]

[redacted]

405. On information and belief, BAT2506's target level of C-terminal variants is 12% to 25% K1 lysine variants, and/or 2% to 10% K2 lysine variants, relative to the total BAT2506 in the preparation. Janssen has a reasonable basis for this belief at least because Defendants [redacted]

[redacted] Defendants have further failed to comply with their obligation under 42 U.S.C. § 262(*l*)(2)(A) to provide such other information that describes the process or processes used to manufacture the BAT2506, despite repeated follow-up requests for this information on [redacted], and [redacted]. On information and belief, Defendants withheld this information because they know or have reason to believe that its target level of C-terminal variants is 12% to 25% K1 lysine variants, relative to the total BAT2506 in the preparation, and/or 2% to 10% K2 lysine variants, relative to the total BAT2506 in the preparation. The level of C-terminal variants can affect the stability of the antibody.

406. Janssen also attempted to ascertain that Defendants' target level of C-terminal variants is 12% to 25% K1 lysine variants, and/or 2% to 10% K2 lysine variants, relative to the total BAT2506 in the preparation, by examining materials that Defendants were obligated to provide under 42 U.S.C. § 262(*l*)(2)(A). Janssen sent a letter to Defendants' counsel on [redacted] requesting more information on t[redacted] However, Defendants failed to provide complete information that describes their process used to manufacture BAT2506. Janssen is entitled to utilize the judicial process and the aid of discovery to obtain such information as is required to confirm its belief that Defendants' target level of C-terminal variants is 12% to 25% K1 lysine variants, relative to the total BAT2506 in the preparation, and/or 2% to 10% K2 lysine variants, relative to the total BAT2506 in the preparation.

407. Defendants produce a preparation of BAT2506 [redacted]

[redacted] On information and belief, Defendants' cell culture media, comprising basal culture media and feed, has 2 g/L lysine to 20 g/L lysine. Janssen has a reasonable basis for this belief at least because Defendants failed to comply with their obligation under 42 U.S.C. § 262(*l*)(2)(A) to provide such other information that describes the process or processes used to manufacture the BAT2506, despite repeated follow-up requests for this information on [redacted], and [redacted]. On information and belief, Defendants withheld this information because they know or have reason to believe that the cell culture media comprise 2 g/L lysine to 20 g/L lysine.

408. Janssen also attempted to ascertain the full composition of the cell culture media by examining materials that Defendants were obligated to provide under 42 U.S.C. § 262(*l*)(2)(A) and 42 U.S.C. § 262(l)(3)(B). Janssen sent a letter to Defendants' counsel on [redacted], requesting more information on the composition of Defendant's cell culture media, specifically identifying [redacted] However, in disclosures pursuant to 42 U.S.C. §§ 262(*l*)(2)(A) and 262(l)(3)(B), Defendants failed to provide complete information that describes the cell culture media used for manufacturing of the BAT2506, including for instance the composition of [redacted] Janssen is entitled to utilize the judicial process and the aid of discovery to obtain such information as is required to confirm its belief that the cell culture media comprise 2 g/L lysine to 20 g/L lysine.

409. Defendants' submission of their aBLA for BAT2506 infringed the '735 patent under 35 U.S.C. § 271(e)(2)(C).

410. Defendants have knowledge of the '735 patent, due to at least Janssen's disclosure of the '735 patent under 42 U.S.C. § 262(*l*)(3)(A) on [redacted] and through the filing of this Complaint. On information and belief, Defendants have been aware of the '735 patent and its relevance to BAT2506 even before Janssen identified it on [redacted]

411. On information and belief, Defendants acted with deliberate and intentional disregard of Janssen's rights under the '735 patent.

412. Janssen has no adequate remedy at law to redress the infringement by Defendants.

413. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the '735 patent.

COUNT XXX

Declaratory Judgment of Infringement of U.S. Patent No. 12,139,735

414. Janssen incorporates by reference the allegations set forth in paragraphs 1-413 above as if fully set forth herein.

415. As set forth in Count XXIX, Defendants would infringe the '735 patent, literally or under the doctrine of equivalents, if BAT2506 is commercially made, used, offered for sale, sold, or imported in the United States.

416. Defendants have knowledge of and/or are willfully blind to the fact that the commercial manufacture, use, sale, offer for sale, and/or importation of BAT2506 will directly infringe one or more claims of the '735 patent, literally or under the doctrine of equivalents.

417. Defendants will knowingly or with willful blindness induce or contribute to another's direct infringement of one or more claims of the '735 patent, literally or under the doctrine of equivalents.

418. By filing the aBLA for BAT2506, [redacted]

419. [redacted] presents a controversy of sufficient immediacy and reality to support declaratory judgment of patent infringement under 35 U.S.C. §§ 271(a)-(c). The BPCIA authorizes a declaratory judgment action for patent infringement due to Defendants' [redacted] failure to comply with their obligations under 42 U.S.C. § 262(*l*)(2)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

420. Janssen therefore seeks declaratory judgment that Defendants will infringe the '735 patent, literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c).

421. Janssen has no adequate remedy at law to redress the infringement by Defendants.

422. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the '735 patent.

COUNT XXXI

Infringement of U.S. Patent No. 12,180,271 Under 35 U.S.C. § 271(e)(2)(C)

423. Janssen incorporates by reference the allegations set forth in paragraphs 1-422 above as if fully set forth herein.

424. U.S. Patent No. 12,180,271 ("the '271 patent") is titled "Manufacturing methods for producing anti-TNF antibody compositions." The '271 patent was duly and legally issued on December 31, 2024. A true and correct copy of the '271 patent is attached hereto as Exhibit Q. JBI is the owner by assignment of the '271 patent.

425. The '271 patent is directed to Anti-TNF antibodies comprising specific amino acid sequences and oligosaccharide profiles and method of manufacturing. The '271 patent includes 12 claims, two of which are independent. Claim 1 is representative and recites:

> 1. Anti-TNF antibodies comprising:
>
> (i) a heavy chain comprising an amino acid sequence of SEQ ID NO:36; and
>
> (ii) a light chain comprising an amino acid sequence of SEQ ID NO:37,
>
> wherein the oligosaccharide profile of the anti-TNF antibodies comprises total neutral oligosaccharide species>99.0% and total charged oligosaccharide species<1.0%.

426. On information and belief, BAT2506 is covered by one or more claims of the '271 patent, literally or under the doctrine of equivalents.

427. [redacted]

[redacted].

429. On information and belief, the oligosaccharide profile of BAT2506 comprises total neutral oligosaccharide species >99.0% and total charged oligosaccharide species<1.0% [redacted]. Therefore, on information and belief, BAT2506 comprises total neutral oligosaccharide species >99.0% and total charged oligosaccharide species <1.0% [redacted], either literally or under the doctrine of equivalents.

430. Janssen also attempted to ascertain details of Defendants' quantification of oligosaccharide species by examining materials that Defendants were obligated to provide under 42 U.S.C. § 262(*l*)(2)(A). Janssen sent a letter to Defendants' counsel on [redacted] requesting more information on [redacted]

[redacted]. Janssen is entitled to utilize the judicial process and the aid of discovery to obtain such information as is required to confirm its belief that BAT2506 comprises total neutral oligosaccharide species >99.0% and total charged oligosaccharide species<1.0%.

431. Defendants' submission of their aBLAs for BAT2506 infringed the '271 patent under 35 U.S.C. § 271(e)(2)(C).

432. Defendants have knowledge of the '271 patent, due to at least Janssen's disclosure of the '271patent under 42 U.S.C. § 262(*l*)(3)(A) on [redacted] and through the filing of this Complaint. On information and belief, Defendants have been aware of the '271 patent and its relevance to BAT2506 even before Janssen identified it on [redacted]

433. On information and belief, Defendants acted with deliberate and intentional disregard of Janssen's rights under the '271 patent.

434. Janssen has no adequate remedy at law to redress the infringement by Defendants.

435. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the '271 patent.

COUNT XXXII

Declaratory Judgment of Infringement of U.S. Patent No. 12,180,271

436. Janssen incorporates by reference the allegations set forth in paragraphs 1-435 above as if fully set forth herein.

437. As set forth in Count XXXI, Defendants would infringe the ’271 patent, literally or under the doctrine of equivalents, if BAT2506 is commercially made, used, offered for sale, sold, or imported in the United States.

438. Defendants have knowledge of and/or are willfully blind to the fact that the commercial manufacture, use, sale, offer for sale, and/or importation of BAT2506 will directly infringe one or more claims of the ’271 patent, literally or under the doctrine of equivalents.

439. Defendants will knowingly or with willful blindness induce or contribute to another’s direct infringement of one or more claims of the ’271 patent, literally or under the doctrine of equivalents.

440. By filing the aBLA for BAT2506, [redacted]

441. [redacted] presents a controversy of sufficient immediacy and reality to support declaratory judgment of patent infringement under 35 U.S.C. §§ 271(a)-(c) and (g). The BPCIA authorizes a declaratory judgment action for patent infringement due to Defendants’ [redacted] failure to comply with their obligations under 42 U.S.C. § 262(*l*)(2)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

442. Janssen therefore seeks declaratory judgment that Defendants will infringe the ’271 patent, literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g).

443. Janssen has no adequate remedy at law to redress the infringement by Defendants.

444. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the ’271 patent.

COUNT XXXIII

Infringement of U.S. Patent No. 12,291,566 Under 35 U.S.C. § 271(e)(2)(C)

445. Janssen incorporates by reference the allegations set forth in paragraphs 1-444 above as if fully set forth herein.

446. U.S. Patent No. 12,291,566 (“the ’566 patent”) is titled “Anti-TNF antibodies, compositions, and methods for the treatment of active ankylosing spondylitis.” The ’566 patent was duly and legally issued on May 6, 2025. A true and correct copy of the ’566 patent is attached hereto as Exhibit R. JBI is the owner by assignment of the ’566 patent.

447. The ’566 patent is directed to and claims methods of treating ankylosing spondylitis with intravenous administration of golimumab. The ’566 patent includes seven claims, three of which are independent. Claim 3 recites:

> 3. A method for treating a TNF related condition, wherein the TNF related condition is active ankylosing spondylitis, the method comprising: administering a composition comprising a safe and effective amount of at least one isolated mammalian anti-TNF antibody comprising:
>
> a. a heavy chain (HC) complementary determining region (CDR) 1 comprising an amino acid sequence of SEQ ID NO: 1;
>
> b. a HC CDR2 comprising an amino acid sequence of SEQ ID NO: 2; wherein position 1 of SEQ ID NO: 2 is phenylalanine, position 2 of SEQ ID NO: 2 is methionine, position 3 of SEQ ID NO: 2 is serine, position 4 of SEQ ID NO: 2 is tyrosine, position 10 of SEQ ID NO: 2 is lysine, position 11 of SEQ ID NO: 2 is tyrosine, and position 17 of SEQ ID NO: 2 is glycine;
>
> c. a HC CDR3 comprising an amino acid sequence of SEQ ID NO: 3; wherein position 4 of SEQ ID NO: 3 is isoleucine, position 5 of

SEQ ID NO: 3 is alanine, and position 9 of SEQ ID NO: 3 is asparagine;

d. a light chain (LC) CDR1 comprising an amino acid sequence of SEQ ID NO: 4; wherein position 7 of SEQ ID NO: 4 is tyrosine;

e. a LC CDR2 comprising an amino acid sequence of SEQ ID NO: 5; and

f. a LC CDR3 comprising an amino acid sequence of SEQ ID NO: 6, and

at least one pharmaceutically acceptable carrier or diluent, wherein said composition is administered via IV infusion at a dose of 2 mg/kg, administered over 30±10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter, and

wherein at week 16 of treatment patients treated with the anti-TNF antibody achieve a mean change from baseline in one or more criteria selected from the group consisting of: Bath Ankylosing Spondylitis Functional Index (BASFI)=−2.4±2.1 Standard Deviation (SD), Bath Ankylosing Spondylitis Metrology Index (BASMI)=−0.4±0.6 SD, 36-item Short-Form Health Survey Physical Component Summary (SF-36 PCS)=8.5±7.5 SD, 36-item Short-Form Health Survey Mental Component Summary (SF-36 MCS)=6.5±9.1 SD, and Ankylosing Spondylitis Qualify of Life questionnaire (ASQoL)=−5.4±5.0 SD.

Claim 5 recites:

5. A method for treating a TNF related condition, wherein the TNF related condition is active ankylosing spondylitis, the method comprising: administering a safe and effective amount of at least one isolated mammalian anti-TNF antibody comprising:

a. a heavy chain (HC) complementary determining region (CDR) 1 comprising an amino acid sequence of SEQ ID NO: 1;

b. a HC CDR2 comprising an amino acid sequence of SEQ ID NO: 2; wherein position 1 of SEQ ID NO: 2 is phenylalanine, position 2 of SEQ ID NO: 2 is methionine, position 3 of SEQ ID NO: 2 is serine, position 4 of SEQ ID NO: 2 is tyrosine, position 10 of SEQ ID NO: 2 is lysine, position 11 of SEQ ID NO: 2 is tyrosine, and position 17 of SEQ ID NO: 2 is glycine;

c. a HC CDR3 comprising an amino acid sequence of SEQ ID NO: 3; wherein position 4 of SEQ ID NO: 3 is isoleucine, position 5 of

SEQ ID NO: 3 is alanine, and position 9 of SEQ ID NO: 3 is asparagine;

d. a light chain (LC) CDR1 comprising an amino acid sequence of SEQ ID NO: 4; wherein position 7 of SEQ ID NO: 4 is tyrosine;

e. a LC CDR2 comprising an amino acid sequence of SEQ ID NO: 5; and

f. a LC CDR3 comprising an amino acid sequence of SEQ ID NO: 6,

wherein said anti-TNF antibody is administered via intravenous (IV) infusion at a dose of 2 mg/kg, administered over 30±10 minutes, at Weeks 0 and 4, and then every 8 weeks (q8w) thereafter, and

wherein ≥65% of patients receiving the treatment achieve Assessment in Ankylosing Spondylitis 20 (ASAS20) at week 16 of treatment.

448. [redacted]

449. [redacted]

450. [redacted].

451. [redacted].

452. [redacted]

453. [redacted]

454. Defendants' submission of their aBLA for BAT2506 infringed the '566 patent under 35 U.S.C. § 271(e)(2)(C).

455. Defendants have knowledge of the '566 patent, due to at least Janssen's disclosure of the '566 patent under 42 U.S.C. § 262(*l*)(3)(A) on [redacted] and through the filing of this Complaint. On information and belief, Defendants have been aware of the '566 patent and its relevance to BAT2506 even before Janssen identified it on [redacted]

456. On information and belief, Defendants acted with deliberate and intentional disregard of Janssen's rights under the '566 patent.

457. Janssen has no adequate remedy at law to redress the infringement by Defendants.

458. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the '566 patent.

COUNT XXXIV

Declaratory Judgment of Infringement of U.S. Patent No. 12,291,566

459. Janssen incorporates by reference the allegations set forth in paragraphs 1-458 above as if fully set forth herein.

460. As set forth in Count XXXIV, Defendants would infringe the '566 patent, either literally or under the doctrine of equivalents, if BAT2506 is commercially made, used, offered for sale, sold, or imported in the United States. On information and belief, Defendants have an affirmative intent to contribute to and actively induce physicians and patients that use BAT2506 to infringe the '566 patent.

461. Defendants have knowledge of and/or are willfully blind to the fact that the use of BAT2506 to treat active ankylosing spondylitis in accordance with Defendants' label will directly infringe one or more claims of the '566 patent, literally or under the doctrine of equivalents.

462. Defendants will knowingly or with willful blindness induce or contribute to another's direct infringement of one or more claims of the '566 patent, literally or under the doctrine of equivalents.

463. By filing the aBLA for BAT2506, [redacted]

[redacted]

464. [redacted] presents a controversy of sufficient immediacy and reality to support declaratory judgment of patent infringement under 35 U.S.C. §§ 271(b)-(c). The BPCIA authorizes a declaratory judgment action for patent infringement due to Defendants' [redacted] failure to comply with their obligations under 42 U.S.C. § 262(*l*)(2)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

465. Janssen therefore seeks declaratory judgment that Defendants will infringe the '566 patent, literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(b)-(c).

466. Janssen has no adequate remedy at law to redress the infringement by Defendants.

467. Janssen will be irreparably harmed if Defendants are not enjoined from infringing the '566 patent.

PRAYER FOR RELIEF

WHEREFORE, Janssen respectfully requests:

A. a judgment that Defendants have infringed the Janssen Patents under 35 U.S.C. § 271(e)(2)(C) by filing their aBLAs for BAT2506;

B. an order that the effective date of approval for BLA No. [redacted] for BAT2506 be no earlier than the date of expiration of the infringed patents, pursuant to 35 U.S.C. § 271(e)(4)(A);

C. a declaration that making, using, offering to sell, selling, or importing BAT2506 in the United States would infringe the Janssen Patents;

D. a preliminary and permanent injunction enjoining Defendants, as well as their officers, agents, servants, employees, and attorneys, together with any other persons who are in active concert or participation with them, from making, using, offering to sell, selling, or importing BAT2506 in the United States;

E. a determination that Defendants' infringement has been willful and that this is an exceptional case;

F. an award to Janssen of its costs and attorneys' fees;

G. any available damages pursuant to 35 U.S.C. § 284 and 35 U.S.C. § 271(e)(4)(C); and

H. such other relief as this Court may deem just and proper.

Dated: March 3, 2026

MCCARTER & ENGLISH, LLP

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