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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

JANSSEN BIOTECH, INC. and JANSSEN SCIENCES IRELAND UC, Plaintiffs, v. ALVOTECH HF. and ALVOTECH USA INC., Defendants.	No. _____ [redacted]

COMPLAINT FOR PATENT INFRINGEMENT

1. Janssen Biotech, Inc. ("JBI"), having an address at 800 Ridgeview Drive, Horsham, Pennsylvania 19044, and Janssen Sciences Ireland UC ("JSI"), having an address at Airton Road, Dublin 24, Ireland, D24WR89 (JBI and JSI collectively, "Janssen"), for their Complaint against Alvotech hf. ("Alvotech hf"), having an address at Sæmundargata 15-19, 102, Reykjavík, Iceland, and Alvotech USA Inc. ("Alvotech USA"), a Virginia corporation with a principal place of business at 1602 Village Market Blvd., Suite 280, Leesburg, Virginia 20175 (Alvotech hf and Alvotech USA collectively, "Alvotech"), allege as follows:

NATURE OF THE ACTION

2. 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)(B).

3. 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

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alpha (TNFα). SIMPONI® is administered subcutaneously and is approved to treat rheumatoid arthritis in combination with methotrexate, psoriatic arthritis alone or in combination with methotrexate, ankylosing spondylitis, and ulcerative colitis. SIMPONI ARIA® is administered intravenously and is approved to treat rheumatoid arthritis in combination with methotrexate, 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.

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

5. Alvotech plans to sell AVT05, its biosimilar copy of SIMPONI® and SIMPONI ARIA®. Alvotech submitted abbreviated Biologics License Application ("aBLA") [redacted] for its biosimilar version of SIMPONI®, referred to herein as "AVT05 SC." Alvotech also submitted aBLA [redacted] for its biosimilar version of SIMPONI ARIA®, referred to herein as "AVT05 IV." AVT05 SC and AVT05 IV are collectively referred to as "AVT05." [redacted]

6. Alvotech did not independently develop AVT05. Rather, Alvotech is seeking regulatory approval based on Janssen's clinical studies and research data for SIMPONI® and SIMPONI ARIA®. By submitting its aBLAs for AVT05 SC and AVT05 IV and taking concrete

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steps to commercially market those products, Alvotech has infringed, and threatens to infringe, Janssen's patents.

THE PARTIES

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

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

9. Alvotech hf is an Icelandic corporation with its principal place of business at Sæmundargata 15-19, 102, Reykjavík, Iceland.

10. Alvotech USA is a Virginia corporation with a principal place of business at 1602 Village Market Blvd., Suite 280, Leesburg, Virginia 20175.

JURISDICTION AND VENUE

11. 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.

12. This Court has personal jurisdiction over Alvotech USA because it is incorporated in Virginia and its principal place of business is located in Virginia.

13. Because Alvotech USA has its principal place of business in this District, venue is proper under 28 U.S.C. §§ 1391 and 1400(b).

14. Alvotech hf is subject to personal jurisdiction in Virginia because, among other reasons, Alvotech hf itself, and through its affiliates Alvotech USA, has purposely availed itself

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of the benefits and protections of Virginia laws such that it should reasonably anticipate being sued in this Court.

15. On information and belief, upon FDA approval, Alvotech intends to market, distribute, offer for sale, and/or sell its biosimilar golimumab products in the United States, including Virginia, deriving substantial revenue therefrom.

16. [redacted]

17. Alvotech seeks regulatory approval to sell AVT05 throughout the United States, including in Virginia. Alvotech plans to direct sales of AVT05 into the United States and this judicial district through its commercialization partner, Teva Pharmaceuticals, Inc. ("Teva"). *See, e.g.*, Alvotech's Registration Statement (Form F-4) (Dec. 20, 2021), Exhibit 10.17, https://www.sec.gov/Archives/edgar/data/1898416/000119312521362501/d193995dex1017.htm. Alvotech currently directs sales of other biosimilar products, including SIMLANDI® and SELARSDI™, into Virginia. Alvotech developed and will manufacture AVT05 for the entire United States market, including Virginia. *Id*.

18. On information and belief, Alvotech has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court and district by filing suit in at least the following action: *e.g.*, *Alvotech USA Inc. et al v. AbbVie Inc. et al*, 1-21-cv-00589.

19. In the alternative, on information and belief, this Court has personal jurisdiction over Alvotech under Federal Rule of Civil Procedure 4(k)(2) because it is not subject to jurisdiction

[redacted]

in any other state's courts of general jurisdiction, and exercising jurisdiction is consistent with the United States Constitution and laws.

20. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400. Alvotech hf is a foreign entity and thus is subject to suit in any judicial district in the United States, including the Eastern District of Virginia.

BACKGROUND

Janssen's SIMPONI® and SIMPONI ARIA® Products

21. 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.

22. 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.

23. SIMPONI® and SIMPONI ARIA® have achieved tremendous market success. In 2025, sales of SIMPONI® and SIMPONI ARIA® in the United States exceeded $1.1 billion.

Janssen's Patents

24. 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.

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25. Janssen holds patents that protect their innovative work relating to 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. 8,852,889,

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. 10,421,986,

U.S. Patent No. 11,225,516,

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

U.S. Patent No. 12,534,524, and

U.S. Patent No. 12,595,454,

collectively, the "Janssen Patents."

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

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The Biosimilar Price Competition and Innovation Act

27. Alvotech applied for regulatory approval of AVT05 SC and AVT05 IV under the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), which established an abbreviated regulatory pathway for certain biosimilar products. But the BPCIA does not give Alvotech license to infringe Janssen's patents. Alvotech remains liable for patent infringement as long as Janssen's patents remain in force. Alvotech's submission of its aBLAs for AVT05 SC and AVT05 IV infringes Janssen's patents under 35 U.S.C. § 271(e)(2)(C).

28. 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.

29. Although Alvotech provided its aBLAs for AVT05 SC and AVT05 IV [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, Alvotech failed to provide complete documentation about [redacted] AVT05.

30. Nevertheless, [redacted] Janssen voluntarily provided to Alvotech 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. Because Alvotech failed to meet its obligation to provide all the information required under 42 U.S.C. § 262(*l*)(2)(A), Janssen was not obligated to provide the lists of patents nor is it subject to the limitations of 35 U.S.C. § 271(e)(6)(C).

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31. Under 42 U.S.C. § 262(*l*)(3)(B), Alvotech was obligated [redacted] to provide detailed statements that describe, on a claim by claim basis, the factual and legal basis of any opinion that the patents Janssen listed are invalid, unenforceable, or will not be infringed by the commercial marketing of AVT05 SC and AVT05 IV, respectively. Alvotech requested an extension to its deadline for making its disclosures [redacted] which Janssen accommodated. But Alvotech subsequently informed Janssen that it did not intend to comply with its obligations under § 262(*l*)(3)(B), even by the extended deadline. On information and belief, Alvotech failed to make the required disclosures under 42 U.S.C. § 262(*l*)(2)(A) and (*l*)(3)(B) in order to impede Janssen's evaluation of Alvotech's infringing products.

32. [redacted] Janssen supplemented its lists of patents for AVT05 SC and AVT05 IV under 42 U.S.C. § 262(*l*)(7). Alvotech had 30 days after each supplement to provide a statement in accordance with 42 U.S.C. § 262(*l*)(3)(B), and Alvotech continued to refuse to engage in the statutory information exchanges.

33. Alvotech's continued failure to comply with its 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 Alvotech infringes the Janssen Patents. *See, e.g.*, *Hoffmann-La Roche Inc. v. Invamed Inc.*, 213 F.3d 1359, 1364 (Fed. Cir. 2000).

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

[redacted]

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35. [redacted]

36. Because Alvotech failed to comply with its obligations under 42 U.S.C. § 262(*l*)(2)(A) and (*l*)(3)(B)(ii), the BPCIA also expressly authorizes Janssen, under 42 U.S.C. § 262(*l*)(9), to seek a declaration that Alvotech infringes the patents that Janssen previously identified under 42 U.S.C. § 262(*l*)(3)(A).

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

Alvotech Submitted Its aBLAs for AVT05 SC and AVT05 IV

38. [redacted] The reference product for AVT05 SC is Janssen's SIMPONI® product.

39. [redacted] The reference product for AVT05 IV is Janssen's SIMPONI ARIA® product.

40. Alvotech resubmitted its BLAs for AVT05 SC and AVT05 IV on or about June 4, 2026. Regulatory approval for these products is expected to be granted in or about December 2026.

41. Alvotech is a submitter of the aBLAs for AVT05 SC and AVT05 IV because it [redacted] intends to directly benefit from the

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aBLAs through the sale of AVT05 SC and AVT05 IV in the United States upon regulatory approval.

42. On information and belief, [redacted] Alvotech USA is a wholly owned subsidiary of Alvotech hf and is Alvotech's agent for service of process in the United States. *See, e.g.*, Alvotech, Annual Report (Form 20-F) (Mar. 27, 2025), https://investors.alvotech.com/node/10726/html. [redacted]

43. [redacted]

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[redacted]

44. Alvotech developed AVT05 and its manufacturing process. For example, Alvotech has been and is responsible for the development of AVT05, including "research, preclinical, non-clinical, and clinical drug development activities" necessary to obtain aBLA approval, and for funding the development costs of AVT05 through regulatory approval. *See, e.g.*, Alvotech's Registration Statement, Exhibit 10.17, https://www.sec.gov/Archives/edgar/data/1898416/000119312521362501/d193995dex1017.htm. Alvotech has and will develop AVT05, including performing all development activities necessary to obtain aBLA approval. *See, e.g.*, *id.*, Exhibit 10.16, https://www.sec.gov/Archives/edgar/data/1898416/000119312521362501/d193995dex1016.htm. Thus, Alvotech has exerted substantial control over the development of AVT05 and its manufacturing process.

45. [redacted]

Alvotech and Teva entered into a Product Supply Agreement, by which Alvotech exclusively manufactures and supplies AVT05 sold in the United States. Alvotech's Registration Statement, Exhibits 10.16 and 10.17, https://www.sec.gov/Archives/edgar/data/1898416/000119312521362501/d193995dex1016.htm; https://www.sec.gov/Archives/edgar/data/1898416/000119312521362501/d193995dex1017.htm. Alvotech is actively involved in the

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manufacture and supply of AVT05 for use and sale in the United States. Thus, Alvotech is involved in the use, sale, and offer for sale of AVT05.

46. Alvotech will financially benefit in a significant manner from regulatory approval of AVT05 SC and AVT05 IV. For example, Alvotech has entered into contracts under which it has received and will receive revenues and other financial compensation for the sale of AVT05 in the United States, including but not limited to license fees, milestone payments, and product sales. *See, e.g.*, Alvotech's Registration Statement, Exhibits 10.16 and 10.17, https://www.sec.gov/Archives/edgar/data/1898416/000119312521362501/d193995dex1016.htm; https://www.sec.gov/Archives/edgar/data/1898416/000119312521362501/d193995dex1017.htm. Alvotech licensed its commercialization, import, and distribution rights for AVT05 in the United States to Teva in exchange for significant revenues in the form of license fees and milestone payments, subject to a requirement to refund fees upon failure to obtain regulatory approval of AVT05 SC and AVT05 IV. *See, e.g.*, Alvotech's Registration Statement, Exhibit 10.17, https://www.sec.gov/Archives/edgar/data/1898416/000119312521362501/d193995dex1017.htm. On information and belief, Alvotech's revenues are driven by the commercial success of its biosimilar products. Thus, Alvotech will directly benefit from the approval of AVT05 SC and AVT05 IV.

47. AVT05 SC and AVT05 IV will be offered for sale and sold by Teva within the United States. *See, e.g.*, Alvotech's Registration Statement, Exhibits 10.16 and 10.17, https://www.sec.gov/Archives/edgar/data/1898416/000119312521362501/d193995dex1016.htm; https://www.sec.gov/Archives/edgar/data/1898416/000119312521362501/d193995dex1017.htm. On information and belief, AVT05 SC and AVT05 IV will be imported by Alvotech and/or Teva

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into the United States. Alvotech's Registration Statement, Exhibit 10.17, https://www.sec.gov/Archives/edgar/data/1898416/000119312521362501/d193995dex1017.htm.

48. Alvotech will actively induce Teva to import, offer to sell and sell AVT05 SC and AVT05 IV by developing, supplying, soliciting purchase orders for, indemnifying, and licensing AVT05 SC and AVT05 IV for Teva to import into, and offer to sell and sell within, the United States. *See, e.g.*, Alvotech's Registration Statement, Exhibits 10.16 and 10.17, https://www.sec.gov/Archives/edgar/data/1898416/000119312521362501/d193995dex1016.htm; https://www.sec.gov/Archives/edgar/data/1898416/000119312521362501/d193995dex1017.htm.

COUNT I

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

49. Janssen incorporates by reference the allegations set forth in paragraphs 1-48 above as if fully set forth herein.

50. 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 A. JBI is the owner by assignment of the '325 patent.

51. 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;

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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.

52. On information and belief, the manufacture of AVT05 SC and AVT05 IV is covered by one or more claims of the '325 patent, literally or under the doctrine of equivalents.

53. [redacted]

54. [redacted]

55. [redacted]

56. [redacted]

57. On information and belief, Alvotech [redacted] Janssen has a reasonable basis for this belief at least because Alvotech failed to comply with its obligation under 42 U.S.C. § 262(*l*)(3)(B) to provide a detailed statement that describes the factual and legal basis of any opinion that the '325 patent will not be infringed by the commercial marketing of AVT05. On information and belief, Alvotech withheld this information because it knows or has reason to believe that [redacted]

[redacted]

58. Janssen also attempted to ascertain [redacted] by examining materials that Alvotech was obligated to provide under 42 U.S.C. § 262(*l*)(2)(A). [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 Alvotech quantitates 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. *See, e.g.*, *Amgen*, 866 F.3d at 1362; *Hoffmann-La Roche*, 213 F.3d at 1364.

59. Alvotech's submission of its aBLAs for AVT05 SC [redacted] and AVT05 IV [redacted] infringed the '325 patent under 35 U.S.C. § 271(e)(2)(C).

60. Alvotech has 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] On information and belief, Alvotech has been aware of the '325 patent and its relevance to AVT05 even before Janssen identified it on [redacted]

61. On information and belief, Alvotech acted with deliberate and intentional disregard of Janssen's rights under the '325 patent.

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

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

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[redacted]

COUNT II

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

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

65. As set forth in Count I, Alvotech would infringe the '325 patent, literally or under the doctrine of equivalents, if AVT05 is used, offered for sale, sold, or imported in the United States.

66. Because Alvotech would only have regulatory approval to sell AVT05 as described in its aBLAs, any imported AVT05 made by the patented process will not be materially changed by subsequent processes nor be a trivial or nonessential component of another product.

67. Alvotech has knowledge of and/or is willfully blind to the fact that the use, sale, offer for sale, and/or importation of AVT05 will directly infringe one or more claims of the '325 patent, literally or under the doctrine of equivalents.

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

69. By filing aBLAs for AVT05 SC and AVT05 IV, [redacted]

70. [redacted] present 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

[redacted]

authorizes a declaratory judgment action for patent infringement due to Alvotech's [redacted] failure to comply with its obligations under 42 U.S.C. § 262(*l*)(2)(A) and (*l*)(3)(B). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

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

72. Janssen has no adequate remedy at law to redress the infringement by Alvotech.

73. Janssen will be irreparably harmed if Alvotech is not enjoined from infringing the '325 patent.

COUNT III

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

74. Janssen incorporates by reference the allegations set forth in paragraphs 1-73 above as if fully set forth herein.

75. 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 B. JBI is the owner by assignment of the '889 patent.

76. 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.

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> 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.

77. On information and belief, the manufacture of AVT05 SC and AVT05 IV is covered by one or more claims of the '889 patent, literally or under the doctrine of equivalents.

78. [redacted]

79. [redacted] On information and belief, [redacted] Janssen has a reasonable basis for this belief at least because Alvotech failed to comply with its obligation

[redacted]

under 42 U.S.C. § 262(*l*)(3)(B) to provide a detailed statement that describes the factual and legal basis of any opinion that the '889 patent will not be infringed by the commercial marketing of AVT05. On information and belief, Alvotech withheld this information because it knows or has reason to believe that [redacted]

80. Janssen also attempted to ascertain [redacted] by examining materials that Alvotech was obligated to provide under 42 U.S.C. § 262(*l*)(2)(A). However, Alvotech 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 [redacted] cell culture media comprise 1.5 g/L lysine to 20 g/L lysine and 1.5 g/L arginine to 20 g/L arginine. *See, e.g.*, *Amgen*, 866 F.3d at 1362; *Hoffmann-La Roche*, 213 F.3d at 1364.

81. [redacted]

82. [redacted]

83. Alvotech's commercial manufacturing of AVT05 is intended to [redacted]

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[redacted]

84. Alvotech is also seeking [redacted]

85. [redacted]

[redacted]

86. Alvotech's submission of its aBLAs for AVT05 SC [redacted] and AVT05 IV [redacted] infringed the '889 patent under 35 U.S.C. § 271(e)(2)(C).

87. Alvotech has 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] On information and belief, Alvotech has been aware of the '889 patent and its relevance to AVT05 even before Janssen identified it on [redacted]

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

89. Janssen has no adequate remedy at law to redress the infringement by Alvotech.

90. Janssen will be irreparably harmed if Alvotech is not enjoined from infringing the '889 patent.

COUNT IV

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

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

92. As set forth in Count III, Alvotech would infringe the '889 patent, literally or under the doctrine of equivalents, if AVT05 is used, offered for sale, sold, or imported in the United States.

93. Because Alvotech would only have regulatory approval to sell AVT05 as described in its aBLAs, any imported AVT05 made by the patented process will not be materially changed by subsequent processes nor be a trivial or nonessential component of another product.

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94. Alvotech has knowledge of and/or is willfully blind to the fact that the use, sale, offer for sale, and/or importation of AVT05 will directly infringe one or more claims of the '889 patent, literally or under the doctrine of equivalents.

95. Alvotech will knowingly or with willful blindness induce another's direct infringement of one or more claims of the '889 patent, literally or under the doctrine of equivalents.

96. By filing aBLAs for AVT05 SC and AVT05 IV, [redacted]

97. [redacted] present 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 Alvotech's [redacted] failure to comply with its obligations under 42 U.S.C. § 262(*l*)(2)(A) and (*l*)(3)(B). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

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

99. Janssen has no adequate remedy at law to redress the infringement by Alvotech.

100. Janssen will be irreparably harmed if Alvotech is not enjoined from infringing the '889 patent.

[redacted]

COUNT V

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

101. Janssen incorporates by reference the allegations set forth in paragraphs 1-100 above as if fully set forth herein.

102. 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 C. JBI is the owner by assignment of the '830 patent.

103. 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;

REDACTED VERSION

[redacted]

(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.

104. On information and belief, the manufacture of AVT05 SC and AVT05 IV is covered by one or more claims of the '830 patent, literally or under the doctrine of equivalents.

105. [redacted]

106. [redacted]

107. [redacted]

108. On information and belief, [redacted] Janssen has a reasonable basis for this belief at least because Alvotech failed to comply with its obligation under 42 U.S.C. § 262(*l*)(3)(B) to provide a detailed statement that describes the factual and legal basis of any opinion that the '830 patent will not be infringed by the commercial marketing of AVT05. On information and belief, Alvotech withheld this information because it knows or has reason to believe that [redacted]

[redacted]

109. Janssen also attempted to ascertain [redacted] by examining materials that Alvotech was obligated to provide under 42 U.S.C. § 262(*l*)(2)(A). However, Alvotech 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 [redacted] cell culture media comprise DMSO. *See, e.g.*, *Amgen*, 866 F.3d at 1362; *Hoffmann-La Roche*, 213 F.3d at 1364.

110. [redacted]

111. On information and belief, [redacted] Janssen has a reasonable basis for this belief at least because Alvotech failed to comply with its obligation under 42 U.S.C. § 262(*l*)(3)(B) to provide a detailed statement that describes the factual and legal basis of any opinion that the '830 patent will not be infringed by the commercial marketing of AVT05. On information and belief, Alvotech withheld this information because it knows or has reason to believe that [redacted]

112. Janssen also attempted to ascertain that [redacted] by examining materials that Alvotech was obligated to provide under 42 U.S.C. § 262(*l*)(2)(A). However,

[redacted]

Alvotech 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 that AVT05 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. *See, e.g.*, *Amgen*, 866 F.3d at 1362; *Hoffmann-La Roche*, 213 F.3d at 1364.

113. Alvotech's commercial manufacturing of AVT05 is intended to produce [redacted]

114. Alvotech is also seeking [redacted]

115. [redacted]

116. On information and belief, [redacted] Janssen has a reasonable basis for this belief at least because Alvotech failed to comply with its obligation under 42 U.S.C. § 262(*l*)(3)(B) to provide a detailed statement that describes the factual and legal basis of any opinion that the '830 patent will not be infringed by the commercial marketing of AVT05. On information and belief, Alvotech withheld this information because it knows or has reason to believe that [redacted]

[redacted]

117. Janssen also attempted to ascertain that [redacted] by examining materials that Alvotech was obligated to provide under 42 U.S.C. § 262(*l*)(2)(A). However, Alvotech 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 Alvotech formulates AVT05 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. *See, e.g.*, *Amgen*, 866 F.3d at 1362; *Hoffmann-La Roche*, 213 F.3d at 1364.

118. Alvotech's submission of its aBLAs for AVT05 SC [redacted] and AVT05 IV [redacted] infringed the '830 patent under 35 U.S.C. § 271(e)(2)(C).

119. Alvotech has 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] On information and belief, Alvotech has been aware of the '830 patent and its relevance to AVT05 even before Janssen identified it on [redacted]

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

121. Janssen has no adequate remedy at law to redress the infringement by Alvotech.

122. Janssen will be irreparably harmed if Alvotech is not enjoined from infringing the '830 patent.

REDACTED VERSION

[redacted]

COUNT VI

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

123. Janssen incorporates by reference the allegations set forth in paragraphs 1-122 above as if fully set forth herein.

124. As set forth in Count V, Alvotech would infringe the '830 patent, literally or under the doctrine of equivalents, if AVT05 is used, offered for sale, sold, or imported in the United States.

125. Because Alvotech would only have regulatory approval to sell AVT05 as described in its aBLAs, any imported AVT05 made by the patented process will not be materially changed by subsequent processes nor be a trivial or nonessential component of another product.

126. Alvotech has knowledge of and/or is willfully blind to the fact that the use, sale, offer for sale, and/or importation of AVT05 will directly infringe one or more claims of the '830 patent, literally or under the doctrine of equivalents.

127. Alvotech will knowingly or with willful blindness induce another's direct infringement of one or more claims of the '830 patent, literally or under the doctrine of equivalents.

128. By filing aBLAs for AVT05 SC and AVT05 IV, [redacted]

129. [redacted] present 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

REDACTED VERSION

[redacted]

BPCIA authorizes a declaratory judgment action for patent infringement due to Alvotech's [redacted] failure to comply with its obligations under 42 U.S.C. § 262(*l*)(2)(A) and (*l*)(3)(B). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

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

131. Janssen has no adequate remedy at law to redress the infringement by Alvotech.

132. Janssen will be irreparably harmed if Alvotech is not enjoined from infringing the '830 patent.

COUNT VII

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

133. Janssen incorporates by reference the allegations set forth in paragraphs 1-132 above as if fully set forth herein.

134. 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 D. JBI is the owner by assignment of the '249 patent.

135. The '249 patent is directed to and claims methods of manufacturing a glycoprotein preparation. 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;

REDACTED VERSION

[redacted]

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.

136. On information and belief, the manufacture of AVT05 SC and AVT05 IV is covered by one or more claims of the '249 patent, literally or under the doctrine of equivalents.

137. [redacted]

138. [redacted]

139. [redacted]

REDACTED VERSION

[redacted]

140. [redacted] Therefore, on information and belief, Alvotech [redacted]

141. Alvotech's submission of its aBLAs for AVT05 SC [redacted] and AVT05 IV [redacted] infringed the '249 patent under 35 U.S.C. § 271(e)(2)(C).

142. Alvotech has 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] On

[redacted]

information and belief, Alvotech has been aware of the '249 patent and its relevance to AVT05 even before Janssen identified it on [redacted]

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

144. Janssen has no adequate remedy at law to redress the infringement by Alvotech.

145. Janssen will be irreparably harmed if Alvotech is not enjoined from infringing the '249 patent.

COUNT VIII

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

146. Janssen incorporates by reference the allegations set forth in paragraphs 1-145 above as if fully set forth herein.

147. As set forth in Count VII, Alvotech would infringe the '249 patent, literally or under the doctrine of equivalents, if AVT05 is used, offered for sale, sold, or imported in the United States.

148. Because Alvotech would only have regulatory approval to sell AVT05 as described in its aBLAs, any imported AVT05 made by the patented process will not be materially changed by subsequent processes nor be a trivial or nonessential component of another product.

149. Alvotech has knowledge of and/or is willfully blind to the fact that the use, sale, offer for sale, and/or importation of AVT05 will directly infringe one or more claims of the '249 patent, literally or under the doctrine of equivalents.

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

REDACTED VERSION

[redacted]

151. By filing aBLAs for AVT05 SC and AVT05 IV, [redacted]

152. [redacted] present 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 Alvotech's [redacted] failure to comply with its obligations under 42 U.S.C. § 262(*l*)(2)(A) and (*l*)(3)(B). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

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

154. Janssen has no adequate remedy at law to redress the infringement by Alvotech.

155. Janssen will be irreparably harmed if Alvotech is not enjoined from infringing the '249 patent.

COUNT IX

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

156. Janssen incorporates by reference the allegations set forth in paragraphs 1-155 above as if fully set forth herein.

REDACTED VERSION

[redacted]

157. 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 E. JBI is the owner by assignment of the '168 patent.

158. 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

[redacted]

preparation of the recombinant protein produced by culturing the cell in the medium not comprising 0.1 mg/L to 10 mg/L putrescine.

159. On information and belief, the manufacture of AVT05 SC and AVT05 IV is covered by one or more claims of the '168 patent, literally or under the doctrine of equivalents.

160. [redacted]

161. [redacted]

162. [redacted] Janssen has a reasonable basis for this belief at least because Alvotech failed to comply with its obligation under 42 U.S.C. § 262(*l*)(3)(B) to provide a detailed statement that describes the factual and legal basis of any opinion that the '168 patent will not be infringed by the commercial marketing of AVT05. On information and belief, Alvotech withheld this information because it knows or has reason to believe that [redacted]

163. Janssen also attempted to ascertain [redacted] by examining materials that Alvotech was obligated to provide under 42 U.S.C.

[redacted]

§ 262(*l*)(2)(A). However, Alvotech 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 [redacted] cell culture media comprise 0.1 mg/L to 10 mg/L putrescine. *See, e.g.*, *Amgen*, 866 F.3d at 1362; *Hoffmann-La Roche*, 213 F.3d at 1364.

164. [redacted]

165. [redacted] Janssen has a reasonable basis for this belief at least because Alvotech failed to comply with its obligation under 42 U.S.C. § 262(*l*)(3)(B) to provide a detailed statement that describes the factual and legal basis of any opinion that the '168 patent will not be infringed by the commercial marketing of AVT05. On information and belief, Alvotech withheld this information because it knows or has reason to believe that [redacted]

REDACTED VERSION

[redacted]

166. Janssen also attempted to ascertain that [redacted] by examining materials that Alvotech was obligated to provide under 42 U.S.C. § 262(*l*)(2)(A). However, Alvotech 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 AVT05 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.*, *Amgen*, 866 F.3d at 1362; *Hoffmann-La Roche*, 213 F.3d at 1364.

167. On information and belief, [redacted] Janssen has a reasonable basis for this belief at least because Alvotech failed to comply with its obligation under 42 U.S.C. § 262(*l*)(3)(B) to provide a detailed statement that describes the factual and legal basis of any opinion that the '168 patent will not be infringed by the commercial marketing of AVT05. On information and belief, Alvotech withheld this information because it knows or has reason to believe that [redacted]

REDACTED VERSION

[redacted]

168. Janssen also attempted to ascertain that [redacted] by examining materials that Alvotech was obligated to provide under 42 U.S.C. § 262(*l*)(2)(A). However, Alvotech 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 AVT05 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.*, *Amgen*, 866 F.3d at 1362; *Hoffmann-La Roche*, 213 F.3d at 1364.

169. Alvotech's submission of its aBLAs for AVT05 SC [redacted] and AVT05 IV [redacted] infringed the '168 patent under 35 U.S.C. § 271(e)(2)(C).

170. Alvotech has 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] On information and belief, Alvotech has been aware of the '168 patent and its relevance to AVT05 even before Janssen identified it on [redacted]

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

172. Janssen has no adequate remedy at law to redress the infringement by Alvotech.

173. Janssen will be irreparably harmed if Alvotech is not enjoined from infringing the '168 patent.

REDACTED VERSION

[redacted]

COUNT X

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

174. Janssen incorporates by reference the allegations set forth in paragraphs 1-173 above as if fully set forth herein.

175. As set forth in Count IX, Alvotech would infringe the '168 patent, literally or under the doctrine of equivalents, if AVT05 is used, offered for sale, sold, or imported in the United States.

176. Because Alvotech would only have regulatory approval to sell AVT05 as described in its aBLAs, any imported AVT05 made by the patented process will not be materially changed by subsequent processes nor be a trivial or nonessential component of another product.

177. Alvotech has knowledge of and/or is willfully blind to the fact that the use, sale, offer for sale, and/or importation of AVT05 will directly infringe one or more claims of the '168 patent, literally or under the doctrine of equivalents.

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

179. By filing aBLAs for AVT05 SC and AVT05 IV, [redacted]

180. [redacted] present 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

[redacted]

authorizes a declaratory judgment action for patent infringement due to Alvotech's [redacted] failure to comply with its obligations under 42 U.S.C. § 262(*l*)(2)(A) and (*l*)(3)(B). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

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

182. Janssen has no adequate remedy at law to redress the infringement by Alvotech.

183. Janssen will be irreparably harmed if Alvotech is not enjoined from infringing the '168 patent.

COUNT XI

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

184. Janssen incorporates by reference the allegations set forth in paragraphs 1-183 above as if fully set forth herein.

185. 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 F. JBI is the owner by assignment of the '858 patent.

186. 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

REDACTED VERSION

[redacted]

> 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.

187. On information and belief, the manufacture of AVT05 SC and AVT05 IV is covered by one or more claims of the '858 patent, literally or under the doctrine of equivalents.

188. [redacted]

189. [redacted]. Janssen has a reasonable basis for this belief at least because Alvotech failed to comply with its obligation under 42 U.S.C. § 262(*l*)(3)(B) to provide a detailed statement that describes the factual and legal basis of any opinion that the '858 patent will not be infringed by

[redacted]

the commercial marketing of AVT05. On information and belief, Alvotech withheld this information because it knows or has reason to believe that [redacted]

190. Janssen also attempted to ascertain [redacted] by examining materials that Alvotech was obligated to provide under 42 U.S.C. § 262(*l*)(2)(A). However, Alvotech 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 [redacted] cell culture media comprise 2 g/L lysine to 8 g/L lysine and 2 g/L arginine to 8 g/L arginine. *See, e.g.*, *Amgen*, 866 F.3d at 1362; *Hoffmann-La Roche*, 213 F.3d at 1364.

191. [redacted]

192. Alvotech's commercial manufacturing of AVT05 is intended to produce [redacted]

193. Alvotech is also seeking [redacted]

[redacted]

194. [redacted]

195. [redacted]

[redacted]

196. Alvotech's submission of its aBLAs for AVT05 SC [redacted] and AVT05 IV [redacted] infringed the '858 patent under 35 U.S.C. § 271(e)(2)(C).

197. Alvotech has 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] On information and belief, Alvotech has been aware of the '858 patent and its relevance to AVT05 even before Janssen identified it on [redacted]

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

199. Janssen has no adequate remedy at law to redress the infringement by Alvotech.

200. Janssen will be irreparably harmed if Alvotech is not enjoined from infringing the '858 patent.

COUNT XII

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

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

[redacted]

202. As set forth in Count XI, Alvotech would infringe the '858 patent, literally or under the doctrine of equivalents, if AVT05 is used, offered for sale, sold, or imported in the United States.

203. Because Alvotech would only have regulatory approval to sell AVT05 as described in its aBLAs, any imported AVT05 made by the patented process will not be materially changed by subsequent processes nor be a trivial or nonessential component of another product.

204. Alvotech has knowledge of and/or is willfully blind to the fact that the use, sale, offer for sale, and/or importation of AVT05 will directly infringe one or more claims of the '858 patent, literally or under the doctrine of equivalents.

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

206. By filing aBLAs for AVT05 SC and AVT05 IV, [redacted]

207. [redacted] present 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 Alvotech's [redacted] failure to comply with its obligations under 42 U.S.C. § 262(*l*)(2)(A) and (*l*)(3)(B). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

[redacted]

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

209. Janssen has no adequate remedy at law to redress the infringement by Alvotech.

210. Janssen will be irreparably harmed if Alvotech is not enjoined from infringing the '858 patent.

COUNT XIII

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

211. Janssen incorporates by reference the allegations set forth in paragraphs 1-210 above as if fully set forth herein.

212. 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 G. JBI is the owner by assignment of the '7810 patent.

213. 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 2 is representative and recites:

> 2. 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 0.1% to 20% high mannose glycans.

REDACTED VERSION

[redacted]

214. On information and belief, the manufacture of AVT05 SC and AVT05 IV is covered by one or more claims of the '7810 patent, literally or under the doctrine of equivalents.

215. [redacted]

216. [redacted]

217. [redacted].

218. On information and belief, [redacted] Janssen has a reasonable basis for this belief at least because Alvotech failed to comply with its obligation under 42 U.S.C. § 262(*l*)(3)(B) to provide a detailed statement that describes the factual and legal basis of any opinion that the '7810 patent will not be infringed by the commercial marketing of AVT05. On information and belief, Alvotech withheld this information because it knows or has reason to believe that [redacted]

219. Janssen also attempted to ascertain [redacted] by examining materials that Alvotech was obligated to provide under 42 U.S.C. § 262(*l*)(2)(A). However, Alvotech 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 [redacted]

[redacted]

[redacted] cell culture media comprise DMSO. *See, e.g.*, *Amgen*, 866 F.3d at 1362; *Hoffmann-La Roche*, 213 F.3d at 1364.

220. [redacted]

221. Alvotech's commercial manufacturing of AVT05 is intended to produce [redacted]

222. Alvotech is also seeking [redacted]

[redacted]

223. [redacted]

224. Alvotech's submission of its aBLAs for AVT05 SC [redacted] and AVT05 IV [redacted] infringed the '7810 patent under 35 U.S.C. § 271(e)(2)(C).

225. Alvotech has 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] On information and belief, Alvotech has been aware of the '7810 patent and its relevance to AVT05 even before Janssen identified it on [redacted]

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

[redacted]

227. Janssen has no adequate remedy at law to redress the infringement by Alvotech.

228. Janssen will be irreparably harmed if Alvotech is not enjoined from infringing the '7810 patent.

COUNT XIV

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

229. Janssen incorporates by reference the allegations set forth in paragraphs 1-228 above as if fully set forth herein.

230. As set forth in Count XIII, Alvotech would infringe the '7810 patent, literally or under the doctrine of equivalents, if AVT05 is used, offered for sale, sold, or imported in the United States.

231. Because Alvotech would only have regulatory approval to sell AVT05 as described in its aBLAs, any imported AVT05 made by the patented process will not be materially changed by subsequent processes nor be a trivial or nonessential component of another product.

232. Alvotech has knowledge of and/or is willfully blind to the fact that the use, sale, offer for sale, and/or importation of AVT05 will directly infringe one or more claims of the '7810 patent, literally or under the doctrine of equivalents.

233. Alvotech will knowingly or with willful blindness induce another's direct infringement of one or more claims of the '7810 patent, literally or under the doctrine of equivalents.

234. By filing aBLAs for AVT05 SC and AVT05 IV, [redacted]

[redacted]

REDACTED VERSION

[redacted]

235. [redacted] present 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 Alvotech's [redacted] failure to comply with its obligations under 42 U.S.C. § 262(*l*)(2)(A) and (*l*)(3)(B). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

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

237. Janssen has no adequate remedy at law to redress the infringement by Alvotech.

238. Janssen will be irreparably harmed if Alvotech is not enjoined from infringing the '7810 patent.

COUNT XV

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

239. Janssen incorporates by reference the allegations set forth in paragraphs 1-238 above as if fully set forth herein.

240. 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 H. JBI is the owner by assignment of the '3810 patent.

REDACTED VERSION

[redacted]

241. 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.

242. On information and belief, the manufacture of AVT05 SC and AVT05 IV is covered by one or more claims of the ’3810 patent, literally or under the doctrine of equivalents.

243. [redacted]

244. [redacted]

245. [redacted]

[redacted] Janssen has a reasonable basis for this belief at least because Alvotech failed to comply with its obligation under 42 U.S.C. § 262(*l*)(3)(B) to provide a detailed statement that describes the factual and legal basis of any opinion that the '3810 patent will not be infringed by the commercial marketing of AVT05. On information and belief, Alvotech withheld this information because it knows or has reason to believe that [redacted]

246. Janssen also attempted to ascertain [redacted] examining materials that Alvotech was obligated to provide under 42 U.S.C. § 262(*l*)(2)(A). However, Alvotech 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 [redacted] cell culture media comprise 0.1 mg/L to 10 mg/L putrescine. *See, e.g.*, *Amgen*, 866 F.3d at 1362; *Hoffmann-La Roche*, 213 F.3d at 1364.

247. [redacted]

248. On information and belief, [redacted] Janssen has a reasonable basis for this belief at least because Alvotech failed to comply with its obligation under 42 U.S.C. § 262(*l*)(3)(B) to provide a detailed statement that describes the factual and legal basis of any opinion that the '3810 patent will not be infringed by the commercial marketing of AVT05. On information and belief, Alvotech withheld this information because it knows or has reason to believe that [redacted]

REDACTED VERSION

[redacted]

249. Janssen also attempted to ascertain that [redacted] by examining materials that Alvotech was obligated to provide under 42 U.S.C. § 262(*l*)(2)(A). However, Alvotech 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 AVT05'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.*, *Amgen*, 866 F.3d at 1362; *Hoffmann-La Roche*, 213 F.3d at 1364.

250. Alvotech's submission of its aBLAs for AVT05 SC [redacted] and AVT05 IV [redacted] infringed the '3810 patent under 35 U.S.C. § 271(e)(2)(C).

251. Alvotech has 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] On information and belief, Alvotech has been aware of the '3810 patent and its relevance to AVT05 even before Janssen identified it on [redacted]

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

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

254. Janssen will be irreparably harmed if Alvotech is not enjoined from infringing the '3810 patent.

[redacted]

COUNT XVI

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

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

256. As set forth in Count XV, Alvotech would infringe the '3810 patent, literally or under the doctrine of equivalents, if AVT05 is used, offered for sale, sold, or imported in the United States.

257. Because Alvotech would only have regulatory approval to sell AVT05 as described in its aBLAs, any imported AVT05 made by the patented process will not be materially changed by subsequent processes nor be a trivial or nonessential component of another product.

258. Alvotech has knowledge of and/or is willfully blind to the fact that the use, sale, offer for sale, and/or importation of AVT05 will directly infringe one or more claims of the '3810 patent, literally or under the doctrine of equivalents.

259. Alvotech will knowingly or with willful blindness induce another's direct infringement of one or more claims of the '3810 patent, literally or under the doctrine of equivalents.

260. By filing aBLAs for AVT05 SC and AVT05 IV, [redacted]

261. [redacted] present a controversy of sufficient immediacy and reality to support

REDACTED VERSION

[redacted]

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 Alvotech's [redacted] failure to comply with its obligations under 42 U.S.C. § 262(*l*)(2)(A) and (*l*)(3)(B). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

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

263. Janssen has no adequate remedy at law to redress the infringement by Alvotech.

264. Janssen will be irreparably harmed if Alvotech is not enjoined from infringing the '3810 patent.

COUNT XVII

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

265. Janssen incorporates by reference the allegations set forth in paragraphs 1-264 above as if fully set forth herein.

266. 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 I. JBI is the owner by assignment of the '410 patent.

267. The '410 patent is directed to and claims methods of manufacturing a glycoprotein preparation. 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:

REDACTED VERSION

[redacted]

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.

268. On information and belief, the manufacture of AVT05 SC and AVT05 IV is covered by one or more claims of the '410 patent, literally or under the doctrine of equivalents.

269. [redacted]

270. [redacted]

271. [redacted]

[redacted]

272. [redacted]

273. Alvotech's submission of its aBLAs for AVT05 SC [redacted] and AVT05 IV [redacted] infringed the '410 patent under 35 U.S.C. § 271(e)(2)(C).

274. Alvotech has 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] On

[redacted]

information and belief, Alvotech has been aware of the '410 patent and its relevance to AVT05 even before Janssen identified it on [redacted]

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

276. Janssen has no adequate remedy at law to redress the infringement by Alvotech.

277. Janssen will be irreparably harmed if Alvotech is not enjoined from infringing the '410 patent.

COUNT XVIII

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

278. Janssen incorporates by reference the allegations set forth in paragraphs 1-277 above as if fully set forth herein.

279. As set forth in Count XVII, Alvotech would infringe the '410 patent, literally or under the doctrine of equivalents, if AVT05 is used, offered for sale, sold, or imported in the United States.

280. Because Alvotech would only have regulatory approval to sell AVT05 as described in its aBLAs, any imported AVT05 made by the patented process will not be materially changed by subsequent processes nor be a trivial or nonessential component of another product.

281. Alvotech has knowledge of and/or is willfully blind to the fact that the use, sale, offer for sale, and/or importation of AVT05 will directly infringe one or more claims of the '410 patent, literally or under the doctrine of equivalents.

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

REDACTED VERSION

[redacted]

283. By filing aBLAs for AVT05 SC and AVT05 IV, [redacted]

284. [redacted] present 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 Alvotech's [redacted] failure to comply with its obligations under 42 U.S.C. § 262(*l*)(2)(A) and (*l*)(3)(B). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

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

286. Janssen has no adequate remedy at law to redress the infringement by Alvotech.

287. Janssen will be irreparably harmed if Alvotech is not enjoined from infringing the '410 patent.

COUNT XIX

Infringement of U.S. Patent No. 10,421,986 Under 35 U.S.C. § 271(e)(2)(C)

288. Janssen incorporates by reference the allegations set forth in paragraphs 1-287 above as if fully set forth herein.

289. U.S. Patent No. 10,421,986 ("the '986 patent") is titled "Method for the clarification of high-density crude cell culture harvest." The '986 patent was duly and legally

[redacted]

issued on September 24, 2019. A true and correct copy of the '986 patent is attached hereto as Exhibit J. JBI is the owner by assignment of the '986 patent.

290. The '986 patent is directed to methods of clarifying a crude cell culture harvest using tangential flow filtration. The '986 patent includes 17 claims, two of which are independent. Claim 1 is representative and recites:

> 1. A method for clarifying a crude cell culture harvest comprising cells as well as a secreted desired protein, wherein the cells are at a cell density at harvest of at least 15×10^6 cells/ml and wherein at least 20% of said cells are viable, said method comprising the steps of:
>
> a. culturing cells in a bioreactor to a cell density of at least 15×10^6 cells/ml in order to obtain a crude cell culture harvest comprising desired secreted proteins;
>
> b. subsequently processing at least 70% of the crude cell culture harvest obtained in step a) by tangential flow filtration (TFF) to form a crude cell broth, wherein the processed volume of said crude cell culture harvest is less than two times the volume of the bioreactor in which the crude cell culture harvest has been produced, and wherein the desired protein is separated from the crude cell broth; and
>
> c. recovering the desired protein in the filtrate.

291. The manufacture of AVT05 SC and AVT05 IV is covered by one or more claims of the '986 patent, literally or under the doctrine of equivalents.

292. [redacted]

293. [redacted]

[redacted]

294. [redacted]

295. [redacted]

296. [redacted]

297. [redacted]

[redacted]

298. Alvotech's submission of its aBLAs for AVT05 SC [redacted] and AVT05 IV [redacted] infringed the '986 patent under 35 U.S.C. § 271(e)(2)(C).

299. Alvotech has knowledge of the '986 patent, due to at least Janssen's disclosure of the '986 patent under 42 U.S.C. § 262(*l*)(3)(A) on [redacted] On information and belief, Alvotech has been aware of the '986 patent and its relevance to AVT05 even before Janssen identified it on [redacted]

300. On information and belief, Alvotech acted with deliberate and intentional disregard of Janssen's rights under the '986 patent.

301. Janssen has no adequate remedy at law to redress the infringement by Alvotech.

302. Janssen will be irreparably harmed if Alvotech is not enjoined from infringing the '986 patent.

COUNT XX

Declaratory Judgment of Infringement of U.S. Patent No. 10,421,986

303. Janssen incorporates by reference the allegations set forth in paragraphs 1-302 above as if fully set forth herein.

304. As set forth in Count XIX, Alvotech would infringe the '986 patent, literally or under the doctrine of equivalents, if AVT05 is used, offered for sale, sold, or imported in the United States.

305. Because Alvotech would only have regulatory approval to sell AVT05 as described in its aBLAs, any imported AVT05 made by the patented process will not be materially changed by subsequent processes nor be a trivial or nonessential component of another product.

REDACTED VERSION

[redacted]

306. Alvotech has knowledge of and/or is willfully blind to the fact that the use, sale, offer for sale, and/or importation of AVT05 will directly infringe one or more claims of the '986 patent, literally or under the doctrine of equivalents.

307. Alvotech will knowingly or with willful blindness induce another's direct infringement of one or more claims of the '986 patent, literally or under the doctrine of equivalents.

308. By filing aBLAs for AVT05 SC and AVT05 IV, [redacted]

309. [redacted] present 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 Alvotech's [redacted] failure to comply with its obligations under 42 U.S.C. § 262(*l*)(2)(A) and (*l*)(3)(B). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

310. Janssen therefore seeks declaratory judgment that Alvotech will infringe the '986 patent, literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(b) and/or 271(g).

311. Janssen has no adequate remedy at law to redress the infringement by Alvotech.

312. Janssen will be irreparably harmed if Alvotech is not enjoined from infringing the '986 patent.

[redacted]

COUNT XXI

Infringement of U.S. Patent No. 11,225,516 Under 35 U.S.C. § 271(e)(2)(C)

313. Janssen incorporates by reference the allegations set forth in paragraphs 1-312 above as if fully set forth herein.

314. U.S. Patent No. 11,225,516 ("the '516 patent") is titled "Transition Analysis Method For Chromatography Column Qualification." The '516 patent was duly and legally issued on January 18, 2022. A true and correct copy of the '516 patent is attached hereto as Exhibit K. JBI is the owner by assignment of the '516 patent.

315. The '516 patent is directed to and claims a method of operating a chromatography column. The '516 patent includes 17 claims, one of which is independent. Claim 1 is representative and recites:

> 1. A method of operating a chromatography column, said method comprising:
>
> collecting a column outlet signal and accumulated flow parameters at two or more intervals of at least one mobile phase transition front during a first operation of the chromatography column comprising column packing;
>
> determining a model gamma cumulative distribution curve based on the collected column outlet signal and accumulated flow parameters for the at least one mobile phase transition front using Formula Ia for a rising transition front or Formula Ib for a falling transition front,
>
> $$C = 1 - \frac{1}{\Gamma(k)}\gamma\left(k, \frac{V - V_i}{\theta}\right)$$ Formula Ia
>
> or
>
> $$C = \frac{1}{\Gamma(k)}\gamma\left(k, \frac{V - V_i}{\theta}\right)$$ Formula Ib
>
> wherein C is the column outlet signal for a given V, V is the accumulated flow divided by the column volume, and k, θ, and Vi

REDACTED VERSION

[redacted]

are the shape, scale, and offset parameters, respectively, used to define the curve;

calculating a height equivalent theoretical plate (HETP) value for the at least one mobile phase transition front using Formula II and the model gamma cumulative distribution curve parameters of k, θ, and Vi,

$$HETP = \frac{\sigma^2}{\mu^2} L$$ Formula II

wherein

$$\mu = k\theta + V_i$$

$$\sigma = \sqrt{k\theta^2}$$

L = column length; and

assessing the quality of the chromatography column packing based on said calculated HETP value.

316. On information and belief, the manufacture of AVT05 SC and AVT05 IV is covered by one or more claims of the '516 patent, literally or under the doctrine of equivalents.

317. [redacted]

318. [redacted] Janssen has a reasonable basis for this belief at least because Alvotech failed to comply with its obligation under 42 U.S.C. § 262(*l*)(3)(B) to provide a detailed

[redacted]

statement that describes the factual and legal basis of any opinion that the '516 patent will not be infringed by the commercial marketing of AVT05. On information and belief, Alvotech withheld this information because it knows or has reason to believe that [redacted]

319. Janssen also attempted to ascertain that [redacted] by examining materials that Alvotech was obligated to provide under 42 U.S.C. § 262(*l*)(2)(A). However, Alvotech 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 Alvotech's operation of chromatography columns includes collecting a column outlet signal and accumulated flow parameters at two or more intervals of at least one mobile phase transition front during a first operation of the chromatography column comprising column packing. *See, e.g.*, *Amgen*, 866 F.3d at 1362; *Hoffmann-La Roche*, 213 F.3d at 1364.

320. [redacted]

REDACTED VERSION

[redacted] Janssen has a reasonable basis for this belief at least because Alvotech failed to comply with its obligation under 42 U.S.C. § 262(*l*)(3)(B) to provide a detailed statement that describes the factual and legal basis of any opinion that the '516 patent will not be infringed by the commercial marketing of AVT05. On information and belief, Alvotech withheld this information because it knows or has reason to believe that [redacted]

321. Janssen also attempted to ascertain that [redacted] by examining materials that Alvotech was obligated to provide under 42 U.S.C. § 262(*l*)(2)(A). However, Alvotech failed to provide complete information that describes [redacted] Janssen is entitled

[redacted]

to utilize the judicial process and the aid of discovery to obtain such information as is required to confirm its belief Alvotech's operation of chromatography columns to produce AVT05 includes determining a model gamma cumulative distribution curve based on the collected column outlet signal and accumulated flow parameters for the at least one mobile phase transition front using Formula Ia for a rising transition front or Formula Ib for a falling transition front as claimed, wherein C is the column outlet signal for a given V, V is the accumulated flow divided by the column volume, and k, θ, and Vi are the shape, scale, and offset parameters, respectively, used to define the curve. *See, e.g.*, *Amgen*, 866 F.3d at 1362; *Hoffmann-La Roche*, 213 F.3d at 1364.

322. [redacted]

Janssen has a reasonable basis for this belief at least because Alvotech failed to comply with its obligation under 42 U.S.C. § 262(*l*)(3)(B) to provide a detailed statement that describes the factual and legal basis of any opinion that the '516 patent will not be infringed by the commercial marketing of AVT05. On information and belief, Alvotech withheld this information because it knows or has reason to believe that [redacted]

[redacted]

323. Janssen also attempted to ascertain that [redacted] by examining materials that Alvotech was obligated to provide under 42 U.S.C. § 262(*l*)(2)(A). However, Alvotech 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 Alvotech's operation of chromatography columns to produce AVT05 includes calculating an HETP value for the at least one mobile phase transition front using Formula II as claimed and the model gamma cumulative distribution curve parameters of k, θ, and Vi, wherein $\mu = k\theta+Vi$, $\sigma = \sqrt{k\,\theta^2}$, and L = column length. *See, e.g.*, *Amgen*, 866 F.3d at 1362; *Hoffmann-La Roche*, 213 F.3d at 1364.

324. [redacted] Janssen has a reasonable basis for this belief at least because Alvotech failed to comply with its obligation under 42 U.S.C. § 262(*l*)(3)(B) to provide a detailed statement that describes the factual and legal basis of any opinion that the '516 patent will not be infringed by the commercial marketing of AVT05. On information and belief, Alvotech withheld this information because it knows or has reason to believe that [redacted]

REDACTED VERSION

[redacted]

325. Janssen also attempted to ascertain that [redacted] by examining materials that Alvotech was obligated to provide under 42 U.S.C. § 262(*l*)(2)(A). However, Alvotech 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 Alvotech's operation of chromatography columns to produce AVT05 includes assessing the quality of the chromatography column packing based on the calculated HETP value. *See, e.g.*, *Amgen*, 866 F.3d at 1362; *Hoffmann-La Roche*, 213 F.3d at 1364.

326. Alvotech's submission of its aBLAs for AVT05 SC [redacted] and AVT05 IV [redacted] infringed the '516 patent under 35 U.S.C. § 217(e)(2)(C).

327. Alvotech has knowledge of the '516 patent, due to at least Janssen's disclosure of the '516 patent under 42 U.S.C. § 262(*l*)(3)(A) on [redacted] On information and belief, Alvotech has been aware of the '516 patent and its relevance to AVT05 even before Janssen identified it on [redacted]

328. On information and belief, Alvotech acted with deliberate and intentional disregard of Janssen's rights under the '516 patent.

329. Janssen has no adequate remedy at law to redress the infringement by Alvotech.

330. Janssen will be irreparably harmed if Alvotech is not enjoined from infringing the '516 patent.

REDACTED VERSION

[redacted]

COUNT XXII

Declaratory Judgment of Infringement of U.S. Patent No. 11,225,516

331. Janssen incorporates by reference the allegations set forth in paragraphs 1-330 above as if fully set forth herein.

332. As set forth in Count XXI, Alvotech would infringe the '516 patent, literally or under the doctrine of equivalents, if AVT05 is used, offered for sale, sold, or imported in the United States.

333. Because Alvotech would only have regulatory approval to sell AVT05 as described in its aBLAs, any imported AVT05 made by the patented process will not be materially changed by subsequent processes nor be a trivial or nonessential component of another product.

334. Alvotech has knowledge of and/or is willfully blind to the fact that the use, sale, offer for sale, and/or importation of AVT05 will directly infringe one or more claims of the '516 patent, literally or under the doctrine of equivalents.

335. Alvotech will knowingly or with willful blindness induce another's direct infringement of one or more claims of the '516 patent, literally or under the doctrine of equivalents.

336. By filing aBLAs for AVT05 SC and AVT05 IV, [redacted]

337. [redacted] present 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

REDACTED VERSION

[redacted]

authorizes a declaratory judgment action for patent infringement due to Alvotech's [redacted] failure to comply with its obligations under 42 U.S.C. § 262(*l*)(2)(A) and (*l*)(3)(B). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

338. Janssen therefore seeks declaratory judgment that Alvotech will infringe the '516 patent, literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(b) and/or 271(g).

339. Janssen has no adequate remedy at law to redress the infringement by Alvotech.

340. Janssen will be irreparably harmed if Alvotech is not enjoined from infringing the '516 patent.

COUNT XXIII

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

341. Janssen incorporates by reference the allegations set forth in paragraphs 1-340 above as if fully set forth herein.

342. 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 L. JBI is the owner by assignment of the '735 patent.

343. 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,

REDACTED VERSION

[redacted]

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.

344. On information and belief, AVT05 SC and AVT05 IV are covered by one or more claims of the '735 patent, literally or under the doctrine of equivalents.

345. [redacted]

346. Alvotech's commercial manufacturing of AVT05 is intended to [redacted]

347. Alvotech is also seeking [redacted]

[redacted]

348. [redacted]

349. [redacted]

[redacted]

350. [redacted] Janssen has a reasonable basis for this belief at least because Alvotech failed to comply with its obligation under 42 U.S.C. § 262(*l*)(3)(B) to provide a detailed statement that describes the factual and legal basis of any opinion that the '735 patent will not be infringed by the commercial marketing of AVT05. On information and belief, Alvotech withheld this information because it knows or has reason to believe that [redacted]

351. Janssen also attempted to ascertain that [redacted] by examining materials that Alvotech was obligated to provide under 42 U.S.C. § 262(*l*)(2)(A). However, Alvotech 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 Alvotech's target level of C-terminal variants is 12% to 25% K1 lysine variants, relative to the total AVT05 in the preparation, and/or 2% to 10% K2 lysine variants, relative to the total AVT05 in the preparation. *See, e.g.*, *Amgen*, 866 F.3d at 1362; *Hoffmann-La Roche*, 213 F.3d at 1364.

352. [redacted]

[redacted] Janssen has a reasonable basis for this belief at least because Alvotech failed to comply with its obligation under 42 U.S.C. § 262(*l*)(3)(B) to provide a detailed statement that describes the factual and legal basis of any opinion that the '735 patent will not be infringed by the commercial marketing of AVT05. On information and belief, Alvotech withheld this information because it knows or has reason to believe that [redacted]

353. Janssen also attempted to ascertain [redacted] by examining materials that Alvotech was obligated to provide under 42 U.S.C. § 262(*l*)(2)(A). However, Alvotech 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 [redacted] cell culture media comprise 2 g/L lysine to 20 g/L lysine. *See, e.g.*, *Amgen*, 866 F.3d at 1362; *Hoffmann-La Roche*, 213 F.3d at 1364.

354. Alvotech's submission of its aBLAs for AVT05 SC [redacted] and AVT05 IV [redacted] infringed the '735 patent under 35 U.S.C. § 271(e)(2)(C).

355. Alvotech has 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] On information and belief, Alvotech has been aware of the '735 patent and its relevance to AVT05 even before Janssen identified it on [redacted]

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

357. Janssen has no adequate remedy at law to redress the infringement by Alvotech.

[redacted]

358. Janssen will be irreparably harmed if Alvotech is not enjoined from infringing the '735 patent.

COUNT XXIV

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

359. Janssen incorporates by reference the allegations set forth in paragraphs 1-358 above as if fully set forth herein.

360. As set forth in Count XXIII, Alvotech would infringe the '735 patent, literally or under the doctrine of equivalents, if AVT05 is commercially made, used, offered for sale, sold, or imported in the United States.

361. Alvotech has knowledge of and/or is willfully blind to the fact that the commercial manufacture, use, sale, offer for sale, and/or importation of AVT05 will directly infringe one or more claims of the '735 patent, literally or under the doctrine of equivalents.

362. Alvotech 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.

363. By filing aBLAs for AVT05 SC and AVT05 IV, [redacted]

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

[redacted]

authorizes a declaratory judgment action for patent infringement due to Alvotech's [redacted] and failure to comply with its obligations under 42 U.S.C. § 262(*l*)(2)(A) and (*l*)(3)(B). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

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

366. Janssen has no adequate remedy at law to redress the infringement by Alvotech.

367. Janssen will be irreparably harmed if Alvotech is not enjoined from infringing the '735 patent.

COUNT XXV

Infringement of U.S. Patent No. 12,534,524 Under 35 U.S.C. § 271(e)(2)(C)

368. Janssen incorporates by reference the allegations set forth in paragraphs 1-367 above as if fully set forth herein.

369. U.S. Patent No. 12,534,524 ("the '524 patent") is titled "Manufacturing methods for producing anti-TNF antibody compositions." The '524 patent was duly and legally issued on January 27, 2026. A true and correct copy of the '524 patent is attached hereto as Exhibit M. JBI is the owner by assignment of the '524 patent.

370. The '524 patent is directed to and claims methods of manufacture for producing anti-TNF antibodies. The '524 patent includes 4 claims, one of which is independent. Claim 1 is representative and recites:

> 1. A method of producing a drug substance (DS) or drug product (DP) comprising an anti-TNF antibody comprising: (i) the heavy chain amino acid sequence of SEQ ID NO:36; and (ii) the light chain amino acid sequence of SEQ ID NO:37, wherein the anti-human

REDACTED VERSION

[redacted]

> TNF antibody comprises an IgG1 heavy chain and a IgG1 light chain, wherein the oligosaccharide profile of the anti-TNF antibody is controlled and the oligosaccharide profile of the anti-TNF antibody comprises total neutral oligosaccharide species ≥82.0% to ≤94.4%, total charged oligosaccharide species ≥5.6% to ≤18.0%, and individual neutral oligosaccharide species G0F≥25.6% to ≤42.2%, G1F≥31.2% to ≤43.6%, and G2F≥5.6% to ≤14.2%, the method comprising: culturing eukaryotic cells in chemically defined medium controlled to contain specified trace metal concentrations of manganese and copper of, Mn^{2+} (manganese) ≥10.0 µg/liter to ≤35.0 µg/liter and Cu^{2+} (copper) ≥1.0 µg/liter to ≤1.8 µg/liter; and expressing the anti-TNF antibody in the eukaryotic cells, wherein the eukaryotic cells are selected from the group consisting of: Sp2/0 cells, wherein the concentrations of manganese and copper are effective at controlling the oligosaccharide profile of the anti-TNF antibody.

371. On information and belief, the manufacture of AVT05 SC and AVT05 IV is covered by one or more claims of the ’524 patent, literally or under the doctrine of equivalents.

372. [redacted]

373. [redacted]

374. [redacted]

375. [redacted]

376. [redacted]

[redacted]

377. [redacted] Janssen has a reasonable basis for this belief at least because Alvotech failed to comply with its obligation under 42 U.S.C. § 262(*l*)(3)(B) to provide a detailed statement that describes the factual and legal basis of any opinion that the '524 patent will not be infringed by the commercial marketing of AVT05. On information and belief, Alvotech withheld this information because it knows or has reason to believe that [redacted]

378. Janssen also attempted to ascertain that [redacted] by examining materials that Alvotech was obligated to provide under 42 U.S.C. § 262(*l*)(2)(A). However, Alvotech 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 chemically defined medium Alvotech uses to produce AVT05

REDACTED VERSION

[redacted]

contains concentrations of Mn^{2+} (manganese) ≥10.0 µg/liter to ≤35.0 µg/liter and concentrations of Cu^{2+} (copper) ≥1.0 µg/liter to ≤1.8 µg/liter. *See, e.g.*, *Amgen*, 866 F.3d at 1362; *Hoffmann-La Roche*, 213 F.3d at 1364.

379. [redacted]

380. [redacted]

381. Alvotech's submission of its aBLAs for AVT05 SC [redacted] and AVT05 IV [redacted] infringed the '524 patent under 35 U.S.C. § 271(e)(2)(C).

382. Alvotech has knowledge of the '524 patent, due to at least Janssen's disclosure of the '524 patent under 42 U.S.C. § 262(*l*)(7) on [redacted] On information and belief, Alvotech has been aware of the '524 patent and its relevance to AVT05 even before Janssen identified it on [redacted]

383. On information and belief, Alvotech acted with deliberate and intentional disregard of Janssen's rights under the '524 patent.

384. Janssen has no adequate remedy at law to redress the infringement by Alvotech.

385. Janssen will be irreparably harmed if Alvotech is not enjoined from infringing the '524 patent.

COUNT XXVI

Declaratory Judgment of Infringement of U.S. Patent No. 12,534,524

386. Janssen incorporates by reference the allegations set forth in paragraphs 1-385 above as if fully set forth herein.

REDACTED VERSION

[redacted]

387. As set forth in Count XXV, Alvotech would infringe the '524 patent, literally or under the doctrine of equivalents, if AVT05 is used, offered for sale, sold, or imported in the United States.

388. Because Alvotech would only have regulatory approval to sell AVT05 as described in its aBLAs, any imported AVT05 made by the patented process will not be materially changed by subsequent processes nor be a trivial or nonessential component of another product.

389. Alvotech has knowledge of and/or is willfully blind to the fact that the use, sale, offer for sale, and/or importation of AVT05 will directly infringe one or more claims of the '524 patent, literally or under the doctrine of equivalents.

390. Alvotech will knowingly or with willful blindness induce another's direct infringement of one or more claims of the '524 patent, literally or under the doctrine of equivalents.

391. By filing aBLAs for AVT05 SC and AVT05 IV, [redacted]

392. [redacted] present 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 Alvotech's [redacted] failure to comply with its obligations under 42 U.S.C. § 262(*l*)(2)(A) and (*l*)(3)(B). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

[redacted]

393. Janssen therefore seeks declaratory judgment that Alvotech will infringe the '524 patent, literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(b) and/or 271(g).

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

395. Janssen will be irreparably harmed if Alvotech is not enjoined from infringing the '524 patent.

COUNT XXVII

Infringement of U.S. Patent No. 12,595,454 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. 12,595,454 ("the '454 patent") is titled "Methods of Continuous Cell Culture." The '454 patent was duly and legally issued on April 7, 2026. A true and correct copy of the '454 patent is attached hereto as Exhibit N. JBI is the owner by assignment of the '454 patent.

398. The '454 patent is directed to and claims continuous culture methods for producing a cell product. The '454 patent includes 19 claims, two of which are independent. Claim 1 is representative and recites:

> 1. A method for culturing a population of shear-sensitive cells comprising:
>
> culturing a population of cells consisting of shear-sensitive cells in a perfusion bioreactor system with at least 100 L of culture media, wherein the culture media has a level of dissolved carbon dioxide that is at most 80 mmHg, and a gas exit velocity that is 10 m/s or less to achieve a steady state viable cell concentration in the culture media within a range of 20×10^6 cells/mL to 15×10^7 cells/mL,
>
> wherein the shear-sensitive cells are HEK 293 cells, fibrosarcoma HT 1080 cells, PER.C6 cells, CAP cells, HKB-11 cells, HuH-7 cells, NS0 cells, or SP 2/0 cells.

REDACTED VERSION

[redacted]

399. On information and belief, the manufacture of AVT05 SC and AVT05 IV is covered by one or more claims of the '454 patent, literally or under the doctrine of equivalents.

400. [redacted]

401. [redacted]

402. [redacted] Janssen has a reasonable basis for this belief at least because Alvotech failed to comply with its obligation under 42 U.S.C. § 262(*l*)(3)(B) to provide a detailed statement that describes the factual and legal basis of any opinion that the '454 patent will not be infringed by the commercial marketing of AVT05. On information and belief, Alvotech withheld this information because it knows or has reason to believe that [redacted]

403. Janssen also attempted to ascertain that [redacted] by examining materials that Alvotech was obligated to provide under 42 U.S.C. § 262(*l*)(2)(A). However,

REDACTED VERSION

[redacted]

Alvotech 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 culture media has a level of dissolved carbon dioxide that is at most 80 mmHg and a gas exit velocity that is 10 m/s or less. *See, e.g.*, *Amgen*, 866 F.3d at 1362; *Hoffmann-La Roche*, 213 F.3d at 1364.

404. [redacted] Janssen has a reasonable basis for this belief at least because Alvotech failed to comply with its obligation under 42 U.S.C. § 262(*l*)(3)(B) to provide a detailed statement that describes the factual and legal basis of any opinion that the '454 patent will not be infringed by the commercial marketing of AVT05. On information and belief, Alvotech withheld this information because it knows or has reason to believe that [redacted]

405. Janssen also attempted to ascertain that [redacted] by examining materials that Alvotech was obligated to provide under 42 U.S.C. § 262(*l*)(2)(A). However, Alvotech 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 Alvotech cultures the population of SP2/0 cells to achieve a steady state viable cell

[redacted]

concentration in the culture media within a range of 20×10^6 cells/mL to 15×10^7 cells/mL. *See, e.g.*, *Amgen*, 866 F.3d at 1362; *Hoffmann-La Roche*, 213 F.3d at 1364.

406. Alvotech's submission of its aBLAs for AVT05 SC [redacted] and AVT05 IV [redacted] infringed the '454 patent under 35 U.S.C. § 271(e)(2)(C).

407. Alvotech has knowledge of the '454 patent, due to at least Janssen's disclosure of the '454 patent under 42 U.S.C. § 262(*l*)(7) on [redacted] On information and belief, Alvotech has been aware of the '454 patent and its relevance to AVT05 even before Janssen identified it on [redacted]

408. On information and belief, Alvotech acted with deliberate and intentional disregard of Janssen's rights under the '454 patent.

409. Janssen has no adequate remedy at law to redress the infringement by Alvotech.

410. Janssen will be irreparably harmed if Alvotech is not enjoined from infringing the '454 patent.

COUNT XXVIII

Declaratory Judgment of Infringement of U.S. Patent No. 12,595,454

411. Janssen incorporates by reference the allegations set forth in paragraphs 1-410 above as if fully set forth herein.

412. As set forth in Count XXVII, Alvotech would infringe the '454 patent, literally or under the doctrine of equivalents, if AVT05 is used, offered for sale, sold, or imported in the United States.

413. Because Alvotech would only have regulatory approval to sell AVT05 as described in its aBLAs, any imported AVT05 made by the patented process will not be materially changed by subsequent processes nor be a trivial or nonessential component of another product.

REDACTED VERSION

[redacted]

414. Alvotech has knowledge of and/or is willfully blind to the fact that the use, sale, offer for sale, and/or importation of AVT05 will directly infringe one or more claims of the '454 patent, literally or under the doctrine of equivalents.

415. Alvotech will knowingly or with willful blindness induce another's direct infringement of one or more claims of the '454 patent, literally or under the doctrine of equivalents.

416. By filing aBLAs for AVT05 SC and AVT05 IV, [redacted]

417. [redacted] present 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 Alvotech's [redacted] failure to comply with its obligations under 42 U.S.C. § 262(*l*)(2)(A) and (*l*)(3)(B). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

418. Janssen therefore seeks declaratory judgment that Alvotech will infringe the '454 patent, literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(b) and/or 271(g).

419. Janssen has no adequate remedy at law to redress the infringement by Alvotech.

420. Janssen will be irreparably harmed if Alvotech is not enjoined from infringing the '454 patent.

[redacted]

PRAYER FOR RELIEF

WHEREFORE, Janssen respectfully requests:

A. a judgment that Alvotech has infringed the Janssen Patents under 35 U.S.C. § 271(e)(2)(C) by filing its aBLAs for AVT05 SC and AVT05 IV;

B. an order that the effective date of approval for BLA [redacted] (for AVT05 SC) and BLA [redacted] (for AVT05 IV) 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 AVT05 SC and AVT05 IV in the United States would infringe the Janssen Patents;

D. a preliminary and permanent injunction enjoining Alvotech and its officers, agents, servants, employees, and attorneys, together with any other persons who are in active concert or participation with them, including but not limited to Teva, from making, using, offering to sell, selling, or importing AVT05 in the United States;

E. a determination that Alvotech's 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.

[redacted]

Dated: June 19, 2026

Respectfully submitted,

/s/ Craig C. Reilly

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