UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ABBVIE INC. and ABBVIE BIOTECHNOLOGY LTD Plaintiffs, v. ALVOTECH HF. Defendant.	Civil Action No. 1:21-cv-2258

COMPLAINT

INTRODUCTION

1. AbbVie's scientists and clinicians invested decades developing the groundbreaking drug HUMIRA®—the first fully human antibody ever approved by the U.S. Food and Drug Administration ("FDA")—and expanding its use into a variety of diseases and patient populations, as well as launching a new formulation that lessens pain upon injection. Over one million patients have benefited from AbbVie's pioneering work, which also has produced a robust portfolio of patents and trade secret manufacturing processes.

2. Numerous biosimilar companies—now including Defendant Alvotech hf. ("Alvotech" or "Defendant")—have taken note of AbbVie's success as well, attempting to make copycat versions of HUMIRA®.

3. The Biosimilar Price Competition and Innovation Act of 2009 ("BPCIA") established an abbreviated process by which such biosimilar applicants could seek FDA approval. But while the BPCIA gives would-be biosimilar makers like Alvotech a regulatory pathway for

their biosimilar versions of HUMIRA®, it does *not* give Alvotech license to infringe AbbVie's patents. And it certainly did not permit Alvotech to steal AbbVie's trade secret manufacturing processes, which is the subject of related case *AbbVie Inc. v. Alvotech hf.*, Civ. No. 1:21-cv-01530 (N.D. Ill. Mar. 19, 2021) (Leinenweber, J.).

4. AbbVie's HUMIRA® patent portfolio is notable for its proven quality. Numerous biosimilar makers have previously filed a total of 20 *inter partes* review ("IPR") petitions challenging 14 of AbbVie's patents at the Patent Trial and Appeal Board ("PTAB") of the United States Patent and Trademark Office ("USPTO"). Despite the lower burden of proof compared to district court proceedings (a preponderance of the evidence rather than clear and convincing evidence, and at the time a broad claim construction standard) and the high invalidation rate in IPRs, AbbVie prevailed on nine of its patents in 13 IPRs, with challenges to two more patents withdrawn. Ultimately, each of the prior biosimilar applicants recognized the strength of the portfolio and sought licenses with AbbVie. Biosimilars to HUMIRA® will enter the U.S. market in 2023.

5. Of particular relevance, the PTAB has already rejected four petitions challenging the validity of one of the AbbVie patents at issue in this proceeding (namely U.S. Patent No. 9,085,619, directed to buffer-free formulations of adalimumab: the active ingredient of HUMIRA®). The PTAB similarly rejected a petition challenging the validity of a related family member of another AbbVie patent at issue, U.S. Patent No. 8,961,973, directed to induction dosing to treat Crohn's disease.

6. In late 2020, Alvotech sought FDA approval to launch its own biosimilar of HUMIRA®, and it contends that AbbVie's patents are invalid, not infringed, and unenforceable.

7. HUMIRA® belongs to a category of drugs known as biologics. Biologics are complex proteins manufactured in living cells rather than by chemical synthesis. These are critically important drugs that are difficult to develop, manufacture, formulate, and administer. In bringing HUMIRA® from the laboratory to patients, AbbVie operated in uncharted territory. In 1996, AbbVie invented the antibody in HUMIRA®. But that was only the first step. Since then, over more than two decades, AbbVie has invested hundreds of millions of dollars in continuing research and innovation.

8. AbbVie's investment in HUMIRA® development includes over 100 clinical trials and has resulted in FDA approval for the treatment of thirteen different disease conditions, including rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, psoriasis, Crohn's disease (adult and pediatric), ulcerative colitis (adult and pediatric), hidradenitis suppurativa (adult and pediatric), uveitis (adult and pediatric), and juvenile idiopathic arthritis. AbbVie has continued to dedicate substantial resources to an extensive clinical trial program, including research specifically to benefit children. For example, in February of this year, AbbVie received FDA approval to treat pediatric patients living with moderately to severely active ulcerative colitis, making HUMIRA® the first and only subcutaneous biologic treatment option for pediatric patients five years and older with this condition. Alvotech seeks to copy, and profit from, the results of AbbVie's clinical development.

9. AbbVie also has continued to improve and develop the HUMIRA® product itself. First, AbbVie invested in and created a subcutaneous, high concentration, liquid formulation of the HUMIRA® antibody. Before AbbVie's launch of HUMIRA®, patients had to go to the hospital to receive their medicine intravenously, or mix batches of their medicine at home (difficult for patients with inflamed joints) and inject themselves twice a week. As a result of AbbVie's

dedication, innovation, and investment, patients were able to inject the medicine at home using pre-filled syringes or automatic injection devices, and take fewer injections. The added convenience and precision improved patients' lives and increased compliance, all without sacrificing HUMIRA®'s outstanding efficacy.

10. But AbbVie did not stop there. Through continuing investment into formulation research, AbbVie developed a new, higher-concentration (100 mg/mL), citrate-free formulation with reduced pain upon injection. AbbVie's inventive new formulation leverages the surprising inventions patented by AbbVie researchers, namely that the active ingredient, adalimumab, can be formulated at high concentrations *without a buffer*, while maintaining solubility and stability—including during long-term storage or other processing steps. It is this latest innovative formulation that Alvotech seeks to copy. Alvotech's founder and Chairman—Robert Wessman—explained earlier this year how Alvotech monitored and sought to replicate AbbVie's advances, switching gears from a 50 mg/mL concentration copy of adalimumab to a 100 mg/mL high-concentration version as soon as Alvotech "heard that AbbVie was getting ready to launch 100mg." Wallace, David, "Celltrion Wins Global First Approval For High-Concentration Humira Biosimilar," Generics Bulletin (Feb. 15, 2021), attached as Exhibit 1 ("We were actually active in developing 50mg three or four years back," Wessman noted, but "when we heard that AbbVie was getting ready to launch 100mg we stopped that and started to focus only on 100mg. We did not even consider 50mg any more.").

11. AbbVie has also spent many years developing and improving the complex manufacturing processes for HUMIRA® and its active ingredient, adalimumab. Again, unlike traditional drugs, HUMIRA® is a complex biologic created in living organisms. So even minor

changes to the manufacturing process can impact the drug's stability, purity, and efficacy. AbbVie obtained patents, as well as trade secrets, covering innovations in manufacturing.

12. Alvotech seeks not only to copy and to profit from the results of AbbVie's innovative manufacturing work, but also has shown a willingness to take improper shortcuts in doing so. On March 19, 2021, AbbVie filed suit against Alvotech for theft of trade secrets related to the commercial manufacturing process for HUMIRA®, crucial to launching a new manufacturing facility. *AbbVie Inc. v. Alvotech hf.*, Civ. No. 1:21-cv-01530, Dkt. 1 at ¶¶ 3, 5, 28, 30 (N.D. Ill. Mar. 19, 2021). Manufacturing a biologic drug—particularly on a commercial scale—requires complex and finely tuned manufacturing techniques that are distinct from the manufacturing, formulation, and indication inventions in AbbVie's patent portfolio. AbbVie invested substantial time and expertise to develop, scale, and fine-tune its proprietary high-volume manufacturing processes, and carefully guards this trade secret information—including sharing it with its employees only on a need-to-know basis.

13. Instead of investing the necessary time and resources to develop its own manufacturing process for its copycat version of HUMIRA®, Alvotech surreptitiously acquired AbbVie's confidential and proprietary trade secrets, including by hiring at least one such employee: Rongzan Ho, a Team Leader for upstream manufacturing at AbbVie, who circumvented AbbVie's security protocols to email himself AbbVie manufacturing trade secrets before leaving to join Alvotech in the very same role. *Id.* at ¶¶ 3, 40, 58, 63. Just before leaving AbbVie, for Alvotech's benefit and at its direction, Mr. Ho transmitted AbbVie's confidential and proprietary trade secret information—including voluminous Excel spreadsheets full of sensitive manufacturing data—to his personal email account. *Id*. at ¶¶ 54-64. These confidential materials contained detailed and closely guarded information concerning AbbVie's upstream manufacturing

process for HUMIRA® which AbbVie had developed over decades of research. *Id*. Alvotech then installed Mr. Ho in the very same role, supervising upstream manufacturing of the exact same product: AVT02, Alvotech's copy of HUMIRA®, for the purpose of using and benefitting from Mr. Ho's intimate knowledge of AbbVie's trade secrets. *Id*. at ¶¶ 54-64, 89.

14. Alvotech has also shown it is unwilling to follow the law in connection with this case. Under the BPCIA, 42 U.S.C. § 262*(l)* outlines a framework for the would-be biosimilar maker (here, Alvotech) and reference product sponsor (here, AbbVie) to resolve patent disputes. Specifically, the BPCIA sets forth requirements for exchange of information between the parties: under the statute, Alvotech must provide not only its abbreviated Biologics License Application (aBLA), but also its manufacturing information to AbbVie. *See* 42 U.S.C. § 262*(l)*(2)(A) (applicant shall provide "such other information that describes the process or processes used to manufacture the biological product that is the subject of such application"). Despite multiple requests, Alvotech has failed to fulfill its obligations and disclose necessary manufacturing information for its biosimilar product. Instead of properly investigating its own records, Alvotech in many instances provided incomplete information, hedging its disclosures about *its own product and processes* with statements like "upon information and belief" and "as will be confirmed through further discovery."

15. The BPCIA provides a mechanism for AbbVie to litigate its patents before Alvotech actually launches its biosimilar product. Through this process, AbbVie identified 62 patents that would be infringed by Alvotech's biosimilar product. Yet this lawsuit involves only four of those 62 patents. This is because Alvotech selected just those four patents for this first phase of litigation, despite the fact that BPCIA specifically allows the biosimilar company to select all patents identified by the innovator, or as many as it would like to litigate. AbbVie expressly and

clearly explained that litigating just those four patents would not resolve Alvotech's patent issues—but Alvotech did not change course, nor did it propose including additional patents in this litigation. As AbbVie explained, if and when Alvotech provides its 180-day Notice of Commercial Marketing, and as circumstances otherwise warrant, AbbVie will have the opportunity to assert the remaining patents. Therefore, this is merely the first round of litigation between the parties, and (by Alvotech's choice) there will necessarily be a second phase of litigation to adjudicate the rest of AbbVie's substantial patent rights relating to HUMIRA®.

16. AbbVie brings this suit to prevent Alvotech from infringing the four patents identified in this Complaint. AbbVie also reserves its rights to seek preliminary injunctive relief in this action and to assert the remaining patents in a second phase, if and when Alvotech provides a Notice of Commercial Marketing, or as circumstances otherwise warrant.

NATURE OF THE ACTION

17. AbbVie Inc. and AbbVie Biotechnology Ltd ("ABL," collectively referred to as "AbbVie" or "Plaintiffs") for their Complaint against Alvotech further allege as follows:

18. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. §§ 1, *et seq.*, including 35 U.S.C. § 271(e)(2)(C).

19. This lawsuit results from Alvotech's infringement of AbbVie patents that concern AbbVie's groundbreaking drug, HUMIRA®.

20. AbbVie Inc. is the holder of Biologic License Application ("BLA") No. 125057 for HUMIRA®, whose active pharmaceutical ingredient is the antibody, adalimumab.

21. In 1996, after many years of intense research, AbbVie's predecessor first created adalimumab. Adalimumab, a biologic, is a fully human, high-affinity, and neutralizing therapeutic antibody against human TNF-α, a protein made by the human body as part of the body's immune

response. The mechanisms by which TNF-α affects the body are complex and not completely understood (even today). Inventing the adalimumab antibody itself, however, was only the first step in a long process. Following the isolation and characterization of adalimumab, AbbVie and its predecessor Abbott Laboratories spent more than two decades and hundreds of millions of dollars on scientific studies and clinical trials to determine how to use HUMIRA® to treat patients for different diseases, how to formulate HUMIRA® for easier administration, how to improve and further develop the formulation, and how to manufacture HUMIRA®. AbbVie's scientific and clinical investments in HUMIRA® continue to this day—leading, for example, to the February 2021 approval of HUMIRA® to treat pediatric patients living with moderately to severely active ulcerative colitis.

22. AbbVie's innovative work has been recognized by the medical and scientific community. For example, in 2007, HUMIRA® was awarded the Galien Prize, perhaps the most prestigious honor in the pharmaceutical and biotechnology world.

23. More importantly, AbbVie's work has benefited patients immensely. Children have gone from wheelchairs to playgrounds, and adults have gone from bed to work. AbbVie is very proud of the fact that HUMIRA® has improved the lives of more than one million patients to date.

24. Although Alvotech had the option of litigating all (or any subset) of the patents identified by AbbVie during the exchanges required under the BPCIA, Alvotech chose instead to limit this lawsuit to only four of AbbVie's 62 identified patents. But while Alvotech can delay justice, it cannot prevent it: pursuant to the BPCIA, AbbVie can seek additional relief, including an injunction, on the remaining patents when Alvotech files a Notice of Commercial Marketing, which it must do at least 180 days prior to launching its biosimilar product.

PARTIES

25. Plaintiff AbbVie Inc. is a corporation organized and existing under the laws of Delaware with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie Inc. employs thousands of people in Illinois—including named inventors of the four patents in suit—and is engaged in the development, sale, and distribution of a broad range of pharmaceutical and biologic drugs, including HUMIRA®. HUMIRA® was developed under the leadership of AbbVie's management in Illinois.

26. Plaintiff ABL is a corporation organized and existing under the laws of Bermuda, with a place of business at Clarendon House, 2 Church Street, Hamilton HM11, Bermuda. Through intermediate organizations, Plaintiff AbbVie Inc. owns Plaintiff ABL.

27. On information and belief, Defendant Alvotech is a company organized and existing under the laws of Iceland, with its principal place of business at Sæmundargata 15-19, 101 Reykjavík, Iceland.

28. Alvotech is in the business of developing, manufacturing, marketing, and selling biologic drugs, including the proposed biosimilar version of AbbVie's HUMIRA® (adalimumab) product, AVT02. Alvotech has taken steps to enable these drugs to be distributed and sold in the State of Illinois, including in this District, and throughout the United States.

JURISDICTION AND VENUE

29. This is an action for patent infringement under the Patent Laws of the United States, Title 35, United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

30. This Court has personal jurisdiction over Alvotech for at least the reasons set forth below.

31. Alvotech has purposefully directed activities at residents of Illinois and this District, and this action arises out of and relates to those activities. For example, Alvotech has taken the costly, significant step of submitting Alvotech's abbreviated Biologics License Application ("Alvotech's aBLA") to the FDA seeking approval to engage in the commercial manufacture, use, sale, and/or distribution of the Alvotech aBLA Product in Illinois, including in this District, and Alvotech will do so upon approval of its aBLA. The submission of Alvotech's aBLA is therefore tightly tied, both in purpose and planned effect, to the deliberate making of sales of Alvotech's aBLA Product in Illinois, including in this District, and reliably indicates that Alvotech's aBLA Product will be marketed in Illinois, including in this District. Furthermore, Alvotech sent Alvotech's aBLA to AbbVie Inc. at its corporate headquarters in North Chicago, Illinois.

32. Alvotech prepared and submitted Alvotech's aBLA and intends to directly benefit from the sale of the Alvotech aBLA product. Prior to the submission of Alvotech's aBLA (and prior to the formation of its wholly-owned U.S. subsidiary, Alvotech USA, Inc. ("Alvotech USA"), Alvotech met with the FDA regarding Alvotech's AVT02. Alvotech prepared, created, approved, and/or assembled documentation in support of Alvotech's aBLA. Alvotech then directed Alvotech USA to act as its agent between the FDA and Alvotech during the regulatory process.

33. Alvotech USA is the "wholly-owned, regulatory affairs, governmental policy and legal subsidiary" of Alvotech. *See* Office Locations, Alvotech, "Our Locations," https://www.alvotech.com/company/office-locations (last visited April 6, 2021), attached as Exhibit 2. On information and belief, Alvotech USA is a small company that is not involved with drug development, manufacturing, or sales. On information and belief, Alvotech USA only has one office with a few thousand square feet on part of one floor of an office building, and has fewer

than 15 employees—none of whom are manufacturing, sales, or marketing employees, but rather work in legal or regulatory positions.

34. Alvotech, not Alvotech USA, created and prepared the information in the aBLA. Indeed, at least one clinical trial for AVT02 began before Alvotech USA even came into existence, and Alvotech communicated and/or met with the FDA before beginning that trial. *Compare* ClinicalTrials.gov, "Comparative Safety, Tolerability, Pharmacokinetic Study of AVT02 (100MG/ML) and Humira (100MG/ML) in Healthy Volunteers (ALVOPAD)," https://clinicaltrials.gov/ct2/show/NCT03579823?term=AVT02&draw=2&rank=1 (last visited Mar. 10, 2021), attached as Exhibit 3 (study start date - May 21, 2018) *with* Exhibit 4 (Alvotech USA incorporated on January 11, 2019). Alvotech has also stated that its aBLA "filings were based on the results of a comprehensive development program and data package comprising of a totality of evidence demonstrating a high degree of similarity of AVT02 compared to its reference product." *See* Press Release, Alvotech, "Alvotech announces that the U.S. FDA and EMA have accepted regulatory submissions for AVT02, a proposed biosimilar to Humira® (adalimumab)," Nov. 19, 2020, https://www.alvotech.com/newsroom/alvotech-announces-that-the-u.s.-fda-and-ema-have-accepted, attached hereto as Exhibit 5.

35. To support its aBLA, Alvotech submitted data generated by clinical trials to the FDA. *See* 42 U.S.C. § 262(k)(2)(A)(i)(I)(cc) ("An application . . . shall include information demonstrating that — the biologic product is a biosimilar to a reference product based upon data derived from . . . a clinical study or studies . . . that are sufficient demonstrate safety, purity, and potency in 1 or more appropriate conditions of use for which the reference product is licensed and intended to be used and for which licensure is sought for the biological product."); *see also* 21 C.F.R. § 601.2(a) ("To obtain a biologics license . . . the manufacturer . . . shall submit data

derived from . . . clinical studies which demonstrate that the manufactured product meets prescribed requirements of safety, purity, and potency . . . .”). For example, Alvotech has and is currently sponsoring, directing, and/or authorizing at least six clinical trials of the Alvotech aBLA Product. Clinical trials for the Alvotech aBLA Product began at least as early as May 21, 2018 and Alvotech manufactured the Alvotech aBLA Product lots that were used in the clinical trials and described in the aBLA. *See* Exhibit 3.

36. Additionally, Alvotech publicized its Phase I and Phase III clinical trials comparing the Alvotech aBLA Product to HUMIRA®. *See* Press Release, Alvotech, “Alvotech announces positive top-line results for two comparative studies for AVT02, a proposed biosimilar to HUMIRA® (adalimumab),” May 12, 2020, https://www.alvotech.com/newsroom/alvotech-announces-positive-top-line-results-for-two-comparative-studies-for-avt02-a-proposed-biosimilar-to-humira-adalimumab, attached hereto as Exhibit 6. Alvotech specifically stated that “Alvotech is developing [the Alvotech aBLA Product] as a proposed biosimilar to HUMIRA® (adalimumab) with high concentration (100 mg/mL) dosage forms.” *Id*.

37. On information and belief, Alvotech will financially benefit in a significant manner from the approval of Alvotech’s aBLA, since Alvotech will engage in the commercial manufacture and supply of the Alvotech aBLA Product in Illinois, including this District. For example, Alvotech and Teva entered into an “exclusive strategic partnership for the commercialization in the U.S.” of the Alvotech aBLA Product and Alvotech will share in profits from sales in the U.S. Press Release, Alvotech, “Alvotech and Teva announce strategic partnership to collaborate in the U.S. biosimilar market,” Aug. 5, 2020, https://www.alvotech.com/newsroom/alvotech-and-teva-announce-strategic-partnership-to, attached as Exhibit 7; *see also* Exhibit 5 (stating that the Alvotech aBLA Product is one of the biosimilar product candidates part of the Alvotech-Teva

strategic partnership). Under the "partnership agreement," Alvotech "will be responsible for the development, registration and supply of the [AVT02], while Teva will be exclusively commercializing [AVT02] in the U.S." Exhibit 7; *see also* Exhibit 5.

38. On information and belief, if Alvotech's aBLA is approved, the Alvotech aBLA Product will be administered to patients in Illinois, and within this District. These activities, as well as Alvotech's manufacturing, marketing, selling, and/or distributing of the Alvotech aBLA Product, will have a substantial effect within Illinois, and within this District, and will constitute infringement of U.S. Patent Nos. 8,420,081, 8,926,975, 8,961,973, and 9,085,619, in the event that the Alvotech aBLA Product is approved before any of these patents expire.

39. For the reasons described above, among others, the submission of Alvotech's aBLA was suit-related conduct with a substantial connection to Illinois and this District, the exercise of personal jurisdiction over Alvotech does not offend traditional notions of fair play and substantial justice, and this Court may properly exercise personal jurisdiction over Alvotech.

D. Venue

40. Venue lies in this District pursuant to 28 U.S.C. § 1391, including because, *inter alia*, Alvotech is a foreign entity, and thus is subject to suit in any jurisdiction in the United States including the Northern District of Illinois. 28 U.S.C. § 1391(c).

THE PARTIES' EXCHANGES UNDER THE BPCIA

41. On information and belief, in late August or early September 2020, Alvotech submitted abbreviated Biologics License Application No. 761205 to the FDA pursuant to the BPCIA, specifically 42 U.S.C. § 262(k), requesting that its biosimilar adalimumab product AVT02 be licensed for commercial sale by relying on AbbVie's demonstration that HUMIRA® is safe, pure, and potent. The BPCIA provides an abbreviated pathway for approval of a biologic product

that is "biosimilar" to a "reference product." Alvotech has demonstrated its intention to utilize AbbVie's data and work discovering and developing adalimumab through the use of the abbreviated BPCIA biosimilar pathway.

42. To facilitate the protection of biologic innovators' patent rights, Congress created an act of infringement related to the submission of an application under subsection 262(k), *see* 35 U.S.C. § 271(e)(2)(C), and enumerated a set of pre-litigation exchanges under the BPCIA that are outlined at 42 U.S.C. § 262*(l)*. The subsection *(l)* procedures are intended to ensure that the maker of an innovative biologic product that is the subject of a biosimilar application will have sufficient time and opportunity to enforce its patent rights before a biosimilar product enters the market. The BPCIA also requires that a subsection (k) applicant give at least 180 days' notice before the first commercial marketing of a biosimilar licensed by the FDA. 42 U.S.C. § 262*(l)*(8)(A). The statute specifically contemplates injunctive relief, including preliminary injunctive relief, to prevent unlawful infringement.

43. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

44. On November 5, 2020, Alvotech contacted AbbVie and indicated that it had submitted an aBLA to the FDA and that the FDA accepted the aBLA for review. Subsequently, in a November 19, 2020 press release, Alvotech announced that the FDA had accepted the aBLA for review.

45. In November 2020, the parties began exchanging information in accordance with the procedures outlined in the BPCIA. On or about November 5, 2020, Alvotech provided outside counsel for AbbVie, and AbbVie's designated in-house attorneys, with access to Alvotech's aBLA.

46. On January 4, 2021, pursuant to 42 U.S.C. § 262*(l)*(3)(A), AbbVie provided Alvotech with its list of patents for which it believed a claim of patent infringement could be reasonably asserted against Alvotech's aBLA Product ("AbbVie's 3A List"). This list identified 63 patents from among the more than 100 patents in the HUMIRA® estate. AbbVie also asked that "[i]n the event that Alvotech asserts that any of the listed patents are either not infringed or invalid pursuant to Section (l)(3)(B)(ii)(I), Alvotech should identify and provide copies of any documentary evidence supporting those assertions to AbbVie's outside counsel . . . so that AbbVie may fully consider it."

47. Despite having a sixty day statutory period to evaluate AbbVie's 3A List, just ten days later, on January 14, 2021, Alvotech responded by providing AbbVie with statements pursuant to 42 U.S.C. § 262*(l)*(3)(B) contesting Alvotech's infringement of certain patents and the validity of those patents. Despite AbbVie's requests, Alvotech did not provide any additional evidence (*e.g.,* additional manufacturing documents or product information beyond that contained in the aBLA) relating to its non-infringement contentions. This lack of information was compounded by the fact that for several patents, Alvotech failed to provide any support for its non-infringement positions.

48. On March 15, 2021, AbbVie provided Alvotech with its detailed statement pursuant to 42 U.S.C. § 262*(l)*(3)(C) (AbbVie's "3C Statement"). AbbVie's nearly 2,000-page 3C Statement shows that AbbVie reasonably believes that the Alvotech aBLA Product, AVT02, would infringe the following 62 AbbVie patents (AbbVie removed one of the patents from its prior list) and that those patent claims are valid and enforceable:

	U.S. Patent No.	Lead Inventor	Title
1.	6,805,686	Fathallah	Autoinjector with Extendable Needle Protector Shroud
2.	8,231,876	Wan	Purified Antibody Composition

	U.S. Patent No.	Lead Inventor	Title
3.	8,420,081	Fraunhofer	Antibody Formulations and Methods of Making Same
4.	8,663,945	Pla	Methods of Producing Anti-TNF-Alpha Antibodies in Mammalian Cell Culture
5.	8,708,968	Julian	Removal of Needle Shields from Syringes and Automatic Injection Devices
6.	8,715,664	Hoffman	Use of Human TNFα Antibodies for Treatment of Erosive Polyarthritis
7.	8,808,700	Hoffman	Use of TNF Alpha Inhibitor for Treatment of Erosive Polyarthritis
8.	8,883,156	Wan	Purified Antibody Composition
9.	8,889,136	Hoffman	Multiple-Variable Dose Regimen for Treating TNFα-Related Disorders
10.	8,895,009	Wan	Purified Antibody Composition
11.	8,906,372	Wan	Purified Antibody Composition
12.	8,906,373	Banerjee	Use of TNF-Alpha Inhibitor for Treatment of Psoriasis
13.	8,906,646	Pla	Fed-Batch Method of Making Human Anti-TNF-Alpha Antibody
14.	8,911,737	Fischkoff	Methods of Administering Anti-TNFα Antibodies
15.	8,911,964	Pla	Fed-Batch Method of Making Human Anti-TNF-Alpha Antibody
16.	8,916,153	Wan	Purified Antibody Composition
17.	8,926,975	Wong	Method of Treating Ankylosing Spondylitis
18.	8,961,973	Hoffman	Multiple-Variable Dose Regimen for Treating TNFα-Related Disorders
19.	8,961,974	Hoffman	Multiple-Variable Dose Regimen for Treating TNFα-Related Disorders
20.	8,974,790	Fischkoff	Methods of Administering Anti-TNFα Antibodies
21.	8,986,693	Hoffman	Use of TNFα Inhibitor for Treatment of Psoriasis
22.	8,992,926	Fischkoff	Methods of Administering Anti-TNFα Antibodies
23.	8,999,337	Medich	Methods for Treating Juvenile Idiopathic Arthritis by Inhibition of TNFα
24.	9,061,005	Hoffman	Multiple-Variable Dose Regimen for Treating Idiopathic Inflammatory Bowel Disease

	U.S. Patent No.	Lead Inventor	Title
25.	9,062,106	Bengea	Methods for Controlling the Galactosylation Profile of Recombinantly-Expressed Proteins
26.	9,067,992	Hoffman	Use of TNFα Inhibitor for Treatment of Psoriatic Arthritis
27.	9,085,618	Ramasubramanyan	Low Acidic Species Compositions and Methods for Producing and Using the Same
28.	9,085,619	Fraunhofer	Anti-TNF Antibody Formulations
29.	9,085,620	Hoffman	Use of TNFα Inhibitor for Treatment of Psoriatic Arthritis
30.	9,090,688	Bengea	Methods for Controlling the Galactosylation Profile of Recombinantly-Expressed Proteins
31.	9,090,689	Hoffman	Use of TNFα Inhibitor for Treatment of Psoriasis
32.	9,090,867	Pla	Fed-Batch Method of Making Anti-TNF-Alpha Antibody
33.	9,096,666	Wan	Purified Antibody Composition
34.	9,102,723	Wan	Purified Antibody Composition
35.	9,150,645	Subramanian	Cell Culture Methods to Reduce Acidic Species
36.	9,181,337	Subramanian	Modulated Lysine Variant Species Compositions and Methods for Producing and Using the Same
37.	9,181,572	Subramanian	Methods to Modulate Lysine Variant Distribution
38.	9,187,559	Hoffman	Multiple-Variable Dose Regimen for Treating Idiopathic Inflammatory Bowel Disease
39.	9,234,032	Pla	Fed-Batch Methods for Producing Adalimumab
40.	9,266,949	Ramasubramanyan	Low Acidic Species Compositions and Methods for Producing and Using the Same
41.	9,273,132	Wan	Purified Antibody Composition
42.	9,284,370	Medich	Methods for Treating Juvenile Idiopathic Arthritis
43.	9,284,371	Pla	Methods of Producing Adalimumab
44.	9,290,568	Rives	Methods to Control Protein Heterogeneity

	U.S. Patent No.	Lead Inventor	Title
45.	9,315,574	Ramasubramanyan	Low Acidic Species Compositions and Methods for Producing and Using the Same
46.	9,328,165	Wan	Purified Antibody Composition
47.	9,334,319	Ramasubramanyan	Low Acidic Species Compositions
48.	9,339,610	Julian	Removal of Needle Shield From Syringes and Automatic Injection Devices
49.	9,346,879	Ramasubramanyan	Protein Purification Methods to Reduce Acidic Species
50.	9,359,434	Subramanian	Cell Culture Methods to Reduce Acidic Species
51.	9,499,614	Hossler	Methods for Modulating Protein Glycosylation Profiles of Recombinant Protein Therapeutics Using Monosaccharides and Oligosaccharides
52.	9,499,616	Subramanian	Modulated Lysine Variant Species Compositions and Methods for Producing and Using the Same
53.	9,505,834	Bengea	Methods for Controlling the Galactosylation Profile of Recombinantly-Expressed Proteins
54.	9,512,216	Hoffman	Use of TNFα Inhibitor
55.	9,522,953	Ramasubramanyan	Low Acidic Species Compositions and Methods for Producing and Using the Same
56.	9,546,212	Fischkoff	Methods of Administering Anti-TNFα Antibodies
57.	9,550,826	Labkovsky	Glycoengineered Binding Protein Compositions
58.	9,624,295	Medich	Uses and Compositions for Treatment of Psoriatic Arthritis
59.	9,669,093	Medich	Methods for Treating Juvenile Idiopathic Arthritis
60.	9,683,033	Subramanian	Cell Culture Methods to Reduce Acidic Species
61.	9,708,400	Subramanian	Methods to Modulate Lysine Variant Distribution
62.	9,957,318	Ramasubramanyan	Protein Purification Methods to Reduce Acidic Species

49. After AbbVie provided its 3C Statement, on March 23, 2021, Alvotech proposed that only four of the 62 patents, namely U.S. Pat. Nos. 8,420,081, 8,926,975, 8,961,973, and

9,085,619, be the subject of the 42 U.S.C. § 262*(l)*(6) suit. Alvotech had the right under the BPCIA to select all 62 patents, or any subset of those patents it wanted, but instead proposed litigating just four in this first round of litigation.

50. On March 29, 2021, AbbVie wrote to Alvotech, explaining that litigating only these four patents would not resolve all issues of patent infringement with respect to the Alvotech aBLA Product and that, unless Alvotech chose to include them in the first phase of litigation, the remaining patents would still need to be addressed in a second phase of litigation as contemplated by the BPCIA. *See* 42 U.S.C. § 262*(l)*(8). Despite this express notice, Alvotech chose to move forward with only four patents as the subject of the initial 42 U.S.C. § 262*(l)*(6) litigation.

51. Consequently, AbbVie will have a second opportunity, if and when Alvotech provides a 180-day Notice of Commercial Marketing (or as circumstances otherwise warrant), to assert its remaining patents. So, while Alvotech's tactics may create delay, it still must face AbbVie's other patents before going to market.

THE ALVOTECH aBLA PRODUCT

52. Alvotech has undertaken the development of a proposed biosimilar to AbbVie's HUMIRA® (adalimumab) product.

53. Alvotech has submitted an aBLA to the FDA seeking approval to market in the United States a biosimilar version of AbbVie's HUMIRA® adalimumab product.

54. On November 19, 2020, Alvotech publicly announced that the FDA had accepted its submission of an aBLA with the FDA for AVT02, a biosimilar candidate to HUMIRA® (adalimumab). *See* Exhibit 5.

55. Alvotech stated that "AVT02 is a monoclonal antibody (mAb) and a proposed biosimilar to HUMIRA® (adalimumab)" and that "AVT02 is highly similar to its reference product

in terms of structure and function." *See id.* Alvotech further stated that "AVT02 is a proposed biosimilar to the reference product HUMIRA® (adalimumab) with high concentration (100mg/mL) dosage forms . . . matching the newest dosage forms of the reference product." *Id.*

56. Alvotech stated that its "filings were based on the results of a comprehensive development program and data package comprising of a totality of evidence demonstrating a high degree of similarity of AVT02 compared to its reference product." *See id.*

57. Alvotech has completed clinical trials with AVT02, testing its use in subjects with moderate to severe chronic psoriasis and has relied on these clinical trials to support Alvotech's aBLA. *See* Exhibit 8; *see also* Exhibit 9. Alvotech is also sponsoring ongoing clinical trials testing the use of AVT02 in subjects with moderate to severe active rheumatoid arthritis.

58. The FDA has not yet approved Alvotech's proposed biosimilar product.

59. Alvotech has committed a statutory act of patent infringement under 35 U.S.C. § 271(e)(2)(C) by submitting an application seeking approval of a biological product with respect to patents identified by AbbVie pursuant to 42 U.S.C. § 262*(l)*(3)(A)(i).

ABBVIE'S ADALIMUMAB PATENTS

60. AbbVie identified 62 patents that it reasonably believes would be infringed by Alvotech's biosimilar product, including its administration, its formulation, and the processes for manufacturing it.

61. Because of Alvotech's selections during the BPCIA process, AbbVie is limited at this stage to asserting the following four patents in the present lawsuit: U.S. Patent No. 8,420,081; 8,926,975; 8,961,973; and 9,085,619 (the "AbbVie Patents").

62. AbbVie asserts the following four patents in this suit.

U.S. Patent No. 8,420,081

63. U.S. Patent No. 8,420,081 (the "'081 patent"), titled "Antibody Formulations and Methods of Making Same," was duly and legally issued by the USPTO on April 16, 2013. A true and correct copy of the '081 patent is attached as Exhibit 10.

64. ABL is the owner by assignment of the '081 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the '081 patent in the United States. ABL and AbbVie Inc. together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the '081 patent.

65. A related family member of the '081 patent, U.S. Patent No. 9,085,619 (see Count IV), was previously subject to four separate IPR challenges before the PTAB (IPR2017-01008, IPR2017-01009, IPR2017-00822, and IPR2017-00823) and its validity was upheld after every challenge.

66. AbbVie included the '081 patent in its disclosures to Alvotech, pursuant to 42 U.S.C. § 262*(l)*(3)(A), as described in Count I below.

67. AbbVie has provided to Alvotech, pursuant to confidential exchanges under U.S.C. § 262*(l)*(3)(C), claim-by-claim infringement contentions for each of the claims described in Count I below.

U.S. Patent No. 8,926,975

68. U.S. Patent No. 8,926,975 (the "'975 patent"), titled "Method of Treating Ankylosing Spondylitis," was duly and legally issued by the USPTO on January 6, 2015. A true and correct copy of the '975 patent is attached as Exhibit 11.

69. ABL is the owner by assignment of the '975 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the

'975 patent in the United States. AbbVie Inc. and ABL together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the '975 patent.

70. AbbVie included the '975 patent in its disclosures to Alvotech, pursuant to 42 U.S.C. § 262*(l)*(3)(A), as described in Count II below.

71. AbbVie has provided to Alvotech, pursuant to confidential exchanges under U.S.C. § 262*(l)*(3)(C), claim-by-claim infringement contentions for each of the claims described in Count II below.

U.S. Patent No. 8,961,973

72. U.S. Patent No. 8,961,973 (the "'973 patent"), titled "Multiple-Variable Dose Regimen for Treating TNFα-Related Disorders," was duly and legally issued by the USPTO on February 24, 2015. A true and correct copy of the '973 patent is attached as Exhibit 12.

73. ABL is the owner by assignment of the '973 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the '973 patent in the United States. AbbVie Inc. and ABL together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the '973 patent.

74. A related family member of the '973 patent, U.S. Patent No. 9,187,559, was previously subject to a separate IPR challenge before the PTAB (IPR2018-00156) and its validity was upheld.

75. AbbVie included the '973 patent in its disclosures to Alvotech, pursuant to 42 U.S.C. § 262*(l)*(3)(A), as described in Count III below.

76. AbbVie has provided to Alvotech, pursuant to confidential exchanges under U.S.C. § 262*(l)*(3)(C), claim-by-claim infringement contentions for each of the claims described in Count III below.

U.S. Patent No. 9,085,619

77. U.S. Patent No. 9,085,619 (the "'619 patent"), titled "Anti-TNF Antibody Formulations," was duly and legally issued by the USPTO on July 21, 2015. A true and correct copy of the '619 patent is attached as Exhibit 13.

78. ABL is the owner by assignment of the '619 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the '619 patent in the United States. AbbVie Inc. and ABL together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the '619 patent.

79. The '619 patent was previously subject to four separate IPR challenges before the PTAB (IPR2017-01008, IPR2017-01009, IPR2017-00822, and IPR2017-00823) and its validity was upheld after every challenge.

80. AbbVie included the '619 patent in its disclosures to Alvotech, pursuant to 42 U.S.C. § 262*(l)*(3)(A), as described in Count IV below.

81. AbbVie has provided to Alvotech, pursuant to confidential exchanges under U.S.C. § 262*(l)*(3)(C), claim-by-claim infringement contentions for each of the claims described in Count IV below.

COUNT I

INFRINGEMENT OF U.S. PATENT NO. 8,420,081

82. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

83. On information and belief, in late August or early September 2020, Alvotech submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, sale, and/or importation of the Alvotech aBLA Product, a biosimilar version of adalimumab.

The reference product for adalimumab is BLA No. 125057. AbbVie Inc. is the holder of BLA No. 125057.

84. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

85. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

86. On information and belief, Alvotech intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product promptly upon receiving FDA approval to do so.

87. Based on confidential information disclosed to AbbVie by Alvotech pursuant to 42 U.S.C. § 262(*l*)(2), Alvotech's submission of its aBLA to obtain approval to engage in the commercial manufacture, use, sale, offer to sell, and/or importation of the Alvotech aBLA Product prior to the expiration of the '081 patent is an act of infringement of one or more of the claims of the '081 patent under 35 U.S.C. § 271(e)(2)(C), either literally or under the doctrine of equivalents.

88. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the indications, dosage, and methods of use for the Alvotech aBLA Product. Based on this confidential information, Alvotech's commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will infringe, actively induce infringement by others, or contribute to the infringement by others of at least claims 25, 33, 57-61, 63-67, 84, 86-89, 91-93, and 95-99 of the '081 patent under 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to U.S.C. § 262*(l)*(3)(C), claim-by-claim infringement contentions for claims 25, 33, 57-61, 63-67, 84, 86-89, 91-93, and 95-99 of the '081 patent. For at least one claim, however, Alvotech's failure to provide sufficient

manufacturing information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '081 patent.

89. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the formulation of the Alvotech aBLA Product directly infringes at least one claim of the '081 patent, either literally or under the doctrine of equivalents.

90. Alvotech has knowledge of and is aware of the '081 patent, including due to AbbVie's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and to the filing of this Complaint.

91. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '081 patent.

92. AbbVie seeks an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Alvotech from the commercial manufacture, use, sale, offer for sale within and/or importation into the United States of the Alvotech aBLA Product.

COUNT II
INFRINGEMENT OF U.S. PATENT NO. 8,926,975

93. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

94. On information and belief, in late August or early September 2020, Alvotech submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, sale, and/or importation of the Alvotech aBLA Product, a biosimilar version of adalimumab. The reference product for adalimumab is BLA No. 125057. AbbVie Inc. is the holder of BLA No. 125057.

95. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

96. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

97. On information and belief, Alvotech intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product promptly upon receiving FDA approval to do so.

98. Based on confidential information disclosed to AbbVie by Alvotech pursuant to 42 U.S.C. § 262(*l*)(2), Alvotech's submission of its aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Alvotech aBLA Product prior to the expiration of the '975 patent is an act of infringement of one or more of the claims of the '975 patent under 35 U.S.C. § 271(e)(2)(C), either literally or under the doctrine of equivalents.

99. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the indications, dosage, and methods of use for the Alvotech aBLA Product. Based on this confidential information and on information and belief, Alvotech's commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will actively induce infringement by others or contribute to infringement by others of at least claims 1-6 of the '975 patent under 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to U.S.C. § 262*(l)*(3)(C), claim-by-claim infringement contentions for claims 1-6 of the '975 patent.

100. On information and belief, Alvotech has an affirmative intent to actively induce or contribute to infringement by others of one or more claims of the '975 patent, either literally or under the doctrine of equivalents.

101. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that patients will administer and/or use and medical practitioners will prescribe

and/or administer the Alvotech aBLA Product to directly infringe at least claims 1-6 of the '975 patent, either literally or under the doctrine of equivalents.

102. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-6 of the '975 patent, either literally or under the doctrine of equivalents.

103. Alvotech has knowledge of and is aware of the '975 patent, including due to AbbVie's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and to the filing of this Complaint.

104. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '975 patent.

105. AbbVie seeks an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Alvotech from the commercial manufacture, use, sale, offer for sale within and/or importation into the United States of the Alvotech aBLA Product.

COUNT III
INFRINGEMENT OF U.S. PATENT NO. 8,961,973

106. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

107. On information and belief, in late August or early September 2020, Alvotech submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, sale, and/or importation of the Alvotech aBLA Product, a biosimilar version of adalimumab. The reference product for adalimumab is BLA No. 125057. AbbVie Inc. is the holder of BLA No. 125057.

108. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

109. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

110. On information and belief, Alvotech intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product promptly upon receiving FDA approval to do so.

111. Based on confidential information disclosed to AbbVie by Alvotech pursuant to 42 U.S.C. § 262(*l*)(2), Alvotech's submission of its aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, sale, and/or importation of the Alvotech aBLA Product prior to the expiration of the '973 patent is an act of infringement of one or more of the claims of the '973 patent under 35 U.S.C. § 271(e)(2)(C), either literally or under the doctrine of equivalents.

112. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the indications, dosage, and methods of use for the Alvotech aBLA Product. Based on this confidential information and on information and belief, Alvotech's commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will actively induce infringement by others or contribute to infringement by others of at least claims 1-30 of the '973 patent under 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to U.S.C. § 262*(l)*(3)(C), claim-by-claim infringement contentions for claims 1-30 of the '973 patent.

113. On information and belief, Alvotech has an affirmative intent to actively induce or contribute to infringement by others of one or more claims of the '973 patent, either literally or under the doctrine of equivalents.

114. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that patients will administer and/or use and medical practitioners will prescribe

and/or administer the Alvotech aBLA Product to directly infringe at least claims 1-30 of the '973 patent, either literally or under the doctrine of equivalents.

115. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-30 of the '973 patent, either literally or under the doctrine of equivalents, by at least Alvotech's proposed package insert for the Alvotech aBLA Product.

116. Alvotech has knowledge of and is aware of the '973 patent, including due to AbbVie's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and to the filing of this Complaint.

117. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '973 patent.

118. AbbVie seeks an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Alvotech from the commercial manufacture, use, sale, offer for sale within, and/or importation into the United States of the Alvotech aBLA Product.

COUNT IV

INFRINGEMENT OF U.S. PATENT NO. 9,085,619

119. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

120. On information and belief, in late August or early September 2020, Alvotech submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, sale, and/or importation of the Alvotech aBLA Product, a biosimilar version of adalimumab. The reference product for adalimumab is BLA No. 125057. AbbVie Inc. is the holder of BLA No. 125057.

121. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

122. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

123. On information and belief, Alvotech intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product promptly upon receiving FDA approval to do so.

124. Based on confidential information disclosed to AbbVie by Alvotech pursuant to 42 U.S.C. § 262(*l*)(2), Alvotech's submission of its aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, sale, and/or importation of the Alvotech aBLA Product prior to the expiration of the '619 patent is an act of infringement of one or more of the claims of the '619 patent under 35 U.S.C. § 271(e)(2)(C), either literally or under the doctrine of equivalents.

125. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(*l*)(2)(A) relating to the indications, dosage, and methods of use for the Alvotech aBLA Product. Based on this confidential information and on information and belief, Alvotech's commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product (either directly or through any affiliates, subsidiaries, and/or agents), once the aBLA is approved by the FDA, will infringe or actively induce infringement by others or contribute to infringement by others of at least claims 1-5 and 16-30 of the '619 patent under 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to U.S.C. § 262*(l)*(3)(C), claim-by-claim infringement contentions for claims 1-5 and 16-30 of the '619 patent.

126. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the formulation of the Alvotech aBLA Product directly infringes at least claims 1-5 and 16-30 of the '619 patent, either literally or under the doctrine of equivalents.

127. Alvotech has knowledge of and is aware of the '619 patent, including due to AbbVie's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and to the filing of this Complaint.

128. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '619 patent.

129. AbbVie seeks an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Alvotech from the commercial manufacture, use, sale, offer for sale within and/or importation into the United States of the Alvotech aBLA Product.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor against Defendant and grant the following relief:

a. a judgment that Alvotech has infringed, induced infringement, or contributed to infringement of one or more claims of the AbbVie Patents under 35 U.S.C. § 271(e)(2)(C);

b. a judgment that Alvotech has or will infringe or has or will induce or contribute to infringement of one or more claims of the AbbVie Patents by engaging in the manufacture, import, offer for sale, sale, or use within the United States of the Alvotech aBLA Product before the expirations of the AbbVie Patents;

c. preliminary and/or permanent equitable relief, including but not limited to an injunction that enjoins Alvotech, its officers, partners, agents, servants, employees, parents, subsidiaries, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with them and/or their successors or assigns from infringing the AbbVie Patents, or contributing to or inducing anyone to do the same, by acts including the manufacture, use, offer to sell, sale, or distribution within the United States, or importation into

the United States, of any current or future versions of the Alvotech aBLA Product, the use or manufacturing of which infringes the AbbVie Patents;

d. a declaration that this is an exceptional case and an award to Plaintiffs of their attorneys' fees, costs, and expenses pursuant to 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285; and

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

Respectfully submitted,

Dated: April 27, 2021

/s/ Sean M. Berkowitz

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