

**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-02899

Hon. John Z. Lee

Magistrate Judge M. David Weisman

**FIRST AMENDED COMPLAINT**

**INTRODUCTION**

1. This is the second action for patent infringement that AbbVie Inc. and AbbVie Biotechnology Ltd (“ABL,” collectively referred to as “AbbVie” or “Plaintiffs”) have brought against Alvotech hf. (“Alvotech”) under the Biosimilar Price Competition and Innovation Act of 2009 (“BPCIA”) in connection with Alvotech’s proposed biosimilar version of AbbVie’s groundbreaking drug HUMIRA<sup>®</sup>. AbbVie brought the first action in this District on April 27, 2021, to adjudicate Alvotech’s infringement of four AbbVie patents that Alvotech selected for the first phase of litigation prescribed by the BPCIA. *See AbbVie Inc. and AbbVie Biotechnology Ltd v. Alvotech hf.*, Civ. No. 1:21-cv-02258 (N.D. Ill. Apr. 27, 2021) (Lee, J.). Rather than answer or otherwise respond to that complaint, however, Alvotech sought an end-run around AbbVie’s choice of forum by filing a declaratory judgment action on those same four patents in the Eastern District of Virginia on May 11, 2021. *Alvotech USA Inc. and Alvotech hf. v. AbbVie Inc. and AbbVie Biotechnology Ltd*, Civ. No. 2:21-cv-00265 (E.D. Va. May 11, 2021) (Jackson, J.). Although that suit has now been transferred to this district and dismissed, *see Alvotech USA Inc.*

*and Alvotech hf. v. AbbVie Inc. and AbbVie Biotechnology Ltd*, Civ. No. 2:21-cv-00265, Dkt. 51 (E.D. Va. May 11, 2021) (Jackson, J.) and *Alvotech USA Inc. and Alvotech hf. v. AbbVie Inc. and AbbVie Biotechnology Ltd*, Civ. No. 1:21-cv-05645, Dkt. 55 (N.D. Ill. Nov. 10, 2021) (notice of voluntary dismissal), Alvotech’s filing and additional actions, discussed below, have triggered this second suit under the BPCIA to protect AbbVie’s rights and promote the orderly disposition of all the patent infringement issues raised by Alvotech’s proposed biosimilar product.

2. AbbVie’s patents at issue in this suit and in the first-filed BPCIA action already pending in this District result from decades of work by AbbVie’s scientists and clinicians developing HUMIRA<sup>®</sup>—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, higher-concentration, citrate-free formulation with reduced injection volume and 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 secrets, including trade secret manufacturing processes.

3. Numerous biosimilar companies—now including Alvotech—have taken note of AbbVie’s success as well, attempting to make biosimilar versions of HUMIRA<sup>®</sup>. Ultimately, each of the prior biosimilar applicants recognized the strength of the portfolio and sought licenses from AbbVie. AbbVie settled with each, allowing market entry years before expiration of many of its patents. As a result, biosimilar versions of HUMIRA<sup>®</sup> will enter the U.S. market in 2023.

4. AbbVie’s HUMIRA<sup>®</sup> patent portfolio is also 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 from AbbVie.

5. Of particular relevance, the PTAB has already rejected five petitions challenging the validity of AbbVie patents at issue in this proceeding. Specifically, the PTAB rejected a petition challenging the validity of U.S. Patent No. 8,911,737, directed to treatment of Crohn's disease. The PTAB also rejected a petition challenging the validity of U.S. Patent No. 9,187,559, directed to induction dosing to treat Crohn's disease. The PTAB similarly rejected a petition challenging the validity of U.S. Patent No. 8,974,790, directed to treatment of ulcerative colitis. The PTAB also rejected two petitions challenging the validity of U.S. Patent No. 9,512,216, directed to treatment of chronic plaque psoriasis.

6. AbbVie's investment in HUMIRA<sup>®</sup> development includes over 100 clinical trials and has resulted in FDA approval for the treatment of 13 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<sup>®</sup> the first and only subcutaneous biologic treatment option for pediatric patients five years and older with this condition.

7. AbbVie also has continued to improve and develop the HUMIRA<sup>®</sup> product itself. First, AbbVie invested in and created a subcutaneous, high concentration, liquid formulation of the HUMIRA<sup>®</sup> antibody. Before AbbVie's launch of HUMIRA<sup>®</sup>, 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<sup>®</sup>'s outstanding efficacy.

8. 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.”).

9. AbbVie has also spent many years developing and improving the complex manufacturing processes for HUMIRA<sup>®</sup> and its active ingredient, adalimumab. Unlike traditional drugs, HUMIRA<sup>®</sup> 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 and developed trade secrets covering innovations in manufacturing.

10. In late 2020, Alvotech filed its abbreviated Biologics License Application (“Alvotech’s aBLA”) seeking FDA approval to launch its own biosimilar of HUMIRA<sup>®</sup>.

11. The BPCIA permits Alvotech to file its aBLA, but it does so only in tandem with a specific framework for innovator companies like AbbVie to litigate their patents before a would-be biosimilar applicant launches its product. In particular, the BPCIA contemplates two waves of litigation. The first wave follows an exchange between the parties under 42 U.S.C. § 262(l)(3) of information about the biosimilar applicant’s proposed product and the reference product sponsor’s patents that the biosimilar product would infringe. After that exchange, the biosimilar applicant can elect how many (and which) of the reference product sponsor’s patents it would like to litigate in the first wave. 42 U.S.C. § 262(l)(4)-(6). The second wave of litigation, which may involve additional patents, is not triggered until the biosimilar applicant provides its notice of commercial marketing, after which the reference product sponsor may sue for relief on its remaining patents. 42 U.S.C. § 262(l)(8)-(9).

12. Alvotech chose to litigate only four patents in the first wave, despite the fact that AbbVie identified 62 patents that would be infringed by Alvotech’s biosimilar product. *See AbbVie Inc. and AbbVie Biotechnology Ltd v. Alvotech hf.*, Civ. No. 1:21-cv-02258 (N.D. Ill. Apr.

27, 2021) (Lee, J.). Yet, Alvotech then abandoned the BPCIA's procedures by seeking to litigate the same four patents in a declaratory judgment action in a different federal court after AbbVie filed its first BPCIA-prescribed suit. On the same day it filed its Eastern District of Virginia complaint, Alvotech provided AbbVie with Alvotech's notice of commercial marketing under 42 U.S.C. § 262(l)(8)(A).

13. Filing a separate suit on the same patents in an effort to change courts is improper. The Eastern District of Virginia recently ended that gambit by transferring the case back to this Court, and Alvotech agreed to dismiss the case without prejudice. *Alvotech USA Inc. and Alvotech hf. v. AbbVie Inc. and AbbVie Biotechnology Ltd*, Civ. No. 2:21-cv-00265, Dkt. 51 (E.D. Va. May 11, 2021) (Jackson, J.).

14. Alvotech's attempt to forum-shop is not the first time it has shown its unwillingness to adhere to the requirements of the BPCIA. As part of the exchanges under 42 U.S.C. § 262(l)(3), Alvotech was required to provide not only its 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 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. Now, Alvotech's decision to provide its notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A) indicates that Alvotech may attempt to market its biosimilar version of HUMIRA<sup>®</sup> at-risk before resolution of AbbVie's related patent infringement action in this

District.<sup>1</sup> Under the BPCIA, that notice of commercial marketing also triggers this declaratory judgment action so AbbVie can enforce the 58 patents that Alvotech declined to litigate in both the related action in this District and its improper declaratory judgment action in the Eastern District of Virginia and any newly issued patents. 42 U.S.C. § 262(l)(7)-(9). Although Alvotech's notice indicated that it might market its biosimilar product as soon as November 2021, to date Alvotech does not have regulatory approval and has agreed to wait to launch its biosimilar product until at least the district court's decision on the August 2022 trial on the ten patents. *See* 9/2/2021 Hearing Tr. at 7:23-9:13; *see also* Dkt. 53 at ¶ 13. The fact that Alvotech seeks to market its biosimilar version of HUMIRA<sup>®</sup> potentially before the expiration of AbbVie's patents and before the conclusion of AbbVie's related patent infringement action reinforces that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant relief, including in the form of a preliminary injunction.

#### NATURE OF THE ACTION

16. Plaintiffs for their Complaint against Alvotech further allege as follows:

17. This civil action arises under the Patent Laws of the United States, 35 U.S.C. §§ 1, *et seq.*, including 35 U.S.C. § 271(a)-(c), (e)(2)(C), and (g), the BPCIA, including 42 U.S.C. § 262(l), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

18. This lawsuit results from Alvotech's infringement of AbbVie patents that concern AbbVie's groundbreaking drug, HUMIRA<sup>®</sup>.

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<sup>1</sup> AbbVie has proposed procedures to consolidate this action with *AbbVie Inc. and AbbVie Biotechnology Ltd v. Alvotech hf.*, Civ. No. 1:21-cv-02258 (N.D. Ill. Apr. 27, 2021) (Lee, J.) for purposes of discovery, claim construction, and the August 2022 trial on the ten patents, although each case would retain its own judgment. Aside from the ten patents in the August 2022 trial, all of the remaining patents would be stayed.

19. AbbVie Inc. is the holder of Biologic License Application (“BLA”) No. 125057 for HUMIRA<sup>®</sup>, whose active pharmaceutical ingredient is the antibody, adalimumab.

20. 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- $\alpha$ , a protein made by the human body as part of the body’s immune response. The mechanisms by which TNF- $\alpha$  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 predecessors spent more than two decades and hundreds of millions of dollars on scientific studies and clinical trials to determine how to use HUMIRA<sup>®</sup> to treat patients for different diseases, how to formulate HUMIRA<sup>®</sup> for easier administration, how to improve and further develop the formulation, how to manufacture HUMIRA<sup>®</sup>, and how to develop devices for administration. AbbVie’s scientific and clinical investments in HUMIRA<sup>®</sup> continue to this day—leading, for example, to the February 2021 approval of HUMIRA<sup>®</sup> to treat pediatric patients living with moderately to severely active ulcerative colitis.

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

22. 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<sup>®</sup> has improved the lives of more than one million patients to date.



23. 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 the initial lawsuit to only four of AbbVie's 62 identified patents. Alvotech then chose to serve a notice of commercial marketing and file a duplicative lawsuit on those same four patents in the Eastern District of Virginia. Pursuant to the BPCIA, AbbVie now brings this suit seeking additional relief, including an injunction, on the remaining patents based on Alvotech's notice of commercial marketing.

### **PARTIES**

24. 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. owns patents relating to HUMIRA<sup>®</sup> and owns Biologics License Application No. 125057 for HUMIRA<sup>®</sup>. AbbVie Inc. also employs thousands of people in Illinois—including named inventors of the patents in suit—and is engaged in the development, sale, and distribution of a broad range of pharmaceutical and biologic drugs, including HUMIRA<sup>®</sup>. Indeed, HUMIRA<sup>®</sup> was developed and is marketed under the leadership of AbbVie's management in Illinois.

25. Plaintiff ABL is a corporation organized and existing under the laws of Bermuda, with a place of business at Harbour Fiduciary Services Limited, Thistle House, 4 Burnaby Street, Hamilton Pembroke HM11, Bermuda. Through intermediate organizations, Plaintiff AbbVie Inc. owns Plaintiff ABL. ABL has licensed its patents relating to HUMIRA<sup>®</sup> to AbbVie Inc. and also maintains extensive business relationships with AbbVie Inc., including supplying AbbVie Inc. with HUMIRA<sup>®</sup> for marketing.

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

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

### **JURISDICTION AND VENUE**

28. This is an action for patent infringement under the Patent Laws of the United States, 35 U.S.C. §§ 1, *et seq.*, including 35 U.S.C. § 271(a)-(c), (e)(2)(C), and (g), the BPCIA, including 42 U.S.C. § 262(l), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201(a), and 2202.

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

30. 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 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. Alvotech also provided notice of commercial marketing indicating its intent to market its product nationwide, including in this District.

31. 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), 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.

32. 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, marketing, 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.

33. 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.

34. 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.

35. 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<sup>®</sup> (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<sup>®</sup> (adalimumab) with high concentration (100 mg/mL) dosage forms.” *Id.*

36. 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 Pharmaceutical Industries Ltd. (“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. *See* 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.

37. 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. 6,805,686, 8,231,876, 8,420,081, 8,663,945, 8,708,968,

8,715,664, 8,808,700, 8,883,156, 8,889,136, 8,895,009, 8,906,372, 8,906,373, 8,906,646, 8,911,737, 8,911,964, 8,916,153, 8,926,975, 8,961,973, 8,961,974, 8,974,790, 8,986,693, 8,992,926, 8,999,337, 9,061,005, 9,062,106, 9,067,992, 9,085,618, 9,085,619, 9,085,620, 9,090,688, 9,090,689, 9,090,867, 9,096,666, 9,102,723, 9,150,645, 9,181,337, 9,181,572, 9,187,559, 9,234,032, 9,266,949, 9,273,132, 9,284,370, 9,284,371, 9,290,568, 9,315,574, 9,328,165, 9,334,319, 9,339,610, 9,346,879, 9,359,434, 9,499,614, 9,499,616, 9,505,834, 9,512,216, 9,522,953, 9,546,212, 9,550,826, 9,624,295, 9,669,093, 9,683,033, 9,708,400, 9,957,318, 11,147,782, and 11,167,030 in the event that the Alvotech aBLA Product is approved before any of these patents expire.<sup>2</sup>

38. 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.

#### VENUE

39. 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

40. On information and belief, in late August or early September 2020, Alvotech submitted aBLA 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

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<sup>2</sup> U.S. Patent Nos. 8,420,081, 8,926,975, 8,961,973, and 9,085,619 are the subject of AbbVie's first infringement suit against Alvotech. *See AbbVie Inc. and AbbVie Biotechnology Ltd v. Alvotech hf.*, Civ. No. 1:21-cv-02258 (N.D. Ill. Apr. 27, 2021) (Lee, J.).

relying on AbbVie's demonstration that HUMIRA<sup>®</sup> 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.

41. 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.

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

43. 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.

44. 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 in North Chicago, with access to Alvotech's aBLA.

45. 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."

46. 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.

47. 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:



	<b>U.S. Patent No.</b>	<b>Lead Inventor</b>	<b>Title</b>
1.	6,805,686	Fathallah	Autoinjector with Extendable Needle Protector Shroud
2.	8,231,876	Wan	Purified Antibody Composition
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 TNF $\alpha$ 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 TNF $\alpha$ -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-TNF $\alpha$ 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 TNF $\alpha$ -Related Disorders
19.	8,961,974	Hoffman	Multiple-Variable Dose Regimen for Treating TNF $\alpha$ -Related Disorders
20.	8,974,790	Fischkoff	Methods of Administering Anti-TNF $\alpha$ Antibodies
21.	8,986,693	Hoffman	Use of TNF $\alpha$ Inhibitor for Treatment of Psoriasis
22.	8,992,926	Fischkoff	Methods of Administering Anti-TNF $\alpha$ Antibodies
23.	8,999,337	Medich	Methods for Treating Juvenile Idiopathic Arthritis by Inhibition of TNF $\alpha$

	<b>U.S. Patent No.</b>	<b>Lead Inventor</b>	<b>Title</b>
24.	9,061,005	Hoffman	Multiple-Variable Dose Regimen for Treating Idiopathic Inflammatory Bowel Disease
25.	9,062,106	Bengea	Methods for Controlling the Galactosylation Profile of Recombinantly-Expressed Proteins
26.	9,067,992	Hoffman	Use of TNF $\alpha$ 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 TNF $\alpha$ 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 TNF $\alpha$ 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

	<b>U.S. Patent No.</b>	<b>Lead Inventor</b>	<b>Title</b>
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 TNF $\alpha$ 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-TNF $\alpha$ 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

48. 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.

49. 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.

50. On April 27, 2021, AbbVie brought the first action in this District to adjudicate Alvotech's infringement of the four AbbVie patents that Alvotech selected for the first phase of litigation prescribed by the BPCIA. *See AbbVie Inc. v. Alvotech hf.*, Civ. No. 1:21-cv-02258 (N.D. Ill. Apr. 27, 2021) (Lee, J.). Alvotech waived service of summons, and its counsel entered appearances shortly thereafter. *Id.* at Dkts. 9-12, 21-24.

51. On May 11, 2021, without answering or otherwise responding to the complaint pending in this District, Alvotech filed an improper declaratory judgment action on those same four patents in the Eastern District of Virginia in an effort to change courts. *Alvotech USA Inc. and Alvotech hf. v. AbbVie Inc. and AbbVie Biotechnology Ltd.*, Civ. No. 2:21-cv-00265 (E.D. Va. May 11, 2021) (Jackson, J.). The Virginia court granted AbbVie's request to transfer the case to this Court, and Alvotech subsequently dismissed its declaratory judgment case without prejudice. *Alvotech USA Inc. and Alvotech hf. v. AbbVie Inc. and AbbVie Biotechnology Ltd.*, Civ. No. 1:21-cv-05645, Dkt. 54 (N.D. Ill. May 11, 2021).

52. On the same day that Alvotech filed its improper declaratory judgment action, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A). After Alvotech provided its notice of commercial marketing, AbbVie requested information regarding the degree of immediacy of Alvotech's marketing plans, but Alvotech declined to provide any such information. In view of Alvotech's notice indicating that it intended 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 and as soon as 180 days from its date of providing the notice, AbbVie brought a second action under 42 U.S.C. § 262(l)(8) on its remaining 58 patents. Although Alvotech has agreed to refrain from marketing until after the court issues a decision on the ten patents that will be subject of the August 2022 trial, Alvotech continues to state that it intends to market AVT02 as soon as possible.

53. On August 10, 2021, the USPTO issued U.S. Pat. No. 11,083,792. AbbVie provided Alvotech notice of the issuance that same day under 42 U.S.C. § 262(l)(7).

54. On September 2, 2021, the Court scheduled a bench trial in August 2022 on ten AbbVie patents from the two filed actions. *See* 9/2/2021 Hearing Tr. at 9:16-22, 16:4-6, 21:17-18, 23:5-7. In addition, the Order indicated that AbbVie would amend its complaint in the second-filed action to add U.S. Patent Nos. 11,083,792 and the patent issuing from U.S. Patent Application No. 17/137,201 (U.S. Patent No. 11,167,030), as well as a third patent that had not yet issued and would not be part of the ten AbbVie patents to be tried in August 2022. Additionally, Alvotech represented to the Court that it would not launch its proposed biosimilar product in the United States prior to the issuance of the Court's decision on the ten patents that will be subject of the August 2022 trial. *Id.* at 7:23-9:13; *see also* Dkt. 53 at ¶ 13. The Court plans to issue its decision by the end of October 2022 on those ten patents. Dkt. 53 at ¶ 13.

55. On September 3, 2021, AbbVie identified the ten patents that will be subject to a first trial: U.S. Patent Nos. 6,805,686, 8,926,975, 8,961,973, 8,999,337, 9,067,992, 9,085,619, 9,187,559, 9,512,216, 11,083,792, and the patent issuing from U.S. Patent Application No. 17/137,201 (U.S. Patent No. 11,167,030).

56. On September 20, 2021, the Court entered a Scheduling and Discovery Order for the first action in this District and the instant action that included parameters for discovery and trial related to the ten patents that will be subject to a first trial. Dkt. 53.

57. On November 9, 2021, the USPTO issued U.S. Pat. No. 11,167,030. AbbVie provided Alvotech notice of the issuance that same day under 42 U.S.C. § 262(l)(7).

#### **THE ALVOTECH aBLA PRODUCT**

58. Alvotech has undertaken the development of a proposed biosimilar to AbbVie's HUMIRA<sup>®</sup> (adalimumab) product.

59. Alvotech has submitted an aBLA to the FDA seeking approval to market in the United States a biosimilar version of AbbVie's HUMIRA<sup>®</sup> (adalimumab) product.

60. 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<sup>®</sup> (adalimumab). *See* Exhibit 5.

61. Alvotech stated that "AVT02 is a monoclonal antibody (mAb) and a proposed biosimilar to HUMIRA<sup>®</sup> (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<sup>®</sup> (adalimumab) with high concentration (100mg/mL) dosage forms . . . matching the newest dosage forms of the reference product." *Id.*

62. 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.*

63. 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.

64. The FDA has not yet approved Alvotech’s proposed biosimilar product.

65. 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**

66. In the course of developing HUMIRA<sup>®</sup>, AbbVie has obtained more than 100 patents related to HUMIRA<sup>®</sup>, including its administration, its formulation, the processes for its manufacture, and the devices for its administration.

67. AbbVie asserts the following 60 patents in this suit (the “AbbVie Patents”).

#### **U.S. Patent No. 6,805,686**

68. U.S. Patent No. 6,805,686 (the “’686 patent”), titled “Autoinjector with Extendable Needle Protector Shroud,” was duly and legally issued by the USPTO on October 19, 2004. A true and correct copy of the ’686 patent is attached as Exhibit 10.

69. AbbVie Inc. is the owner by assignment of the ’686 patent. ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the ’686 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 '686 patent.

**U.S. Patent No. 8,231,876**

70. U.S. Patent No. 8,231,876 (the "'876 patent"), titled "Purified Antibody Composition," was duly and legally issued by the USPTO on July 31, 2012. A true and correct copy of the '876 patent is attached as Exhibit 11.

71. ABL is the owner by assignment of the '876 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the '876 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 '876 patent.

**U.S. Patent No. 8,663,945**

72. U.S. Patent No. 8,663,945 (the "'945 patent"), titled "Methods of Producing Anti-TNF-Alpha Antibodies in Mammalian Cell Culture," was duly and legally issued by the USPTO on March 4, 2014. A true and correct copy of the '945 patent is attached as Exhibit 12.

73. AbbVie Inc. is the owner by assignment of the '945 patent. ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the '945 patent in the United States. AbbVie Inc. and ABL together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the '945 patent.

**U.S. Patent No. 8,708,968**

74. U.S. Patent No. 8,708,968 (the "'968 patent"), titled "Removal of Needle Shields from Syringes and Automatic Injection Devices," was duly and legally issued by the USPTO on April 29, 2014. A true and correct copy of the '968 patent is attached as Exhibit 13.



75. ABL is a co-owner by assignment of the '968 patent. ABL has the right to initiate patent infringement litigation involving the '968 patent against Alvotech and has sole and exclusive control over enforcement and defense of the '968 patent against Alvotech.

**U.S. Patent No. 8,715,664**

76. U.S. Patent No. 8,715,664 (the "'664 patent"), titled "Use of Human TNF $\alpha$  Antibodies for Treatment of Erosive Polyarthritis," was duly and legally issued by the USPTO on May 6, 2014. A true and correct copy of the '664 patent is attached as Exhibit 14.

77. ABL is the owner by assignment of the '664 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the '664 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 '664 patent.

**U.S. Patent No. 8,808,700**

78. U.S. Patent No. 8,808,700 (the "'700 patent"), titled "Use of TNF Alpha Inhibitor for Treatment of Erosive Polyarthritis," was duly and legally issued by the USPTO on August 19, 2014. A true and correct copy of the '700 patent is attached as Exhibit 15.

79. ABL is the owner by assignment of the '700 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the '700 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 '700 patent.

**U.S. Patent No. 8,883,156**

80. U.S. Patent No. 8,883,156 (the "'156 patent"), titled "Purified Antibody Composition," was duly and legally issued by the USPTO on November 11, 2014. A true and correct copy of the '156 patent is attached as Exhibit 16.

81. ABL is the owner by assignment of the '156 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the '156 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 '156 patent.

**U.S. Patent No. 8,889,136**

82. U.S. Patent No. 8,889,136 (the "'136 patent"), titled "Multiple-Variable Dose Regimen for Treating TNF $\alpha$ -Related Disorders," was duly and legally issued by the USPTO on November 18, 2014. A true and correct copy of the '136 patent is attached as Exhibit 17.

83. ABL is the owner by assignment of the '136 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the '136 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 '136 patent.

**U.S. Patent No. 8,895,009**

84. U.S. Patent No. 8,895,009 (the "'009 patent"), titled "Purified Antibody Composition," was duly and legally issued by the USPTO on November 25, 2014. A true and correct copy of the '009 patent is attached as Exhibit 18.

85. ABL is the owner by assignment of the '009 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the '009 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 '009 patent.

**U.S. Patent No. 8,906,372**

86. U.S. Patent No. 8,906,372 (the “’372 patent”), titled “Purified Antibody Composition,” was duly and legally issued by the USPTO on December 9, 2014. A true and correct copy of the ’372 patent is attached as Exhibit 19.

87. ABL is the owner by assignment of the ’372 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the ’372 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 ’372 patent.

**U.S. Patent No. 8,906,373**

88. U.S. Patent No. 8,906,373 (the “’373 patent”), titled “Use of TNF-Alpha Inhibitor for Treatment of Psoriasis,” was duly and legally issued by the USPTO on December 9, 2014. A true and correct copy of the ’373 patent is attached as Exhibit 20.

89. ABL is the owner by assignment of the ’373 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the ’373 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 ’373 patent.

**U.S. Patent No. 8,906,646**

90. U.S. Patent No. 8,906,646 (the “’646 patent”), titled “Fed-Batch Method of Making Human Anti-TNF-Alpha Antibody,” was duly and legally issued by the USPTO on December 9, 2014. A true and correct copy of the ’646 patent is attached as Exhibit 21.

91. AbbVie Inc. is the owner by assignment of the ’646 patent. ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the ’646 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 '646 patent.

**U.S. Patent No. 8,911,737**

92. U.S. Patent No. 8,911,737 (the "'737 patent"), titled "Methods of Administering Anti-TNF $\alpha$  Antibodies," was duly and legally issued by the USPTO on December 16, 2014. A true and correct copy of the '737 patent is attached as Exhibit 22.

93. ABL is the owner by assignment of the '737 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the '737 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 '737 patent.

**U.S. Patent No. 8,911,964**

94. U.S. Patent No. 8,911,964 (the "'964 patent"), titled "Fed-Batch Method of Making Human Anti-TNF-Alpha Antibody," was duly and legally issued by the USPTO on December 16, 2014. A true and correct copy of the '964 patent is attached as Exhibit 23.

95. AbbVie Inc. is the owner by assignment of the '964 patent. ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the '964 patent in the United States. AbbVie Inc. and ABL together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the '964 patent.

**U.S. Patent No. 8,916,153**

96. U.S. Patent No. 8,916,153 (the "'153 patent"), titled "Purified Antibody Composition," was duly and legally issued by the USPTO on December 23, 2014. A true and correct copy of the '153 patent is attached as Exhibit 24.

97. ABL is the owner by assignment of the '153 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the '153 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 '153 patent.

**U.S. Patent No. 8,961,974**

98. U.S. Patent No. 8,961,974 (the "'974 patent"), titled "Multiple-Variable Dose Regimen for Treating TNF $\alpha$ -Related Disorders," was duly and legally issued by the USPTO on February 24, 2015. A true and correct copy of the '974 patent is attached as Exhibit 25.

99. ABL is the owner by assignment of the '974 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the '974 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 '974 patent.

**U.S. Patent No. 8,974,790**

100. U.S. Patent No. 8,974,790 (the "'790 patent"), titled "Methods of Administering Anti-TNF $\alpha$  Antibodies," was duly and legally issued by the USPTO on March 10, 2015. A true and correct copy of the '790 patent is attached as Exhibit 26.

101. ABL is the owner by assignment of the '790 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the '790 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 '790 patent.

**U.S. Patent No. 8,986,693**

102. U.S. Patent No. 8,986,693 (the “’693 patent”), titled “Use of TNF $\alpha$  Inhibitor for Treatment of Psoriasis,” was duly and legally issued by the USPTO on March 24, 2015. A true and correct copy of the ’693 patent is attached as Exhibit 27.

103. ABL is the owner by assignment of the ’693 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the ’693 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 ’693 patent.

**U.S. Patent No. 8,992,926**

104. U.S. Patent No. 8,992,926 (the “’926 patent”), titled “Methods of Administering Anti-TNF $\alpha$  Antibodies,” was duly and legally issued by the USPTO on March 31, 2015. A true and correct copy of the ’926 patent is attached as Exhibit 28.

105. ABL is the owner by assignment of the ’926 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the ’926 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 ’926 patent.

**U.S. Patent No. 8,999,337**

106. U.S. Patent No. 8,999,337 (the “’9337 patent”), titled “Methods for Treating Juvenile Idiopathic Arthritis by Inhibition of TNF $\alpha$ ,” was duly and legally issued by the USPTO on April 7, 2015. A true and correct copy of the ’9337 patent is attached as Exhibit 29.

107. ABL is the owner by assignment of the ’9337 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the

'9337 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 '9337 patent.

**U.S. Patent No. 9,061,005**

108. U.S. Patent No. 9,061,005 (the "'005 patent"), titled "Multiple-Variable Dose Regimen for Treating Idiopathic Inflammatory Bowel Disease," was duly and legally issued by the USPTO on June 23, 2015. A true and correct copy of the '005 patent is attached as Exhibit 30.

109. ABL is the owner by assignment of the '005 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the '005 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 '005 patent.

**U.S. Patent No. 9,062,106**

110. U.S. Patent No. 9,062,106 (the "'106 patent"), titled "Methods for Controlling the Galactosylation Profile of Recombinantly-Expressed Proteins," was duly and legally issued by the USPTO on June 23, 2015. A true and correct copy of the '106 patent is attached as Exhibit 31.

111. AbbVie Inc. is the owner by assignment of the '106 patent. ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the '106 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 '106 patent.

**U.S. Patent No. 9,067,992**

112. U.S. Patent No. 9,067,992 (the "'992 patent"), titled "Use of TNF $\alpha$  Inhibitor for Treatment of Psoriatic Arthritis," was duly and legally issued by the USPTO on June 30, 2015. A true and correct copy of the '992 patent is attached as Exhibit 32.

113. ABL is the owner by assignment of the '992 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the '992 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 '992 patent.

**U.S. Patent No. 9,085,618**

114. U.S. Patent No. 9,085,618 (the "'618 patent"), titled "Low Acidic Species Compositions and Methods for Producing and Using the Same," was duly and legally issued by the USPTO on July 21, 2015. A true and correct copy of the '618 is attached as Exhibit 33.

115. AbbVie Inc. is the owner by assignment of the '618 patent. ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the '618 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 '618 patent.

**U.S. Patent No. 9,085,620**

116. U.S. Patent No. 9,085,620 (the "'620 patent"), titled "Use of TNF $\alpha$  Inhibitor for Treatment of Psoriatic Arthritis," was duly and legally issued by the USPTO on July 21, 2015. A true and correct copy of the '620 patent is attached as Exhibit 34.

117. ABL is the owner by assignment of the '620 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the '620 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 '620 patent.



**U.S. Patent No. 9,090,688**

118. U.S. Patent No. 9,090,688 (the “’688 patent”), titled “Methods for Controlling the Galactosylation Profile of Recombinantly-Expressed Proteins,” was duly and legally issued by the USPTO on July 28, 2015. A true and correct copy of the ’688 patent is attached as Exhibit 35.

119. AbbVie Inc. is the owner by assignment of the ’688 patent. ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the ’688 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 ’688 patent.

**U.S. Patent No. 9,090,689**

120. U.S. Patent No. 9,090,689 (the “’689 patent”), titled “Use of TNF $\alpha$  Inhibitor for Treatment of Psoriasis,” was duly and legally issued by the USPTO on July 28, 2015. A true and correct copy of the ’689 patent is attached as Exhibit 36.

121. ABL is the owner by assignment of the ’689 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the ’689 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 ’689 patent.

**U.S. Patent No. 9,090,867**

122. U.S. Patent No. 9,090,867 (the “’867 patent”), titled “Fed-Batch Method of Making Anti-TNF-Alpha Antibody,” was duly and legally issued by the USPTO on July 28, 2015. A true and correct copy of the ’867 patent is attached as Exhibit 37.

123. AbbVie Inc. is the owner by assignment of the ’867 patent. ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use

methods that would infringe the '867 patent in the United States. AbbVie Inc. and ABL together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the '867 patent.

**U.S. Patent No. 9,096,666**

124. U.S. Patent No. 9,096,666 (the "'666 patent"), titled "Purified Antibody Composition," was duly and legally issued by the USPTO on August 4, 2015. A true and correct copy of the '666 patent is attached as Exhibit 38.

125. ABL is the owner by assignment of the '666 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the '666 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 '666 patent.

**U.S. Patent No. 9,102,723**

126. U.S. Patent No. 9,102,723 (the "'723 patent"), titled "Purified Antibody Composition," was duly and legally issued by the USPTO on August 11, 2015. A true and correct copy of the '723 patent is attached as Exhibit 39.

127. ABL is the owner by assignment of the '723 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the '723 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 '723 patent.

**U.S. Patent No. 9,150,645**

128. U.S. Patent No. 9,150,645 (the "'645 patent"), titled "Cell Culture Methods to Reduce Acidic Species," was duly and legally issued by the USPTO on October 6, 2015. A true and correct copy of the '645 patent is attached as Exhibit 40.

129. AbbVie Inc. is the owner by assignment of the '645 patent. ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the '645 patent in the United States. AbbVie Inc. and ABL together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the '645 patent.

**U.S. Patent No. 9,181,337**

130. U.S. Patent No. 9,181,337 (the "'1337 patent"), titled "Modulated Lysine Variant Species Compositions and Methods for Producing and Using the Same," was duly and legally issued by the USPTO on November 10, 2015. A true and correct copy of the '1337 patent is attached as Exhibit 41.

131. AbbVie Inc. is the owner by assignment of the '1337 patent. ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the '1337 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 '1337 patent.

**U.S. Patent No. 9,181,572**

132. U.S. Patent No. 9,181,572 (the "'572 patent"), titled "Methods to Modulate Lysine Variant Distribution," was duly and legally issued by the USPTO on November 10, 2015. A true and correct copy of the '572 patent is attached as Exhibit 42.

133. AbbVie Inc. is the owner by assignment of the '572 patent. ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the '572 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 '572 patent.

**U.S. Patent No. 9,187,559**

134. U.S. Patent No. 9,187,559 (the "'559 patent"), titled "Multiple-Variable Dose Regimen for Treating Idiopathic Inflammatory Bowel Disease," was duly and legally issued by the USPTO on November 17, 2015. A true and correct copy of the '559 patent is attached as Exhibit 43.

135. ABL is the owner by assignment of the '559 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the '559 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 '559 patent.

**U.S. Patent No. 9,234,032**

136. U.S. Patent No. 9,234,032 (the "'032 patent"), titled "Fed-Batch Methods for Producing Adalimumab," was duly and legally issued by the USPTO on January 12, 2016. A true and correct copy of the '032 patent is attached as Exhibit 44.

137. AbbVie Inc. is the owner by assignment of the '032 patent. ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the '032 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 '032 patent.

**U.S. Patent No. 9,266,949**

138. U.S. Patent No. 9,266,949 (the "'949 patent"), titled "Low Acidic Species Compositions and Methods for Producing and Using the Same," was duly and legally issued by

the USPTO on February 23, 2016. A true and correct copy of the '949 patent is attached as Exhibit 45.

139. AbbVie Inc. is the owner by assignment of the '949 patent. ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the '949 patent in the United States. AbbVie Inc. and ABL together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the '949 patent.

**U.S. Patent No. 9,273,132**

140. U.S. Patent No. 9,273,132 (the "'132 patent"), titled "Purified Antibody Composition," was duly and legally issued by the USPTO on March 1, 2016. A true and correct copy of the '132 patent is attached as Exhibit 46.

141. ABL is the owner by assignment of the '132 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the '132 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 '132 patent.

**U.S. Patent No. 9,284,370**

142. U.S. Patent No. 9,284,370 (the "'370 patent"), titled "Methods for Treating Juvenile Idiopathic Arthritis," was duly and legally issued by the USPTO on March 15, 2016. A true and correct copy of the '370 patent is attached as Exhibit 47.

143. ABL is the owner by assignment of the '370 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the '370 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 '370 patent.

**U.S. Patent No. 9,284,371**

144. U.S. Patent No. 9,284,371 (the “’371 patent”), titled “Methods of Producing Adalimumab,” was duly and legally issued by the USPTO on March 15, 2016. A true and correct copy of the ’371 patent is attached as Exhibit 48.

145. AbbVie Inc. is the owner by assignment of the ’371 patent. ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the ’371 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 ’371 patent.

**U.S. Patent No. 9,290,568**

146. U.S. Patent No. 9,290,568 (the “’568 patent”), titled “Methods to Control Protein Heterogeneity,” was duly and legally issued by the USPTO on March 22, 2016. A true and correct copy of the ’568 patent is attached as Exhibit 49.

147. AbbVie Inc. is the owner by assignment of the ’568 patent. ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the ’568 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 ’568 patent.

**U.S. Patent No. 9,315,574**

148. U.S. Patent No. 9,315,574 (the “’574 patent”), titled “Low Acidic Species Compositions and Methods for Producing and Using the Same,” was duly and legally issued by the USPTO on April 19, 2016. A true and correct copy of the ’574 patent is attached as Exhibit 50.

149. AbbVie Inc. is the owner by assignment of the '574 patent. ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the '574 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 '574 patent.

**U.S. Patent No. 9,328,165**

150. U.S. Patent No. 9,328,165 (the "'165 patent"), titled "Purified Antibody Composition," was duly and legally issued by the USPTO on May 3, 2016. A true and correct copy of the '165 patent is attached as Exhibit 51.

151. ABL is the owner by assignment of the '165 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the '165 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 '165 patent.

**U.S. Patent No. 9,334,319**

152. U.S. Patent No. 9,334,319 (the "'319 patent"), titled "Low Acidic Species Compositions," was duly and legally issued by the USPTO on May 10, 2016. A true and correct copy of the '319 patent is attached as Exhibit 52.

153. AbbVie Inc. is the owner by assignment of the '319 patent. ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the '319 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 '319 patent.

**U.S. Patent No. 9,339,610**

154. U.S. Patent No. 9,339,610 (the “’610 patent”), titled “Removal of Needle Shield from Syringes and Automatic Injection Devices,” was duly and legally issued by the USPTO on May 17, 2016. A true and correct copy of the ’610 patent is attached as Exhibit 53.

155. ABL is a co-owner by assignment of the ’610 patent. ABL has the right to initiate patent infringement litigation involving the ’610 patent against Alvotech and has sole and exclusive control over enforcement and defense of the ’610 patent against Alvotech.

**U.S. Patent No. 9,346,879**

156. U.S. Patent No. 9,346,879 (the “’879 patent”), titled “Protein Purification Methods to Reduce Acidic Species,” was duly and legally issued by the USPTO on May 24, 2016. A true and correct copy of the ’879 patent is attached as Exhibit 54.

157. AbbVie Inc. is the owner by assignment of the ’879 patent. ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the ’879 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 ’879 patent.

**U.S. Patent No. 9,359,434**

158. U.S. Patent No. 9,359,434 (the “’434 patent”), titled “Cell Culture Methods to Reduce Acidic Species,” was duly and legally issued by the USPTO on June 7, 2016. A true and correct copy of the ’434 patent is attached as Exhibit 55.

159. AbbVie Inc. is the owner by assignment of the ’434 patent. ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the ’434 patent in the United States. AbbVie Inc. and ABL together



hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the '434 patent.

**U.S. Patent No. 9,499,614**

160. U.S. Patent No. 9,499,614 (the "'614 patent"), titled "Methods for Modulating Protein Glycosylation Profiles of Recombinant Protein Therapeutics Using Monosaccharides and Oligosaccharides," was duly and legally issued by the USPTO on November 22, 2016. A true and correct copy of the '614 patent is attached as Exhibit 56.

161. AbbVie Inc. is the owner by assignment of the '614 patent. ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the '614 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 '614 patent.

**U.S. Patent No. 9,499,616**

162. U.S. Patent No. 9,499,616 (the "'616 patent"), titled "Modulated Lysine Variant Species Compositions and Methods for Producing and Using the Same," was duly and legally issued by the USPTO on November 22, 2016. A true and correct copy of the '616 patent is attached as Exhibit 57.

163. AbbVie Inc. is the owner by assignment of the '616 patent. ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the '616 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 '616 patent.

**U.S. Patent No. 9,505,834**

164. U.S. Patent No. 9,505,834 (the “’834 patent”), titled “Methods for Controlling the Galactosylation Profile of Recombinantly-Expressed Proteins,” was duly and legally issued by the USPTO on November 29, 2016. A true and correct copy of the ’834 patent is attached as Exhibit 58.

165. AbbVie Inc. is the owner by assignment of the ’834 patent. ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the ’834 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 ’834 patent.

**U.S. Patent No. 9,512,216**

166. U.S. Patent No. 9,512,216 (the “’216 patent”), titled “Use of TNF $\alpha$  Inhibitor,” was duly and legally issued by the USPTO on December 6, 2016. A true and correct copy of the ’216 patent is attached as Exhibit 59.

167. ABL is the owner by assignment of the ’216 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the ’216 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 ’216 patent.

**U.S. Patent No. 9,522,953**

168. U.S. Patent No. 9,522,953 (the “’953 patent”), titled “Low Acidic Species Compositions and Methods for Producing and Using the Same,” was duly and legally issued by the USPTO on December 20, 2016. A true and correct copy of the ’953 patent is attached as Exhibit 60.

169. AbbVie Inc. is the owner by assignment of the '953 patent. ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the '953 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 '953 patent.

**U.S. Patent No. 9,546,212**

170. U.S. Patent No. 9,546,212 (the "'212 patent"), titled "Methods of Administering Anti-TNF $\alpha$  Antibodies," was duly and legally issued by the USPTO on January 17, 2017. A true and correct copy of the '212 patent is attached as Exhibit 61.

171. ABL is the owner by assignment of the '212 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the '212 patent in the United States. AbbVie Inc. and ABL together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the '212 patent.

**U.S. Patent No. 9,550,826**

172. U.S. Patent No. 9,550,826 (the "'826"), titled "Glycoengineered Binding Protein Compositions," was duly and legally issued by the USPTO on January 24, 2017. A true and correct copy of the '826 patent is attached as Exhibit 62.

173. AbbVie Inc. is the owner by assignment of the '826 patent. ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the '826 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 '826 patent.

**U.S. Patent No. 9,624,295**

174. U.S. Patent No. 9,624,295 (the “’295 patent”), titled “Uses and Compositions for Treatment of Psoriatic Arthritis,” was duly and legally issued by the USPTO on April 18, 2017. A true and correct copy of the ’295 patent is attached as Exhibit 63.

175. ABL is the owner by assignment of the ’295 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the ’295 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 ’295 patent.

**U.S. Patent No. 9,669,093**

176. U.S. Patent No. 9,669,093 (the “’093 patent”), titled “Methods for Treating Juvenile Idiopathic Arthritis,” was duly and legally issued by the USPTO on June 6, 2017. A true and correct copy of the ’093 patent is attached as Exhibit 64.

177. ABL is the owner by assignment of the ’093 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the ’093 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 ’093 patent.

**U.S. Patent No. 9,683,033**

178. U.S. Patent No. 9,683,033 (the “’033 patent”), titled “Cell Culture Methods to Reduce Acidic Species,” was duly and legally issued by the USPTO on June 20, 2017. A true and correct copy of the ’033 patent is attached as Exhibit 65.

179. AbbVie Inc. is the owner by assignment of the ’033 patent. ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the ’033 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 '033 patent.

**U.S. Patent No. 9,708,400**

180. U.S. Patent No. 9,708,400 (the "'400 patent"), titled "Methods to Modulate Lysine Variant Distribution," was duly and legally issued by the USPTO on July 18, 2017. A true and correct copy of the '400 patent is attached as Exhibit 66.

181. AbbVie Inc. is the owner by assignment of the '400 patent. ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the '400 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 '400 patent.

**U.S. Patent No. 9,957,318**

182. U.S. Patent No. 9,957,318 (the "'318 patent"), titled "Protein Purification Methods to Reduce Acidic Species," was duly and legally issued by the USPTO on May 1, 2018. A true and correct copy of the '318 patent is attached as Exhibit 67.

183. AbbVie Inc. is the owner by assignment of the '318 patent. ABL is exclusively licensed to import, have imported, manufacture, or have manufactured products, and to use methods that would infringe the '318 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 '318 patent.

**U.S. Patent No. 11,083,792**

184. U.S. Patent No. 11,083,792 (the “’792 patent”), titled “Purified Antibody Composition,” was duly and legally issued by the USPTO on August 10, 2021. A true and correct copy of the ’792 patent is attached as Exhibit 68.

185. ABL is the owner by assignment of the ’792 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the ’792 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 ’792 patent.

**U.S. Patent No. 11,167,030**

186. U.S. Patent No. 11,167,030 (the “’030 patent”), titled “Protein Formulations and Methods of Making Same,” was duly and legally issued by the USPTO on November 9, 2021. A true and correct copy of the ’030 patent is attached as Exhibit 69.

187. ABL is the owner by assignment of the ’030 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the ’030 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 ’030 patent.

188. AbbVie included in its disclosures to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(A) and 42 U.S.C. § 262(l)(7), each of the patents described in Counts I-CXX below.

189. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for each of the claims described in Counts I-CXX below.

**COUNT I.  
INFRINGEMENT OF U.S. PATENT NO. 6,805,686**

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

191. 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.

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

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

194. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

195. 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.

196. 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 '686 patent is an act of infringement of one or more claims of the '686 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

197. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1, 3, 4, 11, 12, 19-21, and 24 of the '686 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1, 3, 4, 11, 12, 19-21, and 24 of the '686 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '686 patent.

198. 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 '686 patent, either literally or under the doctrine of equivalents.

199. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product (including the delivery device) directly infringes at least one claim of the '686 patent, either literally or under the doctrine of equivalents.

200. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1, 3, 4, 11, 12, 19-21, and 24 of the '686 patent, either literally or under the doctrine of equivalents.

201. Alvotech has knowledge of and is aware of the '686 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.

202. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '686 patent.



203. 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.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 6,805,686**

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

205. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

206. 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.

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

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

209. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

210. 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 and 180 days after its notice of commercial marketing.<sup>3</sup>

211. 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 '686 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '686 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

212. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1, 3, 4, 11, 12, 19-21, and 24 of the '686 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for

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<sup>3</sup> With respect to this paragraph and those thereafter concerning Alvotech's intention to launch, Alvotech has agreed not to launch until after the Court's decision on the ten patents that are the subject of the August 2022 trial.

claims 1, 3, 4, 11, 12, 19-21, and 24 of the '686 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '686 patent.

213. 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 '686 patent, either literally or under the doctrine of equivalents.

214. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product (including the delivery device) directly infringes at least one claim of the '686 patent, either literally or under the doctrine of equivalents.

215. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1, 3, 4, 11, 12, 19-21, and 24 of the '686 patent, either literally or under the doctrine of equivalents.

216. Alvotech has knowledge of and is aware of the '686 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.

217. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '686 patent.

218. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '686 patent.

219. AbbVie seeks an injunction 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. 8,231,876**

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

221. 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.

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

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

224. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

225. 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.

226. 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 '876 patent is an act of infringement of one or more claims of the '876 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

227. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 3-8, 10-12 of the '876 patent under at least 35 U.S.C. § 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 3-8 and 10-12 of the '876 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '876 patent.

228. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '876 patent, either literally or under the doctrine of equivalents.

229. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 3-8 and 10-12 of the '876 patent, either literally or under the doctrine of equivalents.

230. Alvotech has knowledge of and is aware of the '876 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.

231. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '876 patent.

232. 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.  
DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,231,876**

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

234. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

235. 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.

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

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

238. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

239. 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 and 180 days after its notice of commercial marketing.

240. 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 '876 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '876 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

241. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 3-8 and 10-12 of the '876 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 3-8 and 10-12 of the '876 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '876 patent.

242. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '876 patent, either literally or under the doctrine of equivalents.

243. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 3-8 and 10-12 of the '876 patent, either literally or under the doctrine of equivalents.

244. Alvotech has knowledge of and is aware of the '876 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.

245. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '876 patent.

246. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '876 patent.

247. AbbVie seeks an injunction 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 V.  
INFRINGEMENT OF U.S. PATENT NO. 8,663,945**

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

249. 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.

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

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

252. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

253. 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.

254. 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 '945 patent is an act of infringement of one or more claims of the '945 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

255. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 at least claims 1-3, 5, 6, 9, 10, 12-14, 16, 17, 20, 21, 23-25, 27, 28, 31, 32, 34, 36, and 38 of the '945 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-

claim infringement contentions for claims 1-3, 5, 6, 9, 10, 12-14, 16, 17, 20, 21, 23-25, 27, 28, 31, 32, 34, 36, and 38 of the '945 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '945 patent.

256. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '945 patent, either literally or under the doctrine of equivalents.

257. Alvotech has knowledge of and is aware of the '945 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.

258. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '945 patent.

259. 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 VI.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,663,945**

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

261. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

262. 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.

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

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

265. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

266. On information and belief as of May 28, 2021, 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.

267. 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 '945 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '945 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

268. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 at least claims 1-3, 5, 6, 9, 10, 12-14, 16, 17, 20, 21, 23-25, 27, 28, 31, 32, 34, 36, and 38 of the '945 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-3, 5, 6, 9, 10, 12-14, 16, 17, 20, 21, 23-25, 27, 28, 31, 32, 34, 36, and 38 of the '945 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '945 patent.

269. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '945 patent, either literally or under the doctrine of equivalents.

270. Alvotech has knowledge of and is aware of the '945 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.

271. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '945 patent.

272. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '945 patent.

273. AbbVie seeks an injunction 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 VII.  
INFRINGEMENT OF U.S. PATENT NO. 8,708,968**

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

275. 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.

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

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

278. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

279. 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.

280. 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 '968 patent is an act of infringement of one or more claims of the '968 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

281. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 22, 24, 25, and 28-30 of the '968 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 22, 24, 25, and 28-30 of the '968 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '968 patent.

282. 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 '968 patent, either literally or under the doctrine of equivalents.

283. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product (including the delivery device) directly infringes at least one claim of the '968 patent, either literally or under the doctrine of equivalents.

284. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 22, 24, 25, and 28-30 of the '968 patent, either literally or under the doctrine of equivalents.

285. Alvotech has knowledge of and is aware of the '968 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.

286. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '968 patent.

287. 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 VIII.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,708,968**

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

289. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

290. 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.

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

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

293. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

294. On information and belief as of May 28, 2021, 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.

295. 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 '968 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '968 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

296. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 22, 24, 25, and 28-30 of the '968 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 22, 24, 25, and 28-30 of the '968 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '968 patent.



297. 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 '968 patent, either literally or under the doctrine of equivalents.

298. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product (including the delivery device) directly infringes at least one claim of the '968 patent, either literally or under the doctrine of equivalents.

299. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 22, 24, 25, and 28-30 of the '968 patent, either literally or under the doctrine of equivalents.

300. Alvotech has knowledge of and is aware of the '968 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.

301. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '968 patent.

302. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '968 patent.

303. AbbVie seeks an injunction 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 IX.**  
**INFRINGEMENT OF U.S. PATENT NO. 8,715,664**

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

305. 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.

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

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

308. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

309. 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.

310. 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 '664 patent is an act of infringement of one or more claims of the '664 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

311. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 11 and 17 of the '664 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 11 and 17 of the '664 patent.

312. 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 '664 patent, either literally or under the doctrine of equivalents.

313. 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 11 and 17 of the '664 patent, either literally or under the doctrine of equivalents.

314. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 11 and 17 of the '664 patent, either literally or under the doctrine of equivalents.

315. Alvotech has knowledge of and is aware of the '664 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.

316. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '664 patent.

317. 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 X.**

**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,715,664**

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

319. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

320. 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.

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

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

323. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

324. On information and belief as of May 28, 2021, 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.

325. 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 '664 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will

infringe one or more of the claims of '664 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

326. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 11 and 17 of the '664 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 11 and 17 of the '664 patent.

327. 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 '664 patent, either literally or under the doctrine of equivalents.

328. 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 11 and 17 of the '664 patent, either literally or under the doctrine of equivalents.

329. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 11 and 17 of the '664 patent, either literally or under the doctrine of equivalents.

330. Alvotech has knowledge of and is aware of the '664 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.

331. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '664 patent.

332. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '664 patent.

333. AbbVie seeks an injunction 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 XI.  
INFRINGEMENT OF U.S. PATENT NO. 8,808,700**

334. 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.

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

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

337. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

338. 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.

339. 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 '700 patent is an act of infringement of one or more claims of the '700 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

340. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-30 of the '700 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-30 of the '700 patent.

341. 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 '700 patent, either literally or under the doctrine of equivalents.

342. 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 '700 patent, either literally or under the doctrine of equivalents.

343. 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 '700 patent, either literally or under the doctrine of equivalents.

344. Alvotech has knowledge of and is aware of the '700 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.

345. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '700 patent.

346. 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 XII.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,808,700**

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

348. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

349. 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.

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

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

352. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

353. On information and belief as of May 28, 2021, 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.

354. 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 '700 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '700 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

355. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-30 of the '700 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-30 of the '700 patent.

356. 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 '700 patent, either literally or under the doctrine of equivalents.

357. 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 '700 patent, either literally or under the doctrine of equivalents.

358. 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 '700 patent, either literally or under the doctrine of equivalents.

359. Alvotech has knowledge of and is aware of the '700 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.

360. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '700 patent.

361. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '700 patent.

362. AbbVie seeks an injunction 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 XIII.  
INFRINGEMENT OF U.S. PATENT NO. 8,883,156**

363. 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.

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

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

366. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

367. 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.

368. 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 '156 patent is an act of infringement of one or more claims of the '156 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

369. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-7 and 10-19 of the '156 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '156 patent.

370. 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 '156 patent, either literally or under the doctrine of equivalents.

371. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '156 patent, either literally or under the doctrine of equivalents.

372. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-7 and 10-19 of the '156 patent, either literally or under the doctrine of equivalents.

373. Alvotech has knowledge of and is aware of the '156 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.

374. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '156 patent.

375. 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 XIV.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,883,156**

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

377. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

378. 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.

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

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

381. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

382. On information and belief as of May 28, 2021, 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.

383. 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 '156 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of the '156 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

384. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-7 and 10-19 of the '156 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '156 patent.

385. 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 '156 patent, either literally or under the doctrine of equivalents.

386. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '156 patent, either literally or under the doctrine of equivalents.

387. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-7 and 10-19 of the '156 patent, either literally or under the doctrine of equivalents.

388. Alvotech has knowledge of and is aware of the '156 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.

389. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '156 patent.

390. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '156 patent.

391. AbbVie seeks an injunction 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 XV.  
INFRINGEMENT OF U.S. PATENT NO. 8,889,136**

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

393. 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.

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

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

396. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

397. 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.

398. 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 '136 patent is an act of infringement of one or more claims of the '136 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

399. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-18 of the '136 patent under at least 35 U.S.C. §§ 271(b) and (c), either



literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-18 of the '136 patent.

400. 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 '136 patent, either literally or under the doctrine of equivalents.

401. 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 1-18 of the '136 patent, either literally or under the doctrine of equivalents.

402. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-18 of the '136 patent, either literally or under the doctrine of equivalents.

403. Alvotech has knowledge of and is aware of the '136 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.

404. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '136 patent.

405. 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 XVI.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,889,136**

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

407. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

408. 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.

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

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

411. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

412. On information and belief as of May 28, 2021, 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.

413. 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 '136 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '136 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's

provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

414. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-18 of the '136 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-18 of the '136 patent.

415. 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 '136 patent, either literally or under the doctrine of equivalents.

416. 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 1-18 of the '136 patent, either literally or under the doctrine of equivalents.

417. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-18 of the '136 patent, either literally or under the doctrine of equivalents.

418. Alvotech has knowledge of and is aware of the '136 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.

419. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '136 patent.

420. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '136 patent.

421. AbbVie seeks an injunction 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 XVII.  
INFRINGEMENT OF U.S. PATENT NO. 8,895,009**

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

423. 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.

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

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

426. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

427. 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.

428. 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 '009 patent is an act of infringement of one or more claims of the '009 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

429. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-7 and 9-13 of the '009 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '009 patent.

430. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '009 patent, either literally or under the doctrine of equivalents.

431. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-7 and 9-13 of the '009 patent, either literally or under the doctrine of equivalents.

432. Alvotech has knowledge of and is aware of the '009 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.

433. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '009 patent.

434. 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 XVIII.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,895,009**

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

436. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

437. 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.

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

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

440. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

441. On information and belief as of May 28, 2021, 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.

442. 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 '009 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '009 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. See 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

443. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-7 and 9-13 of the '009 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. For at least one claim, however, Alvotech's

failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '009 patent.

444. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '009 patent, either literally or under the doctrine of equivalents.

445. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-7 and 9-13 of the '009 patent, either literally or under the doctrine of equivalents.

446. Alvotech has knowledge of and is aware of the '009 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.

447. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '009 patent.

448. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '009 patent.

449. AbbVie seeks an injunction 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 XIX.**  
**INFRINGEMENT OF U.S. PATENT NO. 8,906,372**

450. 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.

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

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

453. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

454. 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.

455. 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 '372 patent is an act of infringement of one or more claims of the '372 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

456. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-7 and 9-19 of the '372 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. For at least one claim, however, Alvotech's

failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '372 patent.

457. 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 '372 patent, either literally or under the doctrine of equivalents.

458. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '372 patent, either literally or under the doctrine of equivalents.

459. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-7 and 9-19 of the '372 patent, either literally or under the doctrine of equivalents.

460. Alvotech has knowledge of and is aware of the '372 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.

461. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '372 patent.

462. 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 XX.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,906,372**

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

464. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

465. 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.

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

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

468. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

469. On information and belief as of May 28, 2021, 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.

470. 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 '372 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of the '372 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's

provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

471. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-7 and 9-19 of the '372 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '372 patent.

472. 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 '372 patent, either literally or under the doctrine of equivalents.

473. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '372 patent, either literally or under the doctrine of equivalents.

474. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-7 and 9-19 of the '372 patent, either literally or under the doctrine of equivalents.

475. Alvotech has knowledge of and is aware of the '372 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.

476. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '372 patent.

477. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '372 patent.

478. AbbVie seeks an injunction 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 XXI.**  
**INFRINGEMENT OF U.S. PATENT NO. 8,906,373**

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

480. 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.

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

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

483. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

484. 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.

485. 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 '373 patent is an act of infringement of one or more claims of the '373 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

486. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 4, 5, and 8 of the '373 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 4, 5, and 8 of the '373 patent.

487. 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 '373 patent, either literally or under the doctrine of equivalents.

488. 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 4, 5, and 8 of the '373 patent, either literally or under the doctrine of equivalents.

489. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 4, 5, and 8 of the '373 patent, either literally or under the doctrine of equivalents.

490. Alvotech has knowledge of and is aware of the '373 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.

491. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '373 patent.

492. 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 XXII.**

#### **DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,906,373**

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

494. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

495. 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.

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

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

498. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

499. On information and belief as of May 28, 2021, 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.

500. 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 '373 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '373 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

501. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 4, 5, and 8 of the '373 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 4, 5, and 8 of the '373 patent.

502. 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 '373 patent, either literally or under the doctrine of equivalents.

503. 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 4, 5, and 8 of the '373 patent, either literally or under the doctrine of equivalents.

504. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 4, 5, and 8 of the '373 patent, either literally or under the doctrine of equivalents.

505. Alvotech has knowledge of and is aware of the '373 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.

506. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '373 patent.

507. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '373 patent.

508. AbbVie seeks an injunction 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 XXIII.**  
**INFRINGEMENT OF U.S. PATENT NO. 8,906,646**

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

510. 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.

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

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

513. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

514. 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.

515. 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 '646 patent is an act of infringement of one or more claims of the '646 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

516. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 at least claims 25-28 of the '646 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 25-28 of the '646 patent.

517. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '646 patent, either literally or under the doctrine of equivalents.

518. Alvotech has knowledge of and is aware of the '646 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.

519. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '646 patent.

520. 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 XXIV.**

**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,906,646**

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

522. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

523. 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.

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

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

526. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

527. On information and belief as of May 28, 2021, 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.

528. 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 '646 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will

infringe one or more of the claims of '646 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

529. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 at least claims 25-28 of the '646 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 25-28 of the '646 patent.

530. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '646 patent, either literally or under the doctrine of equivalents.

531. Alvotech has knowledge of and is aware of the '646 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.

532. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '646 patent.

533. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '646 patent.

534. AbbVie seeks an injunction 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 XXV.  
INFRINGEMENT OF U.S. PATENT NO. 8,911,737**

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

536. 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.

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

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

539. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

540. 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.

541. 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 '737 patent is an act of infringement of one or more claims of the '737 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

542. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-6 of the '737 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-6 of the '737 patent.

543. 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 '737 patent, either literally or under the doctrine of equivalents.

544. 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 '737 patent, either literally or under the doctrine of equivalents.

545. 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 '737 patent, either literally or under the doctrine of equivalents.

546. Alvotech has knowledge of and is aware of the '737 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.

547. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '737 patent.

548. 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 XXVI.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,911,737**

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

550. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

551. 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.

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

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

554. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).



555. On information and belief as of May 28, 2021, 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.

556. 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 '737 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '737 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

557. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-6 of the '737 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-6 of the '737 patent.

558. 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 '737 patent, either literally or under the doctrine of equivalents.

559. 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 '737 patent, either literally or under the doctrine of equivalents.

560. 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 '737 patent, either literally or under the doctrine of equivalents.

561. Alvotech has knowledge of and is aware of the '737 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.

562. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '737 patent.

563. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '737 patent.

564. AbbVie seeks an injunction 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 XXVII.**  
**INFRINGEMENT OF U.S. PATENT NO. 8,911,964**

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

566. 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.

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

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

569. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

570. 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.

571. 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 '964 patent is an act of infringement of one or more claims of the '964 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

572. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 at least claims 23, 24, 26, 27, and 29 of the '964 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 23, 24, 26, 27, and 29 of the '964 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '964 patent.

573. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '964 patent, either literally or under the doctrine of equivalents.

574. Alvotech has knowledge of and is aware of the '964 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.

575. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '964 patent.

576. 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 XXVIII.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,911,964**

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

578. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

579. 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.

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

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

582. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

583. On information and belief as of May 28, 2021, 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.

584. 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 '964 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '964 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

585. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 at least claims 23, 24, 26, 27, and 29 of the '964 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 23, 24, 26, 27, and 29 of the '964 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '964 patent.

586. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '964 patent, either literally or under the doctrine of equivalents.

587. Alvotech has knowledge of and is aware of the '964 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.

588. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '964 patent.

589. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '964 patent.

590. AbbVie seeks an injunction 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 XXIX.**  
**INFRINGEMENT OF U.S. PATENT NO. 8,916,153**

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

592. 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.

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

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

595. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

596. 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.

597. 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 '153 patent is an act of infringement of one or more claims of the '153 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

598. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-8 and 11-14 of the '153 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '153 patent.

599. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '153 patent, either literally or under the doctrine of equivalents.

600. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-8 and 11-14 of the '153 patent, either literally or under the doctrine of equivalents.

601. Alvotech has knowledge of and is aware of the '153 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.



602. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '153 patent.

603. 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 XXX.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,916,153**

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

605. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

606. 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.

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

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

609. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

610. On information and belief as of May 28, 2021, 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.

611. 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 '153 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '153 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. See 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

612. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-8 and 11-14 of the '153 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '153 patent.

613. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '153 patent, either literally or under the doctrine of equivalents.

614. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-8 and 11-14 of the '153 patent, either literally or under the doctrine of equivalents.

615. Alvotech has knowledge of and is aware of the '153 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.

616. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '153 patent.

617. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '153 patent.

618. AbbVie seeks an injunction 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 XXXI.**  
**INFRINGEMENT OF U.S. PATENT NO. 8,961,974**

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

620. 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.

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

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

623. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

624. 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.

625. 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 '974 patent is an act of infringement of one or more claims of the '974 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

626. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-28 of the '974 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-28 of the '974 patent.

627. 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 '974 patent, either literally or under the doctrine of equivalents.

628. 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 1-28 of the '974 patent, either literally or under the doctrine of equivalents.

629. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-28 of the '974 patent, either literally or under the doctrine of equivalents.

630. Alvotech has knowledge of and is aware of the '974 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.

631. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '974 patent.

632. 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 XXXII.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,961,974**

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

634. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

635. 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.

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

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

638. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

639. On information and belief as of May 28, 2021, 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.

640. 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 '974 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '974 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

641. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-28 of the '974 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-28 of the '974 patent.

642. 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 '974 patent, either literally or under the doctrine of equivalents.

643. 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 1-28 of the '974 patent, either literally or under the doctrine of equivalents.

644. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-28 of the '974 patent, either literally or under the doctrine of equivalents.

645. Alvotech has knowledge of and is aware of the '974 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.

646. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '974 patent.

647. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '974 patent.

648. AbbVie seeks an injunction 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 XXXIII.  
INFRINGEMENT OF U.S. PATENT NO. 8,974,790**

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

650. 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.

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

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

653. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

654. 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.

655. 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 '790 patent is an act of infringement of one or more claims of the '790 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

656. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-6 of the '790 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-6 of the '790 patent.

657. 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 '790 patent, either literally or under the doctrine of equivalents.

658. 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 '790 patent, either literally or under the doctrine of equivalents.

659. 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 '790 patent, either literally or under the doctrine of equivalents.

660. Alvotech has knowledge of and is aware of the '790 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.

661. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '790 patent.

662. 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 XXXIV.**

**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,974,790**

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

664. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

665. 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.

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

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

668. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

669. On information and belief as of May 28, 2021, 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.

670. 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 '790 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '790 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

671. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-6 of the '790 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-6 of the '790 patent.

672. 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 '790 patent, either literally or under the doctrine of equivalents.

673. 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 '790 patent, either literally or under the doctrine of equivalents at least one claim of the '790 patent, either literally or under the doctrine of equivalents.

674. 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 '790 patent, either literally or under the doctrine of equivalents.

675. Alvotech has knowledge of and is aware of the '790 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.

676. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '790 patent.

677. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '790 patent.

678. AbbVie seeks an injunction 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 XXXV.  
INFRINGEMENT OF U.S. PATENT NO. 8,986,693**

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

680. 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.

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

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

683. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

684. 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.

685. 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 '693 patent is an act of infringement of one or more claims of the '693 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

686. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-8 of the '693 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-8 of the '693 patent.

687. 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 '693 patent, either literally or under the doctrine of equivalents.

688. 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 1-8 of the '693 patent, either literally or under the doctrine of equivalents.

689. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-8 of the '693 patent, either literally or under the doctrine of equivalents.

690. Alvotech has knowledge of and is aware of the '693 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.

691. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '693 patent.

692. 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 XXXVI.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,986,693**

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

694. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

695. 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.

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

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

698. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

699. On information and belief as of May 28, 2021, 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.

700. 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 '693 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '693 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

701. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-8 of the '693 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-8 of the '693 patent.

702. 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 '693 patent, either literally or under the doctrine of equivalents.

703. 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 1-8 of the '693 patent, either literally or under the doctrine of equivalents.



704. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-8 of the '693 patent, either literally or under the doctrine of equivalents.

705. Alvotech has knowledge of and is aware of the '693 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.

706. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '693 patent.

707. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '693 patent.

708. AbbVie seeks an injunction 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 XXXVII.  
INFRINGEMENT OF U.S. PATENT NO. 8,992,926**

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

710. 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.

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

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

713. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

714. 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.

715. 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 '926 patent is an act of infringement of one or more claims of the '926 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

716. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-4 of the '926 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-4 of the '926 patent.

717. 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 '926 patent, either literally or under the doctrine of equivalents.

718. 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 1-4 of the '926 patent, either literally or under the doctrine of equivalents.

719. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-4 of the '926 patent, either literally or under the doctrine of equivalents.

720. Alvotech has knowledge of and is aware of the '926 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.

721. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '926 patent.

722. 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 XXXVIII.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,992,926**

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

724. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

725. 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.

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

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

728. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

729. On information and belief as of May 28, 2021, 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.

730. 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 '926 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '926 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

731. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-4 of the '926 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-4 of the '926 patent.

732. 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 '926 patent, either literally or under the doctrine of equivalents.

733. 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 1-4 of the '926 patent, either literally or under the doctrine of equivalents.

734. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-4 of the '926 patent, either literally or under the doctrine of equivalents.

735. Alvotech has knowledge of and is aware of the '926 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.

736. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '926 patent.

737. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '926 patent.

738. AbbVie seeks an injunction 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 XXXIX.**  
**INFRINGEMENT OF U.S. PATENT NO. 8,999,337**

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

740. 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.

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

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

743. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

744. 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.

745. 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 '9337 patent is an act of infringement of one or more claims of the '9337 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

746. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-8, 10, and 14-19 of the '9337 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-8, 10, and 14-19 of the '9337 patent.

747. 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 '9337 patent, either literally or under the doctrine of equivalents.

748. 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 1-8, 10, and 14-19 of the '9337 patent, either literally or under the doctrine of equivalents.

749. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-8, 10, and 14-19 of the '9337 patent, either literally or under the doctrine of equivalents.

750. Alvotech has knowledge of and is aware of the '9337 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.

751. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '9337 patent.

752. 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 XL.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,999,337**

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

754. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

755. 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.

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

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

758. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).



759. On information and belief as of May 28, 2021, 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.

760. 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 '9337 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '9337 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

761. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-8, 10, and 14-19 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-8, 10, and 14-19 of the '9337 patent.

762. 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 '9337 patent, either literally or under the doctrine of equivalents.

763. 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 1-8, 10, and 14-19 of the '9337 patent, either literally or under the doctrine of equivalents.

764. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-8, 10, and 14-19 of the '9337 patent, either literally or under the doctrine of equivalents.

765. Alvotech has knowledge of and is aware of the '9337 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.

766. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '9337 patent.

767. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '9337 patent.

768. AbbVie seeks an injunction 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 XLI.  
INFRINGEMENT OF U.S. PATENT NO. 9,061,005**

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

770. 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.

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

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

773. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

774. 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.

775. 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 '005 patent is an act of infringement of one or more claims of the '005 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

776. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-28 of the '005 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-28 of the '005 patent.

777. 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 '005 patent, either literally or under the doctrine of equivalents.

778. 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 1-28 of the '005 patent, either literally or under the doctrine of equivalents.

779. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-28 of the '005 patent, either literally or under the doctrine of equivalents.

780. Alvotech has knowledge of and is aware of the '005 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.

781. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '005 patent.

782. 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 XLII.**

**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,061,005**

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

784. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

785. 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.

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

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

788. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

789. On information and belief as of May 28, 2021, 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.

790. 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 '005 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will

infringe one or more of the claims of '005 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

791. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-28 of the '005 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-28 of the '005 patent.

792. 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 '005 patent, either literally or under the doctrine of equivalents.

793. 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 1-28 of the '005 patent, either literally or under the doctrine of equivalents.

794. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-28 of the '005 patent, either literally or under the doctrine of equivalents.

795. Alvotech has knowledge of and is aware of the '005 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.

796. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '005 patent.

797. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '005 patent.

798. AbbVie seeks an injunction 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 XLIII.**  
**INFRINGEMENT OF U.S. PATENT NO. 9,062,106**

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

800. 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.

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

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

803. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

804. 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.

805. 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 '106 patent is an act of infringement of one or more claims of the '106 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

806. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 at least claims 1-12, 14-44, and 46-65 of the '106 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-12, 14-44, and 46-65 of the '106 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '106 patent.

807. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '106 patent, either literally or under the doctrine of equivalents.



808. Alvotech has knowledge of and is aware of the '106 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.

809. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '106 patent.

810. 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 XLIV.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,062,106**

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

812. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

813. 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.

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

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

816. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

817. On information and belief as of May 28, 2021, 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.

818. 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 '106 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '106 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

819. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 at least claims 1-12, 14-44, and 46-65 of the '106 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-12, 14-44, and 46-65 of the '106 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '106 patent.

820. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '106 patent, either literally or under the doctrine of equivalents.

821. Alvotech has knowledge of and is aware of the '106 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.

822. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '106 patent.

823. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '106 patent.

824. AbbVie seeks an injunction 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 XLV.  
INFRINGEMENT OF U.S. PATENT NO. 9,067,992**

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

826. 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.

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

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

829. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

830. 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.

831. 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 '992 patent is an act of infringement of one or more claims of the '992 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

832. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 2, 3, 7, and 8 of the '992 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 2, 3, 7, and 8 of the '992 patent.

833. 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 '992 patent, either literally or under the doctrine of equivalents.

834. 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 2, 3, 7, and 8 of the '992 patent, either literally or under the doctrine of equivalents.

835. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 2, 3, 7, and 8 of the '992 patent, either literally or under the doctrine of equivalents.

836. Alvotech has knowledge of and is aware of the '992 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.

837. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '992 patent.

838. 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 XLVI.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,067,992**

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

840. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

841. 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.

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

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

844. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

845. On information and belief as of May 28, 2021, 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.

846. 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 '992 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '992 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

847. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 2, 3, 7, and 8 of the '992 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 2, 3, 7, and 8 of the '992 patent.

848. 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 '992 patent, either literally or under the doctrine of equivalents.

849. 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 2, 3, 7, and 8 of the '992 patent, either literally or under the doctrine of equivalents.

850. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 2, 3, 7, and 8 of the '992 patent, either literally or under the doctrine of equivalents.

851. Alvotech has knowledge of and is aware of the '992 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.

852. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '992 patent.

853. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '992 patent.

854. AbbVie seeks an injunction 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 XLVII.**  
**INFRINGEMENT OF U.S. PATENT NO. 9,085,618**

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

856. 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.

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

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

859. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

860. 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.



861. 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 '618 patent is an act of infringement of one or more claims of the '618 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

862. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 7, 8, and 22 of the '618 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 7, 8, and 22 of the '618 patent.

863. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '618 patent, either literally or under the doctrine of equivalents.

864. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 7, 8, and 22 of the '618 patent, either literally or under the doctrine of equivalents.

865. Alvotech has knowledge of and is aware of the '618 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.

866. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '618 patent.

867. 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 XLVIII.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,085,618**

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

869. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

870. 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.

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

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

873. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

874. On information and belief as of May 28, 2021, 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.

875. 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 '618 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '618 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

876. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 7, 8, and 22 of the '618 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 7, 8, and 22 of the '618 patent.

877. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '618 patent, either literally or under the doctrine of equivalents.

878. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 7, 8, and 22 of the '618 patent, either literally or under the doctrine of equivalents.

879. Alvotech has knowledge of and is aware of the '618 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.

880. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '618 patent.

881. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '618 patent.

882. AbbVie seeks an injunction 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 XLIX.**  
**INFRINGEMENT OF U.S. PATENT NO. 9,085,620**

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

884. 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.

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

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

887. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

888. 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.

889. 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 '620 patent is an act of infringement of one or more claims of the '620 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

890. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1, 4, 7, 10, 13, 16, 19, 22, 25, 27, and 29 of the '620 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided

to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1, 4, 7, 10, 13, 16, 19, 22, 25, 27, and 29 of the '620 patent.

891. 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 '620 patent, either literally or under the doctrine of equivalents.

892. 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, 4, 7, 10, 13, 16, 19, 22, 25, 27, and 29 of the '620 patent, either literally or under the doctrine of equivalents.

893. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1, 4, 7, 10, 13, 16, 19, 22, 25, 27, and 29 of the '620 patent, either literally or under the doctrine of equivalents.

894. Alvotech has knowledge of and is aware of the '620 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.

895. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '620 patent.

896. 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 L.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,085,620**

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

898. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

899. 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.

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

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

902. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

903. On information and belief as of May 28, 2021, 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.

904. 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 '620 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '620 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's

provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

905. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1, 4, 7, 10, 13, 16, 19, 22, 25, 27, and 29 of the '620 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1, 4, 7, 10, 13, 16, 19, 22, 25, 27, and 29 of the '620 patent.

906. 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 '620 patent, either literally or under the doctrine of equivalents.

907. 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, 4, 7, 10, 13, 16, 19, 22, 25, 27, and 29 of the '620 patent, either literally or under the doctrine of equivalents.

908. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1, 4, 7, 10, 13, 16, 19, 22, 25, 27, and 29 of the '620 patent, either literally or under the doctrine of equivalents.



909. Alvotech has knowledge of and is aware of the '620 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.

910. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '620 patent.

911. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '620 patent.

912. AbbVie seeks an injunction 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 LI.  
INFRINGEMENT OF U.S. PATENT NO. 9,090,688**

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

914. 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.

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

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

917. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

918. 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.

919. 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 '688 patent is an act of infringement of one or more claims of the '688 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

920. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 at least claims 1-26 and 28-48 of the '688 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-26 and 28-48 of the '688 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '688 patent.

921. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '688 patent, either literally or under the doctrine of equivalents.

922. Alvotech has knowledge of and is aware of the '688 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.

923. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '688 patent.

924. 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 LII.**

#### **DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,090,688**

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

926. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

927. 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.

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

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

930. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

931. On information and belief as of May 28, 2021, 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.

932. 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 '688 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '688 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

933. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 at least claims 1-26 and 28-48 of the '688 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-26 and 28-48 of the '688 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '688 patent.

934. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '688 patent, either literally or under the doctrine of equivalents.

935. Alvotech has knowledge of and is aware of the '688 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.

936. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '688 patent.

937. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '688 patent.

938. AbbVie seeks an injunction 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 LIII.**  
**INFRINGEMENT OF U.S. PATENT NO. 9,090,689**

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

940. 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.

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

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

943. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

944. 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.

945. 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 '689 patent is an act of infringement of one or more claims of the '689 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

946. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1, 4, 7, 10, 13, 16, and 19 of the '689 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1, 4, 7, 10, 13, 16, and 19 of the '689 patent.

947. 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 '689 patent, either literally or under the doctrine of equivalents.

948. 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, 4, 7, 10, 13, 16, and 19 of the '689 patent, either literally or under the doctrine of equivalents.

949. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1, 4, 7, 10, 13, 16, and 19 of the '689 patent, either literally or under the doctrine of equivalents.

950. Alvotech has knowledge of and is aware of the '689 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.

951. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '689 patent.

952. 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 LIV.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,090,689**

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

954. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

955. 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.

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

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

958. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

959. On information and belief as of May 28, 2021, 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.

960. 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 '689 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '689 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.



961. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1, 4, 7, 10, 13, 16, and 19 of the '689 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1, 4, 7, 10, 13, 16, and 19 of the '689 patent.

962. 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 '689 patent, either literally or under the doctrine of equivalents.

963. 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, 4, 7, 10, 13, 16, and 19 of the '689 patent, either literally or under the doctrine of equivalents.

964. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1, 4, 7, 10, 13, 16, and 19 of the '689 patent, either literally or under the doctrine of equivalents.

965. Alvotech has knowledge of and is aware of the '689 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.

966. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '689 patent.

967. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '689 patent.

968. AbbVie seeks an injunction 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 LV.  
INFRINGEMENT OF U.S. PATENT NO. 9,090,867**

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

970. 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.

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

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

973. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

974. 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.

975. 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 '867 patent is an act of infringement of one or more claims of the '867 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

976. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 at least claims 1-12, 16-26, and 30 of the '867 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-12, 16-26, and 30 of the '867 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '867 patent.

977. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '867 patent, either literally or under the doctrine of equivalents.

978. Alvotech has knowledge of and is aware of the '867 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.

979. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '867 patent.

980. 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 LVI.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,090,867**

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

982. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

983. 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.

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

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

986. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

987. On information and belief as of May 28, 2021, 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.

988. 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 '867 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '867 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

989. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 at least claims 1-12, 16-26, and 30 of the '867 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-12, 16-26, and 30 of the '867 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '867 patent.

990. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '867 patent, either literally or under the doctrine of equivalents.

991. Alvotech has knowledge of and is aware of the '867 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.

992. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '867 patent.

993. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '867 patent.

994. AbbVie seeks an injunction 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 LVII.  
INFRINGEMENT OF U.S. PATENT NO. 9,096,666**

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

996. 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.

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

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

999. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1000. 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.

1001. 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 '666 patent is an act of infringement of one or more claims of the '666 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

1002. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-7, 9-13, 15-19, 21-25, and 27-30 of the '666 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-7, 9-13, 15-19, 21-25, and 27-30 of the '666 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '666 patent.

1003. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '666 patent, either literally or under the doctrine of equivalents.

1004. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-7, 9-13, 15-19, 21-25, and 27-30 of the '666 patent, either literally or under the doctrine of equivalents.

1005. Alvotech has knowledge of and is aware of the '666 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.

1006. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '666 patent.

1007. 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 LVIII.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,096,666**

1008. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1009. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1010. 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.

1011. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1012. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1013. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1014. On information and belief as of May 28, 2021, 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.

1015. 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 '666 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '666 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

1016. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-7, 9-13, 15-19, 21-25, and 27-30 of the '666 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-7, 9-13, 15-19, 21-25, and 27-30 of the '666 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '666 patent.

1017. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '666 patent, either literally or under the doctrine of equivalents.

1018. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-7, 9-13, 15-19, 21-25, and 27-30 of the '666 patent, either literally or under the doctrine of equivalents.

1019. Alvotech has knowledge of and is aware of the '666 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.

1020. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '666 patent.

1021. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '666 patent.

1022. AbbVie seeks an injunction 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 LIX.**  
**INFRINGEMENT OF U.S. PATENT NO. 9,102,723**

1023. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1024. 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.

1025. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1026. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1027. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1028. 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.

1029. 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 '723 patent is an act of infringement of one or more claims of the '723 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

1030. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1, 9, 11-14, 16-17, and 19-28 of the '723 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1, 9, 11-14, 16-17, and 19-28 of the '723 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '723 patent.

1031. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '723 patent, either literally or under the doctrine of equivalents.

1032. Alvotech has knowledge of and is aware of the '723 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.

1033. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '723 patent.

1034. 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 LX.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,102,723**

1035. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1036. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1037. 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.

1038. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1039. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1040. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1041. On information and belief as of May 28, 2021, 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.

1042. 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 '723 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '723 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

1043. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1, 9, 11-14, 16-17, and 19-28 of the '723 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1, 9, 11-14, 16-17, and 19-28 of the '723 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '723 patent.

1044. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '723 patent, either literally or under the doctrine of equivalents.

1045. Alvotech has knowledge of and is aware of the '723 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.

1046. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '723 patent.

1047. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '723 patent.

1048. AbbVie seeks an injunction 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 LXI.**  
**INFRINGEMENT OF U.S. PATENT NO. 9,150,645**

1049. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1050. 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.

1051. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1052. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1053. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1054. 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.

1055. 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 '645 patent is an act of infringement of one or more claims of the '645 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

1056. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-34, 36-44, 46-55 of the '645 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-34, 36-44, 46-55 of the '645 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '645 patent.

1057. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '645 patent, either literally or under the doctrine of equivalents.



1058. Alvotech has knowledge of and is aware of the '645 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.

1059. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '645 patent.

1060. 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 LXII.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,150,645**

1061. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1062. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1063. 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.

1064. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1065. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1066. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1067. On information and belief as of May 28, 2021, 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.

1068. 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 '645 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '645 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

1069. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-34, 36-44, 46-55 of the '645 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-34, 36-44, 46-55 of the '645 patent. For at least one claim, however, Alvotech's failure to provide sufficient

information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '645 patent.

1070. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '645 patent, either literally or under the doctrine of equivalents.

1071. Alvotech has knowledge of and is aware of the '645 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.

1072. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '645 patent.

1073. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '645 patent.

1074. AbbVie seeks an injunction 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 LXIII.**  
**INFRINGEMENT OF U.S. PATENT NO. 9,181,337**

1075. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1076. 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.

1077. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1078. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1079. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1080. 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.

1081. 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 '1337 patent is an act of infringement of one or more claims of the '1337 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

1082. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-5, 7-10, 12-13, 15-29 of the '1337 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-5, 7-10, 12-13, 15-29 of the '1337 patent. For at least one claim, however, Alvotech's

failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '1337 patent.

1083. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '1337 patent, either literally or under the doctrine of equivalents.

1084. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-5, 7-10, 12-13, 15-29 of the '1337 patent, either literally or under the doctrine of equivalents.

1085. Alvotech has knowledge of and is aware of the '1337 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.

1086. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '1337 patent.

1087. 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 LXIV.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,181,337**

1088. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1089. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1090. 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.

1091. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1092. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1093. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1094. On information and belief as of May 28, 2021, 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.

1095. 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 '1337 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of the '1337 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

1096. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-5, 7-10, 12-13, 15-29 of the '1337 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-5, 7-10, 12-13, 15-29 of the '1337 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '1337 patent.

1097. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '1337 patent, either literally or under the doctrine of equivalents.

1098. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-5, 7-10, 12-13, 15-29 of the '1337 patent, either literally or under the doctrine of equivalents.

1099. Alvotech has knowledge of and is aware of the '1337 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.

1100. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '1337 patent.

1101. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '1337 patent.

1102. AbbVie seeks an injunction 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 LXV.  
INFRINGEMENT OF U.S. PATENT NO. 9,181,572**

1103. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1104. 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.

1105. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1106. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1107. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1108. 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.



1109. 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 '572 patent is an act of infringement of one or more claims of the '572 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

1110. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-10, 12-27 and 29-30 of the '572 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-10, 12-27 and 29-30 of the '572 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '572 patent.

1111. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '572 patent, either literally or under the doctrine of equivalents.

1112. Alvotech has knowledge of and is aware of the '572 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.

1113. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '572 patent.

1114. 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 LXVI.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,181,572**

1115. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1116. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1117. 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.

1118. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1119. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1120. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1121. On information and belief as of May 28, 2021, 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.

1122. 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 '572 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '572 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

1123. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-10, 12-27 and 29-30 of the '572 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-10, 12-27 and 29-30 of the '572 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '572 patent.

1124. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '572 patent, either literally or under the doctrine of equivalents.

1125. Alvotech has knowledge of and is aware of the '572 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.

1126. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '572 patent.

1127. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '572 patent.

1128. AbbVie seeks an injunction 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 LXVII.  
INFRINGEMENT OF U.S. PATENT NO. 9,187,559**

1129. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1130. 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.

1131. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1132. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1133. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1134. 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.

1135. 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 '559 patent is an act of infringement of one or more claims of the '559 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

1136. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-30 of the '559 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-30 of the '559 patent.

1137. 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 '559 patent, either literally or under the doctrine of equivalents.

1138. 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 '559 patent, either literally or under the doctrine of equivalents.

1139. 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 '559 patent, either literally or under the doctrine of equivalents.

1140. Alvotech has knowledge of and is aware of the '559 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.

1141. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '559 patent.

1142. 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 LXVIII.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,187,559**

1143. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1144. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1145. 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.

1146. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1147. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1148. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1149. On information and belief as of May 28, 2021, 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.

1150. 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 '559 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '559 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

1151. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-30 of the '559 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-30 of the '559 patent.

1152. 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 '559 patent, either literally or under the doctrine of equivalents.

1153. 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 '559 patent, either literally or under the doctrine of equivalents.

1154. 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 '559 patent, either literally or under the doctrine of equivalents.

1155. Alvotech has knowledge of and is aware of the '559 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.

1156. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '559 patent.

1157. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '559 patent.



1158. AbbVie seeks an injunction 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 LXIX.**  
**INFRINGEMENT OF U.S. PATENT NO. 9,234,032**

1159. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1160. 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.

1161. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1162. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1163. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1164. 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.

1165. 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 '032 patent is an act of infringement of one or more claims of the '032 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

1166. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 at least claims 1-3, 5, 11, 13, 15-18, and 20-23 of the '032 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-3, 5, 11, 13, 15-18, and 20-23 of the '032 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '032 patent.

1167. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '032 patent, either literally or under the doctrine of equivalents.

1168. Alvotech has knowledge of and is aware of the '032 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.

1169. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '032 patent.

1170. 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 LXX.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,234,032**

1171. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1172. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1173. 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.

1174. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1175. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1176. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1177. On information and belief as of May 28, 2021, 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.

1178. 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 '032 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '032 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

1179. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 at least claims 1-3, 5, 11, 13, 15-18, and 20-23 of the '032 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-3, 5, 11, 13, 15-18, and 20-23 of the '032 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '032 patent.

1180. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '032 patent, either literally or under the doctrine of equivalents.

1181. Alvotech has knowledge of and is aware of the '032 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.

1182. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '032 patent.

1183. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '032 patent.

1184. AbbVie seeks an injunction 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 LXXI.**  
**INFRINGEMENT OF U.S. PATENT NO. 9,266,949**

1185. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1186. 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.

1187. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1188. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1189. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1190. 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.

1191. 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 '949 patent is an act of infringement of one or more claims of the '949 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

1192. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-30 of the '949 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-30 of the '949 patent.

1193. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '949 patent, either literally or under the doctrine of equivalents.

1194. Alvotech has knowledge of and is aware of the '949 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.

1195. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '949 patent.

1196. 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 LXXII.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,266,949**

1197. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1198. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1199. 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.

1200. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1201. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1202. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1203. On information and belief as of May 28, 2021, 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.

1204. 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 '949 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '949 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

1205. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-30 of the '949 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-30 of the '949 patent.

1206. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '949 patent, either literally or under the doctrine of equivalents.



1207. Alvotech has knowledge of and is aware of the '949 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.

1208. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '949 patent.

1209. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '949 patent.

1210. AbbVie seeks an injunction 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 LXXIII.  
INFRINGEMENT OF U.S. PATENT NO. 9,273,132**

1211. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1212. 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.

1213. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1214. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1215. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1216. 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.

1217. 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 '132 patent is an act of infringement of one or more claims of the '132 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

1218. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-7, 10-13, and 16-25 of the '132 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-7, 10-13, and 16-25 of the '132 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '132 patent.

1219. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '132 patent, either literally or under the doctrine of equivalents.

1220. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-7, 10-13, and 16-25 of the '132 patent, either literally or under the doctrine of equivalents.

1221. Alvotech has knowledge of and is aware of the '132 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.

1222. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '132 patent.

1223. 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 LXXIV.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,273,132**

1224. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1225. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1226. 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.

1227. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1228. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1229. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1230. On information and belief as of May 28, 2021, 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.

1231. 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 '132 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '132 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

1232. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-7, 10-13, and 16-25 of the '132 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech,

pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-7, 10-13, and 16-25 of the '132 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '132 patent.

1233. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '132 patent, either literally or under the doctrine of equivalents.

1234. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-7, 10-13, and 16-25 of the '132 patent, either literally or under the doctrine of equivalents.

1235. Alvotech has knowledge of and is aware of the '132 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.

1236. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '132 patent.

1237. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '132 patent.

1238. AbbVie seeks an injunction 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 LXXV.  
INFRINGEMENT OF U.S. PATENT NO. 9,284,370**

1239. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1240. 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.

1241. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1242. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1243. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1244. 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.

1245. 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 '370 patent is an act of infringement of one or more claims of the '370 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

1246. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-5, 7, 9-12, 14, 16-21, 23, 25-26, 28-32, 34, and 36-37 of the '370 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-5, 7, 9-12, 14, 16-21, 23, 25-26, 28-32, 34, and 36-37 of the '370 patent.

1247. 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 '370 patent, either literally or under the doctrine of equivalents.

1248. 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 1-5, 7, 9-12, 14, 16-21, 23, 25-26, 28-32, 34, and 36-37 of the '370 patent, either literally or under the doctrine of equivalents.

1249. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-5, 7, 9-12, 14, 16-21, 23, 25-26, 28-32, 34, and 36-37 of the '370 patent, either literally or under the doctrine of equivalents.

1250. Alvotech has knowledge of and is aware of the '370 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.

1251. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '370 patent.

1252. 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 LXXVI.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,284,370**

1253. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1254. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1255. 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.

1256. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1257. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1258. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1259. On information and belief as of May 28, 2021, 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.

1260. 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 '370 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '370 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

1261. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-5, 7, 9-12, 14, 16-21, 23, 25-26, 28-32, 34, and 36-37 of the '370 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-5, 7, 9-12, 14, 16-21, 23, 25-26, 28-32, 34, and 36-37 of the '370 patent.

1262. 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 '370 patent, either literally or under the doctrine of equivalents.

1263. 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 1-5, 7, 9-12, 14, 16-21, 23, 25-26, 28-32, 34, and 36-37 of the '370 patent, either literally or under the doctrine of equivalents.

1264. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-5, 7, 9-12, 14, 16-21, 23, 25-26, 28-32, 34, and 36-37 of the '370 patent, either literally or under the doctrine of equivalents.

1265. Alvotech has knowledge of and is aware of the '370 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.

1266. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '370 patent.

1267. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '370 patent.

1268. AbbVie seeks an injunction 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 LXXVII.  
INFRINGEMENT OF U.S. PATENT NO. 9,284,371**

1269. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1270. 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.

1271. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1272. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1273. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1274. 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.

1275. 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 '371 patent is an act of infringement of one or more claims of the '371 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

1276. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 at least claims 1, 2, 5, 8-16, 21, 22, 26, 27, and 29 of the '371 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for

claims 1, 2, 5, 8-16, 21, 22, 26, 27, and 29 of the '371 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '371 patent.

1277. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '371 patent, either literally or under the doctrine of equivalents.

1278. Alvotech has knowledge of and is aware of the '371 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.

1279. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '371 patent.

1280. 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 LXXVIII.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,284,371**

1281. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1282. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1283. 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.

1284. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1285. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1286. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1287. On information and belief as of May 28, 2021, 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.

1288. 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 '371 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '371 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

1289. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 at least claims 1, 2, 5, 8-16, 21, 22, 26, 27, and 29 of the '371 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1, 2, 5, 8-16, 21, 22, 26, 27, and 29 of the '371 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '371 patent.

1290. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '371 patent, either literally or under the doctrine of equivalents.

1291. Alvotech has knowledge of and is aware of the '371 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.

1292. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '371 patent.

1293. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '371 patent.

1294. AbbVie seeks an injunction 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 LXXIX.**  
**INFRINGEMENT OF U.S. PATENT NO. 9,290,568**

1295. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1296. 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.

1297. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1298. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1299. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1300. 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.

1301. 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 '568 patent is an act of infringement of one or more claims of the '568 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

1302. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 at least claims 1-8 and 21-28 of the '568 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-8 and 21-28 of the '568 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '568 patent.

1303. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '568 patent, either literally or under the doctrine of equivalents.

1304. Alvotech has knowledge of and is aware of the '568 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.

1305. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '568 patent.

1306. 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 LXXX.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,290,568**

1307. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.



1308. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1309. 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.

1310. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1311. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1312. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1313. On information and belief as of May 28, 2021, 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.

1314. 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 '568 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '568 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's

provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

1315. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 at least claims 1-8 and 21-28 of the '568 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-8 and 21-28 of the '568 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '568 patent.

1316. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '568 patent, either literally or under the doctrine of equivalents.

1317. Alvotech has knowledge of and is aware of the '568 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.

1318. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '568 patent.

1319. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '568 patent.

1320. AbbVie seeks an injunction 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 LXXXI.  
INFRINGEMENT OF U.S. PATENT NO. 9,315,574**

1321. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1322. 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.

1323. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1324. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1325. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1326. 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.

1327. 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 '574 patent is an act of infringement of one or more claims of the '574 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

1328. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-3, 5, and 19-25 of the '574 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-3, 5, and 19-25 of the '574 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '574 patent.

1329. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '574 patent, either literally or under the doctrine of equivalents.

1330. Alvotech has knowledge of and is aware of the '574 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.

1331. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '574 patent.

1332. 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 LXXXII.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,315,574**

1333. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1334. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1335. 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.

1336. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1337. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1338. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1339. On information and belief as of May 28, 2021, 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.

1340. 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 '574 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '574 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

1341. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-3, 5, and 19-25 of the '574 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-3, 5, and 19-25 of the '574 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '574 patent.

1342. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '574 patent, either literally or under the doctrine of equivalents.

1343. Alvotech has knowledge of and is aware of the '574 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.

1344. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '574 patent.

1345. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '574 patent.

1346. AbbVie seeks an injunction 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 LXXXIII.  
INFRINGEMENT OF U.S. PATENT NO. 9,328,165**

1347. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1348. 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.

1349. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1350. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1351. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1352. 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.

1353. 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 '165 patent is an act of infringement of one or more claims of the '165 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

1354. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1, 2, 9, 15, and 21 of the '165 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1, 2, 9, 15, and 21 of the '165 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '165 patent.

1355. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '165 patent, either literally or under the doctrine of equivalents.



1356. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1, 2, 9, 15, and 21 of the '165 patent, either literally or under the doctrine of equivalents.

1357. Alvotech has knowledge of and is aware of the '165 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.

1358. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '165 patent.

1359. 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 LXXXIV.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,328,165**

1360. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1361. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1362. 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.

1363. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1364. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1365. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1366. On information and belief as of May 28, 2021, 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.

1367. 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 '165 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '165 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

1368. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1, 2, 9, 15, and 21 of the '165 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant

to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1, 2, 9, 15, and 21 of the '165 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '165 patent.

1369. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '165 patent, either literally or under the doctrine of equivalents.

1370. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1, 2, 9, 15, and 21 of the '165 patent, either literally or under the doctrine of equivalents.

1371. Alvotech has knowledge of and is aware of the '165 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.

1372. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '165 patent.

1373. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '165 patent.

1374. AbbVie seeks an injunction 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 LXXXV.  
INFRINGEMENT OF U.S. PATENT NO. 9,334,319**

1375. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1376. 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.

1377. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1378. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1379. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1380. 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.

1381. 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 '319 patent is an act of infringement of one or more claims of the '319 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

1382. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 3-14, 17, 19, 26-37, 40, and 42 of the '319 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 3-14, 17, 19, 26-37, 40, and 42 of the '319 patent.

1383. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '319 patent, either literally or under the doctrine of equivalents.

1384. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 3-14, 17, 19, 26-37, 40, and 42 of the '319 patent, either literally or under the doctrine of equivalents.

1385. Alvotech has knowledge of and is aware of the '319 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.

1386. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '319 patent.

1387. 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 LXXXVI.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,334,319**

1388. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1389. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1390. 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.

1391. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1392. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1393. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1394. On information and belief as of May 28, 2021, 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.

1395. 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 '319 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '319 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's

provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

1396. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 3-14, 17, 19, 26-37, 40, and 42 of the '319 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 3-14, 17, 19, 26-37, 40, and 42 of the '319 patent.

1397. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '319 patent, either literally or under the doctrine of equivalents.

1398. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 3-14, 17, 19, 26-37, 40, and 42 of the '319 patent, either literally or under the doctrine of equivalents.

1399. Alvotech has knowledge of and is aware of the '319 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.

1400. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '319 patent.

1401. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '319 patent.

1402. AbbVie seeks an injunction 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 LXXXVII.  
INFRINGEMENT OF U.S. PATENT NO. 9,339,610**

1403. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1404. 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.

1405. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1406. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1407. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1408. 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.

1409. 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 '610 patent is an act of infringement of one or more claims of the '610 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

1410. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1, 5-13, 15, 18, 19, 21, and 22 of the '610 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1, 5-13, 15, 18, 19, 21, and 22 of the '610 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '610 patent.

1411. 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 '610 patent, either literally or under the doctrine of equivalents.

1412. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product (including the delivery device) directly infringes at least one claim of the '610 patent, either literally or under the doctrine of equivalents.

1413. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1, 5-13, 15, 18, 19, 21, and 22 of the '610 patent, either literally or under the doctrine of equivalents.

1414. Alvotech has knowledge of and is aware of the '610 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.

1415. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '610 patent.

1416. 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 LXXXVIII.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,339,610**

1417. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1418. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1419. 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.

1420. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1421. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1422. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1423. On information and belief as of May 28, 2021, 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.

1424. 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 '610 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '610 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

1425. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1, 5-13, 15, 18, 19, 21, and 22 of the '610 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to

Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1, 5-13, 15, 18, 19, 21, and 22 of the '610 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '610 patent.

1426. 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 '610 patent, either literally or under the doctrine of equivalents.

1427. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product (including the delivery device) directly infringes at least one claim of the '610 patent, either literally or under the doctrine of equivalents.

1428. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1, 5-13, 15, 18, 19, 21, and 22 of the '610 patent, either literally or under the doctrine of equivalents.

1429. Alvotech has knowledge of and is aware of the '610 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.

1430. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '610 patent.

1431. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '610 patent.

1432. AbbVie seeks an injunction 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 LXXXIX.  
INFRINGEMENT OF U.S. PATENT NO. 9,346,879**

1433. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1434. 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.

1435. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1436. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1437. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1438. 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.

1439. 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 '879 patent is an act of infringement of one or more claims of the '879 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

1440. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-3, 5, 14-15, and 19-22 of the '879 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-3, 5, 14-15, and 19-22 of the '879 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '879 patent.

1441. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '879 patent, either literally or under the doctrine of equivalents.

1442. Alvotech has knowledge of and is aware of the '879 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.

1443. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '879 patent.

1444. 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 XC.**

**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,346,879**

1445. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1446. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1447. 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.

1448. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1449. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1450. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1451. On information and belief as of May 28, 2021, 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.

1452. 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 '879 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '879 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

1453. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-3, 5, 14-15, and 19-22 of the '879 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-3, 5, 14-15, and 19-22 of the '879 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '879 patent.

1454. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '879 patent, either literally or under the doctrine of equivalents.



1455. Alvotech has knowledge of and is aware of the '879 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.

1456. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '879 patent.

1457. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '879 patent.

1458. AbbVie seeks an injunction 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 XCI.**  
**INFRINGEMENT OF U.S. PATENT NO. 9,359,434**

1459. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1460. 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.

1461. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1462. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1463. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1464. 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.

1465. 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 '434 patent is an act of infringement of one or more claims of the '434 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

1466. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-30 of the '434 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-30 of the '434 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '434 patent.

1467. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '434 patent, either literally or under the doctrine of equivalents.

1468. Alvotech has knowledge of and is aware of the '434 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.

1469. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '434 patent.

1470. 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 XCII.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,359,434**

1471. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1472. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1473. 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.

1474. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1475. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1476. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1477. On information and belief as of May 28, 2021, 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.

1478. 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 '434 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '434 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

1479. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-30 of the '434 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-30 of the '434 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by

the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '434 patent.

1480. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '434 patent, either literally or under the doctrine of equivalents.

1481. Alvotech has knowledge of and is aware of the '434 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.

1482. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '434 patent.

1483. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '434 patent.

1484. AbbVie seeks an injunction 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 XCIII.**  
**INFRINGEMENT OF U.S. PATENT NO. 9,499,614**

1485. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1486. 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.

1487. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1488. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1489. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1490. 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.

1491. 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 '614 patent is an act of infringement of one or more claims of the '614 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

1492. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 at least claims 1-4 and 10-22 of the '614 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-4 and 10-22 of the '614 patent. For at least one claim, however, Alvotech's failure to provide sufficient

information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '614 patent.

1493. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '614 patent, either literally or under the doctrine of equivalents.

1494. Alvotech has knowledge of and is aware of the '614 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.

1495. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '614 patent.

1496. 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 XCIV.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,499,614**

1497. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1498. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1499. 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.

1500. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1501. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1502. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1503. On information and belief as of May 28, 2021, 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.

1504. 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 '614 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '614 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

1505. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 at least claims 1-4 and 10-22 of the '614 patent under at least 35 U.S.C.



§ 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-4 and 10-22 of the '614 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '614 patent.

1506. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '614 patent, either literally or under the doctrine of equivalents.

1507. Alvotech has knowledge of and is aware of the '614 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.

1508. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '614 patent.

1509. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '614 patent.

1510. AbbVie seeks an injunction 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 XCV.  
INFRINGEMENT OF U.S. PATENT NO. 9,499,616**

1511. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1512. 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.

1513. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1514. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1515. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1516. 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.

1517. 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 '616 patent is an act of infringement of one or more claims of the '616 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

1518. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-16, 18-27, and 29-30 of the '616 patent under at least 35 U.S.C. § 271(g),

either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-16, 18-27, and 29-30 of the '616 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '616 patent.

1519. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '616 patent, either literally or under the doctrine of equivalents.

1520. Alvotech has knowledge of and is aware of the '616 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.

1521. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '616 patent.

1522. 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 XCVI.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,499,616**

1523. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1524. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1525. 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.

1526. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1527. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1528. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1529. On information and belief as of May 28, 2021, 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.

1530. 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 '616 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '616 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

1531. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-16, 18-27, and 29-30 of the '616 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-16, 18-27, and 29-30 of the '616 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '616 patent.

1532. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '616 patent, either literally or under the doctrine of equivalents.

1533. Alvotech has knowledge of and is aware of the '616 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.

1534. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '616 patent.

1535. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '616 patent.

1536. AbbVie seeks an injunction 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 XCVII.  
INFRINGEMENT OF U.S. PATENT NO. 9,505,834**

1537. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1538. 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.

1539. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1540. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1541. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1542. 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.

1543. 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 '834 patent is an act of infringement of one or more claims of the '834 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

1544. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 at least claims 1-30 of the '834 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-30 of the '834 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '834 patent.

1545. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '834 patent, either literally or under the doctrine of equivalents.

1546. Alvotech has knowledge of and is aware of the '834 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.

1547. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '834 patent.

1548. 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 XCVIII.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,505,834**

1549. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1550. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1551. 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.

1552. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1553. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1554. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1555. On information and belief as of May 28, 2021, 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.

1556. 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 '834 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '834 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's



provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

1557. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 at least claims 1-30 of the '834 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-30 of the '834 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '834 patent.

1558. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '834 patent, either literally or under the doctrine of equivalents.

1559. Alvotech has knowledge of and is aware of the '834 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.

1560. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '834 patent.

1561. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '834 patent.

1562. AbbVie seeks an injunction 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 XCIX.**  
**INFRINGEMENT OF U.S. PATENT NO. 9,512,216**

1563. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1564. 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.

1565. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1566. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1567. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1568. 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.

1569. 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 '216 patent is an act of infringement of one or more claims of the '216 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

1570. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-3, 6, 9-11, and 14 of the '216 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-3, 6, 9-11, and 14 of the '216 patent.

1571. 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 '216 patent, either literally or under the doctrine of equivalents.

1572. 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 1-3, 6, 9-11, and 14 of the '216 patent, either literally or under the doctrine of equivalents.

1573. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-3, 6, 9-11, and 14 of the '216 patent, either literally or under the doctrine of equivalents.

1574. Alvotech has knowledge of and is aware of the '216 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.

1575. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '216 patent.

1576. 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 C.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,512,216**

1577. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1578. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1579. 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.

1580. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1581. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1582. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1583. On information and belief as of May 28, 2021, 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.

1584. 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 '216 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '216 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

1585. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-3, 6, 9-11, and 14 of the '216 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-3, 6, 9-11, and 14 of the '216 patent.

1586. 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 '216 patent, either literally or under the doctrine of equivalents.

1587. 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 1-3, 6, 9-11, and 14 of the '216 patent, either literally or under the doctrine of equivalents.

1588. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-3, 6, 9-11, and 14 of the '216 patent, either literally or under the doctrine of equivalents.

1589. Alvotech has knowledge of and is aware of the '216 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.

1590. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '216 patent.

1591. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '216 patent.

1592. AbbVie seeks an injunction 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 CI.**  
**INFRINGEMENT OF U.S. PATENT NO. 9,522,953**

1593. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1594. 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.

1595. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1596. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1597. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1598. 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.

1599. 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 '953 patent is an act of infringement of one or more claims of the '953 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

1600. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 6, 8, 26, and 28-30 of the '953 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 6, 8, 26, and 28-30 of the '953 patent.

1601. 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 '953 patent, either literally or under the doctrine of equivalents.

1602. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '953 patent, either literally or under the doctrine of equivalents.

1603. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 6, 8, 26, and 28-30 of the '953 patent, either literally or under the doctrine of equivalents.

1604. Alvotech has knowledge of and is aware of the '953 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.

1605. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '953 patent.

1606. 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 CII.**

**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,522,953**

1607. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1608. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1609. 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.

1610. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1611. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1612. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1613. On information and belief as of May 28, 2021, 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.

1614. 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 '953 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will

infringe one or more of the claims of '953 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(I)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

1615. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(I)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 6, 8, 26, and 28-30 of the '953 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(I)(3)(C), claim-by-claim infringement contentions for claims 6, 8, 26, and 28-30 of the '953 patent.

1616. 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 '953 patent, either literally or under the doctrine of equivalents.

1617. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '953 patent, either literally or under the doctrine of equivalents.

1618. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 6, 8, 26, and 28-30 of the '953 patent, either literally or under the doctrine of equivalents.

1619. Alvotech has knowledge of and is aware of the '953 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.

1620. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '953 patent.

1621. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '953 patent.

1622. AbbVie seeks an injunction 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. 9,546,212**

1623. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1624. 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.

1625. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1626. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1627. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1628. 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.

1629. 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 '212 patent is an act of infringement of one or more claims of the '212 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

1630. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-24 of the '212 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-24 of the '212 patent.

1631. 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 '212 patent, either literally or under the doctrine of equivalents.

1632. 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 1-24 of the '212 patent, either literally or under the doctrine of equivalents.

1633. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-24 of the '212 patent, either literally or under the doctrine of equivalents.

1634. Alvotech has knowledge of and is aware of the '212 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.

1635. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '212 patent.

1636. 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 CIV.**

#### **DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,546,212**

1637. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1638. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1639. 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.

1640. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1641. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1642. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1643. On information and belief as of May 28, 2021, 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.

1644. 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 '212 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '212 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

1645. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-24 of the '212 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-24 of the '212 patent.

1646. 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 '212 patent, either literally or under the doctrine of equivalents.

1647. 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 1-24 of the '212 patent, either literally or under the doctrine of equivalents.

1648. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-24 of the '212 patent, either literally or under the doctrine of equivalents.

1649. Alvotech has knowledge of and is aware of the '212 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.

1650. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '212 patent.

1651. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '212 patent.

1652. AbbVie seeks an injunction 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 CV.  
INFRINGEMENT OF U.S. PATENT NO. 9,550,826**

1653. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1654. 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.

1655. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1656. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1657. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1658. 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.

1659. 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 '826 patent is an act of infringement of one or more claims of the '826 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

1660. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 at least claims 1-9, 11, 14, 16-19, 21, 24, and 26-30 of the '826 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-9, 11, 14, 16-19, 21, 24, and 26-30 of the '826 patent.

1661. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '826 patent, either literally or under the doctrine of equivalents.

1662. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-9, 11, 14, 16-19, 21, 24, and 26-30 of the '826 patent, either literally or under the doctrine of equivalents.

1663. Alvotech has knowledge of and is aware of the '826 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.

1664. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '826 patent.

1665. 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 CVI.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,550,826**

1666. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1667. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1668. 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.

1669. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1670. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1671. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1672. On information and belief as of May 28, 2021, 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.

1673. 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 '826 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will

infringe one or more of the claims of '826 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. See 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

1674. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 at least claims 1-9, 11, 14, 16-19, 21, 24, and 26-30 of the '826 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-9, 11, 14, 16-19, 21, 24, and 26-30 of the '826 patent.

1675. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '826 patent, either literally or under the doctrine of equivalents.

1676. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-9, 11, 14, 16-19, 21, 24, and 26-30 of the '826 patent, either literally or under the doctrine of equivalents.

1677. Alvotech has knowledge of and is aware of the '826 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.

1678. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '826 patent.

1679. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '826 patent.

1680. AbbVie seeks an injunction 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 CVII.**  
**INFRINGEMENT OF U.S. PATENT NO. 9,624,295**

1681. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1682. 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.

1683. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1684. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1685. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1686. 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.

1687. 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 '295 patent is an act of infringement of one or more claims of the '295 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

1688. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-6 of the '295 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-6 of the '295 patent.

1689. 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 '295 patent, either literally or under the doctrine of equivalents.

1690. 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 '295 patent, either literally or under the doctrine of equivalents.

1691. 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 '295 patent, either literally or under the doctrine of equivalents.

1692. Alvotech has knowledge of and is aware of the '295 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.

1693. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '295 patent.

1694. 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 CVIII.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,624,295**

1695. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1696. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1697. 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.

1698. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1699. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1700. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1701. On information and belief as of May 28, 2021, 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.

1702. 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 '295 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '295 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

1703. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-6 of the '295 patent under at least 35 U.S.C. §§ 271(b) and (c), either

literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-6 of the '295 patent.

1704. 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 '295 patent, either literally or under the doctrine of equivalents.

1705. 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 '295 patent, either literally or under the doctrine of equivalents.

1706. 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 '295 patent, either literally or under the doctrine of equivalents.

1707. Alvotech has knowledge of and is aware of the '295 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.

1708. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '295 patent.

1709. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '295 patent.

1710. AbbVie seeks an injunction 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 CIX.**  
**INFRINGEMENT OF U.S. PATENT NO. 9,669,093**

1711. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1712. 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.

1713. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1714. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1715. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1716. 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.

1717. 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 '093 patent is an act of infringement of one or more claims of the '093 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

1718. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-5, 7, 9-12, 14, 16-21, 23, 25-27, 29, and 31 of the '093 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-5, 7, 9-12, 14, 16-21, 23, 25-27, 29, and 31 of the '093 patent.

1719. 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 '093 patent, either literally or under the doctrine of equivalents.

1720. 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 1-5, 7, 9-12, 14, 16-21, 23, 25-27, 29, and 31 of the '093 patent, either literally or under the doctrine of equivalents.

1721. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-5, 7, 9-12, 14, 16-21, 23, 25-27, 29, and 31 of the '093 patent, either literally or under the doctrine of equivalents.

1722. Alvotech has knowledge of and is aware of the '093 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.

1723. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '093 patent.

1724. 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 CX.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,669,093**

1725. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1726. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1727. 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.

1728. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1729. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1730. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1731. On information and belief as of May 28, 2021, 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.

1732. 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 '093 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '093 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

1733. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-5, 7, 9-12, 14, 16-21, 23, 25-27, 29, and 31 of the '093 patent under at least 35 U.S.C. §§ 271(b) and (c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-5, 7, 9-12, 14, 16-21, 23, 25-27, 29, and 31 of the '093 patent.

1734. 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 '093 patent, either literally or under the doctrine of equivalents.

1735. 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 1-5, 7, 9-12, 14, 16-21, 23, 25-27, 29, and 31 of the '093 patent, either literally or under the doctrine of equivalents.

1736. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-5, 7, 9-12, 14, 16-21, 23, 25-27, 29, and 31 of the '093 patent, either literally or under the doctrine of equivalents.

1737. Alvotech has knowledge of and is aware of the '093 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.

1738. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '093 patent.

1739. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '093 patent.

1740. AbbVie seeks an injunction 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 CXI.**  
**INFRINGEMENT OF U.S. PATENT NO. 9,683,033**

1741. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1742. 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.

1743. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1744. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1745. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1746. 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.

1747. 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 '033 patent is an act of infringement of one or more claims of the '033 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

1748. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 5 and 22 of the '033 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 5 and 22 of the '033 patent.

1749. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '033 patent, either literally or under the doctrine of equivalents.

1750. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 5 and 22 of the '033 patent, either literally or under the doctrine of equivalents.

1751. Alvotech has knowledge of and is aware of the '033 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.

1752. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '033 patent.

1753. 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 CXII.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,683,033**

1754. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1755. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1756. 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.

1757. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1758. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1759. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1760. On information and belief as of May 28, 2021, 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.

1761. 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 '033 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '033 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

1762. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 5 and 22 of the '033 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 5 and 22 of the '033 patent.

1763. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '033 patent, either literally or under the doctrine of equivalents.

1764. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 5 and 22 of the '033 patent, either literally or under the doctrine of equivalents.

1765. Alvotech has knowledge of and is aware of the '033 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.

1766. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '033 patent.

1767. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '033 patent.

1768. AbbVie seeks an injunction 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 CXIII.  
INFRINGEMENT OF U.S. PATENT NO. 9,708,400**

1769. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1770. 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.

1771. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1772. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1773. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1774. 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.

1775. 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 '400 patent is an act of infringement of one or more claims of the '400 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

1776. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-5, 7-13, 15-18, and 20-30 of the '400 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-5, 7-13, 15-18, and 20-30 of the '400 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '400 patent.

1777. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '400 patent, either literally or under the doctrine of equivalents.

1778. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-5, 7-13, 15-18, and 20-30 of the '400 patent, either literally or under the doctrine of equivalents.

1779. Alvotech has knowledge of and is aware of the '400 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.

1780. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '400 patent.

1781. 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 CXIV.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,708,400**

1782. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1783. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1784. 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.

1785. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1786. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1787. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1788. On information and belief as of May 28, 2021, 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.

1789. 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 '400 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '400 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

1790. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-5, 7-13, 15-18, and 20-30 of the '400 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 1-5, 7-13, 15-18, and 20-30 of the '400 patent. For at least one claim, however, Alvotech's failure to provide sufficient information, as required by the BPCIA, has prevented AbbVie from learning relevant facts that could further support AbbVie's allegation of infringement of the '400 patent.

1791. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '400 patent, either literally or under the doctrine of equivalents.

1792. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-5, 7-13, 15-18, and 20-30 of the '400 patent, either literally or under the doctrine of equivalents.

1793. Alvotech has knowledge of and is aware of the '400 patent, including due to AbbVie's disclosure of patents pursuant to 42 U.S.C. § 262(I)(3)(A) and to the filing of this Complaint.

1794. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '400 patent.

1795. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '400 patent.

1796. AbbVie seeks an injunction 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 CXV.  
INFRINGEMENT OF U.S. PATENT NO. 9,957,318**

1797. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1798. 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.

1799. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1800. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1801. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1802. 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.

1803. 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 '318 patent is an act of infringement of one or more claims of the '318 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

1804. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 5-9 and 23-27 of the '318 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42 U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 9,957,318 of the '318 patent.

1805. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '318 patent, either literally or under the doctrine of equivalents.

1806. Alvotech has knowledge of and is aware of the '318 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.

1807. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '318 patent.

1808. 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 CXVI.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,957,318**

1809. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1810. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1811. 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.

1812. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.



1813. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1814. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1815. On information and belief as of May 28, 2021, 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.

1816. 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 '318 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '318 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

1817. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 5-9 and 23-27 of the '318 patent under at least 35 U.S.C. § 271(g), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech, pursuant to 42

U.S.C. § 262(l)(3)(C), claim-by-claim infringement contentions for claims 5-9 and 23-27 of the '318 patent.

1818. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '318 patent, either literally or under the doctrine of equivalents.

1819. Alvotech has knowledge of and is aware of the '318 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.

1820. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '318 patent.

1821. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '318 patent.

1822. AbbVie seeks an injunction 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 CXVII.  
INFRINGEMENT OF U.S. PATENT NO. 11,083,792**

1823. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1824. 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.

1825. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1826. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1827. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1828. 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.

1829. 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 '792 patent is an act of infringement of one or more claims of the '792 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

1830. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-4, 7, and 13-17 of the '792 patent under at least 35 U.S.C. § 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech claim-by-claim infringement contentions for claims 1-4, 7, and 13-17 of the '792 patent.

1831. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '792 patent, either literally or under the doctrine of equivalents.

1832. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-4, 7, and 13-17 of the '792 patent, either literally or under the doctrine of equivalents.

1833. Alvotech has knowledge of and is aware of the '792 patent, including due to AbbVie's August 10, 2021 letter providing a supplemental patent list pursuant to 42 U.S.C. § 262(l)(7); AbbVie's service of Plaintiffs' Initial Infringement Contentions on September 10, 2021; and the filing of this Complaint.

1834. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '792 patent.

1835. 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 CXVIII.  
DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 11,083,792**

1836. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1837. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1838. 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.

1839. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1840. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1841. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1842. 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 and the Court's decision on the ten patents that will be subject to a first trial in August 2022. The Court plans to issue its decision by the end of October 2022. Dkt. 53 at ¶ 13.

1843. 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 '792 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '792 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

1844. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 1-4, 7, and 13-17 of the '792 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech claim-by-claim infringement contentions for claims 1-4, 7, and 13-17 of the '792 patent.

1845. On information and belief, Alvotech is aware, has knowledge, and/or is willfully blind to the fact that the manufacture of the Alvotech aBLA Product directly infringes at least one claim of the '792 patent, either literally or under the doctrine of equivalents.

1846. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 1-4, 7, and 13-17 of the '792 patent, either literally or under the doctrine of equivalents.

1847. Alvotech has knowledge of and is aware of the '792 patent, including due to AbbVie's August 10, 2021 letter providing a supplemental patent list pursuant to 42 U.S.C. § 262(l)(7); AbbVie's service of Plaintiffs' Initial Infringement Contentions on September 10, 2021; and the filing of this Complaint.

1848. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '792 patent.

1849. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '792 patent.

1850. AbbVie seeks an injunction 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 CXIX.**  
**INFRINGEMENT OF U.S. PATENT NO. 11,167,030**

1851. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1852. 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.

1853. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1854. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1855. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1856. 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.

1857. 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 '030 patent is an act of infringement of one or more claims of the '030 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

1858. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 15-18 of the '030 patent under at least 35 U.S.C. § 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech claim-by-claim infringement contentions for claims 15-18 of the '030 patent.

1859. 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 '030 patent, either literally or under the doctrine of equivalents.

1860. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 15-18 of the '030 patent, either literally or under the doctrine of equivalents.

1861. Alvotech has knowledge of and is aware of the '030 patent, including due to AbbVie's service of Plaintiffs' Initial Infringement Contentions on September 10, 2021; AbbVie's November 9, 2021 letter providing a supplemental patent list pursuant to 42 U.S.C. § 262(l)(7); and the filing of this Complaint.

1862. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '030 patent.



1863. 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 CXX.**  
**DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 11,167,030**

1864. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

1865. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

1866. 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.

1867. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

1868. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

1869. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A).

1870. 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.

1871. 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 '030 patent and Alvotech's notice of commercial marketing, create an actual, immediate, and real controversy within the Declaratory Judgment Act that Alvotech will infringe one or more of the claims of '030 patent, literally or under the doctrine of equivalent equivalents. This declaratory judgment action is also authorized by the BPCIA due to Alvotech's provision of a notice of commercial marketing. *See* 42 U.S.C. § 262(l)(9)(A). A judicial determination of infringement is necessary and appropriate to resolve this controversy.

1872. Alvotech has provided information to AbbVie pursuant to 42 U.S.C. § 262(l)(2)(A) relating to the manufacture, indications, dosage, and methods of use and administration 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 15-18 of the '030 patent under at least 35 U.S.C. §§ 271(a)-(c), either literally or under the doctrine of equivalents. AbbVie has provided to Alvotech claim-by-claim infringement contentions for claims 15-18 of the '030 patent.

1873. 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 '030 patent, either literally or under the doctrine of equivalents.

1874. On information and belief, Alvotech will knowingly or with willful blindness induce or contribute to another's direct infringement of at least claims 15-18 of the '030 patent, either literally or under the doctrine of equivalents.

1875. Alvotech has knowledge of and is aware of the '030 patent, including due to AbbVie's service of Plaintiffs' Initial Infringement Contentions on September 10, 2021; AbbVie's November 9, 2021 letter providing a supplemental patent list pursuant to 42 U.S.C. § 262(l)(7); and the filing of this Complaint.

1876. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '030 patent.

1877. AbbVie seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of the Alvotech aBLA Product will infringe the '030 patent.

1878. AbbVie seeks an injunction 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 CXXI.  
WILLFUL INFRINGEMENT**

1879. Alvotech is on notice of each of the patents and acts of infringement set forth in Counts I-CXX. It has nonetheless expressed its intention to begin commercial marketing without awaiting a judicial decision on infringement or validity. Alvotech's infringement under each of the above counts is willful under 35 U.S.C. § 284.

**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 and declaration 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. a judgment and declaration that Alvotech's infringement is willful under 35 U.S.C. § 284;

d. preliminary and/or permanent equitable relief, including but not limited to a preliminary and permanent 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;

e. 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;

f. any available damages pursuant to 35 U.S.C. § 284; and

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

Dated: November 12, 2021

/s/ Sean M. Berkowitz

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