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

ABBVIE INC. and ABBVIE BIOTECHNOLOGY LTD.,	)	
Plaintiffs,	)	Case No. 1:21-cv-2899
v.	)	Hon. Judge John Z. Lee
ALVOTECH HF.,	)	Magistrate Judge M. David Weisman
Defendant.	)	

DEFENDANT ALVOTECH HF.'S ANSWER TO PLAINTIFFS' SECOND AMENDED COMPLAINT AND COUNTERCLAIMS

Defendant and Counterclaim-Plaintiff, Alvotech hf., by its undersigned attorneys, hereby responds to the complaint of Plaintiffs and Counterclaim-Defendants AbbVie Inc. and AbbVie Biotechnology Ltd. as follows.

All references in Defendant's Answer, Defenses, and Counterclaims to Alvotech hf. (or "Defendant"), Alvotech USA (Defendant's subsidiary, Alvotech USA, Inc.), AbbVie Inc., and AbbVie Biotechnology Ltd. mean the individual entity.

ANSWER AND DEFENSES

Defendant denies all allegations in the complaint, whether express or implied, that are not specifically admitted below. Any factual allegation admitted below is admitted only as to the specifically admitted facts, and not as to any purported conclusions, characterizations, implications, or speculations that may arguably follow from the admitted facts. Many of Plaintiffs' allegations and characterizations in the complaint are vague and/or ambiguous, including, as an example, Plaintiffs' use of the terms "Alvotech" and "AbbVie." To the extent any allegation in

Plaintiffs' complaint is vague and/or ambiguous, Defendant denies the allegation in question. Moreover, much of AbbVie's complaint does not comply with the Rule 8 requirement for a short and plain statement of the claim, with limited facts inextricably intertwined with AbbVie argument.

INTRODUCTION[1]

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 ground-breaking drug HUMIRA®. 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.

ANSWER:

To the extent paragraph 1 implicates legal conclusions, no response is required. To the extent a response is required, Defendant admits that on April 27, 2021, Plaintiffs filed a complaint against Defendant in this District pursuant to the BPCIA in connection with a proposed biosimilar to Humira®. Defendant further admits that it joined its U.S. subsidiary, Alvotech USA, in filing a declaratory judgement action against Plaintiffs in the Eastern District of Virginia, which was

[1] Defendant substantially mirrors the headings set forth in the Complaint in order to simplify comparison of the Complaint and this Response. In doing so, Defendant makes no admission regarding the substance of the headings or any other allegations of the Complaint. Unless otherwise stated, to the extent a particular heading can be construed as an allegation, Defendant specifically denies all such allegations.

subsequently transferred to this District and voluntarily dismissed. Defendant denies any remaining allegations in paragraph 1.

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®—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.

ANSWER:

On information and belief, Defendant admits that Humira® was the first fully human antibody ever approved by the FDA. Defendant also admits that AbbVie's advertising materials tout that the 100 mg/ml "citrate-free" formulation causes less pain than the 50 mg/ml formulation. Defendant denies any remaining characterizations and allegations in paragraph 2.

3. Numerous biosimilar companies—now including Alvotech—have taken note of AbbVie's success as well, attempting to make biosimilar versions of HUMIRA®. 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® will enter the U.S. market in 2023.

ANSWER:

On information and belief, Defendant admits that public information indicates that AbbVie has settled with a number of biosimilar applicants referencing Humira® for U.S. entry dates in 2023. Defendant denies any remaining characterizations and allegations in paragraph 3.

4. AbbVie's HUMIRA® 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.

ANSWER:

To the extent paragraph 4 implicates legal conclusions, no response is required. Defendant admits that third parties have filed IPR petitions requesting review of patents relating to adalimumab. Defendant admits that public information indicates that AbbVie has settled with a number of biosimilar applicants. Defendant denies any remaining characterizations and allegations in paragraph 4.

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.

ANSWER:

To the extent paragraph 5 implicates legal conclusions, no response is required. Defendant admits that third parties have filed IPR petitions requesting review of patents relating to adalimumab. Otherwise denied.

6. AbbVie's investment in HUMIRA® 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® the first and only subcutaneous biologic treatment option for pediatric patients five years and older with this condition.

ANSWER:

Defendant admits that the FDA has approved Humira® for the treatment of different disease conditions set forth on the Humira® prescribing information. For the remaining allegations and

characterizations, Defendant does not have information sufficient to respond and therefore denies them.

7. AbbVie also has continued to improve and develop the HUMIRA® product itself. First, AbbVie invested in and created a subcutaneous, high concentration, liquid formulation of the HUMIRA® antibody. Before AbbVie's launch of HUMIRA®, patients had to go to the hospital to receive their medicine intravenously, or mix batches of their medicine at home (difficult for patients with inflamed joints) and inject themselves twice a week. As a result of AbbVie's dedication, innovation, and investment, patients were able to inject the medicine at home using pre-filled syringes or automatic injection devices, and take fewer injections. The added convenience and precision improved patients' lives and increased compliance, all without sacrificing HUMIRA®'s outstanding efficacy.

ANSWER:

Defendant admits that Humira® was first approved for use supplied in a single-use, 1 mL pre-filled glass syringe and also 2 mL glass vials as a sterile, preservative-free solution for subcutaneous administration. For the remaining allegations and characterizations, Defendant does not have information sufficient to respond and therefore denies them. Defendant denies that Plaintiffs are entitled to any relief pursuant to their claims. Defendant denies the remaining allegations of paragraph 7.

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.").

ANSWER:

Defendant admits FDA approved a 100 mg/ml formulation of Humira® in 2015. Defendant admits that it independently developed a biosimilar of the 100 mg/ml version of Humira®, known as AVT02. Defendant admits that David Wallace attributed quotes to Robert Wessman in an article titled "Celltrion Wins Global First Approval For High-Concentration Humira Biosmilar," published in Generics Bulletin on February 15, 2021. For the remaining allegations and characterizations regarding AbbVie, Defendant does not have information sufficient to respond and therefore denies them. Defendant denies that Plaintiffs are entitled to any relief pursuant to their claims. Defendant denies the remaining allegations of paragraph 8.

9. AbbVie has also spent many years developing and improving the complex manufacturing processes for HUMIRA® and its active ingredient, adalimumab. Unlike traditional drugs, HUMIRA® is a complex biologic created in living organisms. So even minor changes to the manufacturing process can impact the drug's stability, purity, and efficacy. AbbVie obtained patents and developed trade secrets covering innovations in manufacturing.

ANSWER:

Defendant admits that Humira® is a biologic drug, and its active ingredient, adalimumab, is created in living cells. For the remaining allegations, Defendant does not have information sufficient to respond and therefore denies them. Defendant denies that Plaintiffs are entitled to any relief pursuant to their claims.

10. In late 2020, Alvotech filed its abbreviated Biologics License Application ("Alvotech's aBLA") seeking FDA approval to launch its own biosimilar of HUMIRA®.

ANSWER:

Defendant admits that on September 4, 2020, its subsidiary Alvotech USA applied to the FDA for licensure of AVT02. Defendant denies any remaining allegations of paragraph 9.

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).

ANSWER:

To the extent paragraph 11 implicates legal conclusions, no response is required. To the extent a response is required, denied.

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).

ANSWER:

To the extent paragraph 12 implicates legal conclusions, no response is required. Defendant admits that its subsidiary, Alvotech USA, engaged in the disclosure process outlined by the BPCIA. Defendant responds that those disclosures speak for themselves. Defendant admits that Plaintiffs filed an action against Defendant in this District for infringement of four patents. Defendant further admits that on May 11, 2021, Alvotech USA provided AbbVie Inc. with its notice of commercial marketing for AVT02. Defendant further admits that it joined Alvotech USA in filing a declaratory judgement action against Plaintiffs in the Eastern District of Virginia on May 11, 2021. Defendant denies any remaining characterizations and allegations in paragraph 12.

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).

ANSWER:

To the extent paragraph 13 implicates legal conclusions, no response is required. Defendant admits that the Eastern District of Virginia transferred the declaratory judgment suit to this District, and Defendant and Alvotech USA filed a voluntary notice to dismiss the case without prejudice. Defendant denies any remaining characterizations and allegations in paragraph 13.

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."

ANSWER:

To the extent paragraph 14 implicates legal conclusions, no response is required. To the extent a response is required, denied.

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® at-risk before resolution of AbbVie's related patent infringement action in this District.[2] 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® potentially before the expiration of AbbVie's patents and before

[2] 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.

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 realityto warrant relief, including in the form of a preliminary injunction.

ANSWER:

To the extent paragraph 15 implicates legal conclusions, no response is required. To the extent a response is required, Defendant admits that on May 11, 2021, Alvotech USA provided AbbVie Inc. with its notice of commercial marketing for AVT02, opening the door for Alvotech USA to launch AVT02 180 days later. Defendant admits FDA has not yet approved Alvotech USA's BLA for AVT02 due to a COVID-19 related delay in inspection of facilities. Defendant further admits that a substantial controversy exists between Alvotech hf. and AbbVie, in which the parties have adverse legal interests of sufficient immediacy and reality to warrant the issue of a declaratory judgment from this Court. Defendant denies that Plaintiffs are entitled to any relief pursuant to their claims. Defendant denies any remaining characterizations and allegations in paragraph 15.

NATURE OF THE ACTION

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

ANSWER:

No response is required to the preamble of this section of the Complaint. To the extent a response is required, denied.

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.

ANSWER:

Defendant admits that Plaintiffs purport to assert claims under 35 U.S.C. § 271(a)-(c), (g) and § 271(e)(2)(C). Defendant denies that Plaintiffs are entitled to any relief pursuant to their claims.

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

ANSWER:

On information and belief, Defendant admits that Plaintiffs purport to assert patent infringement claims against Defendant relating to Humira®. Defendant denies that Plaintiffs are entitled to any relief pursuant to their claims.

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

ANSWER:

On information and belief, Defendant admits the allegations in paragraph 19.

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

ANSWER:

On information and belief, Defendant admits that in around 1995, a German company, BASF AG, filed a patent application disclosing adalimumab and methods of using it to treat TNFα-related autoimmune diseases, and AbbVie's predecessor, Abbott Laboratories, later purchased the rights held by BASF. Defendant admits that adalimumab is a tumor necrosis factor blocker and a recombinant human IgG1 monoclonal antibody with human derived heavy and light chain variable

regions and human IfF1:k constant regions. Defendant also admits that Humira® is approved by FDA for the indications described in the Humira® label. Otherwise, denied.

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

ANSWER:

On information and belief, Abbott Laboratories received the 2007 Galien Prize for the 50 mg/ml version of Humira®. Defendant lacks knowledge or information sufficient to form a belief about the remaining allegations in paragraph 21 and therefore denies them.

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® has improved the lives of more than one million patients to date.

ANSWER:

Defendant admits that Humira® is FDA approved as indicated on the label to treat certain autoimmune diseases in both adults and children. Defendant lacks knowledge or information sufficient to form a belief about the remaining allegations in paragraph 22 and therefore denies them.

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.

ANSWER:

To the extent paragraph 23 implicates legal conclusions, no response is required. Defendant admits that its subsidiary Alvotech USA engaged in the disclosure process outlined by the BPCIA. Defendant responds that those disclosures speak for themselves. Defendant admits

that Plaintiffs filed an action against Defendant in this District for infringement of four patents. Defendant admits that on May 11, 2021, Alvotech USA provided AbbVie Inc. with its notice of commercial marketing for AVT02 and on the same day Alvotech hf. and Alvotech USA filed a declaratory judgment suit against AbbVie in the Eastern District of Virginia, and that complaint speaks for itself. Defendant lacks knowledge or information sufficient to form a belief about the remaining allegations of paragraph 23 and they are denied. Defendant denies that Plaintiffs are entitled to any relief pursuant to their claims.

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® and owns Biologics License Application No. 125057 for HUMIRA®. 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®. Indeed, HUMIRA® was developed and is marketed under the leadership of AbbVie's management in Illinois.

ANSWER:

On information and belief, AbbVie Inc. is a corporation organized and existing under the laws of Delaware with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. On information and belief, Defendant admits that BLA No. 125057 is held by Plaintiff AbbVie Inc. Defendant does not have information sufficient to respond to the other allegations in paragraph 24 and therefore denies them.

25. Plaintiff ABL is a corporation organized and existing under the laws of Bermuda, with a place of business at Harbour Fiduciary Services Limitd, 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® to AbbVie Inc. and also maintains extensive business relationships with AbbVie Inc., including supplying AbbVie Inc. with HUMIRA® for marketing.

ANSWER:

On information and belief, Defendant admits that AbbVie Biotechnology Ltd. is a corporation organized and existing under the laws of Bermuda, with a place of business at Harbour Fiduciary Services Limitd, Thistle House, 4 Burnaby Street, Hamilton Pembroke HM11, Bermuda, and that through intermediate organizations, Plaintiff AbbVie Inc. owns Plaintiff AbbVie Biotechnology Ltd. Defendant does not have knowledge or information sufficient to respond to the remaining allegations in paragraph 25 and therefore denies them.

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.

ANSWER:

Admitted.

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.

ANSWER:

Defendant admits it is in the business of developing and manufacturing biologic drugs, including the proposed biosimilar version of Humira® (adalimumab) product, AVT02. Defendant admits that its subsidiary, Alvotech USA, applied to the FDA for licensure of AVT02. Defendant denies the remaining allegations in paragraph 28.

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.

ANSWER:

Paragraph 28 states a legal conclusion for which no response is required. To the extent a response is required, Defendant admits, on information and belief, that Plaintiffs purport to assert claims under the Patent Laws of the United States, Title 35, United States Code. Defendant denies that this Court has subject matter jurisdiction pursuant for the purposes of this action, as explained in its pending motion to dismiss and accompanying briefing (*see* D.I. 28-30, 45, 91, 138). Defendant denies that Plaintiffs are entitled to any relief pursuant to their claims.

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

ANSWER:

Paragraph 29 states a legal conclusion for which no response is required. To the extent a response is required, Defendant denies that this Court has personal jurisdiction over it as explained in Defendant's pending motion to dismiss and accompanying briefing (*see* D.I. 28-30, 45, 91, 138).

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.

ANSWER:

Paragraph 30 states a legal conclusion for which no response is required. To the extent a response is required, Defendant admits that its subsidiary, Alvotech USA applied to the FDA for licensure of AVT02 and provided Plaintiff AbbVie Inc. with the AVT02 BLA and voluminous other information required under 42 U.S.C. § 262(*l*)(A). Defendant also admits that on May 11, 2021, Alvotech USA provided AbbVie Inc. with its notice of commercial marketing for AVT02.

Defendant further admits that AVT02 cannot be sold within the United States, including in this District and Illinois, before FDA approval of the AVT02 BLA. Otherwise, denied.

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.

ANSWER:

To the extent paragraph 31 implicates legal conclusions, no response is required. To the extend a response is required, Defendant admits that its subsidiary Alvotech USA, which is responsible for the Alvotech family's legal, governmental policy, and regulatory affairs, is the applicant for AVT02 BLA No. 761205. Defendant also admits that it is named in the AVT02 BLA as the drug substance and drug product manufacturer. Defendant further admits that before Alvotech USA incorporated, Defendant representatives and representatives of Alvotech Swiss AG met with the FDA regarding AVT02. Defendant further admits that distribution of AVT02 will provide benefits, including to patients. Defendant denies the remaining allegations in paragraph 32.

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.

ANSWER:

Defendant admits that Alvotech USA is a wholly-owned subsidiary of Alvotech hf. Defendant further admits that Alvotech USA employees are responsible for the Alvotech family's legal, governmental policy, and regulatory affairs (among other things), centered in Alexandria,

Virginia. Defendant also admits that the website and document cited in paragraph 32 contains the quoted language. Otherwise, denied.

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.

ANSWER:

Defendant admits that at least one clinical trial for AVT02 commenced before Alvotech USA incorporated. Defendant further admits that before Alvotech USA incorporated, Defendant's representatives and representatives of Alvotech Swiss AG met with the FDA regarding AVT02. Defendant further admits the documents cited in paragraph 33 include the quoted language and that those cited documents speak for themselves. Defendant denies the remaining allegations in paragraph 33.

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.

ANSWER:

To the extent paragraph 34 implicates legal conclusions, no response is required. To the extent a response is required, Defendant admits that its subsidiary Alvotech USA is the applicant for AVT02 BLA No. 761205. Defendant admits AVT02 clinical trials continue, and that Defendant manufactured or caused to be manufactured the AVT02 lots that were used in the clinical trials. Defendant denies the remaining allegations in paragraph 34.

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® (adalimumab)," May 12, 2020, https://www.alvotech.com/newsroom/alvotech-announces-positive-top-line-results-for-two-comparative-studies-for-avt02-a-proposed-biosimilar-to-humira-adalimumab, attached hereto as Exhibit 6. Alvotech specifically stated that "Alvotech is developing [the Alvotech aBLA Product] as a proposed biosimilar to HUMIRA® (adalimumab) with high concentration (100 mg/mL) dosage forms." *Id*.

ANSWER:

Defendant admits that the document cited in paragraph 35 includes the quoted language, and that document speaks for itself. Defendant further admits that it is developing AVT02, a proposed biosimilar to Humira® (adalimumab) with high concentration (100 mg/mL) dosage forms. Defendant denies any remaining allegations in paragraph 35.

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.

ANSWER:

Defendant admits that it expects to financially benefit from commercialization of AVT02. Defendant further admits that AVT02 will be manufactured in Iceland and that AVT02 will be marketed in the United States. Defendant admits that the documents cited in paragraph 36 are dated August 5, 2020 and November 19, 2020, contain the quoted language, and those documents speak for themselves. Defendant denies the remaining allegations in paragraph 36, including to the extent paragraph 36 implies Defendant specifically targeted Illinois as explained in its pending motion to dismiss and accompanying briefing (*see* D.I. 28-30, 45, 91, 138).

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.[3]

ANSWER:

Paragraph 37 states legal conclusions for which no response is required. To the extent a response is required, and for the allegations in paragraph 37 regarding administration of AVT02, Defendant does not have information sufficient to respond and therefore denies them. Defendant denies the remaining allegations in paragraph 37. Defendant denies Plaintiffs are entitled to any relief pursuant to their claims.

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

[3] 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.).

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.

ANSWER:

Paragraph 38 states legal conclusions for which no response is required. To the extent a response is required, Defendant denies it is subject to personal jurisdiction in this District for the reasons stated in its pending motion to dismiss and accompanying briefing (*see* D.I. 28-30, 45, 91, 138). Defendant denies the remaining allegations in paragraph 38.

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).

ANSWER:

Paragraph 39 states a legal conclusion for which no response is required. To the extent a response is required, Defendant admits that venue is proper in this Court for purposes of adjudicating Plaintiffs' claims against Defendant Alvotech hf. in this action only. Defendant denies that Plaintiffs are entitled to any relief pursuant to their claims. Defendant denies any remaining allegations of paragraph 39.

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 relying on AbbVie's demonstration that HUMIRA® is safe, pure, and potent. The BPCIA provides an abbreviated pathway for approval of a biologic product that is "biosimilar" to a "reference product." Alvotech has demonstrated its intention to utilize AbbVie's data and work discovering and developing adalimumab through the use of the abbreviated BPCIA biosimilar pathway.

ANSWER:

To the extent paragraph 40 implicates legal conclusions, no response is required. To the extent a response is required, Defendant admits that on September 4, 2020, its subsidiary Alvotech

USA applied to the FDA for licensure of AVT02, and the FDA assigned BLA No. 761205 for Alvotech USA's AVT02 application. Defendant denies any remaining allegations of paragraph 40.

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.

ANSWER:

To the extent paragraph 41 implicates legal conclusions, no response is required. Defendant denies any remaining allegations in paragraph 41.

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

ANSWER:

Defendant admits that on November 3, 2020, the FDA notified Alvotech USA that Alvotech USA's application was sufficiently complete to permit substantive review by the FDA. Defendant denies the remaining allegations in paragraph 42.

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.

ANSWER:

Defendant admits that on November 5, 2020, Alvotech USA's Chief IP Counsel and Deputy General Counsel contacted AbbVie Inc. to inform it that the FDA had accepted Alvotech USA's application and assigned it BLA No. 761205. Defendant also admits that the document

cited in paragraph 43 relates to the FDA's acceptance of the AVT02 BLA, the document is dated November 19, 2020, and that document speaks for itself. Defendant denies the remaining allegations in paragraph 43.

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.

ANSWER:

Defendant admits that the exchange of information pursuant to the procedures outlined in the BPCIA began in November 2020 and that on November 5, 2020, Defendant's subsidiary Alvotech USA provided designated individuals from AbbVie Inc. with BLA No. 761205, totaling 118,846 pages of documents. Defendant further admits that Alvotech USA also provided AbbVie Inc. with hundreds of additional manufacturing documents, totaling over 25,000 pages, including batch and laboratory records. Defendant denies the remaining allegations in paragraph 44.

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."

ANSWER:

Defendant admits that its subsidiary Alvotech USA received a letter from AbbVie Inc. dated January 4, 2021 identifying 63 patents purportedly pursuant to 42 U.S.C. § 262(*l*)(3)(A), and that letter speaks for itself. Defendant denies the remaining allegations in paragraph 45.

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.

ANSWER:

Defendant admits that on January 14, 2021 and pursuant to 42 U.S.C. § 262(*l*)(3)(B), counsel for its subsidiary Alvotech USA provided counsel for AbbVie Inc. with detailed statements, including over 6,000 pages of explanation and claim charts, with citations to Alvotech USA's AVT02 BLA and manufacturing documents, that describe on a claim by claim basis for each of the 63 patents, the factual and legal basis why each claim of the 63 patents is invalid, unenforceable, and/or will not be infringed by the commercial marketing of AVT02 ("Alvotech USA's 3B statement"). Defendant denies the remaining allegations in paragraph 46.

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:

	U.S. Patent No.	Lead Inventor	Title
1.	6,805,686	Fathallah	Autoinjector with Extendable Needle Protector Shroud
2.	8,231,876	Wan	Purified Antibody Composition
3.	8,420,081	Fraunhofer	Antibody Formulations and Methods of Making Same
4.	8,663,945	Pla	Methods of Producing Anti-TNF-Alpha Antibodies in Mammalian Cell Culture
5.	8,708,968	Julian	Removal of Needle Shields from Syringes and Automatic Injection Devices
6.	8,715,664	Hoffman	Use of Human TNFα Antibodies for Treatment of Erosive Polyarthritis
7.	8,808,700	Hoffman	Use of TNF Alpha Inhibitor for Treatment of Erosive Polyarthritis
8.	8,883,156	Wan	Purified Antibody Composition
9.	8,889,136	Hoffman	Multiple-Variable Dose Regimen for Treating TNFα-Related Disorders
10.	8,895,009	Wan	Purified Antibody Composition
11.	8,906,372	Wan	Purified Antibody Composition

12.	8,906,373	Banerjee	Use of TNF-Alpha Inhibitor for Treatment of Psoriasis
13.	8,906,646	Pla	Fed-Batch Method of Making Human Anti-TNF-Alpha Antibody
14.	8,911,737	Fischkoff	Methods of Administering Anti-TNFα Antibodies
15.	8,911,964	Pla	Fed-Batch Method of Making Human Anti-TNF-Alpha Antibody
16.	8,916,153	Wan	Purified Antibody Composition
17.	8,926,975	Wong	Method of Treating Ankylosing Spondylitis
18.	8,961,973	Hoffman	Multiple-Variable Dose Regimen for Treating TNFα-Related Disorders
19.	8,961,974	Hoffman	Multiple-Variable Dose Regimen for Treating TNFα-Related Disorders
20.	8,974,790	Fischkoff	Methods of Administering Anti-TNFα Antibodies
21.	8,986,693	Hoffman	Use of TNFα Inhibitor for Treatment of Psoriasis
22.	8,992,926	Fischkoff	Methods of Administering Anti-TNFα Antibodies
23.	8,999,337	Medich	Methods for Treating Juvenile Idiopathic Arthritis by Inhibition of TNFα
24.	9,061,005	Hoffman	Multiple-Variable Dose Regimen for Treating Idiopathic Inflammatory Bowel Disease
25.	9,062,106	Bengea	Methods for Controlling the Galactosylation Profile of Recombinantly-Expressed Proteins
26.	9,067,992	Hoffman	Use of TNFα Inhibitor for Treatment of Psoriatic Arthritis
27.	9,085,618	Ramasubramanyan	Low Acidic Species Compositions and Methods for Producing and Using the Same
28.	9,085,619	Fraunhofer	Anti-TNF Antibody Formulations
29.	9,085,620	Hoffman	Use of TNFα Inhibitor for Treatment of Psoriatic Arthritis
30.	9,090,688	Bengea	Methods for Controlling the Galactosylation Profile of Recombinantly-Expressed Proteins
31.	9,090,689	Hoffman	Use of TNFα Inhibitor for Treatment of Psoriasis
32.	9,090,867	Pla	Fed-Batch Method of Making Anti-TNF-Alpha Antibody
33.	9,096,666	Wan	Purified Antibody Composition
34.	9,102,723	Wan	Purified Antibody Composition

35.	9,150,645	Subramanian	Cell Culture Methods to Reduce Acidic Species
36.	9,181,337	Subramanian	Modulated Lysine Variant Species Compositions and Methods for Producing and Using the Same
37.	9,181,572	Subramanian	Methods to Modulate Lysine Variant Distribution
38.	9,187,559	Hoffman	Multiple-Variable Dose Regimen for Treating Idiopathic Inflammatory Bowel Disease
39.	9,234,032	Pla	Fed-Batch Methods for Producing Adalimumab
40.	9,266,949	Ramasubramanyan	Low Acidic Species Compositions and Methods for Producing and Using the Same
41.	9,273,132	Wan	Purified Antibody Composition
42.	9,284,370	Medich	Methods for Treating Juvenile Idiopathic Arthritis
43.	9,284,371	Pla	Methods of Producing Adalimumab
44.	9,290,568	Rives	Methods to Control Protein Heterogeneity
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	Hoffman	Use of TNFa Inhibitor
53.	9,505,834	Bengea	Methods for Controlling the Galactosylation Profile of Recombinantly-Expressed Proteins
54.	9,512,216	Hoffman	Use of TNFα Inhibitor
55.	9,522,953	Ramasubramanyan	Low Acidic Species Compositions and Methods for Producing and Using the Same
56.	9,546,212	Fischkoff	Methods of Administering Anti-TNFα Antibodies

57.	9,550,826	Labkovsky	Glycoengineered Binding Protein Compositions
58.	9,624,295	Medich	Uses and Compositions for Treatment of Psoriatic Arthritis
59.	9,669,093	Medich	Methods for Treating Juvenile Idiopathic Arthritis
60.	9,683,033	Subramanian	Cell Culture Methods to Reduce Acidic Species
61.	9,708,400	Subramanian	Methods to Modulate Lysine Variant Distribution
62.	9,957,318	Ramasubramanyan	Protein Purification Methods to Reduce Acidic Species

ANSWER:

To the extent paragraph 47 implicates a legal conclusion, no response is required. To the extent a response is required, Defendant admits that on March 15, 2021, counsel for Plaintiffs purported to respond to Alvotech USA's 3B statement ("the 3C statement"), but Defendant denies that AbbVie Inc. satisfied its statutory obligations under § 262(*l*)(3)(C). Defendant denies the remaining allegations in paragraph 47.

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.

ANSWER:

To the extent paragraph 48 implicates a legal conclusion, no response is required. To the extent a response is required, Defendant admits that notwithstanding AbbVie Inc.'s deficiencies, starting no later than March 17, 2021, Defendant's subsidiary Alvotech USA engaged in good faith negotiations under 42 U.S.C. § 262(*l*)(4)(A) to identify patents on AbbVie's 3A List that should be the subject of "the immediate patent infringement action" authorized under 42 U.S.C. § 262(*l*)(6), and on March 23, 2021, counsel for Defendant's subsidiary Alvotech USA proposed fairly limiting a litigation to the following four patents: U.S. Patent Nos. 8,420,081; 8,926,975;

8,961,973; and 9,085,619. Defendant denies the remaining allegations in paragraph 48.

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.

ANSWER:

Defendant admits that on March 29, 2021, counsel for AbbVie wrote to counsel for Defendant's subsidiary Alvotech USA stating "if Alvotech wants to resolve *all* issues in round 1, it needs to pick *all* patents," despite failing to propose additional patents to litigate beyond the four proposed by Alvotech USA. Defendant denies the remaining allegations in paragraph 49.

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.

ANSWER:

Defendant admits that on April 27, 2021, Plaintiffs filed a complaint against Defendant in this District on four patents pursuant to the BPCIA in connection with a proposed biosimilar to Humira®. Defendant further admits that on May 7, 2021, it waived service of summons and on May 6, 2021, its counsel first entered appearances. Defendant denies any remaining allegations in paragraph 50.

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 Virigina 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).

ANSWER:

To the extent paragraph 51 implicates a legal conclusion, no response is required. Defendant admits that on May 11, 2021, it joined its U.S. subsidiary, Alvotech USA, in filing a declaratory judgement action against Plaintiffs in the Eastern District of Virginia. Defendant further admits that the Eastern District of Virginia transferred the declaratory judgment suit to this District, and Defendant and Alvotech USA subsequently filed a voluntary notice to dismiss the case without prejudice. Defendant denies any remaining characterizations and allegations in paragraph 51.

52. On that same day, 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 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.

ANSWER:

To the extent paragraph 52 implicates legal conclusions, no response is required. Defendant admits that on May 11, 2021, Alvotech USA provided AbbVie Inc. with its notice of commercial marketing for AVT02. Defendant further admits that the parties, through their outside counsel, exchanged communications regarding the notice of commercial marketing, and those communications speak for themselves. Defendant further admits that Plaintiffs filed a complaint on May 28, 2021 against Alvotech hf., purportedly brought pursuant to 42 U.S.C. § 262(*l*)(8) and alleging infringement of 58 patents. Defendant further admits that Defendant has "agreed not to launch AVT02 in the United States prior to the issuance of the Court's decision," which the Court plans to issue by the end of October 2022 (*see* Case No. 21-02258, D.I. 63). Defendant denies any remaining characterizations and allegations in paragraph 52.

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).

ANSWER:

Defendant admits that U.S. Pat. No. 11,083,792 issued on August 10, 2021. Defendant further admits that its counsel received a letter dated August 10, 2021, providing a "supplemental patent list" purportedly made pursuant to 42 U.S.C. § 262(*l*)(7). Defendant denies any remaining characterizations and allegations in paragraph 53.

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, i.e., the patent issuing from U.S. Patent Application No. 17/137,246 (U.S. Patent No. 11,191,834). Dkt. 53 at 3. 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.

ANSWER:

Admitted.

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).

ANSWER:

Defendant admits that its outside counsel received a letter dated September 3, 2021 regarding *AbbVie et al. v. Alvotech hf.*, Case Nos. 1-21-cv-2258, 1-21-cv-2899 (N.D. Ill.) identifying 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 U.S. patent application no. 17/137,201 as "patents for the first stage of the litigation." Defendant denies any remaining allegations in paragraph 55.

56. On September 20, 2021, the Court entered a Scheduling and Discovery Order (9/20/21 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.

ANSWER:

Admitted.

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).

ANSWER:

Defendant admits that U.S. Pat. No. 11,167,030 issued on November 9, 2021. Defendant further admits that its counsel received a letter dated November 9, 2021, providing a "supplemental patent list" purportedly made pursuant to 42 U.S.C. § 262(*l*)(7). Defendant denies any remaining characterizations and allegations in paragraph 57.

58. On November 12, 2021, AbbVie filed a first amended complaint in the instant action to add U.S. Patent Nos. 11,083,792 and 11,167,030 pursuant to the 9/20/21 Order. Dkt. 53 at 3.

ANSWER:

Defendant admits that on November 12, 2021, AbbVie filed a first amended complaint in this litigation. As to the AbbVie's reasons for amendment, Defendant does not have knowledge or information sufficient to respond to the remaining characterizations and allegations in paragraph 58 and therefore denies them.

59. On December 7, 2021, the USPTO issued U.S. Pat. No. 11,191,834. AbbVie provided Alvotech notice of the issuance that same day under 42 U.S.C. § 262(*l*)(7).

ANSWER:

Defendant admits that U.S. Pat. No. 11,191,834 issued on December 7, 2021. Defendant further admits that its counsel received a letter dated December 7, 2021, providing a "supplemental patent list" purportedly made pursuant to 42 U.S.C. § 262(*l*)(7). Defendant denies any remaining characterizations and allegations in paragraph 59.

THE ALVOTECH aBLA PRODUCT

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

ANSWER:

Defendant admits that Alvotech hf. and its subsidiaries have developed AVT02, a proposed biosimilar to Humira® (adalimumab). Defendant denies the remaining allegations of paragraph 58.

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

ANSWER:

To the extent paragraph 59 implicates a legal conclusion regarding "submitted," no response is required. To the extent a response is required, Defendant admits that its subsidiary Alvotech USA applied to the FDA seeking approval to market in the United States a biosimilar version of AbbVie Inc.'s Humira® (adalimumab) product. Defendant denies any remaining allegations in paragraph 59.

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

ANSWER:

Defendant admits that the document cited in paragraph 60 is dated November 19, 2020, refers to the acceptance of the AVT02 BLA by the FDA, and that document speaks for itself. Defendant denies the remaining allegations in paragraph 60.

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

ANSWER:

Defendant admits that the document cited in paragraph 61 includes the quoted language.

Defendant denies any remaining allegations in paragraph 61.

64. 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.*

ANSWER:

Defendant admits that the document cited in paragraph 62 includes the quoted language. Defendant denies the remaining allegations in paragraph 62.

65. 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.

ANSWER:

Defendant admits that clinical trials have been conducted with regard to the use of AVT02 for the treatment of moderate to severe chronic psoriasis and data from those clinical trials was submitted in connection with the AVT02 BLA. Defendant further admits that clinical trials with regard to the use of AVT02 for the treatment of moderate to severe active rheumatoid arthritis are ongoing. Defendant denies the remaining allegations in paragraph 63.

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

ANSWER:

Defendant admits that as of the date Plaintiffs filed their complaint, the FDA has yet to approve AVT02. Defendant denies any remaining allegations in paragraph 64.

67. 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).

ANSWER:

Denied.

ABBVIE'S ADALIMUMAB PATENTS

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

ANSWER:

Defendant admits that Plaintiffs purport to have more than 100 patents related to Humira®. Defendant does not have knowledge or information sufficient to respond to the allegations regarding AbbVie and therefore denies them. Defendant denies the remaining allegations in paragraph 66.

69. AbbVie asserts the following 61 patents in this suit (the "AbbVie Patents").

ANSWER:

Defendant admits that Plaintiffs purport to assert infringement of the following 60 U.S. patents against Alvotech hf. in this lawsuit. Defendant denies Plaintiffs are entitled to any relief pursuant to their claims.

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

70. 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.

ANSWER:

Defendant admits that on October 19, 2004, the '686 patent, titled "Autoinjector with Extendable Needle Protector Shroud," was issued by the USPTO, and that Exhibit 10 appears to be a copy of the '686 patent. Defendant denies the remaining allegations in paragraph 68.

71. 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.

ANSWER:

Defendant admits that Abbott Laboratories is listed as the assignee on the face of the '686 patent. Defendant does not have knowledge or information sufficient to respond to the remaining allegations in paragraph 69 and therefore denies them.

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

72. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

73. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

74. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

75. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

76. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

77. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

78. U.S. Patent No. 8,715,664 (the "'664 patent"), titled "Use of Human TNFα 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

79. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response

is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

80. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

81. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

82. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

83. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

84. U.S. Patent No. 8,889,136 (the "'136 patent"), titled "Multiple-Variable Dose Regimen for Treating TNFα-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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

85. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

86. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

87. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted,

Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

88. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

89. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

90. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity,

and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

91. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

92. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

93. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

94. U.S. Patent No. 8,911,737 (the "'737 patent"), titled "Methods of Administering Anti-TNFα 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

95. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted,

Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

96. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

97. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

98. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity,

and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

99. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

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

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

101. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

102. U.S. Patent No. 8,974,790 (the "'790 patent"), titled "Methods of Administering Anti-TNFα 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

103. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

104. U.S. Patent No. 8,986,693 (the "'693 patent"), titled "Use of TNFα 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

105. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

106. U.S. Patent No. 8,992,926 (the "'926 patent"), titled "Methods of Administering Anti-TNFα 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters

are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

107. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

108. U.S. Patent No. 8,999,337 (the "'9337 patent"), titled "Methods for Treating Juvenile Idiopathic Arthritis by Inhibition of TNFα," 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.

ANSWER:

Defendant admits that on April 7, 2015, the '9337 patent, titled "Methods for Treating Juvenile Idiopathic Arthritis by Inhibition of TNFα," was issued by the USPTO, and that Exhibit 29 appears to be a copy of the '9337 patent. Defendant denies the remaining allegations in paragraph 106.

109. 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.

ANSWER:

Defendant admits that AbbVie Biotechnology Ltd. is listed as the assignee on the face of

the '9337 patent. Defendant does not have knowledge or information sufficient to respond to the remaining allegations in paragraph 107 and therefore denies them.

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

110. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

111. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

112. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

113. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

114. U.S. Patent No. 9,067,992 (the "'992 patent"), titled "Use of TNFα 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.

ANSWER:

Defendant admits that on June 30, 2015, the '992 patent, titled "Use of TNFα Inhibitor for Treatment of Psoriatic Arthritis," was issued by the USPTO, and that Exhibit 32 appears to be a copy of the '992 patent. Defendant denies the remaining allegations in paragraph 112.

115. 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.

ANSWER:

Defendant admits that AbbVie Biotechnology Ltd. is listed as the assignee on the face of the '992 patent. Defendant does not have knowledge or information sufficient to respond to the remaining allegations in paragraph 113 and therefore denies them.

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

116. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

117. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

118. U.S. Patent No. 9,085,620 (the "'620 patent"), titled "Use of TNFα 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

119. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

120. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters

are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

121. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

122. U.S. Patent No. 9,090,689 (the "'689 patent"), titled "Use of TNFα 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

123. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

124. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

125. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

126. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

127. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

128. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters

are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

129. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

130. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

131. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

132. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

133. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted,

Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

134. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

135. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

136. 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.

ANSWER:

Defendant admits that on November 17, 2015, the '559 patent, titled "Multiple-Variable Dose Regimen for Treating Idiopathic Inflammatory Bowel Disease," was issued by the USPTO, and that Exhibit 43 appears to be a copy of the '559 patent. Defendant denies the remaining allegations in paragraph 134.

137. 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.

ANSWER:

Defendant admits that AbbVie Biotechnology Ltd. is listed as the assignee on the face of the '559 patent. Defendant does not have knowledge or information sufficient to respond to the remaining allegations in paragraph 135 and therefore denies them.

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

138. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

139. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

140. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

141. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

142. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

143. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

144. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters

are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

145. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

146. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

147. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

148. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

149. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

150. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

151. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

152. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity,

and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

153. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

154. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

155. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

156. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

157. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted,

Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

158. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

159. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

160. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity,

and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

161. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

162. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

163. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

164. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

165. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters

are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

166. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

167. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

168. U.S. Patent No. 9,512,216 (the "'216 patent"), titled "Use of TNFα 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.

ANSWER:

Defendant admits that on December 6, 2016, the '216 patent, titled "Use of TNFα Inhibitor," was issued by the USPTO, and that Exhibit 59 appears to be a copy of the '216 patent. Defendant denies the remaining allegations in paragraph 166.

169. 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.

ANSWER:

Defendant admits that AbbVie Biotechnology Ltd. is listed as the assignee on the face of the '216 patent. Defendant does not have knowledge or information sufficient to respond to the remaining allegations in paragraph 167 and therefore denies them.

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

170. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

171. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

172. U.S. Patent No. 9,546,212 (the "'212 patent"), titled "Methods of Administering Anti-TNFα 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

173. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters

are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

174. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

175. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

176. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

177. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

178. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

179. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

180. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

181. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters

are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

182. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

183. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

184. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

185. 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.

ANSWER:

The only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) Because this patent is not one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed to by the parties and/or as ordered by the Court.

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

186. 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.

ANSWER:

Defendant admits that on August 10, 2021, the '792 patent, titled "Purified Antibody Composition," was issued by the USPTO, and that Exhibit 68 appears to be a copy of the '792 patent. Defendant denies the remaining allegations in paragraph 184.

187. 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.

ANSWER:

Defendant admits that AbbVie Biotechnology Ltd. is listed as the assignee on the face of the '792 patent. Defendant does not have knowledge or information sufficient to respond to the remaining allegations in paragraph 185 and therefore denies them.

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

188. 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.

ANSWER:

Defendant admits that on November 9, 2021, the '030 patent, titled "Protein Formulations and Methods of Making Same," was issued by the USPTO, and that Exhibit 69 appears to be a copy of the '030 patent. Defendant denies the remaining allegations in paragraph 186.

189. 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.

ANSWER:

Defendant admits that AbbVie Biotechnology Ltd. is listed as the assignee on the face of the '030 patent. Defendant does not have knowledge or information sufficient to respond to the remaining allegations in paragraph 187 and therefore denies them.

U.S. Patent No. 11,191,834

190. U.S. Patent No. 11,191,834 (the "'1834 patent"), titled "Protein Formulations and Methods of Making Same," was duly and legally issued by the USPTO on December 7, 2021. A true and correct copy of the '1834 patent is attached as Exhibit 71.

ANSWER:

Defendant admits that on December 7, 2021, the '1834 patent, titled "Protein Formulations

and Methods of Making Same," was issued by the USPTO, and that Exhibit 71 appears to be a copy of the '1834 patent. Defendant denies the remaining allegations in paragraph 190.

191. ABL is the owner by assignment of the '1834 patent. AbbVie Inc. is exclusively licensed to offer for sale, sell, or have sold through distributors products that would infringe the '1834 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 '1834 patent.

ANSWER:

Defendant admits that AbbVie Biotechnology Ltd. is listed as the assignee on the face of the '1834 patent. Defendant does not have knowledge or information sufficient to respond to the remaining allegations in paragraph 191 and therefore denies them.

192. 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-CXXII below.

ANSWER:

Defendant admits that AbbVie Inc. included each of the patents described in Counts 1-CXXII in its disclosures to Defendant's subsidiary Alvotech USA purportedly made pursuant to 42 U.S.C. § 262(*l*)(3)(A) or 42 U.S.C. § 262(*l*)(7), but Defendant denies that AbbVie Inc. satisfied its statutory obligation under § 262(*l*)(3)(C) or 42 U.S.C. § 262(*l*)(7). Defendant denies the remaining allegations in paragraph 192.

193. 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-CXXII below.

ANSWER:

Defendant admits that AbbVie Inc. purported to provide responses pursuant to 42 U.S.C. § 262(*l*)(3)(C) for certain patents described in Counts 1-CXXII below, but Defendant denies that AbbVie Inc. satisfied its statutory obligation under § 262(*l*)(3)(C). Defendant denies the remaining allegations in paragraph 193.

ANSWER TO COUNT I

(Alleged Infringement of U.S. Patent No. 6,805,686)

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

ANSWER:

No response is required to the incorporation by reference of the preceding paragraphs. To the extent a response is required, Defendant re-alleges and incorporates by reference each of its foregoing responses as if fully set forth herein.

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

ANSWER:

Defendant admits that on September 4, 2020, its subsidiary Alvotech USA applied to the FDA for licensure of AVT02, a biosimilar to Humira® (adalimumab). Defendant admits that the reference product for AVT02 is Humira® (adalimumab), BLA No. 125057. On information and belief, Defendant admits that BLA No. 125057 is held by Plaintiff AbbVie Inc. Defendant denies the remaining allegations in paragraph 191.

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

ANSWER:

Defendant admits that on November 5, 2020, the FDA notified Defendant's subsidiary Alvotech USA that Alvotech's application was sufficiently complete to permit substantive review by the FDA. Defendant denies the remaining allegations in paragraph 192.

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

ANSWER:

Defendant admits that on November 5, 2020, Defendant's subsidiary Alvotech USA provided AbbVie Inc. with the AVT02 BLA application and voluminous other information required under 42 U.S.C. § 262(*l*)(2)(A). Defendant denies the remaining allegations in paragraph 193.

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

ANSWER:

Defendant admits that on May 11, 2021, Defendant's subsidiary Alvotech USA provided AbbVie Inc. with its notice of commercial marketing for AVT02. Defendant denies the remaining allegations in paragraph 194.

199. 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.

ANSWER:

Defendant admits that it will manufacture AVT02 in Iceland and that AVT02 will be used, sold, offered for sale, and/or imported in the U.S. after the FDA approves the AVT02 BLA. Defendant denies the remaining allegations in paragraph 195.

200. 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.

ANSWER:

Denied.

201. 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.

ANSWER:

Defendant admits that its subsidiary Alvotech USA provided AbbVie Inc. with information relating to the manufacture, indications, dosage, and methods of use of AVT02 pursuant to 42 U.S.C. § 262(*l*)(2)(A). Defendant denies the remaining allegations in paragraph 197.

202. 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.

ANSWER:

Denied.

203. 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.

ANSWER:

Denied.

204. 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.

ANSWER:

Denied.

205. 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.

ANSWER:

Admitted.

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

ANSWER:

Denied.

207. 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.

ANSWER:

Defendant admits that Plaintiffs purport to seek an injunction pursuant to 35 U.S.C. § 271(e)(4)(B). Defendant denies Plaintiffs are entitled to any relief pursuant to their claims including injunctive relief, in the least because one who seeks equity must do equity. *See, e.g.*, *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945) ("[H]e who comes into equity must come with clean hands.").

ANSWER TO COUNT II

(Alleged Declaratory Judgment of Infringement of U.S. Patent No. 6,805,686)

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

ANSWER:

No response is required to the incorporation by reference of the preceding paragraphs. To the extent a response is required, Defendant re-alleges and incorporates by reference each of its foregoing responses as if fully set forth herein.

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

ANSWER:

Paragraph 205 states a legal conclusion for which no response is required. To the extent a

response is required, Defendant admits, on information and belief, that Plaintiffs purport to assert claims under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Defendant denies Plaintiffs are entitled to any relief pursuant to their claims.

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

ANSWER:

Defendant admits that on September 4, 2020, its subsidiary Alvotech USA applied to the FDA for licensure of AVT02, a biosimilar to Humira® (adalimumab). Defendant admits that the reference product for AVT02 is Humira® (adalimumab), BLA No. 125057. On information and belief, Defendant admits that BLA No. 125057 is held by Plaintiff AbbVie Inc. Defendant denies the remaining allegations in paragraph 206.

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

ANSWER:

Defendant admits that on November 5, 2020, the FDA notified Defendant's subsidiary Alvotech USA that Alvotech's application was sufficiently complete to permit substantive review by the FDA. Defendant denies the remaining allegations in paragraph 207.

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

ANSWER:

Defendant admits that on November 5, 2020, Defendant's subsidiary Alvotech USA provided AbbVie Inc. with the AVT02 BLA application and voluminous other information required under 42 U.S.C. § 262(*l*)(2)(A). Defendant denies the remaining allegations in paragraph 208.

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

ANSWER:

Defendant admits that on May 11, 2021, Defendant's subsidiary Alvotech USA provided AbbVie Inc. with its notice of commercial marketing for AVT02. Defendant denies the remaining allegations in paragraph 209.

214. 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.[4]

ANSWER:

Defendant admits that it will manufacture AVT02 in Iceland and that AVT02 will be used, sold, offered for sale, and/or imported in the U.S. after the FDA approves the AVT02 BLA. Defendant denies the remaining allegations in paragraph 210.

215. 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.

ANSWER:

Paragraph 211 states legal conclusions for which no response is required. To the extent a response is required, Defendant admits only that a substantial controversy exists between Alvotech hf. and AbbVie, in which the parties have adverse legal interests of sufficient immediacy and reality to warrant the issue of a declaratory judgment from this Court. Otherwise, denied.

[4] With respect to this paragraph and those therafter [*sic*] 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.

216. 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.

ANSWER:

Defendant admits that its subsidiary Alvotech USA provided AbbVie Inc. with information relating to the indications, dosage, and methods of use of AVT02 pursuant to 42 U.S.C. § 262(*l*)(2)(A). Defendant denies the remaining allegations in paragraph 212.

217. 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.

ANSWER:

Denied.

218. 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.

ANSWER:

Denied.

219. 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.

ANSWER:

Denied.

220. 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.

ANSWER:

Admitted.

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

ANSWER:

Denied.

222. 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.

ANSWER:

Defendant admits that Plaintiffs purport to seek a declaratory judgment. Defendant denies Plaintiffs are entitled to any relief pursuant to their claims including a declaratory judgment. Defendant denies any remaining allegations in paragraph 218.

223. 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.

ANSWER:

Defendant admits that Plaintiffs purport to seek an injunction. Defendant denies Plaintiffs are entitled to any relief pursuant to their claims including injunctive relief, in the least because one who seeks equity must do equity. *See, e.g.*, *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945) ("[H]e who comes into equity must come with clean hands.").

ANSWER TO COUNTS III-XXXVIII

Paragraphs 224-742 relate only to stayed patents. (*See* 21-2258, D.I. 63.) Because none of these patents are one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as

agreed by the parties and/or as ordered by the Court."

ANSWER TO COUNT XXXIX

(Alleged Infringement of U.S. Patent No. 8,999,337)

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

ANSWER:

No response is required to the incorporation by reference of the preceding paragraphs. To the extent a response is required, Defendant re-alleges and incorporates by reference each of its foregoing responses as if fully set forth herein.

744. 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.

ANSWER:

Defendant admits that on September 4, 2020, its subsidiary Alvotech USA applied to the FDA for licensure of AVT02, a biosimilar to Humira® (adalimumab). Defendant admits that the reference product for AVT02 is Humira® (adalimumab), BLA No. 125057. On information and belief, Defendant admits that BLA No. 125057 is held by Plaintiff AbbVie Inc. Defendant denies the remaining allegations in paragraph 744.

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

ANSWER:

Defendant admits that on November 5, 2020, the FDA notified Defendant's subsidiary Alvotech USA that Alvotech's application was sufficiently complete to permit substantive review by the FDA. Defendant denies the remaining allegations in paragraph 745.

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

ANSWER:

Defendant admits that on November 5, 2020, Defendant's subsidiary Alvotech USA provided AbbVie Inc. with the AVT02 BLA application and voluminous other information required under 42 U.S.C. § 262(*l*)(2)(A). Defendant denies the remaining allegations in paragraph 746.

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

ANSWER:

Defendant admits that on May 11, 2021, Defendant's subsidiary Alvotech USA provided AbbVie Inc. with its notice of commercial marketing for AVT02. Defendant denies the remaining allegations in paragraph 747.

748. 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.

ANSWER:

Defendant admits that it will manufacture AVT02 in Iceland and that AVT02 will be used, sold, offered for sale, and/or imported in the U.S. after the FDA approves the AVT02 BLA. Defendant denies the remaining allegations in paragraph 748.

749. 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.

ANSWER:

Denied.

750. 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.

ANSWER:

Defendant admits that its subsidiary Alvotech USA provided AbbVie Inc. with information relating to the manufacture, indications, dosage, and methods of use of AVT02 pursuant to 42 U.S.C. § 262(*l*)(2)(A). Defendant denies the remaining allegations in paragraph 750.

751. 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.

ANSWER:

Denied.

752. 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.

ANSWER:

Denied.

753. 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.

ANSWER:

Denied.

754. 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.

ANSWER:

Admitted.

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

ANSWER:

Denied.

756. 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.

ANSWER:

Defendant admits that Plaintiffs purport to seek an injunction pursuant to 35 U.S.C. § 271(e)(4)(B). Defendant denies Plaintiffs are entitled to any relief pursuant to their claims including injunctive relief, in the least because one who seeks equity must do equity. *See, e.g.*, *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945) ("[H]e who comes into equity must come with clean hands.").

ANSWER TO COUNT XL

(Alleged Declaratory Judgment of Infringement Of U.S. Patent No. 8,999,337)

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

ANSWER:

No response is required to the incorporation by reference of the preceding paragraphs. To the extent a response is required, Defendant re-alleges and incorporates by reference each of its foregoing responses as if fully set forth herein.

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

ANSWER:

Paragraph 758 states a legal conclusion for which no response is required. To the extent a response is required, Defendant admits, on information and belief, that Plaintiffs purport to assert

claims under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Defendant denies Plaintiffs are entitled to any relief pursuant to their claims.

759. 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.

ANSWER:

Defendant admits that on September 4, 2020, its subsidiary Alvotech USA applied to the FDA for licensure of AVT02, a biosimilar to Humira® (adalimumab). Defendant admits that the reference product for AVT02 is Humira® (adalimumab), BLA No. 125057. On information and belief, Defendant admits that BLA No. 125057 is held by Plaintiff AbbVie Inc. Defendant denies the remaining allegations in paragraph 759.

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

ANSWER:

Defendant admits that on November 5, 2020, the FDA notified Defendant's subsidiary Alvotech USA that Alvotech's application was sufficiently complete to permit substantive review by the FDA. Defendant denies the remaining allegations in paragraph 760.

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

ANSWER:

Defendant admits that on November 5, 2020, Defendant's subsidiary Alvotech USA provided AbbVie Inc. with the AVT02 BLA application and voluminous other information required under 42 U.S.C. § 262(*l*)(2)(A). Defendant denies the remaining allegations in paragraph 761.

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

ANSWER:

Defendant admits that on May 11, 2021, Defendant's subsidiary Alvotech USA provided AbbVie Inc. with its notice of commercial marketing for AVT02. Defendant denies the remaining allegations in paragraph 762.

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

ANSWER:

Defendant admits that it will manufacture AVT02 in Iceland and that AVT02 will be used, sold, offered for sale, and/or imported in the U.S. after the FDA approves the AVT02 BLA. Defendant denies the remaining allegations in paragraph 763.

764. 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.

ANSWER:

Paragraph 764 states legal conclusions for which no response is required. To the extent a response is required, Defendant admits only that a substantial controversy exists between Alvotech hf. and AbbVie, in which the parties have adverse legal interests of sufficient immediacy and reality to warrant the issue of a declaratory judgment from this Court. Otherwise, denied.

765. 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.

ANSWER:

Defendant admits that its subsidiary Alvotech USA provided AbbVie Inc. with information relating to the indications, dosage, and methods of use of AVT02 pursuant to 42 U.S.C. § 262(*l*)(2)(A). Defendant denies the remaining allegations in paragraph 765.

766. 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.

ANSWER:

Denied.

767. 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.

ANSWER:

Denied.

768. 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.

ANSWER:

Denied.

769. 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.

ANSWER:

Admitted.

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

ANSWER:

Denied.

771. 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.

ANSWER:

Defendant admits that Plaintiffs purport to seek a declaratory judgment. Defendant denies Plaintiffs are entitled to any relief pursuant to their claims including a declaratory judgment. Defendant denies any remaining allegations in paragraph 771.

772. 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.

ANSWER:

Defendant admits that Plaintiffs purport to seek an injunction. Defendant denies Plaintiffs are entitled to any relief pursuant to their claims including injunctive relief, in the least because one who seeks equity must do equity. *See, e.g.*, *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945) ("[H]e who comes into equity must come with clean hands.").

ANSWER TO COUNTS XLI-XLIV

Paragraphs 773-828 relate only to stayed patents. (*See* 21-2258, D.I. 63.) Because none of these patents are one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed by the parties and/or as ordered by the Court."

ANSWER TO COUNT XLV

(Alleged Infringement of U.S. Patent No. 9,067,992)

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

ANSWER:

No response is required to the incorporation by reference of the preceding paragraphs. To the extent a response is required, Defendant re-alleges and incorporates by reference each of its foregoing responses as if fully set forth herein.

830. 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.

ANSWER:

Defendant admits that on September 4, 2020, its subsidiary Alvotech USA applied to the FDA for licensure of AVT02, a biosimilar to Humira® (adalimumab). Defendant admits that the reference product for AVT02 is Humira® (adalimumab), BLA No. 125057. On information and belief, Defendant admits that BLA No. 125057 is held by Plaintiff AbbVie Inc. Defendant denies the remaining allegations in paragraph 830.

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

ANSWER:

Defendant admits that on November 5, 2020, the FDA notified Defendant's subsidiary Alvotech USA that Alvotech's application was sufficiently complete to permit substantive review by the FDA. Defendant denies the remaining allegations in paragraph 831.

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

ANSWER:

Defendant admits that on November 5, 2020, Defendant's subsidiary Alvotech USA provided AbbVie Inc. with the AVT02 BLA application and voluminous other information required under 42 U.S.C. § 262(*l*)(2)(A). Defendant denies the remaining allegations in paragraph 832.

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

ANSWER:

Defendant admits that on May 11, 2021, Defendant's subsidiary Alvotech USA provided AbbVie Inc. with its notice of commercial marketing for AVT02. Defendant denies the remaining allegations in paragraph 833.

834. 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.

ANSWER:

Defendant admits that it will manufacture AVT02 in Iceland and that AVT02 will be used, sold, offered for sale, and/or imported in the U.S. after the FDA approves the AVT02 BLA. Defendant denies the remaining allegations in paragraph 834.

835. 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.

ANSWER:

Denied.

836. 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.

ANSWER:

Defendant admits that its subsidiary Alvotech USA provided AbbVie Inc. with information relating to the manufacture, indications, dosage, and methods of use of AVT02 pursuant to 42 U.S.C. § 262(*l*)(2)(A). Defendant denies the remaining allegations in paragraph 836.

837. 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.

ANSWER:

Denied.

838. 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.

ANSWER:

Denied.

839. 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.

ANSWER:

Denied.

840. 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.

ANSWER:

Admitted.

841. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '992 patent.

ANSWER:

Denied.

842. 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.

ANSWER:

Defendant admits that Plaintiffs purport to seek an injunction pursuant to 35 U.S.C. § 271(e)(4)(B). Defendant denies Plaintiffs are entitled to any relief pursuant to their claims including injunctive relief, in the least because one who seeks equity must do equity. *See, e.g.*, *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945) ("[H]e who comes into equity must come with clean hands.").

ANSWER TO COUNT XLVI

(Alleged Declaratory Judgment of Infringement of U.S. Patent No. 9,067,992)

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

ANSWER:

No response is required to the incorporation by reference of the preceding paragraphs. To the extent a response is required, Defendant re-alleges and incorporates by reference each of its foregoing responses as if fully set forth herein.

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

ANSWER:

Paragraph 844 states a legal conclusion for which no response is required. To the extent a response is required, Defendant admits, on information and belief, that Plaintiffs purport to assert

claims under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Defendant denies Plaintiffs are entitled to any relief pursuant to their claims.

845. 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.

ANSWER:

Defendant admits that on September 4, 2020, its subsidiary Alvotech USA applied to the FDA for licensure of AVT02, a biosimilar to Humira® (adalimumab). Defendant admits that the reference product for AVT02 is Humira® (adalimumab), BLA No. 125057. On information and belief, Defendant admits that BLA No. 125057 is held by Plaintiff AbbVie Inc. Defendant denies the remaining allegations in paragraph 845.

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

ANSWER:

Defendant admits that on November 5, 2020, the FDA notified Defendant's subsidiary Alvotech USA that Alvotech's application was sufficiently complete to permit substantive review by the FDA. Defendant denies the remaining allegations in paragraph 846.

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

ANSWER:

Defendant admits that on November 5, 2020, Defendant's subsidiary Alvotech USA provided AbbVie Inc. with the AVT02 BLA application and voluminous other information required under 42 U.S.C. § 262(*l*)(2)(A). Defendant denies the remaining allegations in paragraph 847.

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

ANSWER:

Defendant admits that on May 11, 2021, Defendant's subsidiary Alvotech USA provided AbbVie Inc. with its notice of commercial marketing for AVT02. Defendant denies the remaining allegations in paragraph 848.

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

ANSWER:

Defendant admits that it will manufacture AVT02 in Iceland and that AVT02 will be used, sold, offered for sale, and/or imported in the U.S. after the FDA approves the AVT02 BLA. Defendant denies the remaining allegations in paragraph 849.

850. 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.

ANSWER:

Paragraph 850 states legal conclusions for which no response is required. To the extent a response is required, Defendant admits only that a substantial controversy exists between Alvotech hf. and AbbVie, in which the parties have adverse legal interests of sufficient immediacy and reality to warrant the issue of a declaratory judgment from this Court. Otherwise, denied.

851. 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.

ANSWER:

Defendant admits that its subsidiary Alvotech USA provided AbbVie Inc. with information relating to the indications, dosage, and methods of use of AVT02 pursuant to 42 U.S.C. § 262(*l*)(2)(A). Defendant denies the remaining allegations in paragraph 851.

852. 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.

ANSWER:

Denied.

853. 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.

ANSWER:

Denied.

854. 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.

ANSWER:

Denied.

855. 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.

ANSWER:

Admitted.

856. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '992 patent.

ANSWER:

Denied.

857. 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.

ANSWER:

Defendant admits that Plaintiffs purport to seek a declaratory judgment. Defendant denies Plaintiffs are entitled to any relief pursuant to their claims including a declaratory judgment. Defendant denies any remaining allegations in paragraph 857.

858. 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.

ANSWER:

Defendant admits that Plaintiffs purport to seek an injunction. Defendant denies Plaintiffs are entitled to any relief pursuant to their claims including injunctive relief, in the least because one who seeks equity must do equity. *See, e.g.*, *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945) ("[H]e who comes into equity must come with clean hands.").

ANSWER TO COUNTS XLVII-LXVI

Paragraphs 859-1132 relate only to stayed patents. (*See* 21-2258, D.I. 63.) Because none of these patents are one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed by the parties and/or as ordered by the Court."

ANSWER TO COUNT LXVII

(Alleged Infringement of U.S. Patent No. 9,187,559)

1133. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

ANSWER:

No response is required to the incorporation by reference of the preceding paragraphs. To the extent a response is required, Defendant re-alleges and incorporates by reference each of its foregoing responses as if fully set forth herein.

1134. 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.

ANSWER:

Defendant admits that on September 4, 2020, its subsidiary Alvotech USA applied to the FDA for licensure of AVT02, a biosimilar to Humira® (adalimumab). Defendant admits that the reference product for AVT02 is Humira® (adalimumab), BLA No. 125057. On information and belief, Defendant admits that BLA No. 125057 is held by Plaintiff AbbVie Inc. Defendant denies the remaining allegations in paragraph 1134.

1135. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

ANSWER:

Defendant admits that on November 5, 2020, the FDA notified Defendant's subsidiary Alvotech USA that Alvotech's application was sufficiently complete to permit substantive review by the FDA. Defendant denies the remaining allegations in paragraph 1135.

1136. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

ANSWER:

Defendant admits that on November 5, 2020, Defendant's subsidiary Alvotech USA provided AbbVie Inc. with the AVT02 BLA application and voluminous other information required under 42 U.S.C. § 262(*l*)(2)(A). Defendant denies the remaining allegations in paragraph 1136.

1137. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A).

ANSWER:

Defendant admits that on May 11, 2021, Defendant's subsidiary Alvotech USA provided AbbVie Inc. with its notice of commercial marketing for AVT02. Defendant denies the remaining allegations in paragraph 1137.

1138. 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.

ANSWER:

Defendant admits that it will manufacture AVT02 in Iceland and that AVT02 will be used, sold, offered for sale, and/or imported in the U.S. after the FDA approves the AVT02 BLA. Defendant denies the remaining allegations in paragraph 1138.

1139. 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.

ANSWER:

Denied.

1140. 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.

ANSWER:

Defendant admits that its subsidiary Alvotech USA provided AbbVie Inc. with information relating to the manufacture, indications, dosage, and methods of use of AVT02 pursuant to 42 U.S.C. § 262(*l*)(2)(A). Defendant denies the remaining allegations in paragraph 1140.

1141. 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.

ANSWER:

Denied.

1142. 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.

ANSWER:

Denied.

1143. 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.

ANSWER:

Denied.

1144. 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.

ANSWER:

Admitted.

1145. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '559 patent.

ANSWER:

Denied.

1146. 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.

ANSWER:

Defendant admits that Plaintiffs purport to seek an injunction pursuant to 35 U.S.C. § 271(e)(4)(B). Defendant denies Plaintiffs are entitled to any relief pursuant to their claims including injunctive relief, in the least because one who seeks equity must do equity. *See, e.g.*, *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945) ("[H]e who comes into equity must come with clean hands.").

ANSWER TO COUNT LXVIII

(Alleged Declaratory Judgment of Infringement of U.S. Patent No. 9,187,559)

1147. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

ANSWER:

No response is required to the incorporation by reference of the preceding paragraphs. To the extent a response is required, Defendant re-alleges and incorporates by reference each of its foregoing responses as if fully set forth herein.

1148. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER:

Paragraph 1148 states a legal conclusion for which no response is required. To the extent a response is required, Defendant admits, on information and belief, that Plaintiffs purport to assert

claims under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Defendant denies Plaintiffs are entitled to any relief pursuant to their claims.

1149. 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.

ANSWER:

Defendant admits that on September 4, 2020, its subsidiary Alvotech USA applied to the FDA for licensure of AVT02, a biosimilar to Humira® (adalimumab). Defendant admits that the reference product for AVT02 is Humira® (adalimumab), BLA No. 125057. On information and belief, Defendant admits that BLA No. 125057 is held by Plaintiff AbbVie Inc. Defendant denies the remaining allegations in paragraph 1149.

1150. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

ANSWER:

Defendant admits that on November 5, 2020, the FDA notified Defendant's subsidiary Alvotech USA that Alvotech's application was sufficiently complete to permit substantive review by the FDA. Defendant denies the remaining allegations in paragraph 1150.

1151. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

ANSWER:

Defendant admits that on November 5, 2020, Defendant's subsidiary Alvotech USA provided AbbVie Inc. with the AVT02 BLA application and voluminous other information required under 42 U.S.C. § 262(*l*)(2)(A). Defendant denies the remaining allegations in paragraph 1151.

1152. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A).

ANSWER:

Defendant admits that on May 11, 2021, Defendant's subsidiary Alvotech USA provided AbbVie Inc. with its notice of commercial marketing for AVT02. Defendant denies the remaining allegations in paragraph 1152.

1153. 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.

ANSWER:

Defendant admits that it will manufacture AVT02 in Iceland and that AVT02 will be used, sold, offered for sale, and/or imported in the U.S. after the FDA approves the AVT02 BLA. Defendant denies the remaining allegations in paragraph 1153.

1154. 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.

ANSWER:

Paragraph 1154 states legal conclusions for which no response is required. To the extent a response is required, Defendant admits only that a substantial controversy exists between Alvotech hf. and AbbVie, in which the parties have adverse legal interests of sufficient immediacy and reality to warrant the issue of a declaratory judgment from this Court. Otherwise, denied.

1155. 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.

ANSWER:

Defendant admits that its subsidiary Alvotech USA provided AbbVie Inc. with information relating to the indications, dosage, and methods of use of AVT02 pursuant to 42 U.S.C. § 262(*l*)(2)(A). Defendant denies the remaining allegations in paragraph 1155.

1156. 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.

ANSWER:

Denied.

1157. 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.

ANSWER:

Denied.

1158. 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.

ANSWER:

Denied.

1159. 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.

ANSWER:

Admitted.

1160. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '559 patent.

ANSWER:

Denied.

1161. 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.

ANSWER:

Defendant admits that Plaintiffs purport to seek a declaratory judgment. Defendant denies Plaintiffs are entitled to any relief pursuant to their claims including a declaratory judgment. Defendant denies any remaining allegations in paragraph 1161.

1162. 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.

ANSWER:

Defendant admits that Plaintiffs purport to seek an injunction. Defendant denies Plaintiffs are entitled to any relief pursuant to their claims including injunctive relief, in the least because one who seeks equity must do equity. *See, e.g.*, *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945) ("[H]e who comes into equity must come with clean hands.").

ANSWER TO COUNTS LXIX-XCVIII

Paragraphs 1163-1566 relate only to stayed patents. (*See* 21-2258, D.I. 63.) Because none of these patents are one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed by the parties and/or as ordered by the Court."

ANSWER TO COUNT XCIX

(Alleged Infringement of U.S. Patent No. 9,512,216

1567. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

ANSWER:

No response is required to the incorporation by reference of the preceding paragraphs. To the extent a response is required, Defendant re-alleges and incorporates by reference each of its foregoing responses as if fully set forth herein.

1568. 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.

ANSWER:

Defendant admits that on September 4, 2020, its subsidiary Alvotech USA applied to the FDA for licensure of AVT02, a biosimilar to Humira® (adalimumab). Defendant admits that the reference product for AVT02 is Humira® (adalimumab), BLA No. 125057. On information and belief, Defendant admits that BLA No. 125057 is held by Plaintiff AbbVie Inc. Defendant denies the remaining allegations in paragraph 1568.

1569. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

ANSWER:

Defendant admits that on November 5, 2020, the FDA notified Defendant's subsidiary Alvotech USA that Alvotech's application was sufficiently complete to permit substantive review by the FDA. Defendant denies the remaining allegations in paragraph 1569.

1570. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

ANSWER:

Defendant admits that on November 5, 2020, Defendant's subsidiary Alvotech USA provided AbbVie Inc. with the AVT02 BLA application and voluminous other information required under 42 U.S.C. § 262(*l*)(2)(A). Defendant denies the remaining allegations in paragraph 1570.

1571. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A).

ANSWER:

Defendant admits that on May 11, 2021, Defendant's subsidiary Alvotech USA provided AbbVie Inc. with its notice of commercial marketing for AVT02. Defendant denies the remaining allegations in paragraph 1571.

1572. 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.

ANSWER:

Defendant admits that it will manufacture AVT02 in Iceland and that AVT02 will be used, sold, offered for sale, and/or imported in the U.S. after the FDA approves the AVT02 BLA. Defendant denies the remaining allegations in paragraph 1572.

1573. 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.

ANSWER:

Denied.

1574. 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.

ANSWER:

Defendant admits that its subsidiary Alvotech USA provided AbbVie Inc. with information

relating to the manufacture, indications, dosage, and methods of use of AVT02 pursuant to 42 U.S.C. § 262(*l*)(2)(A). Defendant denies the remaining allegations in paragraph 197.

1575. 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.

ANSWER:

Denied.

1576. 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.

ANSWER:

Denied.

1577. 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.

ANSWER:

Denied.

1578. 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.

ANSWER:

Admitted.

1579. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '216 patent.

ANSWER:

Denied.

1580. 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.

ANSWER:

Defendant admits that Plaintiffs purport to seek an injunction pursuant to 35 U.S.C. § 271(e)(4)(B). Defendant denies Plaintiffs are entitled to any relief pursuant to their claims including injunctive relief, in the least because one who seeks equity must do equity. *See, e.g.*, *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945) ("[H]e who comes into equity must come with clean hands.").

ANSWER TO COUNT C

(Alleged Declaratory Judgment of Infringement of U.S. Patent No. 9,512,216)

1581. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

ANSWER:

No response is required to the incorporation by reference of the preceding paragraphs. To the extent a response is required, Defendant re-alleges and incorporates by reference each of its foregoing responses as if fully set forth herein.

1582. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER:

Paragraph 1582 states a legal conclusion for which no response is required. To the extent a response is required, Defendant admits, on information and belief, that Plaintiffs purport to assert claims under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Defendant denies Plaintiffs are entitled to any relief pursuant to their claims.

1583. 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.

ANSWER:

Defendant admits that on September 4, 2020, its subsidiary Alvotech USA applied to the FDA for licensure of AVT02, a biosimilar to Humira® (adalimumab). Defendant admits that the reference product for AVT02 is Humira® (adalimumab), BLA No. 125057. On information and belief, Defendant admits that BLA No. 125057 is held by Plaintiff AbbVie Inc. Defendant denies the remaining allegations in paragraph 1583.

1584. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

ANSWER:

Defendant admits that on November 5, 2020, the FDA notified Defendant's subsidiary Alvotech USA that Alvotech's application was sufficiently complete to permit substantive review by the FDA. Defendant denies the remaining allegations in paragraph 1584.

1585. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

ANSWER:

Defendant admits that on November 5, 2020, Defendant's subsidiary Alvotech USA provided AbbVie Inc. with the AVT02 BLA application and voluminous other information required under 42 U.S.C. § 262(*l*)(2)(A). Defendant denies the remaining allegations in paragraph 1585.

1586. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A).

ANSWER:

Defendant admits that on May 11, 2021, Defendant's subsidiary Alvotech USA provided AbbVie Inc. with its notice of commercial marketing for AVT02. Defendant denies the remaining allegations in paragraph 1586.

1587. 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.

ANSWER:

Defendant admits that it will manufacture AVT02 in Iceland and that AVT02 will be used, sold, offered for sale, and/or imported in the U.S. after the FDA approves the AVT02 BLA. Defendant denies the remaining allegations in paragraph 1587.

1588. 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.

ANSWER:

Paragraph 1588 states legal conclusions for which no response is required. To the extent a response is required, Defendant admits only that a substantial controversy exists between Alvotech hf. and AbbVie, in which the parties have adverse legal interests of sufficient immediacy and reality to warrant the issue of a declaratory judgment from this Court. Otherwise, denied.

1589. 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.

ANSWER:

Defendant admits that its subsidiary Alvotech USA provided AbbVie Inc. with information relating to the indications, dosage, and methods of use of AVT02 pursuant to 42 U.S.C. § 262(*l*)(2)(A). Defendant denies the remaining allegations in paragraph 1589.

1590. 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.

ANSWER:

Denied.

1591. 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.

ANSWER:

Denied.

1592. 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.

ANSWER:

Denied.

1593. 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.

ANSWER:

Admitted.

1594. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '216 patent.

ANSWER:

Denied.

1595. 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.

ANSWER:

Defendant admits that Plaintiffs purport to seek a declaratory judgment. Defendant denies

Plaintiffs are entitled to any relief pursuant to their claims including a declaratory judgment. Defendant denies any remaining allegations in paragraph 1595.

1596. 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.

ANSWER:

Defendant admits that Plaintiffs purport to seek an injunction. Defendant denies Plaintiffs are entitled to any relief pursuant to their claims including injunctive relief, in the least because one who seeks equity must do equity. *See, e.g.*, *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945) ("[H]e who comes into equity must come with clean hands.").

ANSWER TO COUNTS CI-CXVI

Paragraphs 1597-1826 relate only to stayed patents. (*See* 21-2258, D.I. 63.) Because none of these patents are one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed by the parties and/or as ordered by the Court."

ANSWER TO COUNT CXVII

(Alleged Infringement of U.S. Patent No. 11,083,792)

1827. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

ANSWER:

No response is required to the incorporation by reference of the preceding paragraphs. To the extent a response is required, Defendant re-alleges and incorporates by reference each of its foregoing responses as if fully set forth herein.

1828. 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.

ANSWER:

Defendant admits that on September 4, 2020, its subsidiary Alvotech USA applied to the FDA for licensure of AVT02, a biosimilar to Humira® (adalimumab). Defendant admits that the reference product for AVT02 is Humira® (adalimumab), BLA No. 125057. On information and belief, Defendant admits that BLA No. 125057 is held by Plaintiff AbbVie Inc. Defendant denies the remaining allegations in paragraph 1828.

1829. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

ANSWER:

Defendant admits that on November 5, 2020, the FDA notified Defendant's subsidiary Alvotech USA that Alvotech's application was sufficiently complete to permit substantive review by the FDA. Defendant denies the remaining allegations in paragraph 1829.

1830. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

ANSWER:

Defendant admits that on November 5, 2020, Defendant's subsidiary Alvotech USA provided AbbVie Inc. with the AVT02 BLA application and voluminous other information required under 42 U.S.C. § 262(*l*)(2)(A). Defendant denies the remaining allegations in paragraph 1830.

1831. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A).

ANSWER:

Defendant admits that on May 11, 2021, Defendant's subsidiary Alvotech USA provided AbbVie Inc. with its notice of commercial marketing for AVT02. Defendant denies the remaining

allegations in paragraph 1831.

1832. 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.

ANSWER:

Defendant admits that it will manufacture AVT02 in Iceland and that AVT02 will be used, sold, offered for sale, and/or imported in the U.S. after the FDA approves the AVT02 BLA. Defendant denies the remaining allegations in paragraph 1832.

1833. 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.

ANSWER:

Denied.

1834. 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.

ANSWER:

Defendant admits that its subsidiary Alvotech USA provided AbbVie Inc. with information relating to the manufacture, indications, dosage, and methods of use of AVT02 pursuant to 42 U.S.C. § 262(*l*)(2)(A). Defendant denies the remaining allegations in paragraph 1834.

1835. 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.

ANSWER:

Denied.

1836. 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.

ANSWER:

Denied.

1837. 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.

ANSWER:

Admitted.

1838. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '792 patent.

ANSWER:

Denied.

1839. 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.

ANSWER:

Defendant admits that Plaintiffs purport to seek an injunction pursuant to 35 U.S.C. § 271(e)(4)(B). Defendant denies Plaintiffs are entitled to any relief pursuant to their claims including injunctive relief, in the least because one who seeks equity must do equity. *See, e.g.*, *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945) ("[H]e who comes into equity must come with clean hands.").

ANSWER TO COUNT CXVIII

(Alleged Declaratory Judgment of Infringement of U.S. Patent No. 11,083,792)

1840. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

ANSWER:

No response is required to the incorporation by reference of the preceding paragraphs. To the extent a response is required, Defendant re-alleges and incorporates by reference each of its foregoing responses as if fully set forth herein.

1841. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER:

Paragraph 1841 states a legal conclusion for which no response is required. To the extent a response is required, Defendant admits, on information and belief, that Plaintiffs purport to assert claims under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Defendant denies Plaintiffs are entitled to any relief pursuant to their claims.

1842. 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.

ANSWER:

Defendant admits that on September 4, 2020, its subsidiary Alvotech USA applied to the FDA for licensure of AVT02, a biosimilar to Humira® (adalimumab). Defendant admits that the reference product for AVT02 is Humira® (adalimumab), BLA No. 125057. On information and belief, Defendant admits that BLA No. 125057 is held by Plaintiff AbbVie Inc. Defendant denies the remaining allegations in paragraph 1842.

1843. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

ANSWER:

Defendant admits that on November 5, 2020, the FDA notified Defendant's subsidiary Alvotech USA that Alvotech's application was sufficiently complete to permit substantive review by the FDA. Defendant denies the remaining allegations in paragraph 1843.

1844. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

ANSWER:

Defendant admits that on November 5, 2020, Defendant's subsidiary Alvotech USA provided AbbVie Inc. with the AVT02 BLA application and voluminous other information required under 42 U.S.C. § 262(*l*)(2)(A). Defendant denies the remaining allegations in paragraph 1844.

1845. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A).

ANSWER:

Defendant admits that on May 11, 2021, Defendant's subsidiary Alvotech USA provided AbbVie Inc. with its notice of commercial marketing for AVT02. Defendant denies the remaining allegations in paragraph 1845.

1846. 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.

ANSWER:

Defendant admits that it will manufacture AVT02 in Iceland and that AVT02 will be used, sold, offered for sale, and/or imported in the U.S. after the FDA approves the AVT02 BLA. Defendant denies the remaining allegations in paragraph 1846.

1847. 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.

ANSWER:

Paragraph 1847 states legal conclusions for which no response is required. To the extent a response is required, Defendant admits only that a substantial controversy exists between Alvotech hf. and AbbVie, in which the parties have adverse legal interests of sufficient immediacy and reality to warrant the issue of a declaratory judgment from this Court. Otherwise, denied.

1848. 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 claimby- claim infringement contentions for claims 1-4, 7, and 13-17 of the '792 patent.

ANSWER:

Defendant admits that its subsidiary Alvotech USA provided AbbVie Inc. with information relating to the indications, dosage, and methods of use of AVT02 pursuant to 42 U.S.C. § 262(*l*)(2)(A). Defendant denies the remaining allegations in paragraph 1848.

1849. 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.

ANSWER:

Denied.

1850. 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.

ANSWER:

Denied.

1851. 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.

ANSWER:

Admitted.

1852. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '792 patent.

ANSWER:

Denied.

1853. 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.

ANSWER:

Defendant admits that Plaintiffs purport to seek a declaratory judgment. Defendant denies Plaintiffs are entitled to any relief pursuant to their claims including a declaratory judgment. Defendant denies any remaining allegations in paragraph 1853.

1854. 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.

ANSWER:

Defendant admits that Plaintiffs purport to seek an injunction. Defendant denies Plaintiffs are entitled to any relief pursuant to their claims including injunctive relief, in the least because one who seeks equity must do equity. *See, e.g.*, *Precision Instrument Mfg. Co. v. Auto. Maint.*

Mach. Co., 324 U.S. 806, 814 (1945) ("[H]e who comes into equity must come with clean hands.").

ANSWER TO COUNT CXIX

(Alleged Infringement of U.S. Patent No. 11,167,030)

1855. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

ANSWER:

No response is required to the incorporation by reference of the preceding paragraphs. To the extent a response is required, Defendant re-alleges and incorporates by reference each of its foregoing responses as if fully set forth herein.

1856. 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.

ANSWER:

Defendant admits that on September 4, 2020, its subsidiary Alvotech USA applied to the FDA for licensure of AVT02, a biosimilar to Humira® (adalimumab). Defendant admits that the reference product for AVT02 is Humira® (adalimumab), BLA No. 125057. On information and belief, Defendant admits that BLA No. 125057 is held by Plaintiff AbbVie Inc. Defendant denies the remaining allegations in paragraph 1856.

1857. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

ANSWER:

Defendant admits that on November 5, 2020, the FDA notified Defendant's subsidiary Alvotech USA that Alvotech's application was sufficiently complete to permit substantive review by the FDA. Defendant denies the remaining allegations in paragraph 192.

1858. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

ANSWER:

Defendant admits that on November 5, 2020, Defendant's subsidiary Alvotech USA provided AbbVie Inc. with the AVT02 BLA application and voluminous other information required under 42 U.S.C. § 262(*l*)(2)(A). Defendant denies the remaining allegations in paragraph 1858.

1859. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A).

ANSWER:

Defendant admits that on May 11, 2021, Defendant's subsidiary Alvotech USA provided AbbVie Inc. with its notice of commercial marketing for AVT02. Defendant denies the remaining allegations in paragraph 1859.

1860. 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.

ANSWER:

Defendant admits that it will manufacture AVT02 in Iceland and that AVT02 will be used, sold, offered for sale, and/or imported in the U.S. after the FDA approves the AVT02 BLA. Defendant denies the remaining allegations in paragraph 1860.

1861. 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.

ANSWER:

Denied.

1862. 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.

ANSWER:

Defendant admits that its subsidiary Alvotech USA provided AbbVie Inc. with information relating to the manufacture, indications, dosage, and methods of use of AVT02 pursuant to 42 U.S.C. § 262(*l*)(2)(A). Defendant denies the remaining allegations in paragraph 1862.

1863. 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.

ANSWER:

Denied.

1864. 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.

ANSWER:

Denied.

1865. 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.

ANSWER:

Admitted.

1866. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '030 patent.

ANSWER:

Denied.

1867. 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.

ANSWER:

Defendant admits that Plaintiffs purport to seek an injunction pursuant to 35 U.S.C. § 271(e)(4)(B). Defendant denies Plaintiffs are entitled to any relief pursuant to their claims including injunctive relief, in the least because one who seeks equity must do equity. *See, e.g.*, *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945) ("[H]e who comes into equity must come with clean hands.").

ANSWER TO COUNT CXX

(Alleged Declaratory Judgment of Infringement of U.S. Patent No. 11,167,030)

1868. AbbVie incorporates by reference each of the preceding paragraphs as if fully set forth herein.

ANSWER:

No response is required to the incorporation by reference of the preceding paragraphs. To the extent a response is required, Defendant re-alleges and incorporates by reference each of its foregoing responses as if fully set forth herein.

1869. AbbVie's claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER:

Paragraph 1869 states a legal conclusion for which no response is required. To the extent a response is required, Defendant admits, on information and belief, that Plaintiffs purport to assert claims under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Defendant denies Plaintiffs are entitled to any relief pursuant to their claims.

1870. 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.

ANSWER:

Defendant admits that on September 4, 2020, its subsidiary Alvotech USA applied to the FDA for licensure of AVT02, a biosimilar to Humira® (adalimumab). Defendant admits that the reference product for AVT02 is Humira® (adalimumab), BLA No. 125057. On information and belief, Defendant admits that BLA No. 125057 is held by Plaintiff AbbVie Inc. Defendant denies the remaining allegations in paragraph 1870.

1871. Alvotech represents that the FDA accepted Alvotech's aBLA for the Alvotech aBLA Product for review on or before November 5, 2020.

ANSWER:

Defendant admits that on November 5, 2020, the FDA notified Defendant's subsidiary Alvotech USA that Alvotech's application was sufficiently complete to permit substantive review by the FDA. Defendant denies the remaining allegations in paragraph 1871.

1872. On November 5, 2020, Alvotech provided AbbVie with a copy of its aBLA.

ANSWER:

Defendant admits that on November 5, 2020, Defendant's subsidiary Alvotech USA provided AbbVie Inc. with the AVT02 BLA application and voluminous other information required under 42 U.S.C. § 262(*l*)(2)(A). Defendant denies the remaining allegations in paragraph 1872.

1873. On May 11, 2021, Alvotech provided AbbVie a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A).

ANSWER:

Defendant admits that on May 11, 2021, Defendant's subsidiary Alvotech USA provided AbbVie Inc. with its notice of commercial marketing for AVT02. Defendant denies the remaining

allegations in paragraph 1873.

1874. 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.

ANSWER:

Defendant admits that it will manufacture AVT02 in Iceland and that AVT02 will be used, sold, offered for sale, and/or imported in the U.S. after the FDA approves the AVT02 BLA. Defendant denies the remaining allegations in paragraph 1874.

1875. 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.

ANSWER:

Paragraph 1875 states legal conclusions for which no response is required. To the extent a response is required, Defendant admits only that a substantial controversy exists between Alvotech hf. and AbbVie, in which the parties have adverse legal interests of sufficient immediacy and reality to warrant the issue of a declaratory judgment from this Court. Otherwise, denied.

1876. 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.

ANSWER:

Defendant admits that its subsidiary Alvotech USA provided AbbVie Inc. with information

relating to the indications, dosage, and methods of use of AVT02 pursuant to 42 U.S.C. § 262(*l*)(2)(A). Defendant denies the remaining allegations in paragraph 1876.

1877. 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.

ANSWER:

Denied.

1878. 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.

ANSWER:

Denied.

1879. 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.

ANSWER:

Admitted.

1880. AbbVie will suffer irreparable injury for which damages are an inadequate remedy unless Alvotech is enjoined from infringing the claims of the '030 patent.

ANSWER:

Denied.

1881. 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.

ANSWER:

Defendant admits that Plaintiffs purport to seek a declaratory judgment. Defendant denies Plaintiffs are entitled to any relief pursuant to their claims including a declaratory judgment. Defendant denies any remaining allegations in paragraph 1881.

1882. 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.

ANSWER:

Defendant admits that Plaintiffs purport to seek an injunction. Defendant denies Plaintiffs are entitled to any relief pursuant to their claims including injunctive relief, in the least because one who seeks equity must do equity. *See, e.g.*, *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945) ("[H]e who comes into equity must come with clean hands.").

ANSWER TO COUNTS CXXI-CXXII

Paragraphs 1883-1909 relate only to stayed patents. (*See* 21-2258, D.I. 63.) Because none of these patents are one of the Ten Patents, no response is required from Defendant as to these allegations at this time. At such time as the stay is lifted, Defendant will amend its answer as agreed by the parties and/or as ordered by the Court."

ANSWER TO COUNT CXXIII

(Alleged Willful Infringement)

1910. 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.

ANSWER:

Alvotech has knowledge of and is aware of the Asserted Patents, 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. Otherwise, denied.

PRAYER FOR RELIEF

Defendant denies that Plaintiffs are entitled to relief of any kind and requests that the Court deny all relief to Plaintiffs, including that requested by Plaintiffs in their Prayer for Relief.

WHEREFORE, Defendant prays that this Court grant the following relief:

A) Dismiss Plaintiffs' claims in their entirety with prejudice;

B) Enter judgment on Plaintiffs' claims in favor of Defendant and against Plaintiffs on all claims;

C) Deny Plaintiffs any and all relief on their claims, including but not limited to the relief sought in Plaintiffs' Prayer For Relief a-e inclusive;

D) Award to Defendant its costs and attorneys' fees of this action to be taxed against Plaintiffs;

E) A declaration that this case is exceptional pursuant to 35 U.S.C. § 285, and an award of attorneys' fees and costs; and

F) Award such further relief as the Court deems just and proper.

JURY TRIAL DEMAND

Defendant hereby demands a jury trial in this action for any issue so triable.

DEFENSES

Without waiver, limitation, or prejudice to the denials set forth in its Answer, and without admitting any allegation of the complaint not expressly admitted herein, Defendant hereby asserts the following affirmative defenses:

FIRST DEFENSE

(Lack of Personal Jurisdiction)

1. This Court does not have personal jurisdiction over Defendant Alvotech hf.

SECOND DEFENSE

(Failure to State a Claim)

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

THIRD DEFENSE

(Non-Infringement of the Asserted Patents)

3. Plaintiffs' claims are barred in whole or in part because Alvotech hf. has not, and does not, directly infringe, induce infringement, or contribute to infringement of any valid and enforceable claim of the Ten Patents,[5] either literally or under the doctrine of equivalents, and has not otherwise committed any acts in violation of 35 U.S.C. § 271.

FOURTH DEFENSE

(Invalidity of the Asserted Patents)

4. Plaintiffs' claims are barred in whole or in part because each asserted claim of the Ten Patents is invalid for failing to meet the requirements of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 112 and/or pursuant to common law and/or equitable doctrines.

FIFTH DEFENSE

(§ 271(e) Safe Harbor)

5. To the extent Plaintiffs claim that the manufacture and clinical use of AVT02 is an act of infringement, Defendant is exempt from liability pursuant to the safe harbor provision of 35 U.S.C. § 271(e).

SIXTH DEFENSE

(No Equitable Relief)

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

[5] As noted above, the only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) As such, Defendant's defenses asserted herein relate only to the Ten Patents set for trial on August 2022. At such time as the stay is lifted, Defendant will amend its answer as agreed by the parties and/or as ordered by the Court.

SEVENTH DEFENSE

(Unclean Hands)

7. Plaintiffs cannot obtain relief, including any injunctive relief, due to their unclean hands, including as described in Defendant's counterclaim at Count I below.

EIGHTH DEFENSE

(Prohibition of Costs)

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

NINTH DEFENSE

(Prosecution History Estoppel)

9. Plaintiffs are estopped from construing any valid claim of the Ten Patents to be infringed or to have been infringed, either literally or by application of the doctrine of equivalents, by any product made, used, imported, sold, and/or offered for sale by Alvotech hf. in view of prior art and/or because of admissions, representations, and/or statements made to the USPTO during prosecution of any application leading to the issuance of the Ten Patents or any related patent because of disclosure or language in the specification of the Ten Patents, and/or because of limitations in the claims of the Ten Patents.

TENTH DEFENSE

(Prosecution Laches)

10. Plaintiffs are barred from asserting any claim of the Ten Patents against Alvotech hf. by the equitable doctrine of prosecution laches. *See, e.g.*, *In re Bogese*, 303 F.3d 1362 (Fed. Cir. 2002).

ELEVENTH DEFENSE

(Inequitable Conduct)

11. Plaintiffs are barred from asserting the claims of the '792 patent due to Plaintiffs' inequitable conduct during prosecution of the '792 patent, including as described in Defendant's counterclaims at Count XV, below.

TWELFTH DEFENSE

(Patent Misuse)

12. Plaintiffs are barred from asserting the claims of the Ten Patents due to Plaintiffs' patent misuse, including as describing in Defendant's counterclaim at Count II, below.

THIRTEENTH DEFENSE

(No Exceptional Case)

13. Defendant's actions related to this suit do not give rise to an exceptional case finding under 35 U.S.C. § 285.

RESERVATION OF DEFENSES

Defendant reserves the right to assert any additional defenses or counterclaims, at law or equity that may exist, and that it reserves the right to seek leave to amend this Answer to add to, amend, withdraw, or modify these defenses as investigation continues and as discovery may require.

COUNTERCLAIMS

Defendant Alvotech hf., through its undersigned counsel, counterclaims and alleges against AbbVie Inc. and AbbVie Biotechnology (collectively, "AbbVie") as follows:

PARTIES

1. Counterclaim Plaintiff Alvotech hf. is a corporation organized and existing under the laws of the Republic of Iceland, with its corporate headquarters at Saemundargata 15-19, 101 Reykjavik, Iceland. Non-party Alvotech USA, Inc. ("Alvotech USA") is a corporation organized and existing under the laws of the Commonwealth of Virginia and a wholly-owned subsidiary of Alvotech hf., with its corporate headquarters and sole physical location in Arlington, Virginia.

2. On information and belief, Counterclaim Defendant 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. is the holder of BLA No. 125057 for Humira®.

3. On information and belief, Counterclaim Defendant AbbVie Biotechnology Ltd. is a corporation organized and existing under the laws of Bermuda, with a place of business at Clarendon House, 2 Church Street, Hamilton HM11, Bermuda. On information and belief, through intermediate organizations, AbbVie Inc. owns AbbVie Biotechnology Ltd.

4. AbbVie Inc. markets Humira® in the United States, and has done so continuously since at least the beginning of 2003. According to AbbVie Inc., the patents-in-suit relate to Humira®. On information and belief, AbbVie Inc. and AbbVie Biotechnology Ltd. together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the patents-in-suit.

JURISDICTION AND VENUE

5. Alvotech hf.'s counterclaims arise under the patent laws of the United States, Title 35, United States Code. This Court has subject matter jurisdiction over Alvotech hf.'s counterclaims under 28 U.S.C. §§ 1331 and 1338(a) and the Declaratory Judgment Act, 28 U.S.C.

§§ 2201 and 2202. A substantial controversy exists between Alvotech hf. and AbbVie, in which the parties have adverse legal interests of sufficient immediacy and reality to warrant the issue of a declaratory judgment from this Court.

6. This Court has personal jurisdiction over AbbVie Inc. and AbbVie Biotechnology Ltd. because, among other reasons, they have subjected themselves to the jurisdiction of this Court at least by commencing the present action for patent infringement against Alvotech hf. in this District.

7. Based solely on AbbVie's filing of the present action, venue is proper in this District under 28 U.S.C. § 1391.

ACTS GIVING RISE TO ALVOTECH HF.'S COUNTERCLAIMS

8. Alvotech hf. brings counterclaims directed to unenforceability for unclean hands, patent misuse, noninfringement and invalidity.

9. AbbVie designed a patent portfolio containing what it hoped to be an insurmountable number of patents (regardless of merit) protecting Humira®. AbbVie wields that portfolio against would-be competitors, including most recently Alvotech, with a goal of forcing capitulation and delaying competition by preventing adjudication of its uniquely large and still expanding patent portfolio and by manipulation of the patent dance and litigation procedure.

10. The first three of Alvotech hf.'s counterclaims address AbbVie's misconduct towards Alvotech hf. in seeking to bury Alvotech hf. in ruinous litigation.

11. Specifically, as detailed further below, AbbVie has no right to enforce its patents, and no claim to equitable relief in relation to Alvotech hf. because, in its longstanding effort to improperly maintain its monopoly on Humira®, it has acted inequitably towards Alvotech hf.

through (1) its improper behavior in the patent dance; (2) its misuse of Alvotech hf. confidential information; and (3) its improper assertion of 58 patents from its "IP minefield."

A. AVT02—the First Biosimilar to 100 mg/mL Humira®

12. The active ingredient in Alvotech hf.'s AVT02 product is adalimumab. Adalimumab belongs to a category of drugs known as biologics. It is a protein manufactured in living cells rather than by chemical synthesis. Adalimumab is a fully human, high-affinity, and neutralizing therapeutic antibody to human TNFα, a protein made by the human body as part of the body's immune response. Many diseases are known to be caused by high levels of TNFα and are treated with anti-TNFα biologics.

13. AbbVie's Humira® is an injectable formulation of adalimumab. The FDA first approved Humira® in 2002 as a treatment for rheumatoid arthritis, a chronic inflammatory disorder that affects the lining of the joints and is caused by high levels of TNFα. Patients with rheumatoid arthritis can suffer from painful swelling that might eventually result in bone erosion and joint deformity, as well as damage to other parts of the body. Humira® is now FDA-approved for other similarly painful and/or disruptive chronic disorders, all of which, like rheumatoid arthritis, are known to be TNFα-related disorders.

14. As first launched by AbbVie's predecessor Abbott Laboratories in 2003, Humira® was a 50 mg/ml formulation that contained, among other things, a phosphate-citrate buffer. In 2018, facing potential competition for the first time, AbbVie began marketing a 100 mg/ml "citrate-free" (as AbbVie calls it) formulation of Humira® in the U.S. In this "citrate-free" formulation, AbbVie eliminated the buffer from the 50 mg/ml formulation. AbbVie's advertising materials tout that the 100 mg/ml "citrate-free" formulation causes less pain upon injection than the 50 mg/ml formulation.

15. Counterclaim Plaintiff Alvotech hf. has developed a biosimilar to the 100 mg/ml formulation of Humira®, known as AVT02. On information and belief, if the FDA approves AVT02, it will be the first biosimilar to the citrate-free, 100 mg/ml formulation of Humira® approved in the United States. Alvotech is committed to bringing its 100 mg/ml, bufferless formulation to market upon FDA approval in order to make the lower-cost alternative available to patients as quickly as possible.

16. The Alvotech family of companies developed AVT02 through years of rigorous testing and development efforts, starting in 2013. After selecting adalimumab for development, the Alvotech companies and their contractors generated expression vectors, genetically modified CHO cells to produce adalimumab, and analyzed thousands of the resulting CHO cell minipools for expression of adalimumab before selecting a unique AVT02 CHO cell clone for adalimumab production. Over the course of several years, scientists at multiple sites in Iceland and Europe developed upstream and downstream manufacturing processes to maximize production output and obtain high quality product. These scientists tested and adjusted parameters and steps, including medium and feeds, feed timing, temperature, culturing time, chromatography resins, loading density and wash steps, and more. The scientists completed the first at-scale GMP drug substance batch of AVT02 by early 2018.

17. In addition, Alvotech's scientists made and tested multiple formulations before settling on the AVT02 formulation. Alvotech's formulation uses different excipients than AbbVie's "citrate-free" formulation.

18. After developing its 100 mg/ml formulation of adalimumab, Alvotech sponsored multiple multicenter, double-blind clinical trials to compare the efficacy, immunogenicity, safety, pharmacokinetics, and tolerability of AVT02 to Humira® in patients. To date, hundreds of patients

have enrolled in Alvotech's clinical trials of AVT02. Alvotech's clinical trials established that there is no clinically meaningful difference between AVT02 and Humira® in the safety, tolerability, and immunogenicity outcome measures. Alvotech's Phase III comparative clinical trial for AVT02 met its primary objective by demonstrating equivalent efficacy to Humira® in the measured parameters. Alvotech's clinical switching study (AVT02-GL-302) is ongoing.

19. Upon conclusion of the initial clinical trials, Alvotech prepared the voluminous documentation required by the FDA for a BLA for AVT02. Alvotech USA filed its application on September 4, 2020, the FDA accepted Alvotech USA's AVT02 BLA on November 3, 2020 and assigned number 761205 to Alvotech USA's AVT02 BLA.

B. AbbVie's Extensive Misconduct Directed at Alvotech

20. Following the submission of the BLA and Alvotech USA's required notice to AbbVie, AbbVie targeted Alvotech with acts of misconduct specific to Alvotech in order to gain a litigation advantage.

1. AbbVie's Misconduct During the Patent Dance

21. On November 5, 2020, Alvotech USA provided AbbVie Inc. with the AVT02 BLA and voluminous other information required under 42 U.S.C. § 262(*l*)(2)(A), initiating a series of statutorily-required disclosures (colloquially known as the "patent dance") between Alvotech USA and AbbVie Inc. The AVT02 BLA and other information provided by Alvotech USA to AbbVie Inc. described in detail the AVT02 drug substance and drug product, the drug delivery device for AVT02, and methods of making, purifying, and testing AVT02.

22. As part of the patent dance, on January 4, 2021, under 42 U.S.C. § 262(*l*)(3)(A), AbbVie Inc. identified 63 patents (AbbVie's "3(A) List"), including the patents-in-suit, which it alleged could reasonably be asserted against Alvotech USA if Alvotech USA were to manufacture, use, offer for sale, sell in the United States, or import into the United States AVT02 without a

license from AbbVie. Despite AVT02 being a 100 mg/ml formulation of adalimumab, AbbVie Inc. included in its 3(A) List one entire patent and several other patents with claims directed to 50 mg/ml formulations that could not reasonably be asserted against AVT02. AbbVie also failed to identify the patents on its 3(A) List that AbbVie would be prepared to license to Alvotech USA, as required by § 262(l)(3)(A); indeed, AbbVie's letter enclosing its 3(A) List was silent on this point.

23. On January 14, 2021, under 42 U.S.C. § 262(*l*)(3)(B), Alvotech USA provided AbbVie Inc. over 6000 pages of detailed statements that describe, on a claim by claim basis for each of the 63 patents, the factual and legal basis why each claim of the 63 asserted patents is invalid, unenforceable, and/or will not be infringed by the commercial marketing of AVT02 (Alvotech USA's "3(B) Statement"). Alvotech USA also cited and produced over 270 pieces of prior art, demonstrating that AbbVie's patents are invalid as anticipated and/or obvious.

24. In response, AbbVie Inc. purported to provided to Alvotech USA a statement of infringement and validity under 42 U.S.C. § 262(*l*)(3)(C) on 62 of their 63 listed patents (AbbVie Inc.'s "3(C) Statement"). In this statement, AbbVie Inc. failed to satisfy its statutory obligation under § 262(*l*)(3)(C). Specifically, on information and belief, AbbVie unilaterally chose to ignore Alvotech USA's contentions for many of the claims in the 62 patents—while expressly reserving the right to assert all claims to respond to Alvotech USA's statement concerning validity and enforceability.

25. Additionally, during the dance, AbbVie conceded that there is no infringement of four AbbVie patents: U.S. Patents Nos. 8,883,156; 8,895,009; 8,906,372; and 8,916,153. Yet despite having the AVT02 BLA, which shows that AVT02 does not infringe those claims and thus,

by AbbVie's own concession, AVT02 cannot infringe those four patents—AbbVie Inc. kept all four patents in the dance and asserted them against Alvotech hf. in the second phase litigation.

26. Notwithstanding AbbVie Inc.'s deficiencies, starting no later than March 17, 2021, Alvotech USA engaged in good faith negotiations under 42 U.S.C. § 262(*l*)(4)(A) to identify the patents on the 3(A) List that should be the subject of "the immediate patent infringement action" authorized under 42 U.S.C. § 262(*l*)(6). AbbVie did not engage in good faith negotiations.

27. After first proposing a mutual exchange, which AbbVie Inc. rejected without any counter-suggestion, Alvotech USA led off the negotiations by providing AbbVie Inc. with a list of the four patents later asserted in the first wave of litigation. Alvotech USA reasonably anticipated that AbbVie Inc. would respond with its own list of patents that should be litigated if AbbVie did not agree with Alvotech USA's list, and then the parties would continue to negotiate. Instead, on March 29, 2021, the last day possible under the statute, AbbVie Inc. provided no substantive response to Alvotech USA's proposal, instead taking the position that Alvotech USA "need[ed] to pick all [62] patents" if it wanted to bring its product to market and that "litigating only those four patents alone will not in any way 'resolve' the issues of patent infringement with respect to Alvotech's product." AbbVie Inc. thus refused to limit its asserted patents in any meaningful way during the BPCIA patent dance, contrary to the underlying purpose of the statute. Consistent with its long-held strategy of attempting to bury its competitors, AbbVie Inc. raised the specter of ruinous litigation if Alvotech USA sought to bring its biosimilar product to market. Notably, in correspondence between the parties, AbbVie Inc. stated it was unwilling to license even a single one of the 63 patents it had originally asserted in the patent dance (and many of which, if not all, it has previously licensed to others)—well after such a licensing statement was statutorily required under § 262(*l*)(3)(A).

2. AbbVie's Misusing Alvotech's Confidential Information During Prosecution of New Patents

28. Under the BPCIA, the confidential information exchanged may be used "for the sole and exclusive purpose of determining . . . whether a claim of patent infringement could reasonably be asserted." 42 U.S.C. § 262(*l*)(1). That section specifically prohibits AbbVie and its attorneys from sharing the information with anyone for whom Alvotech USA has not provided "prior written consent," including even "other outside counsel retained by the reference product sponsor."

29. Because of the highly sensitive nature of the confidential information Alvotech USA was disclosing, Alvotech USA told AbbVie that it would consent to the information being shared beyond AbbVie's litigation counsel only upon "advanced notice of the names" of those with whom it would be shared and only upon AbbVie's confirmation that those with whom it was shared would "not engage, formally or informally, in patent prosecution." Alvotech USA particularly highlighted that the information provided by Alvotech USA during the patent dance "should not be given to AbbVie's prosecution attorneys."

30. Notwithstanding the prohibition on Alvotech's confidential information being shared with AbbVie's prosecution attorneys or used in prosecution, it appears, on information and belief, that AbbVie has done exactly that. This can be seen, for example, in AbbVie's prosecution of two new applications in the same family as the '081 and '619 patents-in-suit, purportedly covering adalimumab formulations. Prior to Alvotech USA's providing AbbVie with Alvotech USA's confidential BLA, AbbVie had not meaningfully pursued prosecution of that patent family for more than 5 years—since the issuance of the '619 patent in 2015. Rather, from 2015 until the end of 2020, AbbVie routinely abandoned each successive application it filed in that family. Then, on December 29, 2020, mere weeks after Alvotech USA provided AbbVie Inc. with its confidential

BLA, AbbVie's prosecuting attorneys at Jones Day filed two new patent applications in the '081/'619 patent family, seeking expedited prosecution of both: U.S. Application Nos. 17/137,201 (the "'201 application"), which issued as U.S. Patent No. 11,167,030 (the "'030 patent") and 17/137,246, which issued as U.S. Patent No. 11,191,864. The PTO issued Notices of Allowance for both patents in August of 2021.

31. Notably, under the BPCIA and Alvotech USA's instructions to AbbVie Inc., AbbVie's patent prosecutors at Jones Day were prohibited from seeing Alvotech USA's confidential BLA. Yet the claims in the new applications are narrower than the claims prosecuted in earlier, related applications, and on information and belief, were drafted to target the confidential AVT02 formulation disclosed in that BLA.

32. The '201 application's narrow focus is noteworthy when contrasted with the breadth of prior claims in the '081/'619 family. For example, here are exemplary independent claims from the asserted '081 patent (claim 1) and '619 patent (claims 16):

> **1**. An aqueous formulation comprising an antibody, or antigen-binding fragment thereof, at a concentration of at least about 20 mg/mL and water, wherein the formulation has a conductivity of less than about 2.5 mS/cm and the antibody, or antigen-binding fragment thereof, has a molecular weight (M_w) greater than about 47 kDa.

> **16**. An aqueous pharmaceutical formulation comprising:
> (a) an anti-tumor necrosis factor alpha antibody comprising a light chain variable region (LCVR) having a CDR3 domain comprising the amino acid sequence of SEQ ID NO:3, a CDR2 domain comprising the amino acid sequence of SEQ ID NO:5, and a CDR1 domain comprising the amino acid sequence of SEQ ID NO: 7, and a heavy chain variable region (HCVR) having a CDR3 domain comprising the amino acid sequence of SEQ ID NO:4, a CDR2 domain comprising the amino acid sequence of SEQ ID NO: 6, and a CDR1 domain comprising the amino acid sequence of SEQ ID NO:8, wherein the concentration of the antibody is 50 to 200 mg/ml; and
> (b) water;
> wherein the formulation does not comprise a buffering system.

33. Notably, AbbVie did not purport to make these narrowing changes to avoid any prior art references.

34. In addition to the similarity between the confidential AVT02 formulation and AbbVie's new claims, the specific arguments presented by AbbVie's prosecuting attorneys demonstrate that prosecution of the new claims was being guided by Alvotech's confidential BPCIA disclosures. AbbVie's treatment of a key piece of prior art—the Gokarn PCT application ("Gokarn PCT")—is particularly significant. On January 14, 2021, Alvotech provided AbbVie with its confidential 3(B) Statement, in which Alvotech relied on Gokarn PCT as a key piece of invalidating prior art for the '081 and '619 patents. Thereafter, on March 18, 2021, the examiner issued a non-final rejection on the '201 application. Although that non-final rejection did not rely on Gokarn PCT, on March 31, 2021, AbbVie injected Gokarn PCT into the prosecution of the '201 Application, stating that "although currently not grounds of rejection in the present Office Action, Applicant would like to pre-emptively point out that the present claims are also not anticipated by Gokarn PCT." Prior to making this preemptive argument, AbbVie had never before sought substantive examination of Gokarn PCT during prosecution of the patent family, and Gokarn PCT had never been the basis for rejection of any claim in that family.

35. On information and belief, AbbVie's preemptive effort to address Gokarn PCT was the result of AbbVie's prosecuting attorneys learning of Alvotech USA's reliance on Gokarn PCT in its confidential 3(B) Statement. On information and belief, by raising Gokarn PCT preemptively with the patent office, AbbVie sought to gain a litigation advantage. On information and belief, AbbVie never informed the patent office that there was pending litigation involving the family of patents that includes the '201 application. By raising Gokarn PCT preemptively with the patent office, AbbVie was able to use a non-adversarial proceeding to obtain the PTO's determination

that the '201 application's claims were patentable over Gokarn PCT. Thus, when in the future, Alvotech presents invalidity arguments on those claims in an adversarial litigation, AbbVie can tell the judge or jury that these patents are "battle-tested" as being patentable over Gokarn PCT. AbbVie identified the patent issuing from the '201 application as one it would asserts against Alvotech hf. as soon as the patent issued, and indeed AbbVie has done so.

36. Another example of AbbVie's improper use of Alvotech's confidential information is illustrated by AbbVie's actions during prosecution of the patent application that eventually issued as U.S. Patent No. 11,083,792 (the "'792 patent"). The application leading to the '792 patent was filed on November 8, 2018. Thereafter, on June 3, 2021, AbbVie amended the claims in the pending application to include a limitation that the claimed composition has "no detectable level" of fluorescent activity. On information and belief, this claim language was added in view of Alvotech's confidential information. The only other time AbbVie had used that claim language was in a single claim in an earlier patent limited to a composition of "50 mg/ml of adalimumab." The new '792 patent contains no such limitation. AbbVie has identified this patent as one it asserts against Alvotech.

3. AbbVie's Assertion of Its Entire "Minefield of IP"

37. AbbVie has sought to overwhelm Alvotech with litigation through its assertion of all of its patents from its 3(C) Statement.

38. Instead of engaging with Alvotech during the patent dance to narrow the list of patents, AbbVie stated that Alvotech USA "need[ed] to pick all [62] patents" if it wanted to bring its product to market. Since serving that initial 3(C) list, AbbVie has identified three more patents it intends to assert against Alvotech.

39. AbbVie brought its first patent suit in on the four patents Alvotech USA identified in the patent dance negotiation phase. *See, e.g.*, Compl., ¶ 15. AbbVie had the chance to identify

and negotiate with Alvotech USA regarding any patents AbbVie felt should be part of that first suit; but AbbVie did not. Instead, it brought suit on those four patents, while continuing to maintain that Alvotech USA must face "the remaining patents in a second phase" in order to "adjudicate the rest of AbbVie's substantial patent rights relating to HUMIRA®." *See id*. at ¶¶ 15-16.

40. On May 11, 2021, Alvotech USA provided AbbVie Inc. with its notice of commercial marketing for AVT02, opening the door for Alvotech USA to launch AVT02 180 days later. In response, on May 28, 2021, AbbVie brought this second infringement action against Alvotech hf., this time asserting the remaining 58 patents on its 3(C) List. AbbVie's assertion of 58 patents in this second litigation was improper for numerous reasons.

41. First, the 58 patents asserted in this second litigation includes the '156, '009, '372, and '153 patents. For each of those patents, AbbVie conceded during the patent dance, based on Alvotech's confidential information, that "there is no infringement." Thus, AbbVie lacks any good faith basis to assert those four patents against Alvotech with respect to AVT02.

42. Second, although asserting all the patents, AbbVie never intended to pursue them all. Under 42 U.S.C. § 262(*l*)(8)(A)-(B), the purposes of a second litigation following the notice of commercial marketing is to "seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale." 42 U.S.C. § 262(*l*)(8)(A)-(B). Yet AbbVie admitted in a letter to this Court that it only intended to seek a preliminary injunction on *some* of the 58 patents, stating that "several" of those patents would be included in a preliminary injunction motion. Despite requests from Alvotech, AbbVie did not identify which "several" of the 58 patent it intended to be the subject of a preliminary injunction motion and never filed a preliminary injunction motion. It was not until the Court ordered a narrowing for trial that AbbVie

identified a narrower list of patents. Thus, from at least July 2, 2021 when AbbVie first raised the issue of a preliminary injunction in a draft status report, to September 2, 2021, when the Court stated it would hold a trial and no preliminary injunction proceeding, Alvotech was forced to prepare to defend a preliminary injunction motion on all 58 patents, rather than just the "several" that AbbVie actually intended to pursue all along.

C. AbbVie's Long History of Misconduct Aimed at Extending its Humira® Monopoly

43. AbbVie's behavior towards Alvotech is consistent with its long practice of bury and delay. The reason is clear. Between 2003 and 2016, when the twelve patents arising from BASF AG's 1995 discovery expired, AbbVie reportedly sold nearly $100 billion worth of Humira® worldwide. To put this in perspective, a drug with annual sales of $1 billion is considered a blockbuster in the pharmaceutical industry. In just the last four years, since its monopoly should have run its course, AbbVie has reported selling over $75 billion worth of Humira® and is forecasted to make an additional nearly $40 billion through 2022.

44. AbbVie protects its monopoly through the acquisition and threatened enforcement of an outrageous number of patents of dubious validity—in excess of 100. AbbVie did not, however, invent anything.

45. Adalimumab was discovered more than twenty years ago. In 1996, a German company, BASF AG, filed a patent application disclosing adalimumab and methods of using it to treat TNFα-related autoimmune diseases. In 2001, after BASF had undertaken years of further development work, AbbVie's predecessor, Abbott Laboratories, purchased the rights to the drug, the patents, and all of BASF's additional work for $6.9 billion.

46. Since then, AbbVie has sought and obtained over 100 additional patents related to adalimumab. The Chief Executive Officer of AbbVie has referred to this excessive number of patents as an "absolute minefield of IP." AbbVie now asserts that minefield of IP against Alvotech.

47. One example of the lack of innovation in AbbVie's minefield can be seen in the numerous patents AbbVie has obtained on methods of treating various TNFα disorders. In the last fifteen years, AbbVie has obtained more than two dozen such patents, all of which post-date the original launch of Humira®. Yet previously, and in reliance on the 1996 disclosure for AbbVie's original adalimumab patents, AbbVie and its predecessors (BASF and Abbott) had already sought and obtained claims covering methods of treating *any* TNFα disorder, and also specifically claimed the majority of disorders for which AbbVie later sought and obtained additional patents. For example, in reliance on the 1996 disclosure, AbbVie obtained claims on any "method for inhibiting human TNFα activity in a human subject suffering from a disorder in which TNFα activity is detrimental" or "treating a subject suffering from a disorder in which TNFα activity is detrimental." (*See, e.g.*, U.S. Patent No. 6,509,015 at claims 1, 36). In addition to those broad independent claims covering treatment of any TNFα disorder, AbbVie also obtained claims arising from the original 1996 application on methods of treating "rheumatoid arthritis," "rheumatoid spondylitis," "Crohn's disease," "ulcerative colitis," "autoimmune uveitis," "inflammatory bowel disorder," "idiopathic inflammatory bowel disease," "an intestinal disorder," "inflammatory bone disorders," (which includes rheumatoid arthritis and ankylosing spondylitis), and "an autoimmune disease." (*See, e.g.*, *id.*; *see also* U.S. Patent Nos. 7,588,761; 8,753,633; 7,223,394; 8,216,714; and U.S. Patent No. 8,372,400).

48. Despite having successfully persuaded the PTO that the original 1996 application supported claims covering methods of using adalimumab to treat any TNFα disorder—and

specifically, methods of treating "rheumatoid arthritis," "rheumatoid spondylitis," "Crohn's disease," "ulcerative colitis," "autoimmune uveitis," "inflammatory bowel disorder," "idiopathic inflammatory bowel disease," "an intestinal disorder," "inflammatory bone disorders," and "an autoimmune disease"—AbbVie has since obtained more than two dozen unrelated patents claiming methods of treating various TNFα disorders with adalimumab. These additional patents, including U.S. Patent Nos. 8,926,975 and 8,961,973, claim later priority dates and thus, extend AbbVie's monopoly beyond the 2016 expiration date of the original adalimumab patents.

49. Any competitor, like Alvotech, that desires to bring a biosimilar version of Humira® to market is threatened with at least 60 patents from AbbVie's "minefield," and prior to Alvotech, each has settled without the merits of any single patent being addressed in court. This scheme has secured AbbVie years of additional time for its monopoly. On information and belief, the size of AbbVie's "minefield" motivates competitors to settle quickly. AbbVie uses those settlements to intimidate the next competitor and bolster its portfolio. For example, AbbVie stated to Alvotech and the Court that there were ten would-be competitors that settled, "each of whom expressly acknowledged the validity of AbbVie's patents and sought and negotiated for licenses to enter the U.S. market starting in 2023." (*See* Dkt. No. 35, ¶ 2, AbbVie's Motion to Reinstate the July 15, 2021 Initial Status Conference or Set One As Soon As Reasonably Possible.) On information and belief, those companies settled not because they conceded the validity of the patents, but because they were intimidated by the size of the portfolio. AbbVie's representations otherwise are another example of litigation misconduct meant only to intimidate.

50. And on information and belief, how AbbVie got that minefield motivates AbbVie to settle quickly. On information and belief, AbbVie recognizes the dubious validity of its patents and avoids any meaningful adjudication of them. For example, AbbVie settled with Boehringer

Ingleheim shortly after AbbVie was required to produce documents that AbbVie had sought to preclude, thereby preventing resolution of related to Boehringer's patent defense of unclean hands.

51. In short, AbbVie has managed to subvert the very process designed to prevent its wrongdoing "by means of the overpowering threat of disastrous litigation." *See Automatic Radio Mfg. v. Hazeltine Research*, 339 U.S. 827, 834 (1950).

52. Finally, even the settlements contributed to AbbVie's overall strategy. Each of AbbVie's settlements has been with biosimilar manufacturers who were seeking approval of 50 mg/ml formulations. As AbbVie settled with those companies, it was busy shifting the market to 100 mg/ml. That market switch is another example of AbbVie's misconduct and why AbbVie now has targeted Alvotech, the only BLA applicant with a 100 mg/ml formulation.

53. Specifically, AbbVie had tested the less painful 100 mg/ml formulation by 2010 and the FDA approved it in 2015. Notwithstanding that formulation's touted benefits to reduce pain, AbbVie waited nearly three years after FDA approval to bring it to market. During that time, biosimilar companies developed 50 mg/ml biosimilar formulations because the 50 mg/ml formulation was the only version on the market. On information and belief, AbbVie waited to launch the 100 mg/ml product until those programs were well underway, in an effort to render obsolete these early competitors' development efforts. AbbVie thus withheld from the market its purportedly less painful formulation until it was strategically and financially favorable to do so in order to extend its monopoly. It now asserts patents purportedly covering those formulations against Alvotech.

THE PATENTS-AT-ISSUE

54. As noted above, the only issues to be addressed in the first phase of litigation are infringement, validity, and enforceability of the Ten Patents. All other patents asserted in the

pleadings in these matters are stayed. (*See* 21-2889, D.I. 53.) As such, Defendant's counterclaims are asserted herein relate only to the Ten Patents set for trial on August 2022. At such time as the stay is lifted, Defendant will amend its counterclaims as agreed by the parties and/or as ordered by the Court.

55. U.S. Patent No. 6,805,686, titled "Autoinjector with Extendable Needle Protector Shroud," issued on October 19, 2004. On information and belief, the '686 patent is assigned to AbbVie Inc. On information and belief, AbbVie Inc. and AbbVie Biotechnology Ltd. together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the '686 patent.

56. U.S. Patent No. 8,999,337, titled "Methods for Treating Juvenile Idiopathic Arthritis By Inhibition of TNFα," issued on April 7, 2015. On information and belief, the '337 patent is assigned to AbbVie Biotechnology Ltd. On information and belief, AbbVie Inc. and AbbVie Biotechnology Ltd. together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the '337 patent.

57. U.S. Patent No. 9,067,992, titled "Use of TNFα Inhibitor for Treatment of Psoriatic Arthritis," issued on June 30, 2015. On information and belief, the '992 patent is assigned to AbbVie Biotechnology Ltd. On information and belief, AbbVie Inc. and AbbVie Biotechnology Ltd. together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the '992 patent.

58. U.S. Patent No. 9,187,559, titled "Multiple-Variable Dose Regimen for Treating Idiopathic Inflammatory Bowel Disease," issued on November 17, 2015. On information and belief, the '559 patent is assigned to AbbVie Biotechnology Ltd. On information and belief,

AbbVie Inc. and AbbVie Biotechnology Ltd. together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the ’559 patent.

59. U.S. Patent No. 9,512,216, titled “Use of TNFα Inhibitor,” issued on December 6, 2016. On information and belief, the ’216 patent is assigned to AbbVie Biotechnology Ltd. On information and belief, AbbVie Inc. and AbbVie Biotechnology Ltd. together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the ’216 patent.

60. U.S. Patent No. 11,083,792, titled “Purified Antibody Composition,” issued on August 10, 2021. On information and belief, the ’792 patent is assigned to AbbVie Biotechnology Ltd. On information and belief, AbbVie Inc. and AbbVie Biotechnology Ltd. together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the ’792 patent.

61. U.S. Patent No. 11,167,030, titled “Protein Formulations and Methods of Making Same,” issued on November 9, 2021. On information and belief, the ’030 patent is assigned to AbbVie Biotechnology Ltd. On information and belief, AbbVie Inc. and AbbVie Biotechnology Ltd. together hold the exclusive right to initiate, control, and defend any patent infringement litigation involving the ’030 patent.

COUNT I

(Unenforceability Due to Unclean Hands)

62. Plaintiffs re-allege the foregoing paragraphs as if fully set forth herein.

63. Each of the patents-in-suit is unenforceable due to AbbVie’s unclean hands. The doctrine of unclean hands “closes the doors of a court of equity to one tainted with inequitableness or bad faith relative to the matter in which he seeks relief.” *Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 814 (1945). Where a patentee’s unclean

hands have impacted the public, the doctrine "assumes even wider and more significant proportions," because it "not only prevents a wrongdoer from enjoying the fruits of his transgressions but averts an injury to the public." *Id*. at 815. Additionally, "[t]he far-reaching social and economic consequences of a patent . . . gives the public a paramount interest in seeing that . . . such monopolies are kept within their legitimate scope." *Id.* at 816. Proof of fraud is unnecessary; unclean hands may be found where a patent holder's misconduct has "reduced a patentee's risk" or otherwise "enhance[d] the claimant's position regarding legal rights that are important to [patent] litigation." *Gilead Scis., Inc. v. Merck & Co.*, 888 F.3d 1231, 1244 (Fed. Cir. 2018).

64. AbbVie has engaged in a pattern of misconduct designed to build and shield its "patent minefield" from meaningful litigation, thus reducing the risk that those patents would undergo the legal scrutiny necessary to ensure that AbbVie's "monopol[y is] kept within their legitimate scope." *See Precision Instrument*, 324 U.S. at 815. This misconduct has included, at least, artificially inflating the size of its patent portfolio, thus giving AbbVie a substantially larger "minefield of IP" with which to intimidate its competitors into staying off the market. With respect to Alvotech specifically, it has included extensive efforts to overwhelm Alvotech with the threat of ruinous litigation, including failing to participate in the patent dance in good faith; asserting patents against Alvotech for which it has conceded there cannot be infringement; and asserting more than 60 total patents against Alvotech, including patents it has no intention of actually pursuing in litigation. This conduct aimed at overwhelming Alvotech has "reduced [the] patentee's risk" or otherwise "enhance[d] the claimant's position regarding legal rights that are important to [patent] litigation." *Gilead*, 888 F.3d at 1244.

65. AbbVie's misconduct also included using Alvotech's confidential information disclosed in the BPCIA patent dance to guide its patent prosecution efforts. Although a patentee may sometimes properly amend claims to cover a competitor's product, doing so constitutes unclean hands if the prosecuting attorney had improper access to the competitor's confidential information and that information "played a significant role in [the prosecuting agent's] actual process of decision-making that led [the agent] to file claims focusing on [the competitor's product]." *Gilead*, 888 F.3d at 1243-44. Here, on information and belief, AbbVie's prosecuting attorneys at Jones Day were improperly given confidential information about Alvotech's AVT02 BLA and Alvotech's 3(B) Statement, which information played a significant role in the decision-making process that led the prosecuting attorneys' to draft claims targeted at AVT02.

66. Additionally, AbbVie engaged in inequitable conduct as it relates to the '792 patent, as described below, and such inequitable conduct is also relevant to AbbVie's unclean hands.

67. The application of unclean hands here is needed to not only prevent AbbVie from enjoying the fruits of its transgressions, but also to avert an injury to the public. *See Precision Instrument*, 324 U.S. at 815 (holding that where a patentee's unclean hands have impacted the public, the doctrine "assumes even wider and more significant proportions," because it "not only prevents a wrongdoer from enjoying the fruits of his transgressions but averts an injury to the public"). The public has spent more money on Humira® than any drug in U.S. history, leaving little doubt as to the far-reaching socioeconomic consequences of AbbVie's adalimumab monopoly. If AbbVie is not stopped, the public will continue to pay unnecessarily high prices beyond 2023 and as far as 2037—when the last of AbbVie's current patent portfolio (it continues to try and get more) is set to expire—at the cost of $20 billion per year or more.

COUNT II

(Unenforceability Due to Patent Misuse)

68. Plaintiffs re-allege the foregoing paragraphs as if fully set forth herein. In particular, paragraphs 58 to 62 of Count I (Unclean Hands) are equally applicable to AbbVie's patent misuse.

69. Each of the patents-in-suit is unenforceable under the doctrine of patent misuse. Patent misuse occurs when a patentee "has impermissibly broadened the 'physical or temporal scope' of the patent grant with anticompetitive effect." *See, e.g.*, *Virginia Panel Corp.*, 133 F.3d 860, 869 (Fed. Cir. 1997). Many kinds of conduct may fall within the scope of patent misuse. One example is where a patentee brings a lawsuit in "bad faith" and with an "improper purpose in bringing the suit." *Glaverbel Societe Anonyme v. Northlake Mktg & Supply Inc.*, 45 F.3d 1550, 1558 (Fed. Cir. 1995). "A purpose is improper if its goal is not to win a favorable judgment, but to harass a competitor and deter others from competition, by engaging the litigation process itself, regardless of outcome." Additionally, although the "mere accumulation of patents, no matter how many, is not ***in and of itself*** illegal," use of a large portfolio to intimidate competitors "by means of the overpowering threat of disastrous litigation," may be patent misuse. *Automatic Radio Mfg. v. Hazeltine Research*, 339 U.S. 827, 834 (1950) (emphasis added).

70. The facts described above show that AbbVie's scheme is to "engage the litigation process itself"—including the enormous expense and uncertainty of that process—to "deter others from competition," and to avoid legal scrutiny of its patents. AbbVie has used the size of its portfolio to intimidate Alvotech and prior competitors "by means of the overpowering threat of disastrous litigation." AbbVie's apparent purpose has not been to win a favorable judgment, but rather to avoid any judgment at all by coercing challengers to abandon litigation. With respect to

Alvotech, AbbVie has pursued those efforts by, among other things, failing to participate in the patent dance in good faith; asserting patents against Alvotech for which it has conceded there cannot be infringement; and asserting more than 60 total patents against Alvotech, including patents it has no intention of actually pursuing in litigation. AbbVie has engaged the litigation process itself—including the time and expense of that process—to harass Alvotech and others in an effort to deter them from competition. To date, AbbVie has settled with every prior competitor, avoiding court scrutiny of its Humira®-related patent portfolio. Thus, AbbVie has impermissibly broadened the physical and temporal scope of its patents, with an anticompetitive effect, and seeks to do so again with Alvotech.

COUNT III

(Declaratory Judgment of Non-infringement of U.S. Patent No. 6,805,686)

71. Alvotech hf. re-alleges the foregoing paragraphs of its counterclaims as if fully set forth herein.

72. Alvotech hf. has not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the ’686 patent under 35 U.S.C. § 271. On September 24, 2021, Alvotech hf. served on AbbVie Inc. and AbbVie Biotechnology Ltd. initial non-infringement contentions pursuant to this District’s Local Patent Rule 2.3 describing Alvotech hf.’s position that it will not infringe the ’686 patent. On November 12, 2021, Alvotech hf. served on AbbVie Inc. and AbbVie Biotechnology Ltd. first amended initial non-infringement contentions. Alvotech hf.’s initial and amended initial non-infringement contentions are within AbbVie’s possession and are incorporated by reference herein. In addition, Alvotech hf. cannot be liable for any infringement of the ’686 patent because it is invalid and unenforceable.

73. On September 10, 2021, and pursuant to this District's Local Patent Rule 2.2, and on October 8, 2021, and pursuant to this District's Local Patent Rule 2.5, AbbVie purported to provide Alvotech hf. with contentions alleging that Alvotech hf. will infringe the '686 patent. AbbVie filed a suit for infringement of the '686 patent against Alvotech hf. on May 28, 2021 in this Court. AbbVie's amended complaints on November 12, 2021 and December 21, 2021 maintained allegations of infringement of the '686 patent.

74. As a result of AbbVie's allegations against Alvotech hf., an actual and justiciable controversy exists between Alvotech hf. and AbbVie at least as to the infringement of the '686 patent.

75. Alvotech hf. is entitled to a judicial declaration that the making, use, offer for sale, sale, or importation into the United States of Alvotech hf.'s biosimilar product does not and will not infringe any valid and enforceable claim of the '686 patent under 35 U.S.C. § 271. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT IV

(Declaratory Judgment of Invalidity of U.S. Patent No. 6,805,686)

76. Alvotech hf. re-alleges the foregoing paragraphs of its counterclaims as if fully set forth herein.

77. The claims of the '686 patent are invalid for failing to meet the requirements of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 112 and/or pursuant to common law and/or equitable doctrines. On September 24, 2021, Alvotech hf. served on AbbVie Inc. and AbbVie Biotechnology Ltd. initial invalidity contentions pursuant to this District's Local Patent Rule 2.3 describing Alvotech hf.'s position that the claims

of the ’686 patent are invalid. Among other reasons, the claims of the ’686 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the ’686 patent, including, for example, the prior art Alvotech hf. produced or otherwise identified to AbbVie with Alvotech hf.’s initial invalidity contentions. On November 12, 2021, Alvotech hf. served on AbbVie Inc. and AbbVie Biotechnology Ltd. first amended initial invalidity contentions. Alvotech hf.’s initial and amended invalidity contentions are within AbbVie’s possession and are incorporated by reference herein.

78. On October 8, 2021, and pursuant to this District’s Local Patent Rule 2.5, AbbVie purported to respond to Alvotech hf.’s initial invalidity contentions regarding the ’686 patent and provided AbbVie’s opinion that the ’686 patent is not invalid. AbbVie purported to serve responses to the 35 U.S.C. § 112 portions of Alvotech hf.’s initial and amended invalidity contentions on November 12, 2021 and December 6, 2021, respectively, providing AbbVie’s opinion that the ’686 patent is not invalid. AbbVie filed a suit for infringement of the ’686 patent against Alvotech hf. on May 28, 2021 in this Court. AbbVie’s amended complaints on November 12, 2021 and December 21, 2021 maintained allegations of infringement of the ’686 patent.

79. As a result of AbbVie’s allegations against Alvotech hf., an actual and justiciable controversy exists between Alvotech hf. and AbbVie as to whether the claims of the ’686 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

80. Alvotech hf. is entitled to a judicial declaration that all claims of the ’686 patent are invalid. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT V

(Declaratory Judgment of Non-infringement of U.S. Patent No. 8,999,337)

81. Alvotech hf. re-alleges the foregoing paragraphs of its counterclaims as if fully set forth herein.

82. Alvotech hf. has not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '337 patent under 35 U.S.C. § 271. On September 24, 2021, Alvotech hf. served on AbbVie Inc. and AbbVie Biotechnology Ltd. initial non-infringement contentions pursuant to this District's Local Patent Rule 2.3 describing Alvotech hf.'s position that it will not infringe the '337 patent. Alvotech hf.'s initial non-infringement contentions are within AbbVie's possession and are incorporated by reference herein. In addition, Alvotech hf. cannot be liable for any infringement of the '337 patent because it is invalid and unenforceable.

83. On September 10, 2021, and pursuant to this District's Local Patent Rule 2.2, and on October 8, 2021, and pursuant to this District's Local Patent Rule 2.5, AbbVie purported to provide Alvotech hf. with contentions alleging that Alvotech hf. will infringe the '337 patent. AbbVie filed a suit for infringement of the '337 patent against Alvotech hf. on May 28, 2021 in this Court. AbbVie's amended complaints on November 12, 2021 and December 21, 2021 maintained allegations of infringement of the '337 patent.

84. As a result of AbbVie's allegations against Alvotech hf., an actual and justiciable controversy exists between Alvotech hf. and AbbVie as to the infringement of the '337 patent.

85. Alvotech hf. is entitled to a judicial declaration that the making, use, offer for sale, sale, or importation into the United States of Alvotech hf.'s biosimilar product does not and will not infringe any valid and enforceable claim of the '337 patent under 35 U.S.C. § 271. Such a

declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT VI

(Declaratory Judgment of Invalidity of U.S. Patent No. 8,999,337)

86. Alvotech hf. re-alleges the foregoing paragraphs of its counterclaims as if fully set forth herein.

87. The claims of the '337 patent are invalid for failing to meet the requirements of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 112 and/or pursuant to common law and/or equitable doctrines. On September 24, 2021, Alvotech hf. served on AbbVie Inc. and AbbVie Biotechnology Ltd. initial invalidity contentions pursuant to this District's Local Patent Rule 2.3 describing Alvotech hf.'s position that the claims of the '337 patent are invalid. Among other reasons, the claims of the '337 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '337 patent, including, for example, the prior art Alvotech hf. produced or otherwise identified to AbbVie with Alvotech hf.'s initial invalidity contentions. Alvotech hf.'s initial invalidity contentions are within AbbVie's possession and are incorporated by reference herein.

88. On October 8, 2021, and pursuant to this District's Local Patent Rule 2.5, AbbVie purported to respond to Alvotech hf.'s initial invalidity contentions regarding the '337 patent and provided AbbVie's opinion that the '337 patent is not invalid. AbbVie filed a suit for infringement of the '337 patent against Alvotech hf. on May 28, 2021 in this Court. AbbVie's amended complaints on November 12, 2021 and December 21, 2021 maintained allegations of infringement of the '337 patent.

89. As a result of AbbVie's allegations against Alvotech hf., an actual and justiciable controversy exists between Alvotech hf. and AbbVie as to whether the claims of the '337 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

90. Alvotech hf. is entitled to a judicial declaration that all claims of the '337 patent are invalid. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT VII

(Declaratory Judgment of Non-infringement of U.S. Patent No. 9,067,992)

91. Alvotech hf. re-alleges the foregoing paragraphs of its counterclaims as if fully set forth herein.

92. Alvotech hf. has not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '992 patent under 35 U.S.C. § 271. On September 24, 2021, Alvotech hf. served on AbbVie Inc. and AbbVie Biotechnology Ltd. initial non-infringement contentions pursuant to this District's Local Patent Rule 2.3 describing Alvotech hf.'s position that it will not infringe the '992 patent. Alvotech hf.'s initial non-infringement contentions are within AbbVie's possession and are incorporated by reference herein. In addition, Alvotech hf. cannot be liable for any infringement of the '992 patent because it is invalid and unenforceable.

93. On September 10, 2021, and pursuant to this District's Local Patent Rule 2.2, and on October 8, 2021, and pursuant to this District's Local Patent Rule 2.5, AbbVie purported to provide Alvotech hf. with contentions alleging that Alvotech hf. will infringe the '992 patent.

AbbVie filed a suit for infringement of the '992 patent against Alvotech hf. on May 28, 2021 in this Court. AbbVie's amended complaints on November 12, 2021 and December 21, 2021 maintained allegations of infringement of the '992 patent.

94. As a result of AbbVie's allegations against Alvotech hf., an actual and justiciable controversy exists between Alvotech hf. and AbbVie as to the infringement of the '992 patent.

95. Alvotech hf. is entitled to a judicial declaration that the making, use, offer for sale, sale, or importation into the United States of Alvotech hf.'s biosimilar product does not and will not infringe any valid and enforceable claim of the '992 patent under 35 U.S.C. § 271. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT VIII

(Declaratory Judgment of Invalidity of U.S. Patent No. 9,067,992)

96. Alvotech hf. re-alleges the foregoing paragraphs of its counterclaims as if fully set forth herein.

97. The claims of the '992 patent are invalid for failing to meet the requirements of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 112 and/or pursuant to common law and/or equitable doctrines. On September 24, 2021, Alvotech hf. served on AbbVie Inc. and AbbVie Biotechnology Ltd. initial invalidity contentions pursuant to this District's Local Patent Rule 2.3 describing Alvotech hf.'s position that the claims of the '992 patent are invalid. Among other reasons, the claims of the '992 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '992 patent, including, for example, the prior art Alvotech hf. produced or otherwise identified to AbbVie with Alvotech hf.'s initial invalidity

contentions. Alvotech hf.'s initial invalidity contentions are within AbbVie's possession and are incorporated by reference herein.

98. On October 8, 2021, and pursuant to this District's Local Patent Rule 2.5, AbbVie purported to respond to Alvotech hf.'s initial invalidity contentions regarding the '992 patent and provided AbbVie's opinion that the '992 patent is not invalid. AbbVie filed a suit for infringement of the '992 patent against Alvotech hf. on May 28, 2021 in this Court. AbbVie's amended complaints on November 12, 2021 and December 21, 2021 maintained allegations of infringement of the '992 patent.

99. As a result of AbbVie's allegations against Alvotech hf., an actual and justiciable controversy exists between Alvotech hf. and AbbVie as to whether the claims of the '992 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

100. Alvotech hf. is entitled to a judicial declaration that all claims of the '992 patent are invalid. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT IX

(Declaratory Judgment of Non-infringement of U.S. Patent No. 9,187,559)

101. Alvotech hf. re-alleges the foregoing paragraphs of its counterclaims as if fully set forth herein.

102. Alvotech hf. has not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '559 patent under 35 U.S.C. § 271. On September 24, 2021, Alvotech hf. served on AbbVie Inc. and AbbVie

Biotechnology Ltd. initial non-infringement contentions pursuant to this District's Local Patent Rule 2.3 describing Alvotech hf.'s position that it will not infringe the '559 patent. Alvotech hf.'s initial non-infringement contentions are within AbbVie's possession and are incorporated by reference herein. In addition, Alvotech hf. cannot be liable for any infringement of the '559 patent because it is invalid and unenforceable.

103. On September 10, 2021, and pursuant to this District's Local Patent Rule 2.2, and on October 8, 2021, and pursuant to this District's Local Patent Rule 2.5, AbbVie purported to provide Alvotech hf. with contentions alleging that Alvotech hf. will infringe the '559 patent. AbbVie filed a suit for infringement of the '559 patent against Alvotech hf. on May 28, 2021 in this Court. AbbVie's amended complaints on November 12, 2021 and December 21, 2021 maintained allegations of infringement of the '559 patent.

104. As a result of AbbVie's allegations against Alvotech hf., an actual and justiciable controversy exists between Alvotech hf. and AbbVie as to the infringement of the '559 patent.

105. Alvotech hf. is entitled to a judicial declaration that the making, use, offer for sale, sale, or importation into the United States of Alvotech hf.'s biosimilar product does not and will not infringe any valid and enforceable claim of the '559 patent under 35 U.S.C. § 271. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT X

(Declaratory Judgment of Invalidity of U.S. Patent No. 9,187,559)

106. Alvotech hf. re-alleges the foregoing paragraphs of its counterclaims as if fully set forth herein.

107. The claims of the '559 patent are invalid for failing to meet the requirements of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 112 and/or pursuant to common law and/or equitable doctrines. On September 24, 2021, Alvotech hf. served on AbbVie Inc. and AbbVie Biotechnology Ltd. initial invalidity contentions pursuant to this District's Local Patent Rule 2.3 describing Alvotech hf.'s position that the claims of the '559 patent are invalid. Among other reasons, the claims of the '559 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '559 patent, including, for example, the prior art Alvotech hf. produced or otherwise identified to AbbVie with Alvotech hf.'s initial invalidity contentions. Alvotech hf.'s initial invalidity contentions are within AbbVie's possession and are incorporated by reference herein.

108. On October 8, 2021, and pursuant to this District's Local Patent Rule 2.5, AbbVie purported to respond to Alvotech hf.'s initial invalidity contentions regarding the '559 patent and provided AbbVie's opinion that the '559 patent is not invalid. AbbVie purported to serve responses to the 35 U.S.C. § 112 portions of Alvotech hf.'s initial invalidity contentions on November 12, 2021, providing AbbVie's opinion that the '559 patent is not invalid. AbbVie filed a suit for infringement of the '559 patent against Alvotech hf. on May 28, 2021 in this Court. AbbVie's amended complaints on November 12, 2021 and December 21, 2021 maintained allegations of infringement of the '559 patent.

109. As a result of AbbVie's allegations against Alvotech hf., an actual and justiciable controversy exists between Alvotech hf. and AbbVie as to whether the claims of the '559 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code,

including without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

110. Alvotech hf. is entitled to a judicial declaration that all claims of the '559 patent are invalid. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT XI

(Declaratory Judgment of Non-infringement of U.S. Patent No. 9,512,216)

111. Alvotech hf. re-alleges the foregoing paragraphs of its counterclaims as if fully set forth herein.

112. Alvotech hf. has not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '216 patent under 35 U.S.C. § 271. On September 24, 2021, Alvotech hf. served on AbbVie Inc. and AbbVie Biotechnology Ltd. initial non-infringement contentions pursuant to this District's Local Patent Rule 2.3 describing Alvotech hf.'s position that it will not infringe the '216 patent. Alvotech hf.'s initial non-infringement contentions are within AbbVie's possession and are incorporated by reference herein. In addition, Alvotech hf. cannot be liable for any infringement of the '216 patent because it is invalid and unenforceable.

113. On September 10, 2021, and pursuant to this District's Local Patent Rule 2.2, and on October 8, 2021, and pursuant to this District's Local Patent Rule 2.5, AbbVie purported to provide Alvotech hf. with contentions alleging that Alvotech hf. will infringe the '216 patent. AbbVie filed a suit for infringement of the '216 patent against Alvotech hf. on May 28, 2021 in this Court. AbbVie's amended complaints on November 12, 2021 and December 21, 2021 maintained allegations of infringement of the '216 patent.

114. As a result of AbbVie's allegations against Alvotech hf., an actual and justiciable controversy exists between Alvotech hf. and AbbVie as to the infringement of the '216 patent.

115. Alvotech hf. is entitled to a judicial declaration that the making, use, offer for sale, sale, or importation into the United States of Alvotech hf.'s biosimilar product does not and will not infringe any valid and enforceable claim of the '216 patent under 35 U.S.C. § 271. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT XII

(Declaratory Judgment of Invalidity of U.S. Patent No. 9,512,216)

116. Alvotech hf. re-alleges the foregoing paragraphs of its counterclaims as if fully set forth herein.

117. The claims of the '216 patent are invalid for failing to meet the requirements of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 112 and/or pursuant to common law and/or equitable doctrines. On September 24, 2021, Alvotech hf. served on AbbVie Inc. and AbbVie Biotechnology Ltd. initial invalidity contentions pursuant to this District's Local Patent Rule 2.3 describing Alvotech hf.'s position that the claims of the '216 patent are invalid. Among other reasons, the claims of the '216 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '216 patent, including, for example, the prior art Alvotech hf. produced or otherwise identified to AbbVie with Alvotech hf.'s initial invalidity contentions. Alvotech hf.'s initial invalidity contentions are within AbbVie's possession and are incorporated by reference herein.

118. On October 8, 2021, and pursuant to this District's Local Patent Rule 2.5, AbbVie purported to respond to Alvotech hf.'s initial invalidity contentions regarding the '216 patent and provided AbbVie's opinion that the '216 patent is not invalid. AbbVie filed a suit for infringement of the '216 patent against Alvotech hf. on May 28, 2021 in this Court. AbbVie's amended complaints on November 12, 2021 and December 21, 2021 maintained allegations of infringement of the '216 patent.

119. As a result of AbbVie's allegations against Alvotech hf., an actual and justiciable controversy exists between Alvotech hf. and AbbVie as to whether the claims of the '216 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

120. Alvotech hf. is entitled to a judicial declaration that all claims of the '216 patent are invalid. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT XII

(Declaratory Judgment of Non-infringement of U.S. Patent No. 11,083,792)

121. Alvotech hf. re-alleges the foregoing paragraphs of its counterclaims as if fully set forth herein.

122. Alvotech hf. has not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '792 patent under 35 U.S.C. § 271. On September 24, 2021, Alvotech hf. served on AbbVie Inc. and AbbVie Biotechnology Ltd. initial non-infringement contentions pursuant to this District's Local Patent Rule 2.3 describing Alvotech hf.'s position that it will not infringe the '792 patent. Alvotech hf.'s

initial non-infringement contentions are within AbbVie's possession and are incorporated by reference herein. In addition, Alvotech hf. cannot be liable for any infringement of the '792 patent because it is invalid and unenforceable.

123. On September 10, 2021, and pursuant to this District's Local Patent Rule 2.2, and on October 8, 2021, and pursuant to this District's Local Patent Rule 2.5, AbbVie purported to provide Alvotech hf. with contentions alleging that Alvotech hf. will infringe the '792 patent. AbbVie amended its complaint to include counts of infringement of the '792 patent by Alvotech hf. on November 12, 2021. AbbVie's second amended complaint on December 21, 2021 maintained allegations of infringement of the '792 patent.

124. As a result of AbbVie's allegations against Alvotech hf., an actual and justiciable controversy exists between Alvotech hf. and AbbVie as to the infringement of the '792 patent.

125. Alvotech hf. is entitled to a judicial declaration that the making, use, offer for sale, sale, or importation into the United States of Alvotech hf.'s biosimilar product does not and will not infringe any valid and enforceable claim of the '792 patent under 35 U.S.C. § 271. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT XIV

(Declaratory Judgment of Invalidity of U.S. Patent No. 11,083,792)

126. Alvotech hf. re-alleges the foregoing paragraphs of its counterclaims as if fully set forth herein.

127. The claims of the '792 patent are invalid for failing to meet the requirements of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 112 and/or pursuant to common law and/or equitable doctrines. On September 24, 2021, Alvotech

hf. served on AbbVie Inc. and AbbVie Biotechnology Ltd. initial invalidity contentions pursuant to this District's Local Patent Rule 2.3 describing Alvotech hf.'s position that the claims of the '792 patent are invalid. Among other reasons, the claims of the '792 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '792 patent, including, for example, the prior art Alvotech hf. produced or otherwise identified to AbbVie with Alvotech hf.'s initial invalidity contentions. On November 12, 2021, Alvotech hf. served on AbbVie Inc. and AbbVie Biotechnology Ltd. first amended initial invalidity contentions. Alvotech hf.'s initial and amended invalidity contentions are within AbbVie's possession and are incorporated by reference herein.

128. On October 8, 2021, and pursuant to this District's Local Patent Rule 2.5, AbbVie purported to respond to Alvotech hf.'s initial invalidity contentions regarding the '792 patent and provided AbbVie's opinion that the '792 patent is not invalid. AbbVie purported to serve responses to the 35 U.S.C. § 112 portions of Alvotech hf.'s initial and amended invalidity contentions on November 12, 2021 and December 6, 2021, respectively, providing AbbVie's opinion that the '792 patent is not invalid. AbbVie amended its complaint to include counts of infringement of the '792 patent by Alvotech hf. on November 12, 2021. AbbVie's second amended complaint on December 21, 2021 maintained allegations of infringement of the '792 patent.

129. As a result of AbbVie's allegations against Alvotech hf., an actual and justiciable controversy exists between Alvotech hf. and AbbVie as to whether the claims of the '792 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

130. Alvotech hf. is entitled to a judicial declaration that all claims of the '792 patent are invalid. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT XV

(Declaratory Judgment of Unenforceability for Inequitable Conduct Regarding U.S. Patent No. 11,083,792)

131. Alvotech hf. re-alleges the foregoing paragraphs of its counterclaims as if fully set forth herein.

132. The family of patents relating to cathepsin L activity, including the '792 patent, are a portion of the 100+ patents that AbbVie used to build its "minefield of IP" to improperly extend its adalimumab monopoly.

133. In order to obtain the claims in this patent family generally and the '792 patent specifically, AbbVie [redacted]. For example, [redacted] and allow the public to determine the boundaries of the claimed subject matter. [redacted]. (Ex. A, ABV-ALV_00244071.) But in drafting the '792 patent, [redacted]. (*See id.* at §§ 4.4 and 4.5.) In addition, AbbVie [redacted]. (*Id.* at § 5.2.2.) On information and belief, AbbVie [redacted]

[redacted] with the specific intent to mislead or deceive the Patent Office and with knowledge that [redacted] was material to patentability.

134. On information and belief, AbbVie knew [redacted]. AbbVie also knew disclosure of [redacted]. But AbbVie made a deliberate decision [redacted] for the purpose of injecting ambiguity into its claims to avoid rejection under certain prior art, such as Follman and Fahrner, "Factorial Screening of Antibody Purification Processes Using Three Chromatography Steps Without Protein A," J. of Chromatography A, 1024 (2004) (Ex. B, ALV0120391). The single most reasonable inference to be drawn from the evidence is that [redacted] material to patentability was done with the intent to deceive the Patent Office.

135. Likewise, AbbVie withheld prior art describing the manufacturing process described in the specification of the patents in the family. Specifically, Min Wan, one of the inventors, gave a presentation entitled "Process Mapping: A Necessary Step in Product Lifecycle" at the BioProcess International Conference & Exhibition held in Boston in October 2004. (Ex. C, ALV0121244 ("Wan Presentation").) In that presentation, Ms. Wan described the steps of the Humira® Recovery Process, including Fractogel S Chromatography, Q Sepharose, and Phenyl Sepharose Chromatography. The presentation chronicled how AbbVie learned through process mapping that it needed to increase load at the Fractogel step to displace host cell proteins ("HCPs") and insert a wash step to enhance HCP clearance and relieve the HCP burden on the Phenyl step. These modifications are chronicled in Process B of the patent specification. On information and

belief, AbbVie knew that the Wan Presentation was material to patentability of this patent family, including the claims in the '792 patent. [redacted]. (Ex. D, ABV-ALV_08797304 at -312-13.)

136. The Wan Presentation described additional modifications to the manufacturing process to "debottleneck" the process for "Financial needs." Process B describes the solution to the bottleneck: increase the load in the Fractogel step and insert a wash step to increase HCP clearance. It turned out that the "debottlenecking" solution had the added benefit of reducing the cathepsin L levels even more. The Wan Presentation disclosed AbbVie's manufacturing process and where that process needed adjustment to resolve HCP issues. AbbVie identified all of these adjustments [redacted].

137. [redacted]. (Ex. D, ABV-ALV_08797304 at -312-313.)

138. AbbVie filed the original provisional patent applications in April 2006, approximately 18 months after the Wan Presentation. The single most reasonable inference able to be drawn from the evidence is that AbbVie (including at least Cristin E. Howley, Ph.D of Lahive & Cockfield, LLP, [redacted]) withheld this information

with the specific intent to mislead or deceive the Patent Office and with knowledge that the withheld information was material to patentability.

139. On information and belief, AbbVie knew the information regarding its manufacturing process and the adjustments made to improve HCP clearance was material to the prosecution of the patent claims. AbbVie also knew disclosure of [redacted]. But AbbVie made a deliberate decision to withhold information about its process to avoid rejection under Wan Presentation and certain prior art, such as Follman and Fahrner, "Factorial Screening of Antibody Purification Processes Using Three Chromatography Steps Without Protein A," J. of Chromatography A, 1024 (2004) (Ex. B, ALV0120391). Knowing the information in the Wan Presentation, a person of skill could have arrived at the claimed inventions using routine skill and without undue experimentation. The single most reasonable inference to be drawn from the evidence is that this withholding of key information material to patentability was done with the intent to deceive the Patent Office.

140. AbbVie did not provide a copy of the Wan Presentation to the Patent Office until December 4, 2017, in a filing that included 62 other references. (Ex. I.) The belated submission to the Patent Office—more than a decade after the original filings and issuance of 9 patents in the family—does not absolve AbbVie's inequitable conduct.

141. Another instance of AbbVie's misconduct was its withholding information from the Patent Office regarding prior art sales of Humira®. The patents in this family claim priority to provisional patent applications filed on April 5th and 6th of 2006. Sales of Humira® before this date constitute prior art to the patents in this patent family. In furtherance of its goal of building a

"minefield of IP," AbbVie intentionally withheld information from the Patent Office regarding the amount of cathepsin L activity in its Humira® product sold before the April 5, 2006.

142. For example, AbbVie filed for and obtained claims in U.S. Patent No. 8,231,876 ("the '876 patent") that cover compositions with "a cathepsin L activity of no greater than about 3.0 RFU/s/mg antibody." On information and belief, AbbVie sold Humira® with "a cathepsin L activity no greater than about 3.0 RFU/s/mg antibody" before the April 2006 filing date.

143. When amending the claims during prosecution of the '876 patent, AbbVie (at least through Cristin Howley Cowles) argued:

> The compositions of Claims 56, 58, 60 and 62-71 have been amended to recite a certain low level of cathepsin L activity, *i.e.*, a cathepsin L activity of no greater than about 3.0 RFU/s/mg antibody, not seen before in compositions containing human anti-TNFa antibodies.

(Ex. H, December 12, 2011 Amendment and Response to Non-Final Office Action, at p. 11.)

144. Upon information and belief, this statement was not true. AbbVie (Ms. Cowles) then had a telephonic interview to discuss the claims. After the interview, the examiner allowed the claims and stated as a reason in the Notice of Allowance:

> Each of the prior art rejections based upon Salfeld et al in view of a secondary reference that shows a purification method that reduces HCP levels in an antibody preparation has been withdrawn because none of the secondary references address the limitation concerning the level of cathepsin-L activity being "no greater than about 3.0 RFUs/mg antibody." There is no expectation from any of these secondary references that the level of cathepsin-L activity would be at this required low level; it is noted in

(*See* Ex. H, March 23, 2012 Notice of Allowance.)

145. Upon information and belief, AbbVie (including at least Ms. Cowles) withheld information regarding the level of cathepsin L activity in Humira® sold before April 2006 with the specific intent to mislead or deceive the Patent Office and with knowledge that the withheld information was material to patentability.

146. During the prosecution of counterpart patents in Europe, AbbVie also filed for claims covering compositions with less than 3.0 RFU/s/mg antibody. In one prosecution, the claims were rejected based in part on commercial Humira®. On September 2, 2013, AbbVie amended the claims to "less than 1.84 RFU/s/mg antibody" pointing to Sample D in Table 13 of the patent disclosure. (Ex. E.) AbbVie argued that the prior art reference (reference D2) was published prior to the improvements of Process B and made by "prior art methods," a reference to Process A in the patent. Because of this, AbbVie argued that D2's adalimumab composition "would not have had the low level of cathepsin L activity recited in substitute claim 1." During an oral hearing on October 2, 2013, AbbVie similarly argued in favor of the amendment stating that 1.84 RFU/s/mg antibody level "was the lowest valued obtained in Tab. 13 with the purification method of the prior art." (Ex. F.)

147. In another prosecution in Europe, AbbVie filed for claims of less than 3.0 RFU/s/mg of antibody, which were also rejected based on commercial Humira®. In this prosecution, AbbVie amended the claims to a level of cathepsin L activity no greater than 1.5 RFU/s/mg antibody on March 17, 2015. (Ex. G.) In support of the amended claims, AbbVie "confirmed" that the prior art compositions (D1 and D2) did not intrinsically exhibit "a level of procathepsin of no greater than that indicated by a cathepsin L activity of 1.5 RFU/s/mg of antibody as measured by a cathepsin L kinetic assay." (*Id.* at p. 5)

148. AbbVie's arguments and statements during patent prosecution in Europe show that it knew that at least some of the Humira® sold before April 2006 had a cathepsin L activity of less than 3.0 RFU/s/mg antibody as measured by its kinetic assay. The single most reasonable inference to be drawn from the evidence is that this withholding of key information material to patentability was done with the intent to deceive the Patent Office.

149. AbbVie filed its First Amended Complaint against Alvotech hf. on November 12, 2021, alleging infringement of the '792 patent. AbbVie filed is Second Amended Complaint against Alvotech hf. on December 21, 2021, and maintained its allegations of infringement of the '792 patent.

150. As a result of AbbVie's allegations against Alvotech hf., an actual and justiciable controversy exists between Alvotech hf. and AbbVie as to whether the claims of the '792 patent are unenforceable due to AbbVie's inequitable conduct.

151. Alvotech hf. is entitled to a judicial declaration that all claims of the '792 patent are unenforceable. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT XVI

(Declaratory Judgment of Non-infringement of U.S. Patent No. 11,167,030)

152. Alvotech hf. re-alleges the foregoing paragraphs of its counterclaims as if fully set forth herein.

153. Alvotech hf. has not infringed and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '030 patent under 35 U.S.C. § 271. On September 24, 2021, Alvotech hf. served on AbbVie Inc. and AbbVie Biotechnology Ltd. initial non-infringement contentions pursuant to this District's Local Patent Rule 2.3 describing Alvotech hf.'s position that it will not infringe the '030 patent. On November 12, 2021, Alvotech hf. served on AbbVie Inc. and AbbVie Biotechnology Ltd. first amended initial non-infringement contentions. Alvotech hf.'s initial and amended initial non-infringement contentions are within AbbVie's possession and are incorporated by reference herein.

In addition, Alvotech hf. cannot be liable for any infringement of the '030 patent because it is invalid and unenforceable.

154. On September 10, 2021, and pursuant to this District's Local Patent Rule 2.2, and on October 8, 2021, and pursuant to this District's Local Patent Rule 2.5, AbbVie purported to provide Alvotech hf. with contentions alleging that Alvotech hf. will infringe the '030 patent. AbbVie amended its complaint to include counts of infringement of the '030 patent by Alvotech hf. on November 12, 2021. AbbVie's second amended complaint on December 21, 2021 maintained allegations of infringement of the '030 patent.

155. As a result of AbbVie's allegations against Alvotech hf., an actual and justiciable controversy exists between Alvotech hf. and AbbVie as to the infringement of the '030 patent.

156. Alvotech hf. is entitled to a judicial declaration that the making, use, offer for sale, sale, or importation into the United States of Alvotech hf.'s biosimilar product does not and will not infringe any valid and enforceable claim of the '030 patent under 35 U.S.C. § 271. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT XVII

(Declaratory Judgment of Invalidity of U.S. Patent No. 11,167,030)

157. Alvotech hf. re-alleges the foregoing paragraphs of its counterclaims as if fully set forth herein.

158. The claims of the '030 patent are invalid for failing to meet the requirements of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 112 and/or pursuant to common law and/or equitable doctrines. On September 24, 2021, Alvotech hf. served on AbbVie Inc. and AbbVie Biotechnology Ltd. initial invalidity contentions pursuant

to this District's Local Patent Rule 2.3 describing Alvotech hf.'s position that the claims of the '030 patent are invalid. Among other reasons, the claims of the '030 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in light of prior art that published or was otherwise available to the public before the earliest possible priority date of the '030 patent, including, for example, the prior art Alvotech hf. produced or otherwise identified to AbbVie with Alvotech hf.'s initial invalidity contentions. On November 12, 2021, Alvotech hf. served on AbbVie Inc. and AbbVie Biotechnology Ltd. first amended initial invalidity contentions. Alvotech hf.'s initial and amended invalidity contentions are within AbbVie's possession and are incorporated by reference herein.

159. On October 8, 2021, and pursuant to this District's Local Patent Rule 2.5, AbbVie purported to respond to Alvotech hf.'s initial invalidity contentions regarding the '030 patent and provided AbbVie's opinion that the '030 patent is not invalid. AbbVie purported to serve responses to the 35 U.S.C. § 112 portions of Alvotech hf.'s initial and amended invalidity contentions on November 12, 2021 and December 6, 2021, respectively, providing AbbVie's opinion that the '030 patent is not invalid. AbbVie amended its complaint to include counts of infringement of the '030 patent by Alvotech hf. on November 12, 2021. AbbVie's second amended complaint on December 21, 2021 maintained allegations of infringement of the '030 patent.

160. As a result of AbbVie's allegations against Alvotech hf., an actual and justiciable controversy exists between Alvotech hf. and AbbVie as to whether the claims of the '030 patent are invalid for failure to comply with the requirements of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 112, and/or pursuant to common law and/or equitable doctrines.

161. Alvotech hf. is entitled to a judicial declaration that all claims of the '030 patent are invalid. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

PRAYER FOR RELIEF

WHEREFORE, Defendant respectfully request that this Court enter judgment in its favor against AbbVie Inc. and AbbVie Biotechnology Ltd. and grant the following relief:

A. Declare that Alvotech hf. has not, does not, and will not infringe any valid and enforceable claim of the patents-in-suit;

B. Declare that the claims of the patents-in-suit are invalid;

C. Declare that all of the patents-in-suit are unenforceable;

D. Enjoin and restrain AbbVie Inc. and AbbVie Biotechnology Ltd. and their officers, agents, servants, employees, attorneys, and those persons in active concert or participation with them from pursuing further charges of infringement or acts of enforcement based on the patents-in-suit against Alvotech hf. or its actual and prospective business partners, customers, suppliers, clinical investigators, and anyone in privity with Alvotech hf.;

E. Deny AbbVie Inc. and AbbVie Biotechnology Ltd. any request for injunctive relief and any other remedy available under Title 35 of the United States Code;

F. Declare that this is an exceptional case in favor of Alvotech hf. and award Alvotech hf. its reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

G. Award Alvotech hf. taxable costs and interest; and

H. Award any and all such relief as the Court determines to be just and proper, including pursuant to 28 U.S.C. § 2202.

JURY DEMAND

Plaintiffs hereby demand a jury trial in this action for any issue so triable.

Date: January 5, 2022

Respectfully submitted,

ALVOTECH HF.

By: */s/ Louis E. Fogel*

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CERTIFICATE OF SERVICE

I hereby certify that on January 5, 2022 I caused a true and correct copy of the foregoing to be electronically served on counsel of record via the Court's CM/ECF system.

/s/ *Louis E. Fogel*
Louis E. Fogel