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

ABBVIE INC. and ABBVIE BIOTECHNOLOGY LTD Plaintiffs, v. ALVOTECH HF. Defendant.	Civil Action No. 1:21-cv-02899

COMPLAINT

INTRODUCTION

1. This is the second action for patent infringement that AbbVie Inc. and AbbVie Biotechnology Ltd ("ABL," collectively referred to as "AbbVie" or "Plaintiffs") have brought against Alvotech hf. ("Alvotech") under the Biosimilar Price Competition and Innovation Act of 2009 ("BPCIA") in connection with Alvotech's proposed biosimilar version of AbbVie's 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.). Alvotech's filing and additional actions, discussed below, have triggered this second suit under

the BPCIA to protect AbbVie's rights and promote the orderly disposition of all the patent infringement issues raised by Alvotech's proposed biosimilar product.

2. AbbVie's patents at issue in this suit and in the first-filed BPCIA action already pending in this District result from decades of work by AbbVie's scientists and clinicians developing HUMIRA®—the first fully human antibody ever approved by the U.S. Food and Drug Administration ("FDA")—and expanding its use into a variety of diseases and patient populations, as well as launching a new, higher-concentration, citrate-free formulation with reduced injection volume and pain upon injection. Over one million patients have benefited from AbbVie's pioneering work, which also has produced a robust portfolio of patents and trade secrets, including trade secret manufacturing processes.

3. Numerous biosimilar companies—now including Alvotech—have taken note of AbbVie's success as well, attempting to make biosimilar versions of HUMIRA®. 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.

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.

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

6. AbbVie's investment in HUMIRA® 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.

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.

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

9. AbbVie has also spent many years developing and improving the complex manufacturing processes for HUMIRA® 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.

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

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

12. Alvotech chose to litigate only four patents in the first wave, despite the fact that AbbVie identified 62 patents that would be infringed by Alvotech's biosimilar product. *See AbbVie Inc. and AbbVie Biotechnology Ltd v. Alvotech hf.*, Civ. No. 1:21-cv-02258 (N.D. Ill. Apr. 27, 2021) (Lee, J.). Yet, Alvotech then abandoned the BPCIA's procedures by seeking to litigate the same four patents in a declaratory judgment action in a different federal court after AbbVie filed its first BPCIA-prescribed suit. On the same day it filed its Eastern District of Virginia

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