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

ABBVIE INC. and ABBVIE BIOTECHNOLOGY LTD,	)	
Plaintiffs,	)	
	)	**No. 21 C 2258**
v.	)	
	)	**Judge John Z. Lee**
ALVOTECH HF.,	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

Plaintiffs AbbVie Inc. and AbbVie Biotechnology Ltd (collectively "Plaintiffs" or "Abbvie") filed suit against Defendant Alvotech hf. pursuant to 35 U.S.C. § 271(e)(2)(C)(i), seeking injunctive relief to prevent Alvotech hf. from infringing certain patents related to the biologic drug, HUMIRA®. In turn, Alvotech hf., which is an Icelandic corporation, moved to dismiss, arguing that the Biosimilar Price Competition and Innovation Act ("BPCIA") requires Abbvie to sue Alvotech hf.'s United States subsidiary, Alvotech USA, instead of or in addition to Alvotech hf. And, because Alvotech USA is at home only in the Eastern District of Virginia, Alvotech hf. further argues that this lawsuit must be dismissed for lack of venue. For the following reasons, Alvotech hf.'s motion is denied.

I. Background[1]

A. HUMIRA®

HUMIRA® is the first fully human antibody ever approved by the U.S. Food and Drug Administration ("FDA"). Compl. ¶ 1, ECF No. 1. It is used to treat several autoimmune conditions, such as rheumatoid arthritis, psoriatic arthritis, psoriasis, Crohn's disease (adult and pediatric), and juvenile idiopathic arthritis. *Id.* ¶ 8.

HUMIRA® belongs to a category of drugs known as biologics. *Id.* ¶ 7. Biologics are comprised of complex proteins manufactured in living cells as opposed to using chemical synthesis, which is how small molecule drugs are derived. *Id.* Abbvie holds the drug's Biologic License Application ("BLA"). *Id.* ¶ 20. The development of HUMIRA® has produced a vast portfolio of patents and trade secret manufacturing processes. *Id.* ¶ 1.

B. The Biosimilar Price Competition and Innovation Act of 2009

In 2009, Congress passed the BPCIA, which establishes an abbreviated process by which nearly identical biologic drugs—called "biosimilars"—can seek FDA approval and enter the market as generics of an already-approved biologic. *Id.* ¶ 3. To do so, an applicant submits an abbreviated Biologics License Application ("aBLA") to the FDA, which provides information about why the generic should be considered a biosimilar of the original drug (the "reference

[1] For the reasons discussed below, the Court accepts all well-pleaded facts as true and draws all reasonable inferences in Abbvie's favor.

product"). *See* 42 U.S.C. § 262(k). This process is abbreviated because the biosimilar product can piggyback off research establishing that the reference product is "safe, pure, and potent." *Id.* § 262(a)(2)(C).

The aBLA applicant—known as the "subsection (k) applicant" because the requirements are laid out in 42 U.S.C. § 262(k)—must provide notice of its aBLA to the "reference product sponsor." *Id.* § 262(*l*)(2). Following that notice, the statute requires the subsection (k) applicant and reference product sponsor to engage in an exchange of information about patents covering the reference product and its manufacture, which is known colloquially as the "patent dance." *Id.* § 262(*l*); *see also* Alvotech hf.'s Mem. Supp. Mot. Dismiss ("Mot. Dismiss") at 1, ECF No. 27.

As part of the exchange, the subsection (k) applicant must provide "a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that [the relevant] patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application." 42 U.S.C. § 262(*l*)(3)(B)(2). Through this process, the parties are encouraged to identify any patent disputes that should be litigated in a declaratory judgment action before the biosimilar drug makes it to the market. *See generally id.* § 262(*l*). At the end of the patent dance, if the parties cannot agree on an out-of-court resolution for their patent disputes, the statute instructs the reference product sponsor to bring

a patent infringement lawsuit with respect to the patents the biosimilar drug would allegedly infringe. *Id.* § 262(*l*)(6).

When Congress passed the BPCIA in 2009, it was not writing on a blank slate. The BPCIA's aBLA procedure closely resembles one that was already available under the Hatch-Waxman Act for small molecule drugs. Under the Hatch-Waxman Act, a party seeking approval of a generic small molecule drug may submit an abbreviated New Drug Application ("ANDA"), which piggybacks off research pertaining to an existing small molecule drug, if the ANDA applicant can demonstrate that the two drugs are "bioequivalent." *See* 21 U.S.C. § 355(j). Like a subsection (k) aBLA applicant, an ANDA applicant must notify the existing drug's relevant patent owners about its application, and the notice must "include a detailed statement of the factual and legal basis of the opinion of the applicant that [any relevant] patent[s] [are] invalid or will not be infringed." 21 U.S.C. § 355(j)(2)(B).

To enable the adjudication of such patent disputes before the ANDA applicant or subsection (k) applicant begins to manufacture, market, or sell its new product, Congress created an "artificial act of infringement," *see Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1672 (2017), as part of the patent statutes. *See* 35 U.S.C. § 271(e)(2). That section states:

> It shall be an act of infringement to submit–
>
> > (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act [*i.e.*, an ANDA] for a drug claimed in a patent or the use of which is claimed in a patent,

> . . . or
>
> (C)(i) with respect to a patent that is identified in the list of patents described in section 351(*l*)(3) of the Public Health Service Act [*i.e.*, a patent identified in the patent dance,] . . . an application seeking approval of a biological product [*i.e.*, an aBLA], or
>
> (ii) if the applicant for the application fails to provide the application and information required under section 351(*l*)(2)(A) of such Act [*i.e.*, fails to participate in the patent dance], an application seeking approval of a biological product [*i.e.*, an aBLA] for a patent that could be identified pursuant to section 351(*l*)(3)(A)(i) of such Act [*i.e.*, a patent that could have been identified in the patent dance],
>
> if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a . . . biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2).[2]

Section 271(e)(2) existed prior to the passage of the BPCIA. And the 2009 Act amended the statute to add subsection (C) to address biologics.

C. The Instant Lawsuit

Alvotech hf. is a company organized and existing under the laws of Iceland, with its principal place of business in Reykjavik. Compl. ¶ 27. Alvotech hf. is in the business of developing, manufacturing, marketing, and selling biologic drugs. *Id.* ¶ 28.

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[2] Subsection (B) governs applications relating to "a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques," and it is not relevant here. *See* 35 U.S.C. § 271(e)(2)(B).

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