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

ABBVIE INC. and ABBVIE BIOTECHNOLOGY LTD,	)	
Plaintiffs,	)	
	)	**No. 21 C 2899**
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. ("Alvotech") 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®. Pursuant to the Biosimilar Price Competition and Innovation Act ("BPCIA"), this litigation consists of two phases. The first phase, before this Court as *AbbVie Inc. v. Alvotech hf.*, 21 C 2258 (N.D. Ill. 2021), focuses on certain contested patents for expeditious litigation. The second phase, the one at issue here, deals with any remaining patents at issue and is not triggered until the U.S. Food and Drug Administration ("FDA") applicant (in this case, Alvotech) provides notice that it will be marketing its product. This Court already has denied a motion to dismiss in the first phase of this litigation. *See AbbVie Inc. v. Alvotech hf.*, No. 21 C 2258, 2021 WL 3737733 (N.D. Ill. Aug. 23, 2021). A substantially similar motion has been filed in this case. For the following reasons, this motion too is denied.

I. Background[1]

A. HUMIRA®

HUMIRA® is the first fully human antibody ever approved by the FDA. Compl. ¶ 2, 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.* ¶ 6.

HUMIRA® belongs to a category of drugs known as biologics. *Id.* ¶ 9. Biologics are comprised of complex proteins manufactured in living cells, as opposed to small molecule drugs derived from chemical synthesis. *Id.* AbbVie holds the drug's Biologic License Application ("BLA"). *Id.* ¶ 21. The development of HUMIRA® has produced a vast portfolio of patents and trade secret manufacturing processes. *Id.* ¶ 3.

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 generic versions of an already-approved biologic. *Id.* ¶ 1. To start the process, an applicant submits an abbreviated Biologics License Application ("aBLA") to the FDA. *See* 42 U.S.C. § 262(k). An aBLA provides information about why the proposed generic drug should be considered a biosimilar of the original drug (the "reference product"). *See id.* 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).

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

The aBLA applicant—also 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" ("RPS"). *Id.* § 262(l)(2). Following that notice, the statute requires the subsection (k) applicant and the RPS 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. 29.

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 its position 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 patent disputes that should be litigated before the applicant commercially markets its biosimilar drug. *See generally id.* § 262(l). At the end of the patent dance, if the parties cannot agree on an out-of-court resolution of their patent disputes, the statute instructs the RPS to bring a first-phase patent infringement lawsuit with respect to the patents that it believes the biosimilar drug would allegedly infringe. *Id.* § 262(l)(6).

Under the BPCIA, the parties select the patents previously identified by the parties under § 262(l)(3) to litigate in the first phase (*i.e.*, before the biosimilar goes to market). *Id.* The remaining patents that were identified in the patent dance may be litigated in the second phase under § 262(l)(8). *Id.* § 262(l)(8). However, the second

phase is triggered only after the applicant notifies the RPS that the biosimilar will be commercially marketed at least 180 days before it does so. *Id.*

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," *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 provides:

> 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
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> (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],
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> 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. *See Sandoz*, 137 S. Ct. at 1670.

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. ¶ 28. Alvotech hf. is in the business of developing, manufacturing, marketing, and selling biologic drugs. *Id.* ¶ 29.

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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* § 271(e)(2)(B).

Beginning in at least May 2018, Alvotech hf. began clinical trials for a biosimilar to Humira, called AVT02. *Id.* ¶ 35. In the early fall of 2020, Alvotech USA[3] submitted an aBLA seeking FDA approval for AVT02. Compl. ¶ 42. As required, Alvotech USA notified AbbVie of its application, and the parties engaged in the patent dance. Compl. ¶¶ 45–52. In the end, the two entities identified four patents to be litigated in the first stage of these proceedings, with another sixty-two to be litigated in the second stage of litigation envisioned by the statute. *Id.* ¶¶ 50–51; *see also* § 262(l)(6)–(8).[4]

AbbVie then filed two complaints to address separately the first and second phases of the litigation. *See* Compl.; *see also AbbVie Inc. v. Alvotech hf.*, No. 21 C 2258, ECF No. 1. Alvotech filed motions to dismiss in each case. *See AbbVie Inc. v. Alvotech hf.*, No. 21 C 2258, ECF No. 26; *AbbVie Inc. v. Alvotech hf.*, No. 21 C 2899, ECF No. 28. The Court denied Alvotech's motion to dismiss in the first-phase litigation. *See AbbVie*, No. 21 C 2258, 2021 WL 3737733. This order considers Alvotech's motion to dismiss the claims raised in AbbVie's second-phase litigation.

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[3] As noted previously, the Court "accept[s] as true all well-pleaded facts alleged" in reviewing a motion to dismiss, *see Tamayo*, 526 F.3d at 1081. But the Court may also "consider documents attached to a motion to dismiss if they are referred to in the plaintiff's complaint and are central to his claim," *Brownmark Films, LLC v. Comedy Partners*, 682 F.3d 687, 690 (7th Cir. 2012) (cleaned up). As such, while AbbVie's complaint does not distinguish between Alvotech hf and Alvotech USA when discussing the aBLA and related patent dance, the Court has considered the aBLA itself, which is attached to Alvotech hf.'s motion to dismiss as Exhibit D. *See* Mot. Dismiss, Ex. D, Application to Market a New or Abbreviated New Drug or Biologic for Human Use ("AVT02 aBLA"), ECF No. 28-4.

[4] The parties ultimately agreed to litigate ten patents in phase one. *See AbbVie Inc. v. Alvotech hf.*, No. 21 C 2258, ECF No. 63.

In its motion, Alvotech hf. seeks to dismiss the complaint pursuant to Rules 12(b)(1) (lack of subject matter jurisdiction); 12(b)(2) (lack of personal jurisdiction); 12(b)(6) (failure to state a claim); and 12(b)(7) (failure to join an indispensable party). All but the first of Alvotech's arguments are identical to those raised in the first-phase motion to dismiss. Accordingly, this order focuses on Alvotech's first argument challenging AbbVie's ability to bring a claim for injunctive relief under 35 U.S.C. § 271(e)(4)(B) in the second-phase litigation.

II. Legal Standard

Under Rule 12(b)(1), a defendant may move to dismiss claims over which the federal court lacks subject-matter jurisdiction. *See Apex Digital, Inc. v. Sears, Roebuck & Co.*, 572 F.3d 440, 443 (7th Cir. 2009); *Perry v. Vill. of Arlington Heights*, 186 F.3d 826, 829 (7th Cir. 1999). A defendant may challenge subject-matter jurisdiction either facially or factually. *Silha v. ACT, Inc.*, 807 F.3d 169, 172 (7th Cir. 2015). Facial challenges, like the one here, "require only that the court look to the complaint and see if the plaintiff has sufficiently alleged a basis of subject matter jurisdiction." *Apex*, 572 F.3d at 443. When considering a facial challenge, "the district court must accept as true all well-pleaded factual allegations, and draw reasonable inferences in favor of the plaintiff." *Ezekiel v. Michel*, 66 F.3d 894, 897 (7th Cir. 1995).

At the same time, to survive a motion to dismiss under Rule 12(b)(6), a complaint must "state a claim to relief that is plausible on its face." *Bell Atl.*

Corp. v. Twombly, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). This standard "is not akin to a probability requirement, but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* (cleaned up). "Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *Id.* (cleaned up).

When considering a motion to dismiss, courts accept "all well-pleaded factual allegations as true and view them in the light most favorable to the plaintiff." *Lavalais v. Vill. of Melrose Park*, 734 F.3d 629, 632 (7th Cir. 2013). But courts are "not bound to accept as true a legal conclusion couched as a factual allegation." *Papasan v. Allain*, 478 U.S. 265, 286 (1986). Accordingly, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice" to state a claim. *Iqbal*, 556 U.S. at 678.

Here, Alvotech's motion to dismiss is raised under both 12(b)(1) and 12(b)(6). But the issue presented is a purely legal one—the type of relief authorized under the BPCIA. Accordingly, the Court's analysis would be the same under either standard.

III. Analysis

A. AbbVie's Second Phase § 271(e)(2)(C) Claims

The Court first turns to the issue of whether AbbVie may bring its § 271(e)(2)(C)(i) claims during the second phase of the BPCIA litigation. Alvotech argues that AbbVie is precluded from asserting its infringement claims during the second phase of litigation, governed by § 262(l)(8), maintaining that as the RPS, AbbVie may only bring declaratory judgement actions in the second phase.

In support, Alvotech relies on differences between the statutory language in § 262(l)(6), the first phase provision, versus the language in §§ 262(l)(8) and (9), which address the second phase. In the former, Alvotech points out, phase one is described as one in which the RPS brings "an action for patent infringement." By contrast, §§ 262(l)(8) and (9) do not include the phrase "an action for patent infringement." Furthermore, § 262(l)(9)(A) appears to describe the second phase action as "an action under section 2201 of Title 28 for a declaration of infringement, validity, or enforceability" of the patents at issue. According to Alvotech, these differences taken together preclude the RPS from seeking injunctive relief pursuant to § 271(e)(4) during the second phase and limits second phase relief to a declaratory judgment and preliminary injunctive relief. But, as explained below, this is much too crabbed a reading of the statutory subsections and disjoins them from their context.

First, any claims for patent infringement that AbbVie may have stem from § 271(e)(2)(C)(i), which provides that it is "an act of infringement to submit . . . an application seeking approval of a biological product." In interpreting this provision,

the Supreme Court has held that it creates an "artificial act of infringement" as to "those [patents] contained in the § 262(l)(3) lists." *Sandoz*, 137 S. Ct. at 1674. The "§ 262(l)(3) lists", in turn, consist of all "patents for which the [RPS] believes a claim of patent infringement could reasonably be asserted by the [RPS]." 42 U.S.C. § 262. Thus, under § 271(e)(2), the submission of a BLA application creates an artificial act of infringement as to *all* patents identified by the RPS pursuant to § 262(l)(3), without regard to whether the patents are asserted in the first phase of the litigation or the second.

Next, § 271(e)(4) sets forth the remedies available to an RPS, like AbbVie. "For an act of infringement described in paragraph [§ 271(e)](2)," § 271(e)(4) provides four remedies: the Court must issue an "order [making] the effective date of any approval of the drug . . . involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed;" "injunctive relief may be granted against an infringer;" "damages or other monetary relief may be awarded;" and/or "the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C)." *Id*. Accordingly, under § 271(e), AbbVie can seek (among other remedies) injunctive relief for any patent artificially infringed by Alvotech's filing of its FDA application. § 271(e)(2)(C)(i); § 271(e)(4)(C).

Against this backdrop, Alvotech argues that, even if § 271(e)(2) provides AbbVie with a cause of action as to the patents to be litigated in the second phase and

§ 271(e)(4) authorizes AbbVie to seek various remedies, the BPCIA expressly limits AbbVie's ability to seek such remedies to the first phase. As Alvotech puts it, "§ 271(e)'s artificial act of infringement is tied to 42 U.S.C. § 262(l)(6) of the BPCIA, and thus may be relied upon by an RPS like AbbVie in the first phase litigation only." Def.'s Mot. Dismiss at 4, ECF No. 29. Its argument appears to go like this: § 262(l)(6) refers to the first phase as "an action for patent infringement;" the "patent infringement" in § 262(l)(6) must equate to the "act of infringement" described in § 271(e)(2); *ergo*, the RPS can only bring an action based upon § 271(e)(2) during the first phase of the litigation created by § 262(l)(6).

But the patents that are litigated in the first phase under § 262(l)(6) are determined under § 262(l)(4), not § 262(l)(3). 42 U.S.C. § 262(l)(6)(A). And although only the final list that results under § 262(l)(4) proceeds to the "*immediate* patent infringement action" under 42 U.S.C. § 262(l)(6) (emphasis added), *all* of the patents listed under § 262(l)(3) are artificially infringing within the meaning of § 271(e)(2)(C)(i) once a subsection (k) applicant files its BLA application. If Congress had wanted to limit § 271(e) patent infringement actions in BPCIA cases only to those patents identified under § 262(l)(4), it easily could have done so. But by including patents identified under § 262(l)(3), Congress extended the artifice of infringement to both groups—patents litigated in the first phase, as well as those litigated in the second phase.

Second, Alvotech notes that § 262(l)(9)(A) describes the second phase as "an action . . . for a declaration of infringement, validity, or enforceability" of the patents

in suit and asks the Court to read this as an exclusive remedy provision that precludes any other relief provided in § 271(e)(4), including injunctive relief. However, nothing in § 262(l)(9) indicates that its reference to an "action . . . for a declaration of infringement, validity, or enforceability" was intended to exclude all other remedies. At the same time, § 271(e)(4) provides a number of different potential remedies to redress an infringement under § 271(e)(2).[5] Indeed, it is more natural to read the BPCIA as first creating an artificial act of infringement with respect to all patents (both those in phase one and phase two), § 271(e)(2)(C); focusing the parties (and the trial court) on the most relevant patents in phase one, as well as the applicability and appropriate scope of any of the remedies available under § 271(e)(4) as to those patents; then encouraging the parties to litigate any remaining relevant patents in phase two, where the RPS can seek a declaratory relief at to those patents, as well as remedies provided by § 271(e)(4).

Alvotech's final argument is that an interpretation, in which second phase patents are considered artificially infringed under § 271(e)(2) and are subject to all the remedies available under § 271(e)(4), would defeat the purpose of the two-phase system created by the BPCIA. Alvotech argues that "[b]ecause the act of infringement under 271(e)(2) occurs at the time of filing, the RPS could immediately

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[5] In this way, this case is distinguishable from *Sandoz,* where the reference product sponsor tried to seek a preliminary injunction to force the subsection (k) applicant to disclose its application and manufacturing information under § 262(l)(2)(A). Noting that such a failure did not constitute an act of artificial infringement under § 271(e)(4), 137 S.Ct. at 1674, as well as "the absence of any other textually specified remedies," *id.* at 1675, the Supreme Court held that an action for declaratory judgment provided in § 262(l)(2)(A) was the exclusive remedy under that subsection. Here, Alvotech's filing triggered § 271(e)(2), which in turn triggered the various remedies set forth in § 274(e)(4).

sue the BLA applicant on all of the paragraph [(l)]3 patents at any time, circumventing the bar on declaratory judgment actions before the notice of commercial marketing and reading § 262(l)(9) out of the statute." Def.'s Mem. at 6.

But this argument ignores the practical realities of the two-phase structure, which confers benefits on both the RPS and the subsection (k) applicant. The BPCIA creates a procedure by which the parties can litigate the most contested and consequential patents immediately, *see* § 262(l)(6), giving both parties what is likely a definitive answer, with lower costs and on an expedited schedule. So, while an RPS may not be statutorily prohibited from filing all of its infringement actions at once, the BPCIA creates a structure and an information-exchange mechanism that encourages the parties to identify and focus on the most salient patents and issues first, before moving on to the rest.[6]

Finally, although the parties are to determine in good faith which patents are litigated in each phase, the subsection (k) applicant retains substantial control over which patents are included in first phase litigation. *See Sandoz,* 137 S. Ct. at 1672 ("This process gives the applicant substantial control over the scope of the first phase of litigation: The number of patents on the sponsor's list is limited to the number contained in the applicant's list"); *Genentech, Inc. v. Amgen Inc.*, Civ. No. 17-1407-CFC, Consol., 2020 WL 636439, at *2 (D. Del. Feb. 11, 2020) ("[T]he BPCIA's process

[6] It also is worth noting that, if an RPS were to file infringement actions on non-§ 262(l)(4) patents before the subsection (k) applicant provides a notice of commercial marketing under §262(l)(8)(A), the presiding court would likely take into account the prohibition on declaratory judgement actions in 262(l)(9)(A), as well as the two-phase structure created by the BPCIA, in determining whether to stay such claims or allow them to proceed.

gives the applicant substantial control over the first phase of litigation."). Thus, if Alvotech's interpretation were adopted, a subsection (k) applicant could employ procedural machinations to severely limit the remedies available to an RPS. Moreover, such a regime would incentivize an RPS to include as many of its patents as possible in the phase one lawsuit, undercutting one of the primary purposes of the Act. Alvotech offers no reason to believe that Congress intended to give potential infringers the power to choose the ways in which they were challenged for patent infringement or to create a procedure that would encourage patent holders to lump all of the relevant patents into the first phase.

B. Remaining Arguments

The remainder of Alvotech's motion to dismiss is substantively similar in all material respects to its submission in phase one of this litigation. *See AbbVie Inc. v. Alvotech hf.*, 21 C 2258 (N.D. Ill. 2021), ECF No. 26. Accordingly, the Court's ruling on each of these issues is identical—all remaining arguments in Alvotech's motion to dismiss are denied. The parties are referred to this Court's phase one ruling, *AbbVie*, No. 21 C 2258, 2021 WL 3737733, for further reasoning on this matter.

CONCLUSION

For the foregoing reasons, Alvotech hf.'s motion to dismiss [28] is denied in its entirety.

IT IS SO ORDERED. **ENTERED: January 26, 2022**

John Z. Lee
United States District Judge