**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.

---

[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).

Beginning in at least May 2018, Alvotech hf. began clinical trials for a biosimilar to Humira, called AVT02. *Id.* ¶ 35. In January 2019, Alvotech USA was incorporated under the laws of Virginia to become the "wholly-owned, regulatory affairs, governmental policy and legal subsidiary" of Alvotech hf. *Id.* ¶¶ 33–34 (quoting Office Locations, Alvotech, "Our Locations," https://www.alvotech.com/company/office-locations (last visited April 6, 2021)). In August 2020, Alvotech hf. and Teva Pharmaceuticals announced a strategic partnership for the commercialization of AVT02 in the United States. *Id.* ¶ 37.

In the early fall of 2020, Alvotech USA[3] submitted an aBLA seeking FDA approval for AVT02. Compl. ¶ 41; AVT02 aBLA at 1. As required, Alvotech USA notified Abbvie of its application, and the parties engaged in the patent dance. Compl. ¶¶ 44–51. 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 a second stage of litigation envisioned by the statute (but not relevant to this decision). *Id.* ¶¶ 49–50; *see also* 42 U.S.C. § 262(*l*)(6), (8).

Abbvie then filed this patent infringement suit, naming Alvotech hf.—but not Alvotech USA—as the defendant. According to Abbvie, it did so because

---

[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.

Alvotech hf., not Alvotech USA, is the entity that will engage in the manufacture, commercialization, marketing, and sale of AVT02, if it is approved. By contrast, Alvotech USA is not involved with drug development, manufacturing, or sales. *Id.* ¶ 38. Abbvie also asserts that Alvotech hf. created and prepared the information in the aBLA, even though Alvotech USA appears as the nominal applicant on the form. *Id.* ¶ 34.

Alvotech hf. has moved 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 four arguments are premised on Alvotech hf.'s contention that Alvotech USA, which is domiciled in Virginia, is the real party in interest and must be joined as a defendant in this case.

## II. Analysis

### A. Alvotech's Invocation of Rule 12(b)(1)

Alvotech hf. first argues that the Court lacks subject matter jurisdiction over this case, because Abbvie named the wrong defendant. In Alvotech hf.'s view, the proper defendant is Alvotech USA, not its Icelandic parent corporation. But such an argument is not jurisdictional in nature and is more properly analyzed under Rule 12(b)(6), rather than Rule 12(b)(1).

Federal courts have "original jurisdiction of any civil action arising under any Act of Congress relating to patents." 28 U.S.C. § 1338(a). The Federal Circuit has emphasized that "while Congress can restrict the federal question jurisdiction

granted in [28 U.S.C.] § 1331 or § 1338, for example by mandating that a certain threshold fact be established in order for the federal court to have jurisdiction over a particular cause of action," "it is critical to distinguish between a statutory limitation that is truly jurisdictional and one that is simply an element of the claim that must be established on the merits." *Litecubes, LLC v. N. Light Prod., Inc.*, 523 F.3d 1353, 1361–62 (Fed. Cir. 2008) (citing *Arbaugh v. Y&H Corp.*, 546 U.S. 500, 515–16 (2006)).

The Supreme Court clarified the difference in *Arbaugh v. Y&H Corp.*, 546 U.S. 500. In that case, the plaintiff brought suit under Title VII of the Civil Rights Act of 1964, which "makes it unlawful 'for an employer . . . to discriminate,' *inter alia*, on the basis of sex." *Id.* at 503 (quoting 42 U.S.C. § 2000e–2(a)(1)). Title VII defines an "'employer' to include only those having 'fifteen or more employees.'" *Id.* (quoting 42 U.S.C. § 2000e(b)). The question presented was "whether the numerical qualification contained in Title VII's definition of "employer" affects federal-court subject-matter jurisdiction or, instead, delineates a substantive ingredient of a Title VII claim for relief." *Id.*

The Supreme Court held that the numerical qualification was not jurisdictional, declaring that "[i]f the Legislature clearly states that a threshold limitation on a statute's scope shall count as jurisdictional, then courts and litigants will be duly instructed and will not be left to wrestle with the issue. But when Congress does not rank a statutory limitation on coverage as jurisdictional,

courts should treat the restriction as nonjurisdictional in character." *Id.* at 515–16 (citation omitted).

In the patent context, the Federal Circuit has held that "[s]ection 271(e)(2) is not a jurisdictional statute in the strict sense of the word." *Allergan, Inc. v. Alcon Lab'ys, Inc.*, 324 F.3d 1322, 1330 (Fed. Cir. 2003). While "section 271(e)(2) 'provide[s] patentees with a defined act of infringement sufficient to [a] create case or controversy,'" "[o]nce Congress creates an act of infringement, jurisdiction in the district court is proper under 28 U.S.C. § 1338(a)." *Allergan*, 324 F.3d at 1330 (quoting *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997)). "Therefore, section 1338(a) provides for jurisdiction in the district court for [a] suit [under § 271(e)]." *Id.* Thus, § 271(e) creates a right of action for an artificial act of infringement, while § 1338(a) confers subject matter jurisdiction over the dispute. *Id.*

*Astrazeneca Pharmaceuticals LP v. Aurobindo Pharma Ltd.*, No. CIV.A. 07-810-JJF-LP, 2009 WL 483131 (D. Del. Feb. 25, 2009), is illustrative. There, one of the defendants, Aurobindo USA, argued that it was not a "submit[ter]" within the meaning of § 271(e). It then asserted that this argument "attack[ed] the factual basis for Plaintiffs' assertion of jurisdiction" under Fed. R. Civ. P. 12(b)(1), and so the court had no duty to accept the complaint's allegations as true. *Id.* at *1.

The court quickly rejected this argument, holding that "the issue of whether [the defendant] submitted the [abbreviated drug approval] application for purposes of Section 271(e)(2) is a question that goes to the merits of one of the

elements of Plaintiffs' infringement claim under Section 271(e)(2)," and so the argument was properly evaluated under Fed. R. Civ. P. 12(b)(6). *Id.* at *3 (considering an ANDA).[4]

As in *Astrazeneca*, the Court concludes that Alvotech hf.'s argument is not appropriately raised under Rule 12(b)(1), but Rule 12(b)(6). *See Thornton v. M7 Aerospace LP*, 796 F.3d 757, 765 (7th Cir. 2015) (citing *Bell v. Hood*¸ 327 U.S. 678, 682 (1946) (holding that "[j]urisdiction is not defeated by the possibility that the allegations might fail to state a cause of action on which a party could actually recover. . . . [t]he failure to state a proper cause of action calls for judgment on the merits and not a dismissal for want of jurisdiction")).[5] Alvotech hf.'s reliance on *Semiconductor Energy Laboratory Co. v. Nagata*, 706 F.3d 1365, 1370 (Fed. Cir. 2013), is misplaced. In that case, the Federal Circuit held that the plaintiff's claim for "assignor estoppel" was, in reality, only a defense and did not exist as a standalone right of action. *Id.* Here, Abbvie relies on § 271(e) to assert its cause

---

[4] Contrary to Alvotech hf.'s assertion, the court's decision did not hinge on the fact that another ANDA applicant was already joined as a defendant; instead, the court relied on the decisions in *Allergan,* 324 F.3d at 1330, *Litecubes*, 523 F.3d 1353, and *Arbaugh*, 546 U.S. 500, as well as § 271(e)'s legislative history, to conclude that there is "no evidence that Congress intended the elements of that section to be jurisdictional prerequisites." *Aurobindo*, 2009 WL 483131, at *2.

[5] Additionally, it is worth noting that Alvotech hf. has not provided any evidence that contradicts the relevant factual allegations pertinent to the Court's exercise of subject matter jurisdiction. The letters between Abbvie and Alvotech USA that Alvotech hf. attached to its motion are not inconsistent with Abbie's assertion that Alvotech hf. created and prepared the information in the AVT02 aBLA. *See* Alvotech hf.'s Mot. Dismiss, Exs. A–I, ECF Nos. 21-1 to 28-9.

of action. Thus, Alovotech's hf.'s request to dismiss the case under Rule 12(b)(1) is denied.

**B. Alvotech hf.'s Motion Under Rule 12(b)(6)**

Turning to the first of Alvotech hf.'s remaining arguments, it contends that the complaint must be dismissed pursuant to Fed. R. Civ. P. 12(b)(6), because Alvotech hf. did not "submit" the aBLA for AVT02 within the meaning of 35 U.S.C. § 271(e)(2).

**1. Legal Standard**

A motion to dismiss under Rule 12(b)(6) challenges whether a plaintiff's complaint "contain[s] sufficient factual matter . . . to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *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." *Id.*

When "reviewing the sufficiency of a complaint under the plausibility standard," courts "accept the well-pleaded facts in the complaint as true." *Alam v. Miller Brewing Co.*, 709 F.3d 662, 665–66 (7th Cir. 2013). At the same time, "allegations in the form of legal conclusions are insufficient to survive a Rule 12(b)(6) motion." *McReynolds v. Merrill Lynch & Co., Inc.*, 694 F.3d 873, 885 (7th Cir. 2012) (citing *Iqbal*, 556 U.S. at 678).

**2. Discussion**

A claim for patent infringement "has long been understood to require no more than the unauthorized use of a patented invention." *Glob.-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 761 n.2 (2011) (distinguishing between direct and induced infringement). As discussed above, 35 U.S.C. § 271(e)(2)(C) provides that it is an act of infringement "to submit . . . an [aBLA] seeking approval of a biological product . . . 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."

Keying off this language, Alvotech hf. asserts that Alvotech USA—not Alvotech hf.— is the entity that "submit[ted]" the aBLA within the meaning of 35 U.S.C. § 271(e)(2)(C), because Alvotech USA is listed as the subsection (k) applicant on the aBLA form. *See* AVT02 aBLA at 1. As Alvotech hf. sees it, because it is not listed as the subsection (k) applicant on the aBLA form, it cannot be the "submit[ter]" of the aBLA under 35 U.S.C. § 271(e)(2)(C).

In response, Abbvie points to a number of courts that have adopted a broader interpretation of the word "submit" as it appears in § 271(e)(2), albeit in the context of the Hatch-Waxman Act (that is, in cases involving § 271(e)(2)(A), rather than § 271(e)(2)(C)). For example, in *Allergan, Inc. v. Teva Pharmaceuticals USA, Inc.,* No. 2:15-cv-1455-WCB, 2016 WL 1572193 (E.D.Tex. Apr. 19, 2016), Mylan Pharmaceuticals Inc., a wholly-owned subsidiary of Mylan Inc., argued the parent

company should be dismissed from the patent infringement suit because the subsidiary—not the parent company—had signed and filed the ANDA. Reciting Allergan's allegation that the Mylan subsidiary and the parent worked in concert to develop, market, and distribute Mylan's pharmaceutical products, the district court denied the motion, holding that "[a]n entity submits an ANDA if it participates in the preparation of the ANDA and intends to benefit directly from the ANDA by selling the ANDA product upon approval." *Id.* at *5.

Similarly, in *Endo Pharmaceuticals Inc. v. Actavis Inc.*, No. 14-1381-RGA, 2017 WL 522825 (D. Del. Feb. 8, 2017), a defendant, Teva Pharmaceuticals, argued that it was improperly sued under § 271(e)(2), because its subsidiary had applied for the ANDA and, therefore, Teva could not be considered the entity that "submitted" the application. The district court made short shrift of this argument, noting that "[t]here is no explicit requirement in § 271(e) that a party must have prepared or filed the ANDA itself in order to be a proper defendant." *Id.* at *1. And, given the "allegations that Defendant Teva is the owner and real party in interest of the ANDA and will benefit from the ANDA if it is approved," the court denied Teva's motion. *Id.*; *see also Otsuka Pharms. Co., Ltd., v. Hetero USA, Inc.*, No. 19-1954-LPS, 2020 WL 6822971, at *2 (D. Del. Nov. 20, 2020) (holding that "whether the entity is a submitter depends on whether it is also going to engage in the commercial manufacture, use, or sale of the proposed generic product" and whether the entity will "financially benefit, in a significant manner, from the FDA's approval of the application" (cleaned up)).

These district court decisions all are grounded in *In re Rosuvastatin Calcium Patent Litigation*, 703 F.3d 511 (Fed. Cir. 2012). In that case, the plaintiff, a brand-name drug manufacturer, brought a patent infringement suit against Apotex U.S., a subsidiary of Apotex Canada, under § 271(e)(2)(A). *See id.* at 527. Apotex U.S. moved to dismiss the case, arguing that it merely signed the ANDA in its capacity as the agent of its parent corporation, Apotex Canada, the actual entity that would be developing and manufacturing the generic drug. Based on this, Apotex U.S. argued, it was not a "submit[ter]" within the meaning of § 271(e)(2)(A).

The Federal Circuit disagreed, adopting the district court's holding that:

> a wholly-owned subsidiary of a foreign ANDA applicant, which signs an ANDA as the agent of its parent-applicant, and which intends to benefit directly if the ANDA is approved by participating in the manufacture, importation, distribution and/or sale of the generic drug [i]s subject to suit under § 271(e) as the one who has "submitted" the ANDA.

*Id.* at 528 (citation omitted). In doing so, the Federal Circuit rejected Apotex U.S.'s argument that the court should look to the statute creating the ANDA process, 21 U.S.C. § 355(j), and its implementing regulation, 21 C.F.R. § 314.3(b), to construe the meaning of "submit" for the purposes of § 271(e)(2). *Id.*[6]

---

[6] This is not altogether surprising given that both 35 U.S.C. § 355 and 21 C.F.R. § 314.3(b) tend to define "applicant" as someone who "submits" an application, leading to a circular argument. *See, e.g.,* 21 U.S.C. §355(b)(1)(A) (noting that an applicant shall "submit" to the Secretary as part of the application certain materials); 21 C.F.R. § 314.3(b) ("Applicant is any person who submits an [application] or ANDA or an amendment or supplement to an NDA or ANDA under this part to obtain FDA approval of a new drug and any person who owns an approved [application] or ANDA.").

Here, Alvotech hf. attempts to distinguish *Rosuvastatin*, arguing that *Rosuvastatin* and the above-referenced district cases involved an ANDA application submitted pursuant to the Hatch-Waxman Act, not an aBLA submitted pursuant to the BPCIA, as we have here. But the word "submit" appears in the general section of § 271(e)(2) and applies equally to § 271(e)(2)(A) (the Hatch-Waxman Act) *and* § 271(e)(2)(C) (the BPCIA). Under Alvotech hf.'s approach, the same word would have two different meanings, violating the basic rule of statutory construction that "identical words used in different parts of the same statute are presumed to have the same meaning." *See Robers v. United States*, 572 U.S. 639, 643 (2014) (cleaned up).[7]

Alvotech hf. also argues that because, under the BPCIA, a party must participate in the patent dance before it is permitted to file a patent infringement action, the *only* parties that can be sued are the ones who previously engaged in the dance. But the language of the BPCIA itself does not bear this out. For example, § 262(*l*)(6) states:

> If the subsection (k) applicant and the reference product sponsor [engage in the patent dance and identify which patents to litigate], the reference product sponsor shall

[7] Additionally, Alvotech hf. points out that this case is unique, because Abbvie has chosen not to sue the actual entity that signed the subsection (k) applicant, while, in the Hatch-Waxman cases discussed above, the actual applicant was joined as a defendant. But, as discussed below, nothing in § 271(e)(2) or § 262(*l*) requires that the actual signatory to the application be so joined. In fact, in *Adverio Pharma GmbH v. Alembic Pharms. Ltd.*, No. CV 18-73-LPS, 2019 WL 581618, at *5 (D. Del. Feb. 13, 2019), the district court concluded that an entity that "merely assists in collecting materials for submission to the FDA, signs the ANDA, presents the ANDA to the FDA for approval, and acts in an ongoing manner as the liaison between the FDA and the applicant during the regulatory process, but will have no involvement with the ANDA product following FDA approval" was not a submitter for the purposes of § 271(e)(2).

> bring an action for patent infringement with respect to each such patent.

42 U.S.C. § 262(*l*)(6).[8] Neither it nor any other provision in BPCIA mandates that the reference product sponsor sue the entity that actually signed and filed the subsection (k) application.

Now, it is true that § 262(*l*)(8)(B) states that "the reference product sponsor may seek a preliminary injunction prohibiting the *subsection (k) applicant* from engaging in the commercial manufacture or sale" of the biosimilar drug in question. 42 U.S.C. § 262(*l*)(8)(B) (emphasis added). But this does not help Alvotech hf. either. First, the language is permissive, not mandatory. Second, the statute defines a "subsection (k) applicant" as "a person that *submits* an application under subsection (k)," 42 U.S.C. § 262(*l*)(1)(A) (emphasis added), leading back to the question of what "submit" means in the context of the BPCIA. Third, under Alvotech hf.'s construction, in a case where the corporate entity that files the subsection (k) application is not involved in the manufacture of the biosimilar drug or its sale (take, for example, a wholly owned subsidiary that is only tasked with obtaining the necessary legal and regulatory approvals), § 262(*l*)(8)(B) would preclude the reference product sponsor from obtaining any

[8] The Court has elided subsections (i) and (ii) of 42 U.S.C. § 262(*l*)(6), which provide for the situation where the subsection (k) applicant and the reference product sponsor agree on which patents to litigate first, and the situation in which they do not agree. The language quoted above is the same in both subsections.

preliminary injunctive relief at all. Congress could not have intended such a nonsensical result.[9]

Furthermore, Alvotech hf.'s argument that direct participation in the patent dance is a prerequisite to being sued ignores the fact that the BPCIA specifically authorizes the reference product sponsor to file suit even when the patent dance does not occur. *See* 42 U.S.C. § 262(*l*)(9) (permitting "the reference product sponsor, but not the subsection (k) applicant, [to] bring an action . . . for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product" where the applicant fails to provide the information required under the Act).

Finally, the Supreme Court's decision in *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664 (2017), is helpful to this analysis. The question presented was whether, in the event that the subsection (k) applicant failed to notify the reference product

---

[9] Alvotech hf. also points out that 42 U.S.C. § 262(*l*)(6)(C)(i) states: "Not later than 30 days after a complaint is served to a subsection (k) applicant in an action for patent infringement described under this paragraph, the subsection (k) applicant shall provide the Secretary with notice and a copy of such complaint." According to Alvotech hf., this implies that the subsection (k) applicant must be a party to this lawsuit. But this is unpersuasive for several reasons. First, this case was filed over thirty days ago, and no party has asserted that notice was not provided in accordance with that section, regardless of the fact that Alvotech USA is not a defendant. Furthermore, as noted above, because 42 U.S.C. § 262(*l*)(1)(A) defines the subsection (k) applicant as one who "submits an application," this provision does not compel the conclusion that Alvotech USA is the only entity responsible for providing the described notice. Finally, the Court notes that, in a similar situation under the Hatch-Waxman Act, where an entity that was dismissed as a defendant was responsible for notifying the FDA when a judgment was entered, the court solved the problem by noting that "[s]hould this case result in entry of judgment against Alembic, and should INC continue not to be a party, [the plaintiff] may ask the Court to exercise whatever authority it has over Alembic to ensure that the FDA receives the required notice of judgment." *See Adverio*, 2019 WL 581618, at *6.

sponsor about the aBLA as mandated by 42 U.S.C. § 262(*l*)(2)(A), the jilted reference product sponsor could sue for injunctive relief to require production of the aBLA and manufacturing information. *Id.* at 1669. In the end, the Supreme Court determined that the Federal Circuit incorrectly concluded that a subsection (k) applicant's failure to disclose its aBLA was an element of the act of artificial infringement under § 271(e)(2). *Id.* at 1674. In reaching its conclusion, the Federal Circuit had focused on the language in § 271(e)(2)(C)(ii):

> "[i]t shall be an act of infringement to submit[,] *if the applicant for the application fails to provide the application and information required under [§ 262(l)(2)(A)],* an application seeking approval of a biological product for a patent that could be identified pursuant to [§ 262(*l*)(3)(A)(i)]"

*Id.* (emphasis in original) (quoting 35 U.S.C. § 271(e)(2)(C)(ii)). But the Supreme Court clarified that "[t]he italicized language merely assists in identifying which patents will be the subject of the artificial infringement suit. It does not define the act of artificial infringement itself." *Id.*

What can be gleaned from this is that the duties and obligations imposed upon the reference product sponsor and the subsection (k) applicant by § 262(k) and (*l*) do not give rise, in and of themselves, to a cause of action for patent infringement. Rather, the source of that authority is 35 U.S.C. § 271(e)(2). Thus, the Federal Circuit's interpretation in *Rosuvastatin* of what it means "to submit" an application under § 271(e)(2) controls, absent any express BPCIA provision to the contrary.

With that, the analysis of whether Alvotech hf. can be deemed a "submitter" under the *Rosuvastatin* decision is straightforward. "Parties actively involved in preparing the ANDA are deemed to have submitted the ANDA, regardless of whether they are the named applicant, especially where the parties involved are in the same corporate family. Active involvement includes marketing and distributing the approved generic drugs in the United States." *Adverio Pharma*, 2019 WL 581618, at *4 (cleaned up) (quoting *Cephalon, Inc. v. Watson Pharms., Inc.*, 629 F. Supp. 2d 338, 349 (D. Del. 2009)). So too does "participating in the [drug's] manufacture [or] importation." *Rosuvastatin*, 703 F.3d at 528 (quoting *In re Rosuvastatin Calcium Pat. Litig.*, 2008 WL 5046424, at *10 (D. Del. Nov. 24, 2008)).

Here, Abbvie alleges that "Alvotech [hf.], 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 [hf.] communicated and/or met with the FDA before beginning the trial." Compl. ¶ 34.[10] Furthermore, Abbvie asserts that "Alvotech will engage in the commercial manufacture and supply of [AVT02]," as well as its "development [and] registration." *Id.* ¶ 37. As a result, Abbvie states that "Alvotech [hf.] will financially benefit in a significant manner from the approval of [the AVT02 aBLA]." *Id.*

[10] Alvotech claims that this statement is false; however, under Rule 12(b)(6), the Court assumes that the complaint's well-pleaded allegations are true.

Based on these allegations, the Court concludes that Abbvie's complaint adequately alleges that Alvotech hf. is a "submit[ter]" of the aBLA within the meaning of 35 U.S.C. § 271(e)(2)(C).[11] Accordingly, Alvotech hf.'s motion to dismiss under Rule 12(b)(6) is denied.

**C. Alvotech hf.'s Motion Under Rule 12(b)(7)**

The Court next considers Alvotech hf.'s argument that the complaint must be dismissed under Fed. R. Civ. P. 12(b)(7). The question is whether Alvotech USA is an indispensable party under Fed. R. Civ. P. 19.

**1. Legal Standard**

Rule 12(b)(7) authorizes the dismissal of a lawsuit if a plaintiff has failed to join a necessary and indispensable party under Rule 19. "Since joinder is an issue not unique to patent law, [courts] apply the law of the regional circuit." *A123 Sys., Inc. v. Hydro-Quebec*, 626 F.3d 1213, 1220 (Fed. Cir. 2010).

"When evaluating a Rule 12(b)(7) motion, the Court accepts all well-pleaded allegations in the complaint as true and may consider extrinsic evidence." *BCBSM, Inc. v. Walgreen Co.*, --- F. Supp. 3d ----, 2021 WL 77233, at *3, (N.D. Ill. Jan. 8, 2021) (citing *Davis Cos. v. Emerald Casino, Inc.*, 268 F.3d 477, 480 n.4 (7th Cir. 2001)). "Dismissal for failure to join a party 'is not the preferred outcome under the Rules.'" *Id.* (quoting *Askew v. Sheriff of Cook Cty.*, 568 F.3d 632, 634

[11] Abbvie also argues that, under the *Rosuvastatin* standard, Alvotech USA is *not* a "submit[ter]" under 35 U.S.C. § 271(e)(2); however, the Court need not address that question in order to resolve the motion to dismiss.

(7th Cir. 2009)). "In a 12(b)(7) motion, the movant bears the burden of demonstrating that the absent party is necessary and indispensable." *Id.*

**2. Discussion**

Rule 19 provides that a party is necessary if: "in that person's absence, the court cannot accord complete relief among existing parties"; or "that person claims an interest relating to the subject of the action and is so situated that disposing of the action in the person's absence may: (i) as a practical matter impair or impede the person's ability to protect the interest; or (ii) leave an existing party subject to a substantial risk of incurring double, multiple, or otherwise inconsistent obligations because of the interest." Fed. R. Civ. P. 19(a).

Rule 19 continues that, if a necessary party "cannot be joined, the court must determine whether, in equity and good conscience, the action should proceed among the existing parties or should be dismissed." Fed. R. Civ. P. 19(b). When evaluating whether the action should proceed, Rule 19 instructs courts to consider several factors: "(1) the extent to which a judgment rendered in the person's absence might prejudice that person or the existing parties; (2) the extent to which any prejudice could be lessened or avoided by [protective measures]; (3) whether a judgment rendered in the person's absence would be adequate; and (4) whether the plaintiff would have an adequate remedy if the action were dismissed for nonjoinder." *Id.*

Abbvie does not challenge Alvotech hf.'s assertion that, if Alvotech USA were a necessary party, it could not be joined as a party in the Northern District

of Illinois because venue here would be improper. *See* Mot. Dismiss at 11. As such, the Court will first consider whether Alvotech USA would be indispensable, assuming it is necessary.[12]

Abbvie's complaint asserts, and Alvotech hf. does not challenge, that Alvotech USA is Alvotech hf.'s wholly owned subsidiary. *See* Compl. ¶ 33. The Seventh Circuit has expressed "great difficulty seeing how a 100 percent subsidiary could *ever* be an indispensable party." *Extra Equipamentos E Exportação Ltda. v. Case Corp.*, 361 F.3d 359, 364 (7th Cir. 2004). Furthermore, in the patent context, courts have held that a parent corporation is presumed to "adequately protect the interests of its wholly-owned subsidiary." *See Simmons*

---

[12] In its opening brief, Alvotech hf. argues that Alvotech USA is "statutorily necessary" under the first stage of the Rule 19 analysis; however, in its reply brief, Alvotech hf. cites the same cases to argue that Alvotech USA is necessary *and indispensable* under Rule 19's second stage. *See* Mot. Dismiss at 10; Alvotech hf.'s Reply Supp. Mot. Dismiss at 11–12, ECF No. 41. "[A]rguments raised for the first time in a reply brief are waived." *Wonsey v. City of Chi.*, 940 F.3d 394, 398 (7th Cir. 2019). Nonetheless, the Court notes that all of the cases cited by Alvotech hf. for the proposition that Alvotech USA is "statutorily necessary" are inapposite. For instance, *Carver v. Sheriff of LaSalle Cty.*, 324 F.3d 947 (7th Cir. 2003), involves the joinder of a state governmental entity in civil rights actions where the entity is responsible for indemnifying the alleged individual tortfeasors. *Id.* at 948 (noting that "a county in Illinois is a necessary party in any suit seeking damages from an independently elected county officer" under 42 U.S.C. § 1983). *Tillman v. City of Milwaukee*, 715 F.2d 354 (7th Cir. 1983), discusses the joinder of a state administrative agency that, by statute, was the only entity that could reinstate the plaintiff to his state-sponsored apprenticeship program with the city. *Id.* at 359. And *Glover v. State Farm Fire & Cas. Co.*, 984 F.2d 259 (8th Cir. 1993), and *Price v. Young Am. Ins. Co.*, No. 20-00149-CV-W-HFS, 2020 WL 4470443 (W.D. Mo. Aug. 4, 2020), simply apply unambiguous language from a Missouri statute concerning the collection of a personal injury judgment from the personal injury defendant's insurer, which states that "if the [personal injury] judgment is not satisfied within thirty days after the date when it is rendered, the judgment creditor [*i.e.*, personal injury plaintiff] may proceed in equity against *the [personal injury] defendant and the insurance company* to reach and apply the insurance money to the satisfaction of the judgment." *See* Mo. Ann. Stat. § 379.200 (emphasis added). In a simple exercise of statutory interpretation, both *Glover* and *Price* hold that the statute requires joinder of both the personal injury defendant and the insurance company. *See Glover*, 984 F.2d at 261; *Price*, 2020 WL 4470443, at *3.

*Bedding Co. v. Leggett & Platt, Inc.*, No. 11-CV-232-WMC, 2012 WL 11909449, at *9 (W.D. Wis. Mar. 27, 2012) (citing *Dainippon Screen Mfg. Co. v. CFMT, Inc.*, 142 F.3d 1266, 1272 (Fed. Cir. 1998)). Where a subsidiary's interests are protected, it is not prejudiced by lack of joinder. As such, Alvotech hf. has not met its burden to establish that the first or second factors under Rule 19(b) weigh in favor of finding indispensability.

Alvotech hf. also claims that this Court cannot render an adequate judgment in Alvotech USA's absence, because Alvotech USA holds the aBLA for AVT02, and § 262(*l*)(8)(B) provides that "the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent." 42 U.S.C. § 262(*l*)(8)(B). But this argument is unpersuasive for the reasons discussed above.

Furthermore, as Abbvie points out, "[p]atent infringement is a tort," and "[i]t is well-settled that joint tortfeasors are not considered required or indispensable parties under Rule 19." *Akoloutheo, LLC v. Sys. Soft Techs., Inc.*, No. 4:20-cv-985, 2021 WL 1947343, at *2 (E.D. Tex. May 14, 2021) (cleaned up); *see also Temple v. Synthes Corp.,* 498 U.S. 5, 7 (1990) ("It has long been the rule that it is not necessary to join all joint tortfeasors to be named as defendants in a single lawsuit."); *Salton, Inc. v. Philips Domestic Appliances & Pers. Care B.V.*, 391 F.3d 871, 877 (7th Cir. 2004) ("A rule automatically deeming joint tortfeasors

indispensable parties to suits against each of them would be inconsistent with this common law principle [of joint and several liability] and is therefore rejected." (citations omitted)). In fact, a parent company "may be liable for patent infringement for selling, offering to sell, making or using the infringing [product], regardless of [its subsidiary's] downstream role." *Akoloutheo*, 2021 WL 1947343, at *2.

Nevertheless, Alvotech hf. protests that Abbvie is attempting to improperly hold it liable for its subsidiary's actions. It cites two cases for the proposition that a subsidiary is an indispensable party when the lawsuit imputes the subsidiary's conduct to the parent company. *See Carnero v. Bos. Sci. Corp.*, 433 F.3d 1, 18 (1st Cir. 2006); *Polanco v. H.B. Fuller Co.*, 941 F. Supp. 1512, 1523 (D. Minn. 1996). But Abbvie is suing Alvotech hf. for its *own* conduct as a submitter of the AVT02 aBLA, and so Alvotech hf.'s reliance on *Carnero* and *Polanco* is unavailing.

For these reasons, the Court finds that Rule 19(b)'s third factor does not weigh in favor of finding indispensability.

Finally, although Abbvie may have an "adequate remedy" in the Eastern District of Virginia if the Court were to require Alvotech USA to be joined, courts are "reluctant to dismiss for failure to join where doing so deprives the plaintiff of his choice of federal forum." *Askew*, 568 F.3d at 634 (cleaned up).

Because Alvotech hf. has failed to meet its burden of establishing that this case must be dismissed for failing to join Alvotech USA, its motion pursuant to Fed. R. Civ. P. 12(b)(7) is denied.

### D. Alvotech hf.'s Motion Under Rule 12(b)(2)

Finally, the Court considers Alvotech hf.'s arguments that dismissal is proper under Rule 12(b)(2). The question is whether the Court has personal jurisdiction over Alvotech hf., an Icelandic company.

#### 1. Legal Standard

Although a complaint generally need not include facts alleging personal jurisdiction, "once the defendant moves to dismiss . . . for lack of personal jurisdiction," the plaintiff bears the burden of demonstrating the existence of jurisdiction." *Purdue Rsch. Found. v. Sanofi-Synthelabo, S.A.*, 338 F.3d 773, 782 (7th Cir. 2003). The precise nature of that burden "depends upon whether an evidentiary hearing has been held." *Id.*

Where, as here, the Court rules on the motion "based on the submission of written materials, without the benefit of an evidentiary hearing," the plaintiff "need only make out a prima facie case of personal jurisdiction." *Id.* (cleaned up). In evaluating whether the prima facie standard has been satisfied, "pleadings and affidavits are to be construed in the light most favorable to [the plaintiff]." *Autogenomics, Inc. v. Oxford Gene Tech. Ltd.*, 566 F.3d 1012, 1017 (Fed. Cir. 2009).

#### 2. Discussion

Determining the existence of personal jurisdiction generally requires a two-part analysis—one statutory and one constitutional. *Id.* With regard to the statutory inquiry, the court applies the law of the state in which the district court

is located; as to the constitutional inquiry, the court applies the law of the Federal Circuit in patent cases. *Id*.

Generally, under Fed. R. Civ. P. 4(k)(1)(A), a district court has personal jurisdiction over a defendant in a patent case if the defendant would be "subject to the jurisdiction of a court of general jurisdiction in the state where the district court is located." *Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755, 759 (Fed. Cir. 2016). For its part, the Illinois long-arm statute allows courts to exercise personal jurisdiction "to the full extent permitted by the Fourteenth Amendment's Due Process Clause," so "the state statutory and federal constitutional inquiries merge." *Tamburo v. Dworkin*, 601 F.3d 693, 700 (7th Cir. 2010) (citing 735 Ill. Comp. Stat. 5/2-209(c)). For constitutional purposes, the key issue is whether a defendant "has certain minimum contacts with the forum such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice." *Acorda*, 817 F.3d 759 (quoting *Int'l Shoe Co. v. Washington,* 326 U.S. 310, 316 (1945)) (cleaned up).

Personal jurisdiction exists in two forms: general and specific. There is no dispute that general personal jurisdiction over Alvotech is lacking; therefore, only the existence of specific jurisdiction is at issue.

"Specific jurisdiction . . . must be based on activities that arise out of or relate to the cause of action." *Autogenomics*, 566 F.3d at 1017. "What conduct is suit-related depends on the relationship among the defendant, the forum, and the litigation, including specifically the nature of the claim

asserted." *Acorda*, 817 F.3d at 759 (cleaned up). "[T]he minimum-contacts requirement is met when the defendant 'purposefully directed' activities at the forum, 'and the litigation results from alleged injuries that arise out of or relate to those activities.'" *Id.* (quoting *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472–73 (1985)).

In *Acorda*, the Federal Circuit held that the submission of an ANDA pursuant to the Hatch-Waxman Act is "'suit-related' and has a 'substantial connection' with [the forum state]" where the defendant "plans to market its proposed drugs in [the forum state] and the lawsuit is about patent constraints on such in-State marketing." 817 F.3d at 760, 762–63 (quoting *Walden v. Fiore*, 571 U.S. 277, 284 (2014)). In the same vein, the Federal Circuit concluded, "ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs." *Id.* And ANDA filings are closely connected to "the real-world acts that approval of the ANDA will allow and that will harm patent-owning brand-name manufacturers." *Id.* Congress demonstrated as much when it "stressed the ANDA filer's 'purpose . . . to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent,'—concrete, non-artificial acts of infringement." *Id.* (quoting 35 U.S.C. § 271(e)(2)(A)). Thus, where the drug that is the subject of the ANDA will be marketed within the forum state, a defendant's ANDA filings are "suit-related, and they have a substantial connection with [the forum state] because they

reliably, non-speculatively predict [forum state] activities by [the submitter]." *Id.* at 762.

Here, Abbvie alleges that Alvotech hf. "will engage in the commercial manufacture and supply of [AVT02] in Illinois, including this District." Compl. ¶ 37. Alvotech hf. has not submitted any documents or affidavits that dispute that proposition, and so the Court accepts it as true. Instead, Alvotech argues that *Acorda*'s focus on the submission of an ANDA means that *Acorda*'s logic does not apply to Alvotech hf., which, in its view, did not "submit" the AVT02 aBLA. However, for the reasons discussed above, the Court finds that Alvotech hf. qualifies as a "submitter" of the AVT02 aBLA, even though it did not sign the application. *See Helsinn Healthcare S.A. v. Hospira, Inc.*, No. CV 15-2077 (MLC), 2016 WL 1338601, at *5–6 (D.N.J. Apr. 5, 2016) (applying *Acorda* to find specific jurisdiction over a non-signatory "submitter").

In *Acorda*, the Federal Circuit viewed the defendant's submission of its ANDA as a concrete step demonstrating the defendant's actual intent to market and sell the infringing drug in the forum state. Here, Alvotech hf.'s role in submitting the AVT02 aBLA demonstrates the same intent. As such, the Court finds that Alvotech hf.'s submission of its aBLA is suit-related. And, because the aBLA submission indicates Alvotech hf.'s intent to market and distribute its biosimilar drug in Illinois, the Court finds that it has specific jurisdiction over it.

Finally, Alvotech hf. urges the Court to find that other factors render jurisdiction unreasonable in light of the considerations of "fair play and

substantial justice." *See Inamed Corp. v. Kuzmak*, 249 F.3d 1356, 1360 (Fed. Cir. 2001) (quoting *Burger King*, 471 U.S. at 476–77). In that scenario, the burden is on Alvotech hf. to "present a compelling case" that this Court's exercise of jurisdiction is unreasonable. *Id.* (cleaned up). This inquiry involves the consideration of several factors: "(1) the burden on the defendant, (2) the interests of the forum State, (3) the plaintiff's interest in obtaining relief, (4) the interstate judicial system's interest in obtaining the most efficient resolution of controversies, and (5) the shared interest of the several States in furthering fundamental substantive social policies." *Id.* at 1363 (citing *Asahi Metal Indus. Co. v. Superior Ct. of Cal.*, 480 U.S. 102, 113 (1987)).

Alvotech hf. argues only that patent infringement cases generally proceed to trial more quickly in the Eastern District of Virginia, and that Alvotech hf. finds it inconvenient to litigate in Chicago as opposed to the Eastern District of Virginia, where Alvotech USA is domiciled. But, as discussed above, Alvotech USA is not an indispensable party to this lawsuit. And "often the interests of the plaintiff and the forum in the exercise of jurisdiction will justify even the serious burdens placed on [an] alien defendant." *Asahi*, 480 U.S. at 114.

Furthermore, there are strong justifications here that outweigh the burden on Alvotech hf.: the plaintiff is domiciled in this district; and Illinois "has an interest in providing a forum to resolve the disputes before [the Court] because they involve the pricing and sale of products in [Illinois] and harms to firms doing business in [Illinois], some of [which are] incorporated or with principal places of

business in [Illinois]." *Acorda*, 817 F.3d at 764. Moreover, "cases where a defendant may defeat otherwise constitutional personal jurisdiction should be limited to the rare situation in which the plaintiff's interest and the state's interest in adjudicating the dispute in the forum are so attenuated that they are clearly outweighed by the burden of subjecting the defendant to litigation within the forum." *Inamed*, 249 F.3d at 1363 (cleaned up). Such is not the case here. Accordingly, Alvotech hf.'s motion to dismiss under Rule 12(b)(2) also is denied

**CONCLUSION**

For the above-stated reasons, Alvotech hf.'s motion to dismiss is denied in its entirety.

**IT IS SO ORDERED.** **ENTERED: 8/23/21**

**JOHN Z. LEE**
**United States District Judge**