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

ABBVIE INC. and ABBVIE BIOTECHNOLOGY LTD.,	)	
	)	Case No. 1:21-cv-2258
Plaintiffs,	)	
	)	Hon. Judge John Z. Lee
v.	)	
	)	Magistrate Judge M. David Weisman
ALVOTECH HF.,	)	
	)	
Defendant.	)	

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT ALVOTECH HF.'S MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION, LACK OF PERSONAL JURISDICTION, FAILURE TO STATE A CLAIM, AND FAILURE TO JOIN A NECESSARY PARTY

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INTRODUCTION

Biosimilar competition is a thorny problem that took Congress years to solve. Congress's answer was 2009's Biologics Price Competition and Innovation Act ("BPCIA"), a complex, detailed statute built around the rights and obligations of two distinct entities. One is the "reference product sponsor" for the branded product—in this case, AbbVie Inc. The other is the "subsection (k) applicant" for the biosimilar product[1]—in this case, Alvotech USA Inc. It is the height of irony that the bar has come to call the BPCIA pre-suit phase "the patent dance" because AbbVie just refuses to dance with the one that brought it. Instead of suing Alvotech USA, the subsection (k) applicant for the AVT02 biosimilar at issue in this case, AbbVie sued Alvotech USA's Icelandic parent company, Alvotech hf. AbbVie did this in the hopes that this Court will bend the rules in AbbVie's favor so it can litigate here, as opposed to where this case should proceed, the Eastern District of Virginia, the home of Alvotech USA.[2] This Court should reject AbbVie's machinations, which violate multiple statutes and rules of procedure.

This lawsuit is governed by the "patent dance" provisions of the BPCIA, which normally result in the reference product sponsor (AbbVie Inc.) filing suit against the subsection (k) applicant (Alvotech USA) on the patents the two parties agree should be litigated. *See* 42 U.S.C. § 262(*l*). AbbVie's actions here, however, are anything but "normal," in its transparent choice not to sue Alvotech USA, and instead sue Alvotech hf. To be sure, Alvotech hf. is Alvotech USA's parent, and will manufacture AVT02. But Congress paid no mind to either of those things when it enacted the BPCIA. Instead, Congress expressly identified the subsection (k) applicant, Alvotech USA, as the responsible party on the biosimilar side. By suing Alvotech hf. instead of Alvotech USA,

[1] In this brief, "subsection (k) applicant" is sometimes referred to as the "BLA applicant."
[2] Under the BPCIA, Alvotech USA and Alvotech hf. filed a declaratory judgment action in the Eastern District of Virginia against Plaintiffs, challenging the same patents-in-suit in relation to AVT02. *See Alvotech USA Inc. et al. v. AbbVie Inc. et al.*, Case No. 2:21-cv-00265-RAJ-DEM (E.D. Va. May 11, 2021).

AbbVie violated the BPCIA and failed to bring a proper infringement action under 42 U.S.C. § 262(*l*), 35 U.S.C. § 271(e)(2)(C), the rules of civil procedure, and the due process requirements of the U.S. Constitution.

AbbVie's motivation for not suing Alvotech USA is plain. Because Alvotech USA resides and does business only in Arlington, Virginia, venue for Alvotech USA is proper only in the Eastern District of Virginia, a district well-known for exceptionally fast resolution of patent cases. Undoubtedly fearful of an expedited schedule, AbbVie hopes to slow resolution of this dispute in this District, which, while an excellent patent litigation forum, is significantly slower than the Eastern District of Virginia. AbbVie benefits immensely from any delay. Its nearly 20 year Humira® monopoly delivers more than $16 billion per year in the United States alone. By delaying adjudication of the patents used to maintain its monopoly, AbbVie gains up to $40 million ***for each and every day*** that it keeps biosimilars off the market. It is for this reason, and this reason alone, that AbbVie has embarked on this illegal course of action. This Court should reject AbbVie's forum shopping and dismiss this case.

BACKGROUND

Alvotech USA and the Filing of the AVT02 BLA

Alvotech USA is part of the broader international Alvotech family of companies, which delivers high-quality, cost-competitive products and services to its partners and its patients worldwide. Different parts of the Alvotech family play different roles in the overall organization. (*See* Dkt. No. 1-3 (Compl., Ex. 2) at 3-5.) For example, Alvotech hf. houses a state-of-the-art biopharmaceutical facility in Reykjavik, Iceland, with personnel specializing in product development and manufacturing. (*See id.* at 4.) In contrast, Alvotech USA is responsible for Alvotech's regulatory, government policy, and legal departments, employing the Head of Regulatory Affairs (Kim Poffenberger), Chief IP Counsel, and Chief Scientific Officer. (*See id.*)

Alvotech USA is incorporated in Virginia and its principal—and *only*—place of business is in Arlington, Virginia. (*See id*.)

As part of its regulatory affairs role, in September 2020, Alvotech USA filed BLA No. 761205 under 42 U.S.C. § 262(k) seeking approval for AVT02. (*See* Dkt. No. 1-6 (Compl., Ex. 5) at 4; Ex. D[3].) Ms. Poffenberger signed the BLA and oversaw its preparation at Alvotech USA in Virginia. (Ex. D at 3.) Indeed, since at least the 2020 filing of the BLA, all AVT02 interactions with FDA have been, and continue to be, the responsibility of Alvotech USA. (*Id*. at 1). Upon approval of AVT02, as the applicant under 42 U.S.C. § 262(k), Alvotech USA will hold the rights necessary for Alvotech hf. to manufacture AVT02 and for commercial partners to sell AVT02. (*See id*.; Ex. I.)

The Statutory Scheme for Resolving Patent Disputes over Biosimilars

Alvotech USA's AVT02 BLA filing is the central part of the BPCIA statutory scheme crafted by Congress for facilitating the introduction of lower-cost, biosimilar versions of biologic drugs. Under the BPCIA, the application provides the opportunity for the BLA applicant to engage in the BPCIA's patent-narrowing dance under 42 U.S.C. § 262(*l*), if the applicant so chooses. *See Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1670–71 (2017). The filing also serves as "an artificial 'act of [patent] infringement'" under 35 U.S.C. § 271(e)(2)(C), in conjunction with the BPCIA, so as to foster speedy resolution of patent disputes by letting "suits [] begin based on the filing of a biosimilar application prior to FDA approval and prior to marketing of the biological product." *Amgen Inc. v. Sandoz Inc.*, 877 F.3d 1315, 1321 (Fed. Cir. 2017).

[3] All exhibits cited herein are attached to Mr. Fogel's declaration filed in support of this motion. Additionally, the Court may take judicial notice of facts that "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b)(2). Judicially noticed documents may be considered in connection with a Rule 12(b)(6) motion to dismiss without converting such a motion into a motion for summary judgment. *See Papasan v. Allain*, 478 U.S. 265, 268 n.1 (1986); *Henson v. CSC Credit Servs.*, 29 F.3d 280, 284 (7th Cir. 1994).

Congress set out procedures for the patent dance built around two distinct entities—the subsection (k) applicant—in this case, Alvotech USA—and the reference product sponsor—in this case, AbbVie Inc.—and no one else. Thus, only Alvotech USA had the power to commence the dance, and only AbbVie Inc. had the power to engage in the dance with Alvotech USA. *See* 42 U.S.C. § 262(*l*). Once Alvotech USA chose to dance, Congress required it to send a copy of the accepted BLA application and other information describing the manufacturing process for AVT02 to AbbVie Inc. *See id*. at § 262(*l*)(2). In return, Congress required AbbVie Inc. to provide to Alvotech USA a list of patents AbbVie believed would be infringed by the biosimilar. *See id*. at § 262(*l*)(3)(A). Congress then required Alvotech USA and AbbVie Inc. to exchange statements on the issues of infringement, invalidity, and unenforceability, *see id*. at § 262(*l*)(3)(B)-(C), and when that was done, required Alvotech USA and AbbVie Inc. to engage in good faith negotiations to reach a list of patents to be litigated. *See id*. at § 262(*l*)(4)-(5). Once that list was agreed to, Congress gave AbbVie Inc. 30 days thereafter to bring an infringement action against Alvotech USA with respect to each patent on the list. *See id*. at § 262(*l*)(6).

Alvotech USA gave notice of its AVT02 BLA to AbbVie on Nov. 5, 2020, starting the patent dance. (Compl., ¶ 44.) Alvotech USA then performed each of the patent dance exchanges with AbbVie Inc., as the BPCIA requires. (Exs. A-C). Thereafter, AbbVie Inc. filed this case, purportedly under 42 U.S.C. § 262(*l*)(6). (*See* Compl., ¶ 50.)

ARGUMENT

I. Because AbbVie Failed to Sue Alvotech USA, the Court Lacks Subject Matter Jurisdiction and the Complaint Does Not State a Claim Under the BPCIA

AbbVie did not sue the statutorily required party—Alvotech USA, the subsection (k) applicant—under the BPCIA. As a result, AbbVie's complaint fails to identify a cause of action over which this Court has subject matter jurisdiction and fails to state a claim under the BPCIA.

Under Rule 12(b)(1), the plaintiff bears the burden of establishing that "the power to decide" the claim has been "conferred upon a federal court." *Shelton v. Ernst & Young, LLP*, 143 F. Supp. 2d 982, 987 (N.D. Ill. 2001). As to Rule 12(b)(6), the facts alleged must establish that the plaintiff has a cause of action under applicable law. *Mercantile Cap. Partners v. Agenzia Sports, Inc.*, 2005 WL 351926, *7 (N.D. Ill. Feb. 10, 2005). AbbVie can satisfy neither standard.

A. The BPCIA Requires Suit Against the "Subsection (k) Applicant"

While Congress created the artificial act of infringement in 35 U.S.C. § 271(e), the BPCIA, 42 U.S.C. § 262(*l*)(6), governs this suit. AbbVie repeatedly affirms that this action arises under the BPCIA, (Compl., ¶¶ 3, 14-15, 24, 41-51), and states that this action is the "42 U.S.C. § 262(*l*)(6) litigation," (*id*. at ¶ 50).

The plain language of the BPCIA required AbbVie to bring this case against Alvotech USA, the subsection (k) applicant. As detailed above, the patent dance concerns the rights and responsibilities of the subsection (k) applicant and the reference product sponsor, culminating in the lawsuit identified in 42 U.S.C. § 262(*l*)(6)(A), which, in its entirety, reads as follows:

> (A) Action if agreement on patent list
>
> If the subsection (k) applicant and the reference product sponsor agree on patents as described in paragraph (4), not later than 30 days after such agreement, the reference product sponsor shall bring an action for patent infringement with respect to each such patent.

The statute's language is plain. Once the subsection (k) applicant and the reference product sponsor agree on the list, the reference product sponsor "shall" bring a lawsuit for patent infringement for each patent on the list to which the subsection (k) applicant and the reference product sponsor agreed. AbbVie failed to do so, choosing instead to file a different lawsuit not against the subsection (k) applicant, but against the subsection (k) applicant's parent company,

which did not participate in the dance and did not agree with AbbVie on anything.

Indeed, the remainder of § 262(*l*)(6) even specifies further responsibilities of the subsection (k) applicant regarding the lawsuit, so that the U.S. government and the public can be apprised of the case. Specifically, § 262(*l*)(6)(C)(i) states that "[n]ot 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." (Emphasis added.) Section 262(*l*)(6)(C)(ii) then requires the Secretary to publish the notice in the Federal Register.

None of this statutory language makes sense if the § 262(*l*)(6) lawsuit is filed not against the actual applicant with respect to the agreed-upon listed patents, but against some other entity that did not apply for approval and agreed to nothing regarding the list of patents. This is because the entire patent dance is structured around resolving patent disputes between the BLA applicant and the reference product sponsor, not other entities. As the Federal Circuit has stated, the BPCIA's process is an "information exchange ***between the biosimilar applicant*** and the [reference product sponsor]," after which the reference product sponsor "may sue ***the biosimilar applicant*** within 30 days." *Amgen*, 877 F.3d at 1321 (emphases added). Under the BPCIA, AbbVie must include a claim against the "applicant" to state a claim.

B. Alvotech USA, Not Alvotech hf., Is the Subsection (k) Applicant

AbbVie does not plead that Alvotech hf. is the statutorily required "subsection (k) applicant." Nor can it. As AbbVie knows, the applicant for the BLA for AVT02 was not Alvotech hf. but Alvotech USA. (*See* Ex. D at 1; *see also* Compl., ¶¶ 32-34; Dkt. No. 1-6 (Compl., Ex. 5) at 4; Ex. A.)

Instead, without any supporting evidence, AbbVie alleged that Alvotech hf. "prepared and submitted" the AVT02 BLA and participated in the patent dance. (*See* Compl., ¶¶ 14-15, 31-32.)

Not only are these allegations not plausible, they simply did not happen.[4] (Dkt. No. 1-6 (Compl., Ex. 5) at 4.) Because Alvotech USA applied for the AVT02 BLA, it will be the BLA license holder upon approval. (*See* Ex. D at 1; Ex. I at 1 ("Applicant Information").) Alvotech USA's Head of Regulatory Affairs signed the BLA, dealt with FDA regarding the BLA, and is ultimately responsible for the BLA. (Ex. D at 3.) Alvotech USA's Chief IP Counsel, based out of Virginia, initiated the patent dance and identified Alvotech USA's outside counsel for any future correspondence on the patent dance disclosures on behalf of Alvotech USA. (Ex. A at 2.) AbbVie has no plausible basis, because none exists, to say that Alvotech hf. is either the BLA applicant or engaged in the patent dance.

Although a foreign "applicant" can use an "authorized U.S. agent" to submit a BLA, that did not happen here. The application form draws a clear distinction between an "applicant" and an "agent." Indeed, the cover page of Alvotech USA's AVT02 BLA form identifies the "Name of Applicant" as "Alvotech USA Inc.," and leaves empty the "Authorized U.S. Agent" section. (Ex. D at 1.)

The lack of a U.S. agent is not surprising because Alvotech hf. is not the Applicant. Alvotech hf. fills a different role, having responsibility for R&D and manufacturing. (Ex. D at 2.) It is common to have one entity within a corporate family seek regulatory approvals while another entity is responsible for R&D and/or manufacturing. Indeed, AbbVie does the same. AbbVie Inc. is an FDA applicant and other entities, such as its subsidiary AbbVie Bioresearch Center Inc. (*see* Ex. E), are responsible for R&D and manufacturing. For example, AbbVie Inc. is the NDA applicant for Rinvoq® (*see* Ex. F) and has stated that Rinvoq® was developed by AbbVie

[4] To the extent AbbVie is relying on sponsorship of clinical studies on AVT02, that also was not Alvotech hf., but instead another Alvotech entity, Alvotech Swiss AG. (*See* Dkt. No. 1-4 (Compl., Ex. 3) at 12; Dkt. No. 1-9 (Compl., Ex. 8) at 10; Dkt. No. 1-10 (Compl., Ex. 9) at 8.)

Bioresearch Center, a "premier biologics [] research and development center" with "more than 400,000 ft^2 of … manufacturing space" (*see* Ex. G). And yet, AbbVie has not contended that AbbVie Bioresearch Center Inc. is a reference product sponsor, and rightly so. (*See* Ex. H.)

While AbbVie pled that Alvotech hf. "submitted" the AVT02 BLA and "directed Alvotech USA to act as its agent between the FDA and Alvotech during the regulatory process," it offered no support for this allegation. (*See* Compl., ¶ 32.) As explained above, none exists. *See Evers v. Astrue*, 536 F.3d 651, 656-57 (7th Cir. 2008) (in determining whether to dismiss for lack of jurisdiction, "[t]he district court may properly look beyond the jurisdictional allegations of the complaint and view whatever evidence has been submitted on the issue"). Indeed, AbbVie knows Alvotech USA is the BLA applicant—it has Alvotech USA's BLA filing. (Compl., ¶ 45.)

Dismissal for Lack of Subject Matter Jurisdiction. Under the BPCIA, subject matter jurisdiction for this lawsuit is predicated by the patent dance process outlined above, culminating in the lawsuit identified in § 262(*l*)(6) against the subsection (k) applicant. Without the applicant, there is no application to consider, no dance that was either completed or not completed, no agreed upon list of patents on which to sue, and no BPCIA patent case to resolve. Accordingly, because AbbVie chose to exclude Alvotech USA, there is no BPCIA subject matter jurisdiction against Alvotech hf. alone. AbbVie's complaint must therefore be dismissed under Rule 12(b)(1). *See Semiconductor Energy Lab. Co. v. Nagata*, 706 F.3d 1365, 1369 (Fed. Cir. 2013) (district court "appropriately dismiss[ed plaintiff's] complaint for lack of subject matter jurisdiction" because plaintiff had "neither established that federal patent law created a cause of action as pleaded nor that federal patent law was a necessary element of its claims").

Dismissal For Failure To State A Claim. Similarly, in order to plead a cause of action under the BPCIA, AbbVie must include Alvotech USA. Alvotech USA is the subsection (k)

applicant and participated in the dance. Without Alvotech USA, there is no applicant nor application; thus, there is no dance nor any agreed-upon patent list. AbbVie cannot simply substitute Alvotech hf. at its whim, merely because Alvotech hf. helped develop the product at issue and will ultimately manufacture it.[5] AbbVie's complaint should thus also be dismissed under Rule 12(b)(6). *See Burda v M. Ecker Co.*, 954 F.2d 434, 439 (7th Cir. 1992) (affirming dismissal of suit brought pursuant to federal statute that required plaintiff to bring claim "against the United States," because "the United States [was] not a party to th[e] action," and therefore, "plaintiff fail[ed] to state a claim upon which relief can be granted").

II. AbbVie's Complaint Fails to Name A Necessary Party: Alvotech USA

Rule 12(b)(7) requires dismissal for "failure to join a party under Rule 19," in order to "permit joinder of all materially interested parties to a single lawsuit so as to protect interested parties and avoid waste of judicial resources." *Williams v. Planet Fitness, Inc.*, 2021 WL 1165101, *3 (N.D. Ill. Mar. 26, 2021). "[C]ourts engage in a two-step inquiry under Rule 12(b)(7), asking: (1) whether a party is necessary under Rule 19(a), and if so, whether its joinder is feasible; and (2) if the party is necessary but cannot be joined, whether litigation can proceed in the party's absence, or alternatively, whether it must be dismissed because of the party's indispensability." *Id.* at *6. Under these standards, AbbVie's complaint should be dismissed.

[5] Based on pre-suit correspondence, Alvotech expects that AbbVie will raise cases under the Hatch-Waxman Act, the statute that deals with generic versions of non-biological drugs, as permitting its course of action in not suing Alvotech USA. In the context of that statute, district courts have come to differing conclusions as to whether parties ***in addition to the actual applicant*** can be liable as a "submitter" of a generic drug application under 35 U.S.C. § 271(e)(2)(A). *Compare Cephalon, Inc. v. Watson Pharms., Inc.*, 629 F. Supp. 2d 338 (D. Del. 2009) (finding potential submitter liability for additional entities) *with In re Rosuvastatin Calcium Pat. Litig.*, 2008 WL 5046424, at *10 (D. Del. Nov. 24, 2008), *adopted in part sub nom. In re Rosuvastatin*, 2009 WL 87409 (D. Del. Jan. 12, 2009), *and adopted in part sub nom. Astrazeneca Pharms. LP v. Aurobindo Pharma Ltd.*, 2009 WL 483131 (D. Del. Feb. 25, 2009) (rejecting potential submitter liability for additional entities). Regardless of this debate, Alvotech is unaware of a court permitting a case to proceed in the absence of the actual applicant under the Hatch-Waxman Act, which, in any event, lacks the detailed "dance" that Congress included in the BPCIA.

A. Alvotech USA Is a Necessary Party

The party that must be sued under the BPCIA statutory framework is the applicant: Alvotech USA. No court has yet addressed this issue under the BPCIA; but that does not make the answer any less clear. Congress identified the "subsection (k) applicant" as the party that should be in the BPCIA litigation. *See* 42 U.S.C. § 262(*l*); *see also Sandoz*, 137 S. Ct. at 1671. And that is not unique in the law. Legislatures in other contexts have defined a statutorily necessary party that courts require be joined. *See Carver v. Sheriff of LaSalle Cty., Ill.*, 324 F.3d 947, 948 (7th Cir. 2003) (vacating county dismissal where "state law requires the county to pay" so county is "indispensable party to the litigation"); *Tillman v. City of Milwaukee*, 715 F.2d 354, 358 (7th Cir. 1983) (affirming necessary party finding where "it is more than obvious" that agency "created by statute" to supervise at-issue program "was a necessary party"); *Glover v. State Farm Fire & Cas. Co.*, 984 F.2d 259, 261 (8th Cir. 1993) (declining to "ignore the plain statutory command" that judgment debtor be joined in action under state statute); *see also Price v. Young Am. Ins. Co.*, 2020 WL 4470443, at *3 (W.D. Mo. Aug. 4, 2020) (granting motion to remand where "judgment debtors are statutorily necessary parties" and judgment debtors did not consent to removal). At bottom, Alvotech USA is the statutorily defined necessary party.

B. AbbVie Seeks Relief That Can Only Apply To the Applicant

In the BPCIA, Congress considered how to protect the rights of the reference product sponsor against a product that infringes a valid patent. The solution: the statute allows AbbVie to "seek a preliminary injunction prohibiting ***the subsection (k) applicant*** from engaging in the commercial manufacture or sale of such biological product … ." 42 U.S.C. § 262(*l*)(8)(B) (emphasis added). AbbVie, knowing that, ***requested*** relief that can ***only*** be granted against Alvotech USA. AbbVie pleads that 42 U.S.C. § 262(*l*)(8)(A) "contemplates injunctive relief, including preliminary injunctive relief," (Compl., ¶ 42) and requests "preliminary … relief,

including but not limited to an injunction" as part of its "Prayer for Relief." Nevertheless, AbbVie excludes Alvotech USA from the litigation and tries to obtain these statutory remedies by reaching through the parent entity in order to get the venue it wants. AbbVie again violates the BPCIA and as a result, the court is powerless to grant AbbVie's requested relief. *See* Fed. R. Civ. P. 19(a)(1)(A).

AbbVie's request for injunctive relief against both Alvotech hf. and a subsidiary, *i.e.*, Alvotech USA, also runs afoul of Rule 65. Courts "have long observed the general rule that a court may not enter an injunction against a person who has not been made a party in the case before it." *Additive Controls & Measurement Sys. Inc. v. Flowdata, Inc.*, 96 F.3d 1390, 1394 (Fed. Cir. 1996). In an attempt to circumvent the venue rules, AbbVie excluded Alvotech USA. But AbbVie cannot have its cake and eat it too—it must sue Alvotech USA or forego a claim for injunctive relief.

C. Alvotech USA Cannot be Joined in this District

Because it resides and exists in Virginia, Alvotech USA cannot be joined in this District. While AbbVie pled the general venue statute as it pertains to Alvotech hf. (*see* Compl., ¶ 40), Alvotech USA is subject to the patent-specific venue statute of 28 U.S.C. § 1400(b). Under that statute, AbbVie cannot establish venue over Alvotech USA in Illinois, which of course, is why AbbVie excluded Alvotech USA. Under § 1400(b), "[a]ny civil action for patent infringement may be brought in [1] the judicial district where the defendant resides, or [2] where the defendant has committed acts of infringement and has a regular and established place of business."

AbbVie can satisfy neither provision of § 1400(b). "[T]he judicial district where the defendant resides … refers only to the State of incorporation." *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514, 1520 (2017). Alvotech USA, incorporated in Virginia, thus "resides" only in Virginia. And setting aside whether Alvotech USA has "committed acts of infringement" in this district—it has not—Alvotech USA indisputably does not have a "regular

and established place of business" in this district. Alvotech USA's business is, and always has been, located in the Eastern District of Virginia. Accordingly, venue is not proper in this district. As a result, Alvotech USA cannot be joined to this litigation under Fed. R. Civ. P. 19(a)(3).

D. Without Alvotech USA, the Case Cannot Proceed

When a "required party" such as Alvotech USA cannot be joined, this 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).

Based on the Rule 19(b) factors, this action should not, and indeed cannot, proceed without Alvotech USA. The BPCIA requires AbbVie to sue Alvotech USA. There is nothing this Court could do to "lessen[] or avoid[]" that prejudice to Alvotech USA, because Alvotech USA's participation is required by statute. Any judgment without Alvotech USA would not "be adequate" because this Court cannot grant the relief under the BPCIA. And AbbVie still "ha[s] an adequate remedy," because it can bring an action (or counterclaims) in the Eastern District of Virginia. Accordingly, this action should be dismissed.

Allowing AbbVie to leave Alvotech USA out of the lawsuit permits AbbVie to circumvent the BPCIA and use a foreign parent entity to reach through to its U.S. subsidiary. A subsidiary is a necessary party when the suit against the parent company imputes the conduct of the subsidiary to the parent, as AbbVie does here. *See, e.g.*, *Carnero v. Bos. Sci. Corp.*, 433 F.3d 1, 18 (1st Cir. 2006) (affirming suit dismissal where employee sued parent company but subsidiary could not be joined); *Polanco v. H.B. Fuller Co.*, 941 F. Supp. 1512, 1523 (D. Minn. 1996) (dismissing suit when Guatemalan citizen sued U.S. parent corporation but subsidiary could not be joined). Just as Alvotech is required to respect AbbVie's corporate distinctions in relation to its patents and to Humira®, so is AbbVie required to respect the distinctions between Alvotech USA and Alvotech hf., and AbbVie is not permitted to "seek the best of both worlds." *See Kagan v. Edison*

Bros. Stores, Inc., 907 F.2d 690, 693 (7th Cir. 1990) (emphasizing the importance of "respect for the corporate form" and holding plaintiff could not "seek the best of both worlds" by treating corporation as existing for some purposes but not for others).

III. AbbVie's Complaint Should Be Dismissed for Lack of Personal Jurisdiction

"[T]he ability to exercise personal jurisdiction over a non-resident defendant is extremely limited." *Liam Lefebvre v. Washington Univ.*, 2021 WL 197388, at *1 (N.D. Ill. Jan. 20, 2021). When a defendant moves to dismiss under Rule 12(b)(2), the plaintiff has the burden of proving jurisdiction. *Matlin v. Spin Master Corp.*, 921 F.3d 701, 705 (7th Cir. 2019).

General Personal Jurisdiction. Alvotech hf. does not have contacts that render it "essentially at home" in Illinois. *See Daimler AG v. Bauman*, 571 U.S. 117, 139 (2014). Indeed, Alvotech hf. has no contacts with Illinois; it is an Icelandic company, headquartered in Iceland. (Compl., ¶ 27.) And AbbVie does not allege that Alvotech hf. has any offices, employees, property, or assets in Illinois. In short, Alvotech hf. is not "at home" in Illinois. *See id.*

Specific Personal Jurisdiction. AbbVie also cannot establish specific personal jurisdiction over Alvotech hf., which "focuses on 'the relationship among the defendant, the forum, and the litigation.'" *Walden v. Fiore*, 571 U.S. 277, 284 (2014). To establish specific personal jurisdiction, AbbVie must show that "(1) the defendant has purposefully directed his activities at the forum state or purposefully availed himself of the privilege of conducting business in that state, and (2) the alleged injury arises out of the defendant's forum-related activities." *Matlin*, 921 F.3d at 705–06. AbbVie has not and cannot make this showing.

Alvotech USA (not Alvotech hf.) filed the BLA for AVT02 and it was Alvotech USA (not Alvotech hf.) that sent the BLA to AbbVie Inc. pursuant to the BPCIA. (*Compare* Ex. A, *with* Compl., ¶¶ 32-34.) AbbVie's allegations otherwise are specious. In essence, AbbVie wants to rely on Alvotech USA for jurisdiction but without pleading a sufficient basis to do so. This Court

cannot exercise personal jurisdiction over Alvotech hf. based on the acts of Alvotech USA absent some legitimate reason. *See Forde v. Arburg Gmbh + Co KG*, 2021 WL 148877, *5 (N.D. Ill. Jan. 15, 2021). As demonstrated above, Alvotech USA is not Alvotech hf.'s agent, and AbbVie has not pled that Alvotech USA is the "alter ego" of Alvotech hf.[6]

AbbVie's complaint makes much of the unremarkable proposition that Alvotech hf. provided information ultimately included in the AVT02 BLA, and as corporate parent, is in some sense, ultimately responsible for the preparation of the AVT02 BLA. (*See* Compl., ¶ 32.) Even accepting that as true, none of that happened in or targeted Illinois. Alvotech hf.'s operations are all in Iceland. A number of Alvotech entities contributed information to the BLA. (*See, e.g.*, Ex. D at 2; Compl., ¶ 34; Dkt. No. 1-4 (Compl., Ex. 3) at 12.) Yet ultimately, Alvotech USA in Virginia was responsible for preparing and filing the BLA with FDA in Maryland. (Ex. D.) Alvotech hf.'s actions have no ties to Illinois. *See Walden*, 571 U.S. at 291 ("it is the defendant, not the plaintiff or third parties, who must create contacts with the forum State"); *Ariel Invs., LLC v. Ariel Cap. Advisors LLC*, 881 F.3d 520, 522 (7th Cir. 2018) ("The connection [to the forum] must be of the defendant's creation …."). Forcing Alvotech hf. to litigate in Illinois under these facts is inconsistent with "fair play and substantial justice." *See Asahi Metal Indus. Co. v. Superior Ct. of California, Solano Cty.*, 480 U.S. 102, 113–14 (1987) (holding assertion of jurisdiction over foreign defendant "unreasonable".)

To the extent that AbbVie analogizes to *Acorda Therapeutics Inc. v. Mylan Pharmaceuticals*, a case under the Hatch-Waxman Act, that case does not support jurisdiction here. 817 F.3d 755 (Fed. Cir. 2016). In *Acorda*, the Federal Circuit held that the submission of an

[6] Indeed, were AbbVie to argue that Alvotech USA is the alter ego of Alvotech hf., venue would be improper in this District as Alvotech hf. would then be doing business in Virginia, and thus venue would lie there.

ANDA under the Hatch-Waxman Act by the Mylan defendants was sufficient to confer personal jurisdiction in Delaware. Notably, the plaintiff had sued the actual applicant for the ANDA approval, in addition to the related corporate entities. Accordingly, the plaintiff was not trying to manipulate the statutory scheme, as AbbVie is here. Under these circumstances, the Federal Circuit found personal jurisdiction by looking to the future activities of the defendants in Delaware, which included the applicant. Here, by contrast, AbbVie has deliberately excluded the applicant from the case for forum-shopping purposes. An extension of *Acorda* to the facts of this case is thus unwarranted.

The exercise of personal jurisdiction in this case is also unreasonable. Additional factors that must be considered include "the plaintiff's interest in obtaining convenient and effective relief." *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 292 (1980). AbbVie's filing of this case is the opposite of "efficient resolution." *See id.* AbbVie could have sued Alvotech USA in Virginia to litigate in a forum that has historically proceeded to trial quickly without any controversy. But AbbVie does not want quick, efficient resolution. AbbVie's strategy here has increased "the burden on the defendant," contrary to "the interstate judicial system's interest in obtaining the most efficient resolution of controversies." *See id.* at 292. The Court should find that considerations of unfairness override any minimum-contacts basis for specific personal jurisdiction over Alvotech hf. *See Asahi Metal*, 480 U.S. at 116.

CONCLUSION

For the foregoing reasons, this Court should grant Alvotech hf.'s motion to dismiss with prejudice.

Date: June 2, 2021

Respectfully submitted,

ALVOTECH HF.

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CERTIFICATE OF SERVICE

I hereby certify that on June 2, 2021 I caused a true and correct copy of the foregoing to be electronically served on counsel of record via the Court's CM/ECF system.

/s/ *Louis E. Fogel*
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