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.	)	

DEFENDANT ALVOTECH HF.'S OPPOSITION TO PLAINTIFFS' MOTION TO DISMISS AND STRIKE DEFENDANT'S COUNTERCLAIMS AND AFFIRMATIVE DEFENSES OF INEQUITABLE CONDUCT, UNCLEAN HANDS, AND PATENT MISUSE

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I. INTRODUCTION

AbbVie's Motion is without merit and should be denied. Alvotech has properly pled that the asserted claims are unenforceable because AbbVie intentionally misled the PTO during patent prosecution, misused Alvotech's confidential information to get new patents, and engaged in a pattern of misconduct designed to build and shield its "minefield of IP" from meaningful litigation.

AbbVie's effort to dismiss these counterclaims is legally deficient and misleading. For example, on inequitable conduct, AbbVie mischaracterizes the Federal Circuit's *Fiskars* decision as holding that "as a matter of law" inequitable conduct cannot arise from a reference cited to the examiner. *Fiskars* does not say that, and in fact, AbbVie's argument has been rejected ***in this district***. As another example, on both unclean hands and patent misuse, AbbVie relies on the Supreme Court's statement in *Automatic Radio* that "the mere accumulation of patents, no matter how many, is not in and of itself illegal" to argue that the assertion of its "minefield of IP" is categorically not actionable. But AbbVie omits that Court's statement in the same case indicating that the result could be different if patents are used to create an "overpowering threat of disastrous litigation"—as AbbVie has done. As a third example, AbbVie repeatedly relies on this district's decision dismissing an ***antitrust*** case—a tacit admission that its motion fails under ***patent*** law. These are just some of the serious flaws with AbbVie's Motion, with others discussed below.

The lack of authority in AbbVie's brief suggests that AbbVie filed the Motion with other strategic interests in mind: specifically, to support its refusal to produce any discovery regarding Alvotech's unclean hands and patent misuse counterclaims. From the beginning of discovery, AbbVie has steadfastly refused to produce any discovery whatsoever regarding those claims, forcing Alvotech to move to compel production. (*See* D.I. 77.) Then, yesterday—only after Alvotech had already borne the time and cost associated with moving to compel—AbbVie stated

that it would produce the information (although it has not yet done so). Delaying tactics of this sort are not unfamiliar territory for AbbVie. AbbVie previously refused to produce any discovery related to the unclean hands defense of another biosimilar maker until the court in that case granted three separate motions to compel and described AbbVie's arguments as "a strawman" and "nonsense." Similarly, in its report on the recent Congressional investigation into AbbVie's conduct regarding Humira®, the Committee concluded that AbbVie had "obstructed the Committee's investigation" and remarked that the Committee had "serious questions about" and would "continue to scrutinize the veracity" of some of the information that AbbVie eventually provided.[1] The lack of merit in AbbVie's present Motion, coupled with its discovery conduct in this case, suggests that AbbVie filed its Motion simply as part of that broader, longstanding strategy of avoiding discovery into its misconduct. In any event, because Alvotech has properly pled its allegations with more than sufficient facts to withstand the pleadings stage, this Court should deny AbbVie's Motion.

II. LEGAL STANDARD

"A complaint may survive a motion to dismiss under Rule 12(b)(6) if it contains sufficient factual allegations to 'state a clam to relief that is plausible on its face." *J&J Sports Prods., Inc. v. Davies*, 2015 WL 4978697, at *1 (N.D. Ill. Aug. 19, 2015) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "[T]he Court must accept as true all well-pleaded factual allegations in the complaint and draw all reasonable inferences in plaintiff's favor." *Id.*

III. ARGUMENT

A. Alvotech's Inequitable Conduct Allegations More-than-Plausibly Show that AbbVie Made Material Misrepresentations with Intent to Deceive the PTO

[1] *See* https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Committee%20on%20Oversight%20and%20Reform%20-%20AbbVie%20Staff%20Report.pdf.

Proving inequitable conduct requires two elements: that the applicant (1) "misrepresented or omitted material information"; and (2) did so "with the specific intent to deceive the PTO." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011).

As Alvotech alleged in its counterclaims ("CC"), while prosecuting U.S. Patent No. 8,889,136 (a parent to the '973 patent-at-issue), AbbVie made misrepresentations of fact to the PTO that it knew were incorrect. In particular, AbbVie repeatedly argued, through its prosecuting attorneys (including Mr. Doss of Ropes & Gray) and in an expert declaration (Dr. Diane Mould), that a person of skill in the art would not have been motivated to use doses of adalimumab greater than 40 mg/ml in view of alleged concerns over "increased rates of infections" in the prior art. (CC at ¶¶ 98, 106-108.) But AbbVie knew the prior art did not teach that such doses were unsafe; it taught the opposite. (CC at ¶¶ 99-104.) Five of AbbVie's own studies (conducted by its predecessor-in-interest, Abbott Laboratories) disclosed that doses of up to ***800 mg*** were well-tolerated, with a safety profile "comparable to that of placebo." (CC at ¶ 99.)

In what can be construed as an attempt to provide cover for its argument to the PTO, AbbVie gave these studies to the PTO, but buried them among hundreds of other references and never directed the examiner's attention to them. (CC at ¶¶ 105, 108.) As a result, none of the studies were ever substantively addressed during examination, AbbVie never had to reconcile its representations with its own contradictory prior art, and the pending claims issued. The above facts, as pled in Alvotech's counterclaims, plausibly show that AbbVie made material misrepresentations of fact during prosecution with the requisite deceptive intent.

1. AbbVie's Arguments on Materiality Mischaracterize Federal Circuit Law and Ignore Case Law from This District

With respect to materiality, AbbVie seemingly argues (1) that Alvotech's claims fail "as a matter of law" because inequitable conduct cannot arise from references that were before the

examiner or from attorney argument about such references; and (2) that Alvotech has not pled materiality because it's allegations do not relate to "any of the ten patents in the August 2022 trial." In making those arguments, AbbVie mischaracterizes the cited cases, fails to inform this Court of contrary precedent, and misstates key facts.

a. Inequitable Conduct Can Arise From Material Misrepresentations Regarding Cited References or From Burying of Cited References

Material misrepresentations regarding a cited reference can give rise to inequitable conduct, even where the PTO is aware of the reference. For example, in *Apotex Inc. v. UCB, Inc.*, 763 F.3d 1354, 1359, 1361 (Fed. Cir. 2014), the Federal Circuit affirmed a finding of inequitable conduct based on "misrepresentations to the PTO," including in "[an expert's] declaration [that] mischaracterized [a cited reference]."

AbbVie's reliance on *Fiskars, Inc. v. Hunt Mfg. Co.*, 221 F.3d 1318, 1327 (Fed. Cir. 2000), is misplaced for several reasons. *Fiskars* addressed only whether a reference that was before the examiner could, nonetheless, be deemed to have been "withheld with deceptive intent." *Id*. at 1327. Unlike here, there was no allegation in *Fiskars* that the applicant made misrepresentations to the PTO or that the applicant had buried a material reference. With respect to misrepresentations, the Federal Circuit's *Apotex* decision confirms that inequitable conduct can arise from misrepresentations regarding a cited reference. The same is true in this district. In *CoStar Realty Info., Inc. v. CIVIX-DDI, LLC*, 946 F. Supp. 2d 766, 777-79 (N.D. Ill. 2013), the court held that *Fiskars* did not bar a finding of inequitable conduct where the applicant had "avoided scrutiny" of a disclosed reference "by deliberately focusing the PTO's attention on [other] references it identified." *Id*. AbbVie's reliance on *Avery Dennison Corp. v. Continental Datalabel, Inc.*, 2010 WL 4932666 (N.D. Ill. Nov. 30, 2010) is unpersuasive because, unlike the cases cited above, that case did not include any allegations that the applicant made misrepresentations to the PTO.

With respect to burying, numerous decisions, including from this district, have considered *Fiskars* and held that it does not bar a finding of inequitable conduct arising from burying a material reference. *See, e.g.*, *CIVIX-DDI, LLC v. Hotels.com, L.P.*, 711 F. Supp. 2d 839, 849 (N.D. Ill. 2010) ("Defendants' factual allegations support a reasonable inference that [the prosecuting attorney] attempted to deceive the PTO examiner by burying the highly relevant … prior art in its submissions to the PTO."); *Coolsystems, Inc. v. Nice Recovery Sys. LLC*, 2016 WL 6091577, at *3-4 (N.D. Cal. Oct 19, 2019) (holding *Fiskars* does not bar claim for inequitable conduct where material reference was "buried" in disclosure with 176 references); *Nomadix, Inc. v. Hospitality Care Services LLC*, 2015 WL 3948804, *9 (C.D. Cal. June 29, 2015) ("*Fiskars* did not deal directly with the burying question and likely does not foreclose an IE claim based on intentional burying.").

AbbVie's related assertion that "attorney argument about references of record cannot, as a matter of law, constitute inequitable conduct" fairs no better. (Mot. at 4-5.) AbbVie supports this assertion through a truncated quote from *Rothman v. Target Corp.*, 556 F.3d 1310, 1328-29 (Fed. Cir. 2009). (Mot. at 5.) The full quote, of which AbbVie quoted only the second half, states that: "***While the law prohibits genuine misrepresentations of material fact***, a prosecuting attorney is free to present argument in favor of patentability without fear of committing inequitable conduct." *Rothman*, 556 F.3d at 1328-29. Here, as discussed above, AbbVie's prosecuting attorney made "misrepresentations of material fact," and supported those misrepresentations through an expert declaration. Thus, this case is akin to *Apotex*, where the court affirmed a finding of inequitable conduct arising from attorney argument and an expert declaration that "cross[ed] the line from legitimate advocacy to genuine misrepresentation of material facts." *Apotex Inc.*, 763 F.3d at 1362.

b. Inequitable Conduct in a Parent Application Can Infect a Child Patent Where, as Here, the Claims are Closely Related

AbbVie's suggestion that Alvotech has not sufficiently pled materiality because its

allegations do not relate to "any of the ten patents in the August 2022 trial" is incorrect. (Mot. at 1, 3.) Alvotech's allegations relate to statements made by AbbVie during prosecution of the parent to the '973 patent—one of the ten patents in the August 2022 trial.[2] And the Federal Circuit held that "inequitable conduct 'early in the prosecution [i.e., in a parent application] may render unenforceable all claims which eventually issue from the same or a related application.'" *Agfa Corp. v. Creo Prods. Inc.*, 451 F.3d 1366, 1379 (Fed. Cir. 2006) (quoting *Fox Indus., Inc. v. Structural Preservation Sys., Inc.*, 922 F.2d 801 (Fed. Cir. 1990)). While that court explained that claims in related applications would not be tainted if "the issued claims have no relation to the omitted prior art," *id.*, that is not the case here. Rather, just like the parent '136 patent, the '973 patent clams 80 mg and 160 mg dosing regimens (*see, e.g.*, Compl. Ex. 12 at claim 1), and thus, AbbVie's deceptive arguments regarding the safety of doses greater than 40 mg taint the '973 patent equally. The lone case cited by AbbVie—*Pharmacia Corp. v. Par Pharm., Inc.*, 417 F.3d 1369 (Fed. Cir. 2005)—is easily distinguishable, holding only that inequitable conduct with respect to one patent did not infect a parent patent that had issued ***before*** the inequitable conduct had occurred. *Id.* at 1375.

2. AbbVie's Arguments on Intent to Deceive Disregard Alvotech's Detailed Allegations and, again, Mischaracterizes the Law

With respect to intent, AbbVie wrongly asserts that Alvotech's sole allegation is "the alleged materiality of references." (Mot. at 5.) This is not so. Rather, Alvotech also pleads that AbbVie's misleading statements contradicted *its own studies*. AbbVie plainly knew about those studies—which it disclosed, but buried—and thus it is plausible that AbbVie knew its statements

[2] AbbVie's assertion that none of Alvotech's inequitable conduct allegations relate to the 10 patents set for trial is misleading because the counterclaims AbbVie seeks to dismiss relate only to the four patents initially asserted in this action. Because the court has not yet ruled on Alvotech's motion to dismiss in the second filed action (Case No. 21-2899, D.I. 28), Alvotech has not yet answered or filed counterclaims with respect to the other patents set for trial in August of 2022.

to the Examiner contradicted those studies. Additionally, Alvotech's allegations show that AbbVie directed the Examiner's attention to *other* references, but not to its own studies. (CC at ¶¶ 106-108.) This satisfies the requirement, at the pleading stage, for Alvotech to "plead sufficient facts that the court 'may reasonably infer' knowledge and intent." *CoStar*, 946 F. Supp. 2d at 778 (quoting *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328-29 & n.5 (Fed. Cir. 2009)).

AbbVie also incorrectly suggests that Alvotech was required to plead sufficient facts to make deceptive intent "the single most reasonable inference able to be drawn from the evidence." (Mot. at 5 (citing *Therasense*, 649 F.3d at 1290).) But that requirement does not apply at this stage of the case. The "single most reasonable inference" requirement relates only to the ***merits*** stage, not the pleading stage. *See CoStar*, 946 F. Supp. 3d at 778.

B. Alvotech's Allegations of Unclean Hands Arises from AbbVie's Numerous Efforts to Overwhelm Alvotech with Ruinous Litigation and From Its Misuse of Alvotech's Confidential Information

The doctrine of unclean hands "closes the doors of a court of equity to one tainted with inequitableness or bad faith relative to the matter in which he seeks relief." *Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 814 (1945). AbbVie asserts that unclean hands requires proof of "scheme[s] to defraud," (Mot. at 6), but this is not so. Rather, unclean hands can arise from any "'misconduct' of a party seeking relief [that] 'has immediate and necessary relation to the equity that he seeks in respect of the matter in litigation.'" *Gilead Scis., Inc. v. Merck & Co., Inc.*, 888 F.3d 1231, 1239 (Fed. Cir. 2018). And AbbVie's argument that unclean hands requires some kind of fraud was already rejected by the court in AbbVie's litigation against another biosimilar manufacturer, where it granted three separate motions compelling AbbVie to produce discovery related to unclean hands. *See AbbVie Inc. v. Boehringer Ingelheim Int'l GmbH*, No. 17-cv-1065, 2018 WL 2604825, at *1 (D. Del. June 4, 2018) ("[A]n unclean hands defense may rest on allegations of unconscionability or bad faith, rather than fraud.")

The doctrine of unclean hands "necessarily gives wide range to the equity court's use of discretion." *Gilead*, 888 F.3d at 1239. As it relates to patent cases in particular, unclean hands can arise from misconduct that has "reduce[d] a patentee's risk" or otherwise "enhance[d] the claimant's position regarding legal rights that are important to [patent] litigation." *Id.* at 1240, 1244, 1247. As detailed in Alvotech's counterclaims, AbbVie engaged in a pattern of misconduct designed to build and shield its "patent minefield" from meaningful litigation, thus reducing the risk that those patents would undergo the legal scrutiny necessary to ensure that AbbVie's "monopol[y is] kept within their legitimate scope." *See Precision Instrument*, 324 U.S. at 815.

As pled, AbbVie's misconduct included, at least, artificially inflating the size of its patent portfolio—including through inequitable conduct, as described herein—to give AbbVie a substantially larger "minefield of IP" with which to intimidate Alvotech and other competitors into staying off the market. It has included extensive efforts to overwhelm Alvotech with the threat of ruinous litigation, including failing to participate in the patent dance in good faith; asserting patents against Alvotech for which it has conceded there cannot be infringement; and asserting more than 60 patents against Alvotech, including patents it has no intention of actually pursuing in litigation. And, on information and belief, it has included misusing Alvotech's confidential information to pursue yet additional patents to assert against Alvotech. (*See* CC at ¶¶ 20-52.) Through all this misconduct, AbbVie has "reduced [it's] risk" or otherwise "enhance[d] [it's] position regarding legal rights that are important to [patent] litigation." *Gilead*, 888 F.3d at 1240, 1244.

Although AbbVie describes Alvotech's unclean hands defense as "a jumble of purported misconduct," it is just that "jumble" that makes AbbVie's misconduct so problematic. This is not a case where AbbVie has stepped over the line once—which might be viewed as an overzealous, if misguided, effort to protect a valuable asset. Rather, this is a case in which AbbVie has engaged

in a widespread and concerted effort to obstruct and overwhelm Alvotech (as it has with others), in hopes of ensuring that Alvotech gives up (as all prior competitors have done) prior to a merits trial such that AbbVie's patents and misconduct can once again avoid judgment day. Thus, while AbbVie's motion to dismiss treats Alvotech's counterclaim as though it raises several distinct and disparate claims, each of which should be evaluated in isolation, such a myopic approach misses the total harm. This Court should instead evaluate AbbVie's conduct as a whole, which reveals a coordinated and pervasive effort at using the threat of overwhelming litigation, and using the litigation process itself, as a weapon to protect its patents and its adalimumab monopoly in the United States. AbbVie's contrary arguments are addressed below.

1. AbbVie's Efforts to Overwhelm Alvotech Through the Assertion of More than 60 Patents Gives Rise to Unclean Hands

As described in Alvotech's counterclaim, during the BPCIA patent dance, AbbVie refused to narrow its list of asserted patents and told Alvotech that it "need[ed] to pick all [62] patents" if it wanted to bring its product to market. (CC at ¶ 37.) Thereafter, when Alvotech declined to choose all 62 patents—consistent with the BPCIA process designed to create a rapid and streamlined litigation—and instead chose four patents for the initial litigation, AbbVie chose to assert the remaining 58 patents against Alvotech in the second wave litigation. AbbVie's assertion of these 58 patents was an abuse of the BPCIA process and is contrary to the purposes of the BPCIA, which is to facilitate streamlined challenges to patents that might impede entry of lower-cost biosimilars.

As Alvotech's counterclaim alleges, AbbVie never intended to pursue all 58 patents against Alvotech and asserted them all only as part of an effort to overwhelm Alvotech. For example, although the purpose of the second wave of litigation is for the reference product sponsor to seek a preliminary injunction, AbbVie admitted to this Court that it would only be seeking a preliminary injunction on "several" of the 58 patents. (D.I. 35 at 3.) Yet despite Alvotech's request, for months

AbbVie refused to identify which of the "several" patents it would include in that motion, forcing Alvotech to continue preparing to defend against all of them. The first time AbbVie finally identified a narrower list of patents was when this Court ordered it to identify only 10 patents for trial. Thus, from May 28, 2021, when AbbVie filed its 58-patent complaint until September 8, 2021, when AbbVie identified the 10 patents for trial, Alvotech was forced to spend time and money preparing to defend against all 58 patents.

AbbVie tries to justify its strategic assertion of 58 patents against Alvotech through reliance on the Supreme Court's statement that "the mere accumulation of patents, no matter how many, is not in and of itself illegal." (Mot. at 7 (quoting *Automatic Radio Mfg. Co. v. Hazeltine Rsch.*, 339 U.S. 827, 834 (1950).) But the Supreme Court's holding is only that the ***accumulation*** of a large number of patents is not illegal ***in and of itself***. The Court specifically left open that those patents could be ***used*** illegally if part of an "overpowering threat of disastrous litigation." *Automatic Radio*, 339 U.S. at 834. While, in that case, the Court found no evidence that the portfolio was being used as an "overpowering threat of disastrous litigation," here, Alvotech's allegations plausibly allege that it is.

Additionally, unlike in *Automatic Radio*, Alvotech has alleged that AbbVie asserted four patents that it conceded could not be infringed. AbbVie denies this, arguing that it "only agreed that these patents would not be infringed if Alvotech confirmed certain facts, which it has not done." (Mot. at 10.) But this is not so. [redacted] This is further evidence that AbbVie's assertions of patents were not part of a good faith effort to actually litigate the validity and

infringement of 60 or more patents, but rather, that they were asserted to create the "overpowering threat of disastrous litigation." *See Automatic Radio*, 339 U.S. at 834

Remarkably, AbbVie also cites its success in getting every prior biosimilar applicant to settle as evidence that its assertion of its "absolute minefield of IP" is reasonable. Those settlements are no more an acknowledgement of reasonableness than is a student handing over his lunch money to the school bully. To the contrary, AbbVie's prior settlements merely illustrates the problem: by asserting its "minefield of IP" against prior biosimilar applicants, AbbVie has thus far ensured that none of its patents ever get scrutinized in a judicial proceeding.

2. AbbVie's Misuse of Confidential Information Shows Unclean Hands

AbbVie does not dispute that shortly after it received Alvotech's confidential BLA and BPCIA disclosures, it sought new claims directed at Alvotech's product. Rather, AbbVie's defense is that information about Alvotech's product had previously been "published for all the world to see" in Alvotech's own patent applications and press releases. (Mot. at 11.) This argument is wrong both factually and legally.

First, Alvotech's published information never identified the particular formulation of its AVT02 biosimilar. [redacted]

Second, even to the extent some information about Alvotech's formulation might have been public, the Federal Circuit has specifically held that unclean hands can arise from an amendment directed to cover a competitor's public product if the ***motivation*** for making that

amendment came from misused confidential information. In *Gilead*, the patent owner, Merck, had learned confidentially about the structure of a molecule developed by Gilead's predecessor-in-interest. Thereafter, Gilead's predecessor published the structure of that molecule in a patent application. After the structure was published, Merck amended claims in a pending application to specifically cover the molecule. Like AbbVie does here, Merck relied on *Kingsdown* to argue that there was nothing wrong in its conduct, because the structure was public and it is permissible to amend claims to cover a competitor's product. *See Gilead Sciences, Inc. v. Merck & Co., Inc.*, 2016 WL 3143943, at *11-34 (N.D. Cal. June 6, 2016). The district court rejected that argument and the Federal Circuit affirmed, explaining that, although the structure was public, the Merck patent agent "would not have written new claims to cover [the published structure]" had he not previously obtained the confidential disclosure of the structure. *Gilead*, 888 F.3d at 1242-43. Thus, the court found Merck's patents unenforceable for unclean hands. *Id.* at 1248.

Here, as in *Gilead*, the alleged facts plausibly show that AbbVie would not have filed new claims directed to AVT02 had it not obtained Alvotech's confidential BLA. In particular, although Alvotech's patent applications had published in 2019, AbbVie did not file claims directed to AVT02 for nearly two years, doing so only weeks after receiving Alvotech's BLA. This plausibly shows that the confidential disclosure of the BLA caused AbbVie to file new claims.

Alvotech's counterclaims also provide detailed allegations showing that AbbVie misused Alvotech's confidential 3(B) Statement provided pursuant to the BPCIA's pre-litigation disclosures. During subsequent prosecution of the '201 application, AbbVie used this confidential statement to apply for a new patent that it now asserts against Alvotech.[3] Specifically, Alvotech's confidential statement revealed Alvotech's arguments about the Gokarn PCT application, a key

[3] AbbVie has identified the patent issuing from the '201 application as one it asserts against Alvotech hf. as soon as the patent issues.

reference that Alvotech relies on as invalidating prior art. Prior to that disclosure, AbbVie had never called out Gokarn PCT to an Examiner for any patent in the family, and it had never been the basis of rejection for any patent in the family. Then, mere weeks after Alvotech provided its confidential 3(B) Statement to AbbVie, AbbVie preemptively raised Gokarn PCT with the Examiner, allowing AbbVie to use the non-adversarial *ex parte* examination proceeding to obtain the PTO's determination that the '201 application was patentable over Gokarn PCT. (CC at ¶¶ 33-34.) Thus, when in the future, Alvotech presents invalidity arguments based on Gokarn PCT in an adversarial litigation, AbbVie can tell the judge or jury that these patents are "battle-tested" as being patentable over Gokarn PCT.

AbbVie's defenses to its misuse of Alvotech's 3(B) Statement miss the mark. First, AbbVie argues that "published references relied on as prior art are not protected information under the BPCIA." (Mot. at 12.) This is a red herring. Alvotech does not allege that it was the public Gokarn PCT reference itself that caused AbbVie to make its preemptive argument to the PTO. Rather, Alvotech plausibly alleges that it was confidential arguments disclosed in Alvotech's 3(B) Statement that caused AbbVie to make its preemptive argument to the PTO.

Second, AbbVie argues that "Gokarn PCT was old news," and had been previously asserted in an IPR. (Mot. at 12.) But as described above and alleged in Alvotech's counterclaims, until receiving Alvotech's confidential 3(B) Statement, AbbVie had never previously sought examination of Gokarn PCT by way of flagging the reference for an Examiner, for example, and the Gokarn PCT had never been the subject of any rejection. Thus, old news or not, that AbbVie preemptively raised Gokarn PCT mere weeks after receiving Alvotech's 3(B) Statement makes it at least plausible—if not probable—that it was Alvotech's confidential disclosure that caused AbbVie to make the preemptive argument.

3. AbbVie's Unclean Hands Are Shown by Allegations of Conduct Directed at Alvotech, Not Others

Contrary to AbbVie's assertion, Alvotech is not relying on "misconduct toward *other* parties," to support its unclean hands defense. Rather, Alvotech's counterclaim specifically identifies AbbVie's misconduct directed at Alvotech, including its failure to participate in the patent dance in good faith, its misuse of Alvotech's confidential information, and its attempt to overwhelm Alvotech by asserting more than 60 patents, including patents it conceded were not infringed and patents obtained through inequitable conduct or other improper means. (CC at ¶¶ 20-41.) Alvotech then also describes how that misconduct is part of a broader pattern of misconduct that started years ago. (*Id.* at ¶¶ 42-52.) That pattern helps to show the culpability of AbbVie's conduct, and shows the plausibility that AbbVie's conduct has been in bad faith.

4. AbbVie's Reliance on the Humira® Antitrust Case is Improper

Although AbbVie repeatedly cites to the decision in *In re Humira (Adalimumab) Antitrust Litig.*, 465 F. Supp. 3d 811 (N.D. Ill. 2020), which dismissed federal antitrust claims against AbbVie, that reliance is misplaced. District Judge Shah's decision held only that a different group of plaintiffs (indirect purchasers of Humira®) had not adequately pled federal antitrust claims. That case, which is currently on appeal to the Seventh Circuit, included ***no*** claims for patent infringement, unclean hands, patents misuse, or inequitable conduct. Thus, it has no bearing on whether the claims and defenses asserted in this case are sufficiently pled.[4]

[4] It is also notable that the court in that case recognized that facts it found insufficient to support a federal antitrust claim might nonetheless sufficiently support other claims covering "unfair and unconscionable conduct," and thus, gave plaintiffs leave to replead state law claims arising from the same conduct. *Id.* at 847-49, 853-54. Thus, any suggestion that *In re Humira* held that AbbVie's conduct was not actionable in any way is wrong. That court held only that AbbVie's conduct did not give rise to a federal antitrust claim.

C. Alvotech's Counterclaims Plead Patent Misuse through AbbVie's Improper Use of the Litigation Process to Avoid Judgment

The Federal Circuit has held that patent misuse may arise, among other ways, where a patentee brings a lawsuit in "bad faith" and with an "improper purpose in bringing the suit." *Glaverbel Societe Anonyme v. Northlake Mktg & Supply Inc.*, 45 F.3d 1550, 1558 (Fed. Cir. 1995). "A purpose is improper if its goal is not to win a favorable judgment, but to harass a competitor and deter others from competition, by engaging the litigation process itself, regardless of outcome." *Id.* As described above with respect to Alvotech's unclean hands defense, the allegations in Alvotech's counterclaims plausibly show that AbbVie's purpose in this litigation—as in all prior BPCIA litigations—is not to win a favorable judgment but, rather, to avoid any judgment whatsoever by using "the litigation process itself" as a weapon.

AbbVie's defense to Alvotech's patent misuse claims is to, once again, rely on the Supreme Court's statement in *Automatic Radio* that the "mere accumulation of patents, no matter how many, is not in and of itself illegal." (Mot. at 15.) But Alvotech is not asserting that AbbVie committed patent misuse through "the mere accumulation of patents." Rather, Alvotech is asserting that AbbVie committed patent misuse by using its enormous portfolio—including patents it has conceded Alvotech cannot infringe and patents obtained through inequitable conduct and other improper means—to create an "overpowering threat of disastrous litigation." *Automatic Radio*, 339 U.S. at 834. The relevant inquiry at the motion to dismiss stage is simply whether the facts alleged ***in this case*** plausibly show that AbbVie is using its portfolio to create an overpowering threat of disastrous litigation. For the reasons already articulated, Alvotech's allegations meet and surpass that standard.

IV. CONCLUSION

For the foregoing reasons, Alvotech respectfully requests that AbbVie's motion be denied.

Date: November 5, 2021

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 5, 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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