CONTAINS CONFIDENTIAL INFORMATION
PURSUANT TO THE PROTECTIVE ORDER AND 42 U.S.C. § 262(l)

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

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

REPLY IN SUPPORT OF PLAINTIFFS' MOTION TO DISMISS AND STRIKE DEFENDANT'S COUNTERCLAIMS AND AFFIRMATIVE DEFENSES OF INEQUITABLE CONDUCT, UNCLEAN HANDS, AND PATENT MISUSE

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Federal Cases **Page(s)**

Federal Statutes

CONTAINS CONFIDENTIAL INFORMATION
PURSUANT TO THE PROTECTIVE ORDER AND 42 U.S.C. § 262(l)

I. INTRODUCTION

Alvotech's conclusory allegations fail to plausibly plead inequitable conduct. Alvotech disagrees with the *opinion* of AbbVie's expert and *arguments* of AbbVie's prosecution attorney, based on prior art publications *provided to the USPTO* or cumulative with references provided to the USPTO. Yet, controlling law has repeatedly held that such activity cannot constitute inequitable conduct because it would arise in just about every patent case. Further, Alvotech's allegations do *not* relate to one of the 10 patents at issue, but instead to a parent patent, reflecting Alvotech's desire to expand the scope of the case.

Alvotech's unclean hands allegation would expand the case ***six-fold***, making it about 65 patents rather than ten. But the Supreme Court has made clear that obtaining even large numbers of patents is not unlawful, and the BPCIA required AbbVie to assert those patents or forfeit substantial rights. Alvotech alleges that AbbVie's "patent thicket" somehow bullied some of the largest companies in the world into submission, but just the opposite is true: several challenged AbbVie's patents and lost. And they all took licenses and agreed to pay, which under the law is not evidence that AbbVie did anything wrong, but instead that its patents are valid. In any event, this very proceeding makes Alvotech's argument implausible: Alvotech was able to challenge AbbVie's patents and obtain a prompt trial, and in the unlikely event it defeats AbbVie's patents and is not enjoined (and its product is approved), it can launch. Alvotech has not pleaded anything that plausibly shows the type of egregious conduct that could support a claim of unclean hands.[1]

Finally and most regrettably, Alvotech accuses AbbVie's lawyers of misusing purportedly confidential information, even though ***Alvotech itself put the relevant information into the public***

[1] Alvotech's new argument concerning production of documents relating to Alvotech's unclean hands claim is moot. *See* Dkt. No. 88 at 1-2. AbbVie entered into a stipulation that has already resulted in the rolling production of millions of pages of documents. Dkt. No. 99.

domain long before this suit began. Alvotech alleges that AbbVie drafted formulation claims based on details Alvotech disclosed during this case, ignoring that Alvotech disclosed and claimed the formula in a public patent application as their preferred embodiment. Alvotech's patent also expressly details how its formulation was derived from AbbVie's commercial formula and AbbVie's patents-at-issue in this case. Not only should the defense be thrown out, but Alvotech should be admonished for making such serious and irresponsible allegations.

Alvotech's legally and factually implausible inequitable conduct, unclean hands, and patent misuse counterclaims and defenses seek to vastly expand the scope of the case beyond the validity and infringement of the 10 patents at issue. As warned by the *en banc* Federal Circuit, such claims "increase the complexity, duration, and cost" of litigation. *Therasense, Inc. v. Becton, Dickinson & Co*., 649 F.3d 1276, 1289-90 (Fed. Cir. 2011) (*en banc*). Alvotech's desire to pursue these claims and defenses conflicts with its stated desire to be ready for trial on the 10 patents at issue in August 2022. And the scatter-shot nature of Alvotech's allegations reflects a determination to sweep in virtually any conduct that Alvotech believes it can portray as improper.

AbbVie respectfully asks the Court to deny Alvotech's effort to multiply the issues in this case exponentially. Alvotech failed to adequately and plausibly plead inequitable conduct, unclean hands, or patent misuse, and those defenses and counterclaims therefore should be stricken and dismissed.

II. ARGUMENT

A. Alvotech Fails to Meet Its Pleading Burden for Inequitable Conduct

Alvotech's allegations of inequitable conduct, as a theory of "fraud" on the USPTO, must be pled with particularity under Rule 9. Conclusory accusations based merely on disagreement with arguments AbbVie made during prosecution do not suffice.

1. Alvotech Fails to Plausibly Plead Materiality

Alvotech's conclusory allegations cannot convert permissible expert opinions and attorney argument during prosecution into factual misrepresentations that meet the high bar required to claim fraud on the USPTO. Otherwise, any party could allege material misrepresentations simply because they disagreed with an applicant's argument. The heightened pleading requirement exists to "ferret out" unsupported inequitable conduct claims. *Therasense,* 649 F.3d at 1302 (J. O'Malley, concurring in part).

Here, as set forth in Alvotech's pleading, AbbVie undertook the common process of submitting an expert opinion to rebut the USPTO's assertion that the pending claims were obvious over, *inter alia,* art that included AbbVie's rheumatoid arthritis clinical trials. Dkt. No. 71 Ex. F, at 6. AbbVie's expert provided her professional *opinion* regarding what a person of ordinary skill would have considered in April 2004 when contemplating a particular dosing regimen. *See, e.g., id.* at 14 ("[I]t is my opinion that one of ordinary skill in the art in April 2004 would have considered these risks … it is also my opinion that it would not have been obvious to one of ordinary skill in the art in April 2004 to modify the adalimumab rheumatoid arthritis treatment regimen…"). It is undisputed that the USPTO reviewed and considered relevant references such that it could assess her opinion, including four of the five allegedly contrary references cited by Alvotech. *See* Dkt. No. 70 at 3, n.1; Dkt. No. 71 at Ex. B.

While Alvotech may disagree with the opinions of AbbVie's expert and arguments from AbbVie's attorney, that does not render the opinions improper or the arguments deceptive—particularly as the USPTO had in front of it the very information Alvotech contends contradicted these opinions. *Id.* Indeed, the Federal Circuit has repeatedly and consistently approved of such advocacy before the USPTO. *E.g. Young v. Lumenis, Inc.,* 492 F.3d 1336, 1348 (Fed. Cir. 2007) ("We therefore fail to see how statements … which consist of attorney argument and an

interpretation of what the prior art discloses, constitute affirmative misrepresentations of material fact."); *Life Techs., Inc. v. Clontech Lab'ys, Inc.,* 224 F.3d 1320, 1326 (Fed. Cir. 2000) (merely advocating "a particular interpretation" of the teachings of the prior art, which the USPTO was free to accept or reject, did not give rise to a finding of misrepresentation)*; see Berry Plastics Corp. v. Intertape Polymer Corp.*, 205 F. Supp. 3d 979, 997 (S.D. Ind. 2016) ("Under Federal Circuit law, where a patentee has submitted a reference for the PTO to review, the patentee 'is free to advocate its interpretation of its claims and the teachings of the prior art,' and the Examiner 'is free to accept or reject the patentee's arguments' based on the Examiner's own review of the prior art. A patentee's arguments regarding the teachings of the reference are not factual representations upon which a claim of inequitable conduct can be based.").

The Federal Circuit has held that an applicant "can not be guilty of inequitable conduct if the reference was cited to the examiner." *Fiskars, Inc. v. Hunt Mfg. Co*., 221 F.3d 1318, 1327 (Fed. Cir. 2000). Alvotech attempts to distinguish *Fiskars* by alleging it did not involve any allegation that information was misrepresented to the USPTO (Dkt. No. 89 at 4), but this again relies on Alvotech's legally incorrect assertion that an expert's *opinion* regarding how a person of ordinary skill would view the prior art can constitute misconduct.

The Federal Circuit has stated that "a prosecuting attorney is free to present argument in favor of patentability without fear of committing inequitable conduct." *Rothman v. Target Corp.,* 556 F.3d 1310, 1328-29 (Fed. Cir. 2009). Alvotech attempts to distinguish *Rothman* by alleging that AbbVie crossed the line from advocacy to misrepresentation. Dkt. No. 89 at 5. But Alvotech's pleading offers nothing but its contrary interpretation of the totality of the teaching in the field. Dkt. No. 60 at ¶¶ 98, 105. Alvotech also erroneously relies on *Apotex Inc. v. UCB, Inc.,* 763 F.3d 1354, 1361 (Fed. Cir. 2014) for the proposition that inequitable conduct may arise out of

"misrepresentations to the PTO." *See* Dkt. No. 89 at 4. There, the Federal Circuit's bases for inequitable conduct included the inventor's ***fabrication*** of experiments, a declaration by an expert who was deliberately "shielded" from the critical prior art references to "perpetuate" the inventor's misconduct, and the withholding of prior art. *Apotex*, 763 F.3d at 1359. Here, in contrast, Alvotech's pleading focuses on an alleged failure to "highlight" purportedly inconsistent references that ***were provided to and considered by the USPTO and cumulative to another reference that served as the basis for a rejection***. Dkt. No. 70 at 1, 3. This is insufficient.

While Alvotech now contends that AbbVie "buried" the relevant prior art, its pleading alleged only a purported "failure to highlight" certain references. *Compare* Dkt. No. 60 at ¶¶ 98, 105, 109 *with* Dkt. No. 89 at 3-5. Moreover, Alvotech's assertion of "burying" is not plausible, for it is premised on the USPTO having overlooked four references submitted to, and considered by, the USPTO. Dkt. No. 60 at ¶¶ 99-105; Dkt. No. 71, Ex. A. Courts also routinely reject similar allegations of "burying" as the basis for a claim of inequitable conduct. *KFx Med., LLC v. Stryker Corp.*, 2019 WL 2012977, at *4-5 (S.D. Cal. 2019) (collecting cases and denying leave to amend to add inequitable conduct claim based on allegedly burying three references on a list of 250); *Seaboard Int'l v. Cameron Int'l Corp.,* 2013 WL 3936889, at *6 (E.D. Cal. July 30, 2013) (references allegedly buried within "hundreds of thousands of pages of patents and litigation papers" insufficient to state a claim for inequitable conduct).

Here, it is undisputed, and Alvotech fails to plead otherwise, that (i) AbbVie provided four of the five identified references in its *first* information disclosure statement submitted to the USPTO (Dkt. No. 71, Ex. B); (ii) *all* of the references were before the USPTO during prosecution or cumulative to other references (Dkt. No. 70 at 3); and (iii) the USPTO explicitly considered

those references (Dkt. No. 71, Ex. B). Alvotech's inequitable conduct allegation fails because Alvotech failed to plausibly plead materiality.

2. Alvotech Fails to Plausibly Plead Intent

Alvotech's conclusory allegations regarding inequitable conduct also fail to support an inference of *intent*, an independent requirement for pleading inequitable conduct. Alvotech's opposition reiterates its allegations of material misrepresentations: namely, that AbbVie's arguments during prosecution were purportedly inconsistent with AbbVie's own prior clinical studies and prior art. Dkt. No. 89 at 6-7. These conclusory allegations of misrepresentations cannot be used to infer that an individual (1) knew of the falsity of the material misrepresentation or (2) misrepresented this information with a specific intent to deceive the USPTO. *Exergen Corp. v. Wal-Mart Stores, Inc.,* 575 F.3d 1312, 1329 n.5 (Fed. Cir. 2009); *Therasense*, 649 F.3d at 1290 ("[A] district court may not infer intent solely from materiality."). Notably, Alvotech does not dispute that materiality cannot be used to establish specific intent.

Here, Alvotech's pleadings are silent with respect to any evidence of specific intent. Nor do they "plausibly suggest any 'deliberate decision to withhold a known material reference' or to make a knowingly false misrepresentation – a necessary predicate for inferring deceptive intent." *Exergen*, 575 F.3d at 1330-31.

CoStar Realty Info., Inc., v. CIVIX-DDI, LLC, 946 F. Supp. 2d 766, 777-79 (N.D. Ill. 2013) is not to the contrary. *See* Dkt. No. 89 at 7. There, the USPTO expressly *requested assistance* from the patent applicant in identifying relevant references, who purportedly misdirected the Office. *CoStar*, 946 F. Supp. 2d at 779. Alvotech fails to plead that any similar request was made here. *See* Dkt. No. 60, ¶¶ 107-109. Indeed, in contrast, AbbVie and the USPTO expressly addressed references disclosing the dosing regimens focused on by Alvotech. *Compare* Dkt. No. 71, Exs. B-G (Exs. D and F citing den Broeder 2002) *with* Dkt. No. 60 Ex. E, den Broeder 2001.

Further, courts have recognized that there is "little basis to find deceptive intent in the routine back and forth between examiner and applicant." *Rothman,* 556 F.3d at 1329. As in *Rothman,* AbbVie's attorney's remarks "show an effort to persuade that does not even approach an effort to deceive the PTO or abuse the prosecution process." *Id.* Here, Alvotech points to nothing more than attorney argument based on the expert's interpretation of the art and conclusions with which it disagrees. But the USPTO was free to "reject or accept an applicant's arguments based on the examiner's own conclusions regarding the prosecution record." *Id.* The statements relied on by Alvotech "betray[] no intent to deceive the PTO and obtain a patent with objectively false information." *Id.* The heightened pleading standard for inequitable conduct exists for a reason. *Exergen,* 575 F.3d at 1326. Alvotech's disagreement regarding the teaching of certain references falls far short of this standard.

Alvotech's allegations here boil down to a disagreement with the opinion of AbbVie's expert and analysis presented by its prosecuting attorney regarding the obviousness of a parent of the '973 patent, including what a person of ordinary skill would understand and consider based on the state of the art in April 2004. While Alvotech is free to challenge the validity of the '973 patent based on obviousness, an invalidity defense is not enough to allege fraud.

3. Alvotech's Allegations Are Directed to a Patent that Is Not in Suit

Alvotech also defies this Court's stay order by seeking to move forward on a theory of inequitable conduct with respect to the '136 patent, which is not one of the ten patents scheduled for trial in August 2022. In its opposition, Alvotech attempts to justify its behavior by arguing that the '973 patent was "infected" by inequitable conduct during the prosecution of the '136 patent. Dkt. No. 89 at 5-6. But Alvotech never actually pleads that theory—only that the '136 patent is a parent of the '973 patent without identifying any "culpable conduct" in the prosecution of the former that extended to the latter. Dkt. No. 60 at ¶¶ 98, 109. Alvotech fails to plead the required

"immediate and necessary relation" between the '973 patent and any alleged inequitable conduct that purportedly occurred during prosecution of the related '136 patent. *Cordis Corp. v. Boston Sci. Corp.*, 188 Fed. Appx. 984, 989 (Fed. Cir. 2006); *see Hoffman-La Roche, Inc. v. Promega Corp.*, 319 F. Supp. 2d 1011, 1021 (N.D. Cal. 2004) (holding that mere similarity in subject matter does not suffice). Alvotech's failure to allege the required elements for "infectious" unenforceability warrants granting AbbVie's motion.

B. Alvotech Fails to Adequately Plead Unclean Hands

1. AbbVie's Mere Assertion of Patents Is Not Misconduct

AbbVie's acquisition and assertion of its patents against infringing biosimilar applicants is not, as Alvotech contends, "egregious misconduct." It is not improper to build a patent portfolio: the "mere accumulation of patents, no matter how many, is not in and of itself illegal." *Automatic Radio Mfg. Co. v. Hazeltine Rsch.,* 339 U.S. 827, 834 (1950), *overruled in part on other grounds by Lear, Inc. v. Adkins,* 395 U.S. 653 (1969). Nor is there anything wrong with asserting the patents one obtains. *C.R. Bard, Inc. v. M3 Sys., Inc.,* 157 F.3d 1340, 1369 (Fed. Cir. 1998) ("The law recognizes a presumption that the assertion of a duly granted patent is made in good faith[.]").

Alvotech cannot transform AbbVie's acquisition and assertion of patents into an intimidation or anticompetitive scheme worthy of unclean hands. Indeed, having sought and been granted *an early trial on a limited number* of patents, Alvotech now implausibly argues that AbbVie's "patent minefield" should be held unenforceable because a party could never get to trial due to the sheer number of patents. This is nonsensical. Alvotech is litigating what it asked to litigate on an expedited schedule it requested. Having been granted this early trial, Alvotech overreaches by additionally asking that it be declared the winner, regardless of whether the patents are valid and infringed, based solely on the number of patents asserted.

Injecting patents into a litigation invites – not shields – validity attacks. As Alvotech well knows, AbbVie's patents have faced a multitude of challenges at the USPTO. *See* Dkt. No. 70 at 8 n.4. And in district court, multiple sophisticated, well-funded biosimilar companies have challenged AbbVie's patents. But Alvotech nonetheless asserts that "AbbVie has thus far ensured that none of its patents ever get scrutinized in a judicial proceeding." Dkt. No. 89 at 11. This is demonstrably false, and thus implausible for pleading purposes. Courts are not obligated to accept as true allegations in a pleading that are self-evidently false. *Word v. Cook Cty. Dep't of Corr.*, No. 95 C 96, 1995 WL 29636, at *2 (N.D. Ill. Jan. 24, 1995). Further, the license and settlement agreements entered into by other entities (where they each licensed and stipulated to the validity of the patents-in-suit) are not an indication of AbbVie's "minefield of IP" but rather speak to the strength of AbbVie's patents. *Institut Pasteur v. Focarino*, 738 F.3d 1337, 1347 (Fed. Cir. 2013) (holding that multiple license agreements provides "probative and cogent evidence" of nonobviousness); *see New W., L.P. v. City of Joliet*, 491 F.3d 717, 722 (7th Cir. 2007) (prior settlement reveals litigation not baseless). Alvotech's allegations are an attempt to circumvent AbbVie's battle-tested patents after arriving late to the adalimumab biosimilar game.

Alvotech's claims of a patent minefield also fail to satisfy the requirement that the conduct complained of must "enhance the claimant's position regarding legal rights that are important to the litigation." *Gilead Scis., Inc. v. Merck & Co., Inc.,* 888 F.3d 1231, 1240 (Fed. Cir. 2018).[2] AbbVie's likelihood of success on the ten patents-in-suit in the "first wave" is not improved in any way by the existence of other patents or how they were procured. *Id.*

[2] Alvotech conspicuously drops arguments relying on allegations of conduct between AbbVie and third parties, claiming instead to be showing a "broader pattern of misconduct." Dkt. No. 89 at 14. Alvotech also disregards entirely its allegations that the timing of AbbVie's launch of HUMIRA® Citrate-Free has any relevance in this case. Dkt. No. 70 at 10-11. It does not.

Nor have AbbVie's patents deterred Alvotech (or other pharmaceutical companies) from making the investment to develop a biosimilar product. Numerous companies have done so. AbbVie's patents also do not prevent competitors from seeking to market their biosimilar products. Unlike in Hatch-Waxman litigation, where suit by the branded drug company automatically triggers a 30-month stay of regulatory approval, *see* 21 U.S.C. § 355(c)(3)(C), under the BPCIA AbbVie's patents do *not* confer a stay of regulatory approval. In other words, unless AbbVie successfully enforces its patents in court, they play no role in stopping competition. Alvotech's attempts to avoid clear infringement liability in favor of an unsupported and sweeping unclean hands defense should be denied.

Alvotech's further arguments that AbbVie's assertion of its remaining patent portfolio under 42 U.S.C. § 262(l)(8) "was an abuse of the BPCIA process" is particularly inappropriate given that Alvotech's *own conduct* – serving its notice of commercial marketing – triggered AbbVie's assertion of the second group of patents. 42 U.S.C. § 262(l)(8)(B) ("After receiving the notice [of commercial marketing], the reference product sponsor may seek a preliminary injunction . . . with respect to any patent that is . . . included in the list provided by the reference product sponsor under paragraph (3)(A)."). AbbVie's response, which was compliant with the statute, was *anything but* an "abuse of the BPCIA process." And Alvotech's allegations that AbbVie has asserted patents that it conceded could not be infringed are blatant mischaracterizations based on selective disclosures of correspondence between the parties. AbbVie reserved its rights to assert four patents in case further information revealed that Alvotech's incomplete representations were false. *See* Dkt. No. 71, Ex. H. AbbVie then asserted those patents to preserve its rights because Alvotech failed to produce sufficient information or proffer a suitable admission to confirm non-infringement. In any event, these four patents are ***not*** among those going to trial next August.

Alvotech's allegations on *In re Humira (Adalimumab) Antitrust Litig.*, 465 F. Supp. 3d 811 (N.D. Ill. 2020) are misplaced. Dkt. No. 89 at 14. Regardless of the specific legal theories at issue in *In re Humira*, the underlying findings directly undermine Alvotech's unclean hands allegations. Indeed, the court found that AbbVie's prior BPCIA patent litigations were not objectively baseless in view of settlement terms that provided substantial value to AbbVie. *In re Humira*, 465 F. Supp. 3d at 833. The court further found that AbbVie was successful in thirteen out of eighteen, or 72.2%, prior IPR proceedings, reflecting the strength of AbbVie's patents. *Id*. at 831.

Alvotech's remaining allegations regarding the BPCIA exchange are far from the intentional, egregious misconduct required for an unclean hands defense and fail to have any direct relationship to the claims in suit. Routine discovery conduct such as that complained of by Alvotech is policed by the Federal Rules governing discovery, not frivolous claims of unclean hands. Dkt. No. 89 at 1-2; *see, e.g., Intel Corp. v. Future Link Sys., LLC*, 2017 WL 3334703, *14 (D. Del. Aug. 3, 2017); *see also Mag Instrument, Inc. v. JS Products, Inc.,* 2008 WL 5251850, *6-*7 (C.D. Cal. Dec. 17, 2008) (granting judgment on the pleadings and dismissing accused infringer's unclean hands defense, without leave to amend, where the accused infringer alleged the patentee had unclean hands from attaching inaccurate pictures of the accused products to its complaint). To this end, while Alvotech complains about AbbVie's conduct during the patent dance, it ignores its own blatant disregard for the process. For example, [redacted] *Compare* Ex. A [redacted]

[redacted] *with* Ex. B [redacted] at 2.[3] The Court should decline Alvotech's invitation for the Court to hold AbbVie to an alleged standard of conduct under the BPCIA that Alvotech is unwilling to follow.

2. There Is No Basis to Infer Misuse of Confidential Information

The Court should also reject Alvotech's attempt to weaponize the confidentiality provisions of the BPCIA. It is not plausible to conclude that AbbVie misused confidential information based solely on the similarity between issued patent claims and Alvotech's formulation because Alvotech's own disclosures prove that *the relevant information is not confidential*. *See* Dkt. No. 70 at 11. Alvotech's patent application shows that it started with AbbVie's commercial formulation, changed one ingredient to an equivalent disclosed in AbbVie's patent, and added a small amount of sodium chloride (NaCl). Alvotech then sought to claim the resulting formulation as its own. *See* Dkt. No. 1, Ex. 13 (U.S. Patent No. 9,085,619) at 28:17-22, 41:61-65; Dkt. No. 71, Ex. I (WO 2019/057631 A1). Now Alvotech alleges that AbbVie misused confidential information, solely on the basis of AbbVie having directed its own patent claims to the formula publicly disclosed in Alvotech's patent. Alvotech offers no specific pleading or allegation to support its conjecture that AbbVie's claims resulted from anything other than Alvotech publicly disclosing its derivation of a lead formulation from AbbVie's.

Alvotech claims that it "has never published that its AVT02 formulation contains sodium chloride." Dkt. No. 89 at 11. That fact (even if taken as true) is irrelevant. Alvotech *published* its patent application *in 2019* claiming an adalimumab formulation containing NaCl. *See* Dkt. No. 71, Ex. I (WO 2019/057631 A1 at Table 4, comparing Alvotech NaCl-containing formulations to

[3] Unless noted otherwise, all exhibits cited herein are attached to Ms. Oulu Wang's declaration filed in support of this motion.

AbbVie's approved 100 mg/ml HUMIRA® formulation). Indeed, its 2019 publication not only *claims* a formulation including sodium chloride, but repeatedly states that the *preferred formulation* contains sodium chloride. *Id.* And *every example* in the publication contains sodium chloride. *Id.* at 7-11. While any reasonable person reviewing Alvotech's patent application would conclude that this was their lead formulation, and the one Alvotech was most likely to pursue in its commercial product, the point is irrelevant, as AbbVie had every right to draft patent claims covering the formulation disclosed in Alvotech's patent, particularly once Alvotech announced that it had submitted an application to make a biosimilar of HUMIRA®. *See* Dkt. No. 70 at 11.

Alvotech cites *Gilead Scis., Inc. v. Merck & Co., Inc*., 2016 WL 3143943, at *11-34 (N.D. Cal. June 6, 2016) in support of its argument that AbbVie improperly used Alvotech's confidential BLA as a motivation to amend its pending claims. Dkt. No. 89 at 11-12. But this argument ignores the much more plausible alternative that, after Alvotech's public announcement in November 2020 that the FDA had accepted its ABLA for review, AbbVie identified WO 2019/057631 and sought new claims directed to Alvotech's published formulation, which was expressly derived from AbbVie's own. Dkt. No. 71, Ex. J. Unlike *Gilead*, Alvotech's far-fetched explanation for this conduct not only recklessly accuses AbbVie and its prosecuting attorney of wrongful conduct but is also the least plausible explanation. Such unsupported speculation cannot meet the threshold for an allegation of unclean hands that would unlock the right to discovery. *Bell Atl. Corp. v. Twombly,* 550 U.S. 544, 555 (2007) (holding that "[f]actual allegations must be enough to raise a right to relief above the speculative level.").

Regarding Gokarn PCT, Alvotech does not dispute that it and related references had been repeatedly asserted in IPRs of AbbVie's patents. Nor does Alvotech dispute that the USPTO was already considering a related Gokarn publication. Dkt. No. 70 at 12; Dkt No. 88 at 12-13. So

Alvotech pleads no facts that make it plausible that the 3B statement had any bearing on the prosecution.

Moreover, Alvotech ignores that the BPCIA does not classify the "arguments" in its 3(B) statement, much less the references themselves, as confidential information, and thus there is no legal basis for its assertion that such information was improperly disclosed to the USPTO. Dkt. No. 89 at 13. Consistent with this, Alvotech recently admitted that [redacted]—indicating that it agrees that its arguments about the prior art are not confidential. *See* Ex. C, [redacted]. Thus, even if Alvotech's disclosure caused AbbVie to raise the Gokarn PCT during prosecution, there would have been nothing improper about doing so because the information was not confidential. Alvotech's brazen claims that AbbVie misused its confidential information are purely speculative, implausible, and false. They should be dismissed.

3. Alvotech's Unclean Hands Allegations Based on Inequitable Conduct Fail

To the extent that Alvotech's unclean hands allegations rely on its claims of inequitable conduct, they fail for the same reasons. *Chamberlain Grp., Inc. v. Techtronic Indus. Co*., 2017 WL 1101092, at *16 (N.D. Ill. Mar. 22, 2017) ("Where an accused infringer's unclean hands defense is based on alleged acts of inequitable conduct, it rises and falls based on those allegations."). There is no basis for finding that AbbVie's alleged litigation conduct is sufficient for a claim of unclean hands and Alvotech's claims to that effect should be dismissed and stricken.

C. Alvotech's Allegations of Patent Misuse Are Duplicative of Its Inequitable Conduct and Unclean Hands Allegations and Fail for the Same Reasons

Alvotech's allegations of patent misuse fail for the same reasons as its allegations of inequitable conduct and unclean hands based on the size of AbbVie's patent portfolio. Simply repeating the unsupported assertion that AbbVie used its patent portfolio to create an

"overpowering threat of disastrous litigation" does not make Alvotech's allegation true or plausible. *Automatic Radio,* 339 U.S. at 834; *Twombly,* 550 U.S. at 555. Alvotech's opposition fails to point to any facts supporting bad faith, improper purpose, or objective baselessness in AbbVie's decision to assert its patents, which Alvotech concedes are required to establish patent misuse. *See* Dkt. No. 89 at 15 (citing *Glaverbel Societe Anonyme v. Northlake Mktg & Supply Inc*., 45 F.3d 1550, 1558 (Fed. Cir. 1995)). On the contrary, AbbVie's patent infringement claims are objectively reasonable and were filed in good faith, as demonstrated by this Court's denial of Alvotech's Motion to Dismiss for, in part, failure to state a claim. Dkt. No. 51. Further, Alvotech ignores the law's recognition of "a presumption that the assertion of a duly granted patent is made in good faith." *C.R. Bard, Inc.*, 157 F.3d at 1369. Alvotech fails to plead any facts to overcome that presumption here.

To the extent that Alvotech's patent misuse allegations rely on its claims of unclean hands and inequitable conduct, they fail for the same reasons. *Chamberlain*, 2017 WL 1101092, at *15 (where an "inequitable conduct counterclaim is insufficiently pleaded, so too is the patent misuse claim to the extent that it relies on inequitable conduct.") (internal quotation marks omitted). This is particularly true given that Alvotech spent only three cursory paragraphs on its patent misuse allegations. *See* Dkt. No. 60 at ¶¶ 63-65.

III. CONCLUSION

For the foregoing reasons, this Court should dismiss and strike Alvotech's counterclaims and affirmative defenses of inequitable conduct, unclean hands, and patent misuse.

Respectfully submitted,

Dated: November 19, 2021

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