

**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

**PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR 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

Knowing that it faces long odds in proving AbbVie's patents invalid or not infringed, Alvotech seeks to shift the focus of this litigation to baseless allegations of improper patent thickets, anticompetitive settlements, and confidentiality breaches. But even if the alleged facts were true, they would not support Alvotech's inequitable conduct, unclean hands, or patent misuse claims and defenses. As such, they should be dismissed under Rule 12(b)(6), so discovery and trial can proceed on the core issues in the case: infringement and validity of AbbVie's patents.

Alvotech's inequitable conduct allegations do not pertain to any of the ten patents in the August 2022 trial. Instead, Alvotech alleges that AbbVie failed to "highlight" certain prior art during prosecution of a different (parent) patent. But there is no such thing as a "no highlighting" defense; where, as here, the art at issue (or cumulative art) was before the U.S. Patent and Trademark Office ("USPTO"), there can be no inequitable conduct as a matter of law. Further, Alvotech fails to plead facts from which the Court could find the specific intent to deceive the USPTO required to establish inequitable conduct. Instead, Alvotech insists that the prior art was so material that the Court should infer deceptive intent. But the Federal Circuit has expressly rejected the argument that even high levels of materiality can establish intent.

Alvotech fares no better on unclean hands. Even accepting Alvotech's allegations as true, AbbVie's actions in asserting its patents, settling cases against other biosimilar companies, and waiting to launch a new version of its product fail to establish any wrongdoing, much less the "particularly egregious misconduct" required for unclean hands. Moreover, AbbVie's patents have already withstood multiple validity challenges—indeed, one of the patents at issue here has withstood four separate challenges—and ten other sophisticated pharmaceutical companies have settled with AbbVie, acknowledging the validity of its patents and agreeing to pay a royalty to market their biosimilar products before the patents expire. Alvotech's unclean hands allegations

relating to the BPCIA patent dance similarly fail because they do not establish non-compliance with the statute or state a claim the court can redress. And Alvotech's assertion that AbbVie misused Alvotech's confidential information during patent prosecution is baseless and reckless, since *Alvotech itself* published relevant materials in press releases and patent applications. It is improper for Alvotech to accuse AbbVie of wrongdoing for using information that Alvotech itself placed in the public domain.

Alvotech's patent misuse counterclaim and defense largely recycle its faulty inequitable conduct and unclean hands allegations, and thus fail for the same reasons. All Alvotech adds are factually unsupported allegations that AbbVie uses its patent portfolio to intimidate companies into delaying biosimilar launch. But this Court and others have rejected the argument that obtaining and asserting patents, no matter how many, constitutes misuse.

Because Alvotech's inequitable conduct, unclean hands, and patent misuse counterclaims and defenses do not satisfy the relevant pleading standards, they should be dismissed and struck.

## **II. LEGAL STANDARDS FOR MOTION TO DISMISS OR STRIKE**

A counterclaim "must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotation omitted). Courts may accept factual allegations as true, but legal conclusions are not entitled to the same presumption. *See Smoke Shop, LLC v. United States*, 761 F.3d 779, 785 (7th Cir. 2014). Indeed, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements," are not taken as true. *Iqbal*, 556 U.S. at 678 (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). The majority view in this district is to apply the *Twombly* and *Iqbal* pleading standard to affirmative defenses. *Maui Jim, Inc. v. SmartBuy Guru Enters.*, 386 F. Supp. 3d 926, 938 (N.D. Ill. 2019), *recons. denied*, 459 F. Supp. 3d 1058 (N.D. Ill. 2020).



A claim or defense based on allegations of fraud, such as inequitable conduct, or any portions of such a claim, must meet a higher standard and be pleaded with particularity under Rule 9(b). *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326-27 (Fed. Cir. 2009) (“Rule 9(b) requires that in all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity.”). Mere information and belief is insufficient, unless the allegations set forth the specific facts on which the belief is based. *Id.* at 1330.

### III. ARGUMENT

#### A. Alvotech Fails to Adequately Plead Inequitable Conduct

Count IX of Alvotech’s Counterclaims and Alvotech’s Tenth Affirmative Defense fail to plead sufficient facts from which the Court could reasonably infer that any attorney or expert (1) affirmatively misrepresented a material fact (2) with the specific intent to deceive the USPTO. Alvotech alleges a failure to “highlight” certain references during prosecution of a parent patent (the ’136 patent) that is currently stayed. Dkt. No. 60 at ¶¶96-109. These allegations are legally insufficient to establish materiality or intent to deceive, particularly as *all the references* were before the USPTO during prosecution or cumulative of other references.<sup>1</sup>

##### 1. Legal Standard for Inequitable Conduct

Establishing inequitable conduct requires clear and convincing evidence that: (1) “the applicant 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) (*en banc*). Under Rule 9(b), inequitable conduct claims must plead with particularity the

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<sup>1</sup> Alvotech does not appear to dispute the cumulative nature of the references, citing all five as examples where “AbbVie’s predecessors sponsored and published results of clinical trials of adalimumab in rheumatoid arthritis patients (called “DE001/003”) that included administration of up to 10 mg/kg adalimumab (approximately 800 mg for a typical 80 kg patient) every other week for up to 2 years.” Dkt. No. 60 at ¶99.

“specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO.” *Exergen*, 575 F.3d at 1327. “Specific intent” to deceive requires that a specific individual (1) knew of the falsity of the material misrepresentation and (2) misrepresented this information with a specific intent to deceive the USPTO. *Id.* at 1328-29. Specific intent to deceive must also be the single most reasonable inference able to be drawn from the evidence. *Therasense*, 649 F.3d at 1290. Inequitable conduct counterclaims and affirmative defenses rise or fall together. *Medline Indus., Inc. v. C.R. Bard, Inc.*, No. 16-CV-3529, 2016 WL 5871501, at \*3 (N.D. Ill. Oct. 7, 2016).

## 2. Alvotech Fails to Plausibly Plead Materiality

Alvotech incorrectly alleges that prosecuting attorneys and an expert misrepresented the “totality of the safety and efficacy data for adalimumab” in explaining concerns raised by the FDA and others about higher doses by failing to “highlight” portions of certain allegedly contrary references during prosecution of a *parent* application to the ’973 patent.<sup>2</sup> Dkt. No. 60 at ¶¶96-109. Even if true, Alvotech’s “failure to highlight” theory fails as a matter of law. *Fiskars, Inc. v. Hunt Mfg. Co.*, 221 F.3d 1318, 1327 (Fed. Cir. 2000) (“An applicant can not be guilty of inequitable conduct if the reference was cited to the examiner, whether or not it was a ground of rejection by the examiner.”); *Avery Dennison Corp. v. Cont’l Datalabel, Inc.*, 2010 WL 4932666, at \*2 (N.D. Ill. 2010) (dismissing claim of inequitable conduct because “[i]t is well settled that an applicant cannot be guilty of inequitable conduct if the reference was cited to the examiner in a previous

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<sup>2</sup> Because the purported misconduct did not occur during prosecution of any of the ten patents currently at issue, Alvotech invokes the rarely-used doctrine of infectious inequitable conduct, stating that the alleged misconduct in one patent “tainted” multiple other patents. Dkt. No. 60 at ¶109. Alvotech fails to plead the necessary “culpable conduct” to support such relief. *Pharmacia Corp. v. Par Pharm., Inc.* 417 F.3d 1369, 1375 (Fed. Cir. 2005) (“[T]his court’s inequitable conduct cases do not extend inequitable conduct in one patent to another patent that was not acquired through culpable conduct.”).

filing.”). Further, attorney argument about references of record cannot, as a matter of law, constitute inequitable conduct. *Rothman v. Target Corp.*, 556 F.3d 1310, 1328-29 (Fed. Cir. 2009) (“[A] prosecuting attorney is free to present argument in favor of patentability without fear of committing inequitable conduct.”). Thus, if the reference was before the USPTO, as here, there can be no inequitable conduct for a so-called “failure to highlight.” *See Ex. A.*<sup>3</sup>

Examiners are presumed to do their jobs, and Alvotech’s suggestion that the USPTO failed to consider all cited references—those identifying safety concerns with higher doses and those that used higher doses—is contrary to law and the facts. *Medline Indus., Inc. v. C.R. Bard, Inc.*, 2018 WL 4333629, at \*4-5 (N.D. Ill. 2018). The prosecution history of the parent of the ’973 patent shows that the USPTO allowed the claims after considering *all* relevant art, including references that discuss the higher dosing regimens relied on by Alvotech. Ex. B; Ex. C at 9-10 (noting dosing regimens of 5-10 mg/kg); Exs. D-G. Again, Alvotech’s pleading fails as a matter of law.

### **3. Alvotech Fails to Plausibly Plead Intent to Deceive**

Alvotech fails to plead facts sufficient to infer that any AbbVie attorney or expert possessed specific intent to deceive the USPTO, much less to make it “the single most reasonable inference able to be drawn from the evidence.” *Therasense*, 649 F.3d at 1290 (internal quotation omitted). Lacking any evidence of intent, Alvotech argues it can be inferred from the alleged materiality of references that AbbVie purportedly did not “highlight.” Dkt. No. 60 at ¶¶96-109. But the Federal Circuit has consistently held that, even at the pleading stage, the materiality of a reference alone

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<sup>3</sup> Unless noted otherwise, all exhibits cited herein are attached to Ms. Oulu Wang’s declaration filed in support of this motion. 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. Further, the prosecution history is a public record subject to judicial notice. 37 C.F.R. § 1.11 (2012); *see* Fed. R. Evid. 201. It is proper for the Court to consider its full history, including the portions that Alvotech omitted, in considering whether Alvotech met its pleading burden. *See, e.g., Venture Assocs. Corp. v. Zenith Data Sys. Corp.*, 987 F.2d 429, 431-32 (7th Cir. 1993); *Mon Aimee Chocolat, Inc. v. Tushiya LLC d/b/a Mon Ame Chocolat*, 2015 WL 6407758 at \*1 (N.D. Ill. Oct. 22, 2015).

cannot suffice to prove deceptive intent. *Exergen*, 575 F.3d at 1331; see also *Optium Corp. v. Emcore Corp.*, 603 F.3d 1313, 1321 (Fed. Cir. 2010).

Because no amount of materiality can establish specific intent, courts routinely dismiss such insufficiently pleaded allegations. See, e.g., *ESCO Corp. v. Cashman Equip. Co.*, 158 F. Supp. 3d 1051, 1062 (D. Nev. Jan. 26, 2016) (“[I]ntent to deceive cannot be inferred solely based upon the failure to disclose known information, even if it is highly material.”) (quoting *iLife Techs. Inc. v. AliphCom*, No. 14-cv-03345-WHO, 2015 WL 890347, at \*7 (N.D. Cal. Feb. 19, 2015)); see also *Accordant Energy, LLC v. Vexor Tech., Inc.*, No. 1:17-cv-411, 2017 WL 4169635, at \*4 (N.D. Ohio Sept. 19, 2017) (dismissing inequitable conduct claims where allegations “simply assert disagreement with the USPTO’s conclusion”). This failure further warrants dismissal.

## **B. Alvotech Fails to Adequately Plead Unclean Hands**

Count I of Alvotech’s Counterclaims and Alvotech’s Seventh Affirmative Defense allege unclean hands based on a jumble of purported misconduct: the threat of overwhelming litigation; an allegedly inflated patent portfolio; supposed improper tactics in pre-suit exchanges, litigations and settlement agreements; purportedly delaying launch of AbbVie’s 100 mg/mL formulation to maintain a monopoly beyond settlement dates; and alleged misuse of confidential information. Dkt. No. 60 at ¶¶20-52, 57-62. In addition to being factually baseless, these allegations fail to adequately plead unclean hands and should be dismissed. *C.R. Bard, Inc. v. Med. Components, Inc.*, 2019 WL 1746309, \*7 (D. Utah 2019) (dismissing unclean hands defense because the pleaded facts did not rise to the level of an “unconscionable act”).

### **1. Legal Standard for Unclean Hands**

Unclean hands is reserved for “particularly egregious misconduct, including perjury, the manufacture of false evidence, and the suppression of evidence,” performed with “deliberately planned and carefully executed scheme[s] to defraud” both the USPTO and the courts. *Therasense*,

649 F.3d at 1287 (alteration in original) (internal citations omitted). The bad conduct must involve “fraud, unconscionability or bad faith toward the party proceeded against,” and must “pertain to the subject matter involved and affect the equitable relations between the litigants.” *Int’l Union, Allied Indus. Workers of Am., v. Local Union No. 589, Allied Indus. Workers of Am.*, 693 F.2d 666, 672 (7th Cir. 1982); *Erfindergemeinschaft UroPep GbR v. Eli Lilly & Co.*, 2017 WL 275465, at \*7-8 (E.D. Tex. 2017) (denying leave to amend to add defense of unclean hands); *see also Maui Jim*, 386 F. Supp. 3d at 956-57. The misconduct must also have immediate and necessary relation to the equity sought. *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 245 (1933).

Unclean hands allegations based on fraud must satisfy the heightened pleading requirements of Rule 9(b). *Manley v. Boat/U.S. Inc.*, No. 13-CV-5551, 2016 WL 1213731, at \*4 (N.D. Ill. Mar. 29, 2016).

## **2. AbbVie’s Assertion of Its Patents Is Not Misconduct**

Alvotech’s allegation that AbbVie has sought to extend its “Humira monopoly” by “artificially inflating the size of its patent portfolio” fails to adequately plead unclean hands. Dkt. No. 60 at ¶¶42-52, 59. Obtaining patents is not “egregious misconduct”; indeed, it is not improper at all. 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). And, just as there is nothing wrong with obtaining patents, there is nothing wrong with asserting them. *See, e.g., 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 alleges that AbbVie’s patent portfolio “motivates competitors to settle quickly” because they are intimidated by the number of patents rather than by their strength. Dkt. No. 60 at ¶48. But AbbVie’s settlements are objectively reasonable. *In re Humira (Adalimumab) Antitrust*

*Litig.*, 465 F. Supp. 3d 811, 833-34 (N.D. Ill. 2020) (lawsuits that settle on terms requiring concessions from both sides and provide substantial value to the plaintiff foreclose a finding of objective baselessness) (citing *New W., L.P. v. City of Joliet*, 491 F.3d 717, 722 (7th Cir. 2007)). Regardless, litigation or settlements with *other parties* cannot support Alvotech's unclean hands arguments as a matter of law. *See, e.g., Aptix Corp. v. Quickturn Design Sys., Inc.*, 269 F.3d 1369, 1376 (Fed. Cir. 2001) (“[A] finding of unclean hands generally does not prejudice the offending party in subsequent cases, but only provides a bar to relief in the case at hand.”); *Keystone*, 290 U.S. at 245 (unclean hands requires that the misconduct must “in some measure affect the equitable relations between the parties in respect of something brought before the court for adjudication.”).

Alvotech's allegations are further belied by the fact that many other sophisticated and well-funded biosimilar companies (including household names like Amgen, Sandoz, and Boehringer Ingelheim) have challenged AbbVie's patents at the USPTO and in district court. But the USPTO denied thirteen separate petitions for review, determining in each instance there was no substantial question of patentability.<sup>4</sup> Each of the challengers ultimately recognized the strength of AbbVie's patents, stipulating to their validity and agreeing to pay royalties when it comes to market. *See generally In re Humira*, 465 F. Supp. 3d 811. And the Court's two-phase approach to the

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<sup>4</sup> *Amgen Inc. v. AbbVie Biotechnology Ltd*, No. IPR2015-01514 (Jan. 14, 2016); *Amgen Inc. v. AbbVie Biotechnology Ltd*, No. IPR2015-01517 (Jan. 14, 2016); *Coherus BioSciences, Inc. v. AbbVie Biotechnology Ltd*, No. IPR2016-01018 (Nov. 7, 2016); *Coherus BioSciences, Inc. v. AbbVie Biotechnology Ltd*, No. IPR2017-00822, 2017 WL 3974063 (Sept. 7, 2017); *Coherus BioSciences, Inc. v. AbbVie Biotechnology Ltd*, No. IPR2017-00823, 2017 WL 3976650 (Sept. 7, 2017); *Coherus BioSciences, Inc. v. AbbVie Biotechnology Ltd*, No. IPR2017-01008, 2017 WL 3974066 (Sept. 7, 2017); *Coherus BioSciences, Inc. v. AbbVie Biotechnology Ltd*, No. IPR2017-01009, 2017 WL 3976652 (Sept. 7, 2017); *Sandoz Inc. v. AbbVie Biotechnology Ltd*, No. IPR2017-01823, 2018 WL 842859 (Feb. 9, 2018); *Sandoz Inc. v. AbbVie Biotechnology Ltd*, No. IPR2017-01824, 2018 WL 842865 (Feb. 9, 2018); *Sandoz Inc. v. AbbVie Biotechnology Ltd et al*, No. IPR2017-01987, 2018 WL 1230583 (Mar. 9, 2018); *Sandoz Inc. v. AbbVie Biotechnology Ltd et al*, No. IPR2017-1988, 2018 WL 1250437 (Mar. 9, 2018); *Sandoz Inc. v. AbbVie Biotechnology Ltd et al*, No. IPR2018-00002, 2018 WL 2087129 (May 3, 2018); *Sandoz Inc. v. AbbVie Biotechnology Ltd et al*, No. IPR2018-00156, 2018 WL 2735468 (June 5, 2018).

management of this case belies Alvotech’s central premise that the number of patents in AbbVie’s portfolio renders it impossible to reach a litigated decision.

What is more, the mere existence of AbbVie’s patents, in and of itself, is not keeping Alvotech—or anyone else—off the market. Unlike in the ANDA context, where an automatic stay applies, AbbVie’s patents cannot prevent biosimilar competition unless AbbVie successfully enforces them in court, as permitted by the statute. 35 U.S.C. § 271(d). As this Court found in dismissing an antitrust complaint that advanced similar arguments regarding AbbVie’s patent portfolio and settlements, “the vast majority of the alleged scheme is immunized from antitrust scrutiny, and what’s left are a few sharp elbows thrown at sophisticated competitors participating in regulated patent and biologic-drug regimes.” *In re Humira*, 465 F. Supp. 3d at 834.

**3. Alvotech Fails to Plead Facts Showing that AbbVie Participated in the “Patent Dance” in Bad Faith**

Alvotech’s allegations of “bad faith” during the BPCIA’s pre-litigation “patent dance” exchanges are legally insufficient to state a claim for unclean hands. First, Alvotech alleges that AbbVie was required—and failed—to provide a list of patents it was prepared to license. Dkt. No. 60 at ¶¶22, 27. But the statute imposes no such requirement. It requires only “an identification of the patents on [the patent owner’s 3A] list that the reference product sponsor would be prepared to license to the subsection (k) applicant.” 42 U.S.C. § 262(l)(3)(A). Because AbbVie did not wish to license any patents to Alvotech at that time, it did not identify any.

Second, Alvotech alleges that AbbVie failed to satisfy its obligation under § 262(l)(3)(C) by ignoring Alvotech’s contentions for certain patent claims and keeping four patents in the patent dance despite allegedly conceding their noninfringement. Dkt. No. 60 at ¶¶24-25. Even if this were true, Alvotech’s allegations are far from “egregious misconduct” that shocks the conscience or could otherwise form an unclean hands counterclaim or defense. *See Therasense*, 649 F.3d at 1287.

Further, in contentions spanning over 2,000 pages, AbbVie addressed *all claims it intended to assert*, reserving its rights for additional claims in the event Alvotech changed its proposed biosimilar product. For the four patents called out by Alvotech, AbbVie only agreed that these patents would not be infringed if Alvotech confirmed certain facts, which it has not done. Ex. H.

Third, Alvotech alleges that AbbVie refused to reduce the number of patents to be litigated, which was “contrary to the purpose of the statute.” Dkt. No. 60 at ¶27. But the BPCIA does *not* require a patent owner to arbitrarily limit the number of asserted patents. It gives *Alvotech*, as the biosimilar applicant, sole discretion to pick the number of patents in the first patent suit, and Alvotech selected four patents. *Id.*; see 42 U.S.C. § 262(l)(5)-(9). Notably, Alvotech also makes the contradictory assertion that AbbVie committed misconduct by indicating that, if it became necessary to seek a preliminary injunction, it would avoid unduly burdening the Court by selecting a subset of patents for that purpose. Dkt. No. 60 at ¶41. In other words, AbbVie is being scolded for *narrowing* the number of injunction patents and *streamlining* the process to assist the Court in resolving this litigation. That’s the antithesis of conduct that could constitute “unclean hands.”

#### **4. AbbVie’s Prior Settlements and Product Launches Cannot Establish Unclean Hands**

Alvotech improperly attempts to rely on alleged misconduct toward *other* parties, through litigation, settlements, or otherwise. Dkt. No. 60 at ¶¶48-52. But alleged actions directed at *other* parties cannot support its unclean hands arguments. *Keystone*, 290 U.S. at 245 (explaining that a finding of unclean hands requires that the misconduct must “in some measure affect the equitable relations between the parties in respect of something brought before the court for adjudication.”).

Similarly, Alvotech’s unsupported allegation that AbbVie “waited to launch the 100 mg/mL product” to “extend its monopoly” is insufficient to plead unclean hands. Dkt. No. 60 at ¶¶51-52. Even if true, the timing of a *product launch* does not relate to procuring or asserting



any of the patents Alvotech alleges are unenforceable. *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1384 (Fed. Cir. 2006) (affirming the district court’s exclusion of alleged unclean hands evidence unrelated to infringement or validity of the patent-in-suit). Further, AbbVie did not withdraw its original product. Regardless, the timing of a product launch having nothing to do with Alvotech cannot constitute “particularly egregious misconduct” that affects “the equitable relations between” AbbVie and Alvotech. *Therasense*, 649 F.3d at 1287; *Int’l Union, Allied Indus. Workers of Am.*, 693 F.2d at 672.

#### **5. There Is No Basis to Infer Misuse of Confidential Information**

Alvotech’s misuse argument is premised on the baseless and reckless allegation that AbbVie’s lawyers misused confidential information by tailoring patent claims to information contained in Alvotech’s confidential BPCIA materials. Dkt. No. 60 at ¶¶28-35. But those claims specifically correspond to information that Alvotech published for all the world to see, *before* any exchange in the patent dance. Alvotech’s pleading simply ignores the alternative explanation that AbbVie’s claims are drawn to publicly disclosed Alvotech information. Because the facts give rise to an alternative explanation, Alvotech’s claims are not plausible and should be dismissed. *Smoke Shop*, 761 F.3d at 785.

Alvotech first alleges that new claims in AbbVie’s ’201 application, directed to adalimumab formulations, were narrower than claims previously obtained and targeted its biosimilar product. Dkt. 60 at ¶¶31-32. Yet Alvotech had already published details about its formulation development in multiple press releases as well as a patent publication. Dkt. No. 60 at 15-17, 26, ¶15 (admitting quoted language from Dkt. No. 1 ¶¶34-36 and Exs. 3 (July 2018), 5 (Nov. 2020), and 6 (May 2020) thereto); Ex. I (published Mar. 28, 2019). There is nothing improper about using *publicly available* information to draft patent claims covering a competitor’s product. *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988).

Second, Alvotech alleges that AbbVie used its confidential information to amend the claims of the '792 patent to state that there was “no detectable level” of fluorescent activity. Dkt. No. 60 at ¶35. Although Alvotech acknowledges that the same limitation appears in an earlier-issued (and thus public) related patent, it argues that, unlike the '792 patent, that earlier patent was limited to 50 mg/ml adalimumab compositions. *Id.* Again, however, this does not suggest misuse of confidential information: Alvotech had repeatedly and *publicly* trumpeted its intention to copy AbbVie’s 100 mg/ml product. Dkt. No. 60 at 15-17, 26, ¶15 (admitting quoted language from Dkt. No. 1 ¶¶34-36 and Exs. 3 (July 2018), 5 (Nov. 2020), and 6 (May 2020) thereto). The Court should dismiss Alvotech’s brazen accusation of misuse of allegedly confidential information that Alvotech had already publicly disclosed. Such unfounded and reckless attacks on the integrity of the members of this Court’s bar should not be tolerated.

Alvotech also argues that AbbVie “pre-emptively” addressed the Gokarn PCT reference during prosecution of the '201 formulation application, purportedly because Alvotech had relied on it in its confidential statements. Dkt. No. 60 at ¶¶33-34. But even if AbbVie had learned of Gokarn PCT from Alvotech, published references relied on as prior art are *not* protected information under the BPCIA. *See* 42 U.S.C. 262 § (1)(2)(A) (protecting the aBLA and related technical information, not published references). Moreover, Gokarn PCT was old news. For example, Gokarn PCT had already been *unsuccessfully* asserted in 2017 as the primary reference by another biosimilar competitor in one of four IPRs challenging the related '619 patent. Dkt. No. 60 at 4; *see Coherus BioSciences, Inc. v. AbbVie Biotechnology Ltd.*, No. IPR2017-00822, 2017 WL 3974063, at \*1 (P.T.A.B. Sept. 7, 2017) (denying institution). Further, the USPTO in the '201 application was already considering a related Gokarn patent publication. Ex. J. So even taking

Alvotech’s allegations as true, they cannot possibly constitute the type of “particularly egregious misconduct” needed to plead unclean hands.

**6. Alvotech’s Unclean Hands Allegations Based on Inequitable Conduct Fail**

As discussed in Section III.A, Alvotech’s inequitable conduct arguments fail because it has not pleaded facts sufficient to prove materiality or specific intent to deceive. Alvotech’s unclean hands allegations based on the same conduct thus fail for the same reasons. Dkt. No. 60 at ¶¶61; *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.”).

In sum, Alvotech’s unclean hands claims and defenses should be dismissed.<sup>5</sup>

**C. Alvotech Fails to Adequately Plead Patent Misuse**

The patent misuse allegations in Count II of Alvotech’s Counterclaims and Alvotech’s Eleventh Affirmative Defense largely recycle Alvotech’s unclean hands allegations, peppered with allegations related to AbbVie’s litigations and settlement agreements with *other parties*. Dkt. No. 60 at ¶¶63-65. But “[t]here is no such thing as misuse in the air. The misuse must be of the patent in suit...” *Princo Corp. v. ITC*, 616 F.3d 1318, 1329 (Fed. Cir. 2010) (internal quotation omitted).

**1. Legal Standard for Patent Misuse**

A patent misuse defense premised on patent enforcement must allege facts justifying a reasonable inference that the suit (1) was brought with bad faith and improper purpose and (2)

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<sup>5</sup> In a prior case, another court denied without prejudice AbbVie’s motion to strike Boehringer’s unclean hands defense. As explained in a discovery order, Boehringer’s claims focused on the number of AbbVie patents and the purported development of a “patent thicket.” *AbbVie Inc. v. Boehringer Ingelheim Int’l GmbH*, Civil No. 17-cv-01065-MSG-RL, 2018 WL 2604825, at \*1 (D. Del. June 4, 2018). But this Court has since rejected analogous allegations, holding that “it is not plausible that AbbVie’s nonimmunized conduct intimidated the other defendants into delaying the launch of their biosimilars.” *In re Humira*, 465 F. Supp. 3d at 835.

impermissibly broadened the scope of the patent grant with anticompetitive effect. *Chamberlain*, 2017 WL 1101092 at \*15 (citing *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc.*, 45 F.3d 1550, 1558 (Fed. Cir. 1995)). Bad faith exists only if the lawsuit is “objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits.” *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993). A purpose is improper only “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 the outcome.” *Glaverbel*, 45 F.3d at 1558 (affirming district court determination of no patent misuse).

## **2. Alvotech’s Unclean Hands Allegations Are Insufficient to Support Patent Misuse**

Alvotech’s patent misuse counterclaim incorporates by reference its unclean hands allegations and adds no distinct factual allegations. Dkt. No. 60 at ¶¶63-65. Alvotech’s unsupported allegations, which do not show any broadening of the scope of AbbVie’s patents or anticompetitive effect, fail to plead misuse for the same reasons discussed above as to unclean hands. *See supra* Section III.B; Dkt. No. 60 at ¶¶63-65. Similarly, to the extent Alvotech incorporates its unsupported inequitable conduct allegations, they cannot establish misuse because they fail to plead facts sufficient to prove materiality or specific intent to deceive the USPTO. *See* Section III.A; Dkt. No. 60 at ¶¶61, 63; *Chamberlain*, 2017 WL 1101092, at \*15 (finding that 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). Alvotech’s counterclaim and affirmative defense of patent misuse thus should be dismissed.

## **3. There Is No Basis to Infer Bad Faith or Improper Purpose in AbbVie Bringing This or Any Other BPCIA Suit**

Alvotech’s baseless allegations cannot transform AbbVie’s acquisition and assertion of patents into misuse. Alvotech concedes that “mere accumulation of patents, no matter how many,

is not in and of itself illegal.” *Automatic Radio*, 339 U.S. at 834. Alvotech crop-quotes *Automatic Radio* (Dkt. No. 60 at ¶64) but omits the Supreme Court’s conclusion that the record did not support the “incendiary, yet vague” allegations regarding the purported “overpowering threat of disastrous litigation.” This Court also squarely rejected this argument for these patents. *See In re Humira*, 465 F. Supp. 3d at 835 (“[I]t is *not plausible* that AbbVie’s nonimmunized conduct *intimidated the other defendants* into delaying the launch of their biosimilars (or otherwise caused any antitrust injury).”) (emphases added).

There is nothing improper with AbbVie asserting patents that are infringed by Alvotech’s AVT02. Because Alvotech has not pleaded facts to establish, for example, that AbbVie brought an objectively baseless lawsuit involving patent infringement claims “no reasonable person could believe,” there is no basis for finding that AbbVie’s alleged litigation conduct is amenable to a patent misuse defense. *Chamberlain*, 2017 WL 1101092 at \*16; *Nalco Co. v. Turner Designs, Inc.*, 2014 WL 645365 at \*12-13 (N.D. Cal. 2014).

#### **IV. CONCLUSION**

This Court should strike Alvotech’s counterclaims and affirmative defenses of inequitable conduct, unclean hands, and patent misuse.

Respectfully submitted,

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