

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

ABBVIE INC. and ABBVIE
BIOTECHNOLOGY LTD,

Plaintiffs,

v.

ALVOTECH HF.

Defendant.

Case No. 1:21-cv-02258

Case No. 1:21-cv-02899

Hon. John Z. Lee

Magistrate Judge M. David Weisman

**PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR MOTION TO STRIKE
DEFENDANT'S FINAL INVALIDITY AND UNENFORCEABILITY CONTENTIONS**

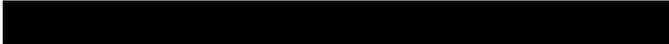


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Pursuant to Local Patent Rules 2.3 and 3.1, AbbVie respectfully moves this Court to strike Alvotech’s improper Final Contentions. AbbVie further requests that the Court reset the deadline for AbbVie’s responsive contentions for three weeks after Alvotech serves compliant contentions, the interval provided in the Scheduling and Discovery Order. Given the accelerated schedule and deadlines, AbbVie concurrently moves to expedite briefing and consideration of this motion.

I. INTRODUCTION

For years, Alvotech has studied AbbVie’s patents, intent on paving the way for its HUMIRA[®] biosimilar. In November 2020, AbbVie and Alvotech began the “patent dance”—a statutory exchange of infringement, invalidity, and unenforceability positions. For the patents scheduled for trial in August 2022, Alvotech served almost 750 pages of contentions and cited over 150 references. Alvotech leveraged that early exchange to secure an expedited case schedule. As Alvotech told the Court, a super-accelerated schedule was feasible because “[AbbVie] had our contentions on invalidity for seven months.” *See* Aug. 12, 2021 Hearing Tr. at 45:10-11.

AbbVie prepared its case in reliance on those patent dance disclosures and Alvotech’s (highly similar) September 2021 Initial Contentions and the unenforceability claims and defenses pleaded in Alvotech’s two answers. These contentions shaped the discovery AbbVie took, AbbVie’s selection of 50—and then 20—claims to narrow the scope of the dispute (per the Local Patent Rules), and AbbVie’s overall litigation strategy, including the claim terms it proposed for construction, its work with experts, and its trial preparation.

On February 11, 2022, Alvotech served Final Contentions that would drastically overhaul and expand its invalidity and unenforceability case. The breadth of Alvotech’s new arguments is astonishing: **50** new references, **40** new invalidity theories, and several new inequitable conduct and misuse charges—all this after claim construction briefing and a hearing, AbbVie’s two motions to dismiss, AbbVie’s final narrowing of asserted claims, on the eve of the close of fact



discovery, and just weeks before opening expert reports.

Unless Alvotech’s improper and untimely disclosures are stricken, AbbVie will be severely prejudiced. AbbVie requests that the Court strike three categories of Alvotech’s contentions:

- Alvotech cites **132 references** in its Final Contentions, more than **five times** the number permitted by Local Patent Rule 3.1(b), **50** of which had **never been disclosed before**. “Only by order of the Court upon a showing of good cause and absence of unfair prejudice to opposing parties” can Alvotech surpass the 25-reference limit. *Id.* Alvotech sought no such relief from the Court. It simply disregarded the rule. Alvotech should be required to pick 25 references, just as AbbVie was required to pick 20 claims.
- Alvotech asserts 24 new invalidity grounds relying on 23 new references for three asserted patents: U.S. Patent Nos. 6,805,686 (the “’686 Patent”), 9,085,619 (the “’619 Patent”), and 11,167,030 (the “’030 Patent”). These references have been publicly available for years, so Alvotech has no justification for this last-minute gamesmanship. These theories should be stricken and the references should be excluded from the 25 Alvotech ultimately selects.²
- Alvotech asserts new inequitable conduct allegations against U.S. Patent Nos. 9,187,559 (the “’559 Patent”) and 9,512,216 (the “’216 Patent”) and numerous “misuse” allegations—none of which are in its pleadings. Alvotech’s last-minute theories are an impermissible end run around the heightened pleading burden. They should be stricken.

AbbVie played by the rules, significantly **narrowing** the case by selecting just 20 patent claims. In contrast, Alvotech’s Final Contentions significantly **expand** the case with new prior art, invalidity theories, and inequitable conduct assertions. This violates Alvotech’s representations to the Court and the letter and spirit of the Local Rules. AbbVie requests that Alvotech be required to abide by the Local Patent Rules’ 25-reference limit, Alvotech’s new theories be stricken, AbbVie be allowed to serve its responsive contentions three weeks after Alvotech serves proper contentions, and consideration of this motion be expedited in light of the upcoming deadlines.

II. FACTUAL BACKGROUND

Alvotech is a “fully integrated specialty pharmaceutical company focused exclusively

² Although Alvotech raises new references and invalidity theories for other patents, AbbVie limits its motion to Alvotech’s complete overhaul of invalidity theories for the ’686, ’619, and ’030 Patents, as those are the most egregious and prejudicial.

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on development and manufacturing of high-quality biosimilar medicines.” See Alvotech, *About Us*, <https://www.alvotech.com/about-us>, (last accessed February 17, 2022). Alvotech’s leading pipeline product is AVT02, a biosimilar of AbbVie’s HUMIRA® and the accused product here.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Indeed, Alvotech’s experts testified that the experts have been working on this matter for nearly two years. Ex. 3 at 13:1-5; Ex. 17 at 12:17-14:6.

Starting in November 2020, AbbVie and Alvotech engaged in the “patent dance,” a statutory framework where the parties exchange confidential information and substantive contentions. Alvotech was required to provide “a detailed statement that describes, on a claim-by-claim basis, the factual and legal basis of its position that [AbbVie’s] patents [are] invalid, unenforceable, or will not be infringed by the commercial marketing” of AVT02. See *AbbVie v. Alvotech hf.*, C.A. No. 21-cv-02899, 2022 WL 225881, at *2 (N.D. Ill. Jan. 26, 2022) (Ex. 21). Alvotech’s “3B” disclosure was intended to inform AbbVie “why it could not be held liable for infringement of the relevant patents.” *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1671 (2017).

On January 14, 2021, Alvotech provided its 3B disclosure to AbbVie, detailing its non-infringement, invalidity, and unenforceability bases for patents that AbbVie identified as infringed by AVT02. Alvotech dedicated over 200 pages to the ’686 and ’619 Patents alone. See, e.g., Ex. 4; Ex. 5. After the patent dance, AbbVie sued Alvotech on April 27, 2021 on four patents (“2258”) and on May 31, 2021 on the remaining patents identified during the patent dance (“2899”).

Alvotech was far behind its biosimilar competitors, who are licensed to enter the U.S.



market starting January 2023, so Alvotech pushed for a super-compressed schedule, especially for such a large patent case. *See* Sep. 2, 2021 Hearing Tr. at 8:18-24. To justify its breakneck schedule, Alvotech assured the Court that “this isn’t like a typical patent case where the parties are starting cold” because—as Alvotech’s lead counsel stated—“[AbbVie] had our contentions on invalidity for seven months.” *See* Aug. 12, 2021 Hearing Tr. at 45:9-14. Based on Alvotech’s representations, the Court set trial for August 2022 on AbbVie’s first ten asserted patents, with just six months for fact discovery. Dkt. 63 (2258) at 2 (setting close of fact discovery as March 2, 2022). The Court further ordered opening expert reports be served on March 17, 2022. *Id.*

Alvotech answered AbbVie’s 2258 Complaint in September 2021 but opted to wait until January 2022 to answer the 2899 Complaint. Notably, Alvotech did *not* assert inequitable conduct against the ’559 or ’216 Patents and limited its patent misuse or unclean hands claims against the ’619 and ’030 Patents to its baseless assertion that AbbVie misused Alvotech’s confidential information received during the patent dance. *See* Dkt. 60 (2258) at ¶ 136 (Seventh Affirmative Defense), ¶ 139 (Tenth Affirmative Defense), ¶ 140 (Eleventh Affirmative Defense), Counterclaims at ¶¶ 57-62 (unclean hands), ¶¶ 63-65 (patent misuse), ¶¶ 96-112 (inequitable conduct against U.S. Patent No. 8,961,973 (“’973 Patent”)); Dkt. 143 (2899) at ¶ 12 (Twelfth Affirmative Defense), Counterclaims at ¶¶ 62-67 (unclean hands), ¶¶ 68-70 (patent misuse), ¶¶ 131-51 (inequitable conduct against U.S. Patent No. 11,083,792 (“’792 Patent”)). AbbVie moved to dismiss these meritless allegations. Dkt. 69 (2258); Dkt. 214 (2899). At no point did Alvotech move to amend its answers to allege additional unenforceability claims or defenses.

On September 24, 2021, Alvotech served its initial non-infringement, invalidity, and unenforceability contentions under Local Patent Rule 2.3. *See* Ex. 6. Here again, Alvotech did not raise any inequitable conduct allegations against the ’559 or ’216 Patents or additional unclean



hands or misuse allegations against the '619 and '030 Patents. Consistent with its representations to the Court that AbbVie “had [its] contentions on invalidity for seven months,” Aug. 12, 2021 Hearing Tr. at 45:9-14, Alvotech’s initial invalidity contentions largely tracked its 3B patent dance disclosures, relying on the same references and obviousness grounds for the '686 and '619 Patents.³ Compare Ex. 7 and Ex. 19; compare Ex. 8 and Ex. 20.

On February 11, 2022, less than three weeks before the end of fact discovery, the parties exchanged final contentions under Local Patent Rule 3.1. Alvotech’s featured 132 references (including an unspecified and undocumented reference to “Amgen’s prior work”), raised 40 new prior art invalidity grounds, identified 50 new (but publicly available) references, and asserted new inequitable conduct claims against the '559 and '216 Patents and vague allegations of misconduct against the '619 and '030 Patents. Ex. 16 at 16, 30-32. AbbVie’s responses to these excessive and in many cases entirely new contentions are due on March 4, 2022, three weeks after receipt of Alvotech’s contentions. See Feb. 4, 2022 Hearing Tr. at 232:22-233:14.

AbbVie promptly objected to this belated disclosure. Ex. 10. The parties met and conferred on February 16 and 17, 2022 by teleconference and email but reached an impasse. Ex. 18.

III. LEGAL STANDARDS

“The [local patent] rules are essentially a series of case management orders” and courts may “refus[e] to allow [a] disobedient party to support or oppose designated claims or defenses, or prohibit[] that party from introducing designated matters in evidence.” *O2 Micro Int’l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1363 (Fed. Cir. 2006). Local Patent Rule 2.3(b)(1) governs initial invalidity contentions and requires defendants to identify “with particularity, . . . up

³ Because the '030 Patent issued after the parties completed the patent dance, Alvotech never provided a 3B disclosure for this patent. However, Alvotech’s September 2021 Initial Contentions for the '030 Patent relied on the same prior art as for the related '619 Patent. Ex. 8; Ex. 9.

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to twenty five (25) items of prior art per asserted patent that allegedly invalidates each asserted claim.” Local Patent Rule 3.1(b) governs final invalidity contentions and requires defendants to further limit their defenses. It deletes the “per asserted patent” language, thus limiting defendants to **a total** of 25 prior art references, absent a Court order to the contrary, which would require “a showing of good cause and absence of unfair prejudice to the opposing parties.” LPR 3.1(b).

Compliance with these rules is strictly enforced. Courts—including in this District—routinely strike contentions that violate the letter and spirit of their orders, including local patent rules. *See, e.g. Nat’l Steel Car. Ltd. v. FreightCar Am., Inc.*, C.A. No. 15-cv-03418, Dkt. 142 (N.D. Ill. Oct. 19, 2016) (Ex. 22) (striking references that exceed the limit imposed by Local Patent Rule 3.1(b)); *CoStar Realty Information, Inc. v. CIVIX-DDI LLC*, C.A. No. 12-cv-04968, Dkt. 141 (N.D. Ill. May 21, 2013) (Ex. 23) (same); *Convolve, Inc. v. Compaq Computer Corp.*, C.A. No. 00-cv-05141, 2006 WL 2527773, at *3-6 (S.D.N.Y. Aug. 31, 2006) (Ex. 24) (striking newly cited references in invalidity contentions served without leave of court); *Finjan, Inc. v. Proofpoint, Inc.*, C.A. No. 13-cv-05808, 2015 WL 7959890, at *4 (N.D. Cal. Dec. 4, 2015) (Ex. 25) (striking prior art not previously identified in the accused infringer’s primary election of references); *Erfindergemeinschaft UroPep GbR v. Eli Lilly & Co.*, C.A. No. 2:15-cv-01202, 2017 WL 1393525, at *1-2 (E.D. Tex. Apr. 13, 2017) (Ex. 26) (striking previously undisclosed references in violation of local patent rules).

As to Alvotech’s new unenforceability theories, the law is clear that claims or defenses based on allegations of fraud, including inequitable conduct and unclean hands, must be pleaded with particularity under Rule 9(b). *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326 (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.”); *Manley v. Boat/U.S. Inc.*, C.A.



No. 13-cv-05551, 2016 WL 1213731, at *4 (N.D. Ill. Mar. 29, 2016) (Ex. 27). The pleadings must identify with particularity the “specific who, what, when, where, and how” of the equitable defense. *Exergen*, 575 F.3d at 1327.

IV. ARGUMENT

A. The Court Should Strike Alvotech’s References Exceeding the Limits Imposed by the Local Patent Rules

There is no way around it: Alvotech simply ignored the Local Patent Rules, which expressly required it to narrow to a total of no more than 25 prior art references in its Final Contentions. And not by a little bit—Alvotech included *132 references*, more than five times the number permitted by the Local Patent Rules. Of these 132 references, at least *50* are references Alvotech had *never disclosed before*. This was a flagrant and blatant violation of the Local Rules. “[O]nly by order of the Court upon a showing of good cause and absence of unfair prejudice to opposing parties” could Alvotech surpass the 25-reference limit. *Id.* Alvotech sought no such order. With fact discovery closing and opening expert reports due in barely four weeks, it is time for Alvotech to narrow its case, not expand and change it. The Court should strike each of Alvotech’s references that exceed the limit imposed by Local Patent Rule 3.1(b) and require Alvotech to select 25 references, which would be more than enough if Alvotech had meritorious positions.

Courts in this district routinely grant motions to strike final invalidity contentions in multi-patent cases to conform with the requirements of Local Patent Rule 3.1(b). For example, in *Nat’l Steel Car. Ltd. v. FreightCar Am., Inc.*, the court limited the accused infringer “to 25 charted references” to be used “across different patents and claims.” C.A. No. 15-cv-03418, Dkt. 142 (N.D. Ill. Oct. 19, 2016) (Ex. 22); *see also id.* at Dkt. 152 (Ex. 28) at 14:4-14:7 (“The point of the local patent rules is to force these disputes into narrower channels *and force the parties to make tough*



decisions about what and how they’re going to present their case.”). Likewise, in *CoStar Realty Information, Inc. v. CIVIX-DDI LLC*, the court struck references, limiting the accused infringer’s contentions to 25 references in a case involving three patents and 24 asserted claims. C.A. No. 12-cv-04968, Dkt. 141 (N.D. Ill. May 21, 2013) (Ex. 23) (requiring the accused infringer to limit its contentions from 132 references to 25); *see also id.* at Dkt. 137 (Ex. 29) at 1 (24 asserted claims in 3 patents).

This authority carries particular weight here. Alvotech did not just *quintuple* the limit prescribed by the Local Patent Rules, it did so without leave of the Court.⁴ Alvotech’s attempt to not only overhaul but also drastically expand its invalidity case runs afoul of the letter and spirit of this Court’s rules. *See Nat’l Steel Car.*, C.A. No. 15-cv-03418, Dkt. 152 at 13:12-14:20 (Ex. 28); *see also* LPR 1.6, Committee Comments (noting that the purpose of invalidity contentions “is to identify likely issues in the case,” enabling parties to “focus and narrow their discovery requests.”). Such expansive, last-minute contentions also renege on the assurances Alvotech made to the Court to secure an accelerated schedule.

Nor can Alvotech show “good cause” *and* “the absence of prejudice to the opposing party” necessary to assert more than 25 references. *See* LPR 3.1(b). Any belated attempt by Alvotech to do so now fails for two reasons. *See CoStar Realty Info., Inc. v. CIVIX-DDI, LLC*, C.A. No. 12-cv-04968, 2013 WL 12221613, at *1-2 (N.D. Ill. Aug. 8, 2013) (Ex. 31) (party that “moved six

⁴ To the extent Alvotech contends that its “background” art does not count against its 25-reference limit, Alvotech is wrong—Local Patent Rule 3.1(b) counts these references towards this limit. *See Kove IO, Inc. v. Amazon Web Servs., Inc.*, C.A. No. 18-cv-08175, 2021 WL 4515480, at *5 (N.D. Ill. Sept. 17, 2021) (Ex. 30) (granting motion to strike references not contained in the list of 25 references in second amended final infringement contentions and rejecting argument that these references were “background historical materials that appear in [the] discussion of [a prior art system that] are not independent pieces of prior art”). In any event, Alvotech’s primary and secondary references (i.e., its “non-background” art) also greatly exceed the 25-reference limit.



weeks after the [Local Patent Rule 3.1(b)] deadline” and after serving final contentions with more than 25 references not allowed to exceed the 25-reference limit because “[t]o allow [the party] more additional references at this time would merely reward their dilatory tactics in their disclosures”).

First, there is no good cause for Alvotech’s disregard of the Court’s rules.⁵ To begin, Alvotech never moved the Court to exceed 25 references in its Final Contentions. This alone is fatal. *CoStar*, 2013 WL 12221613, at *1-2 (Ex. 31); *see also Finjan, Inc. v. Proofpoint, Inc.*, C.A. No. 13-cv-05808, 2015 WL 7959890, at *2 (N.D. Cal. Dec. 4, 2015) (Ex. 25) (“*Before* amending invalidity contentions, a party must make a *timely* showing of good cause and seek permission from the Court”). Moreover, Alvotech’s Final Contentions dramatically *expanded* the scope of the parties’ dispute. At no point did Alvotech explain to the Court—or AbbVie—its need for 50 new references for the now narrowed set of asserted claims. Just as in *CoStar*, where there were even more claims at issue, this district has stricken references that surpass the limits imposed by Local Patent Rule 3.1(b). *See* C.A. 12-cv-04968, Dkt. 141 (Ex. 23). The same should happen here.

Second, Alvotech’s voluminous Final Contentions severely prejudice AbbVie. AbbVie is conducting over twenty depositions during the last three weeks of fact discovery. And the March 17 deadline for opening expert reports is rapidly approaching. At this late stage, unless this Court grants AbbVie relief, Alvotech’s Final Contentions would force AbbVie to undergo the arduous task of responding to nearly five-fold the permitted number of references, including 50 brand new references while diligently completing fact discovery. Alvotech should not be permitted to sandbag AbbVie with a reinvented—and substantially expanded—invalidity case with just two weeks of

⁵ . This leaves two possibilities: (1) Alvotech intentionally misled AbbVie or (2) Alvotech failed to diligently prepare its case until the last minute. Neither would constitute good cause.



fact discovery remaining and an imminent opening expert report deadline.

The Court should not indulge Alvotech’s flagrant disregard of its rules. AbbVie requests that the Court strike these excessive references from Alvotech’s Final Contentions and require Alvotech to conform them to the 25-reference limit in Local Patent Rule 3.1(b).

B. The Court Should Strike Alvotech’s Belatedly Disclosed Invalidity Theories for the ’619, ’030, and ’686 Patents

Setting aside the excessive number of references, Alvotech waited until the eleventh hour—months after the parties identified claim terms for construction, just weeks before the close of fact discovery, and on the eve of opening expert reports—to disclose an almost entirely new invalidity case. Alvotech’s Final Contentions disclose *for the first time* 24 invalidity grounds and 23 new references against the ’619, ’030, and ’686 Patents. This complete overhaul of Alvotech’s invalidity case flouts Alvotech’s representation that AbbVie has “had [Alvotech’s] contentions on invalidity for [over a year]” as the basis for an expedited case schedule. *See* Aug. 12, 2021 Hearing Tr. at 45:10-11. There can be no question that Alvotech’s abrupt pivot significantly prejudices AbbVie. The Court should strike each newly identified invalidity ground and reference for the ’619, ’030, and ’686 Patents for two reasons.

First, there is no justification for Alvotech’s belated disclosure. As noted, courts routinely strike late-disclosed invalidity grounds and references where, as here, there is no excuse for delay. For example, in *Convolve*, the court struck 72 new prior art references and 30 associated invalidity contentions where the accused infringer was aware of the patentee’s claim construction position, and thus should “have crystallized their invalidity theory early in the case and should not be allowed to change their theory at this point in the litigation.” 2006 WL 2527773, at *3-6 (Ex. 24). Likewise, the *UroPep* Court struck late-identified references “in violation of the Local Patent Rules and without justification.” 2017 WL 1393525, at *1-2 (Ex. 26). There, the court reasoned

[REDACTED]

that the accused infringer’s delay was inexcusable because nothing prevented it from citing the references in its original invalidity contentions. *Id.* Moreover, in *Finjan*, the court struck “all anticipation and obviousness combinations [in the accused infringer’s] final election that include prior art references not previously identified in the preliminary election.” 2015 WL 7959890, at *4 (Ex. 25); *see also Impact Engine, Inc. v. Google LLC*, C.A. No. 19-cv-01301, Dkt. 149 at 2 (S.D. Cal. Feb. 16, 2021) (Ex. 32) (“Defendant is admonished that amended final invalidity contentions ***should not introduce new prior art that has not previously been disclosed to plaintiff . . .***”).

The same result is warranted here. Just as the accused infringer in *Convolve*, Alvotech has known of AbbVie’s infringement positions since January 2021. Ex. 12; Ex. 13. Alvotech pushed for a compressed schedule based on its similarly early disclosure of detailed invalidity contentions. *See* Aug. 12, 2021 Hearing Tr. at 45:9-14. [REDACTED]

[REDACTED]

[REDACTED]. Ex. 2 at 4. Indeed, Alvotech included allegations against the claims of the ’030 Patent in its September 14, 2021 answer. Dkt. 60 (2258) at Counterclaims ¶¶ 30-35 (discussing the ’201 Application, which issued as the ’030 Patent).

Alvotech’s delay is particularly egregious given that—with the exception of the unknown, unspecified, and unbounded “Amgen’s prior work”—each of Alvotech’s newly identified references ***have been publicly available for many years***. Just as in *UroPep*, there is no excuse for Alvotech’s delay: Alvotech could have identified them in its September 2021 contentions or the patent dance disclosures. 2017 WL 1393525, at *1-2 (Ex. 26). Alvotech’s delay runs against the weight of authority compelling early contention disclosure. *See Finjan*, 2015 WL 7959890, at *4 (Ex. 25) (striking references not identified in initial prior art election); *see also Impact Engine, Inc.*



v. *Google LLC*, C.A. No. 19-cv-01301, Dkt. 149 at 2 (S.D. Cal. Feb. 16, 2021) (Ex. 32) (admonishing accused infringer to not try to introduce references for the first time in its final contentions). This delay is especially damaging here where the Court *relied on* Alvotech’s supposed early disclosure to set the aggressive schedule that accelerated claim construction to occur after initial contentions rather than after final contentions. Aug. 12, 2021 Hearing Tr. at 45:9-14; LPR 4.1(a) (claim terms are identified for construction “fourteen (14) days after service of the Final Invalidation Contentions”).

Second, Alvotech’s gamesmanship left unchecked will significantly prejudice AbbVie. The scope of the belated disclosure is significant and these are the most egregious examples:

Patent	Number of New Invalidation Grounds	Number of New References Identified
'619 Patent	<ul style="list-style-type: none"> • 5 new obviousness combinations grounds • 2 new § 112 grounds (enablement and written description) • 1 new § 101 ground (patent eligibility) 	15 (out of 26 total)
'030 Patent	<ul style="list-style-type: none"> • 5 new obviousness combination grounds • 2 new § 112 grounds (enablement and written description) 	15 (out of 26 total)
'686 Patent	<ul style="list-style-type: none"> • 7 new prior art invalidity grounds 	6 (out of 8 total)

AbbVie relied on Alvotech’s assurances to the Court that AbbVie “had [its] contentions on invalidity for seven months.” *See* Aug. 12, 2021 Hearing Tr. at 45:9-14. AbbVie relied on Alvotech’s contentions when selecting claims to assert, claim terms to construe, and discovery to pursue. And AbbVie relied on those contentions when developing case strategies and working with experts. But it turns out that Alvotech’s assurances were false. Given the substantial ramp up to this litigation, Alvotech *should and could have* disclosed these grounds and references in January 2021 (during the patent dance), or at least by September of 2021 (in its initial infringement contentions). AbbVie now faces preparing responses to entirely new contentions within just three weeks. All while navigating nearly two dozen depositions, responding to discovery requests, and



preparing for opening expert reports. Alvotech cannot justify this prejudice.

The full scope of Alvotech’s new invalidity case—and prejudice to AbbVie—is still an open question. One of Alvotech’s new grounds for the ’619 and ’030 Patents refers generically to “Amgen’s prior work.” Ex. 14 at 34, 67-69. As Alvotech has known all along, Amgen was an earlier biosimilar applicant for HUMIRA® and assignee of several references cited in Alvotech’s 3B disclosures and September 2021 contentions. Yet Alvotech waited until just a month before the close of fact discovery to serve a subpoena on Amgen. Ex. 15. Alvotech (apparently) intends to rely on whatever (still unknown) document(s), if any, it receives from Amgen in an eleventh-hour attempt to bolster its invalidity arguments. Ex. 14 at 67 n.4. (reserving the right to rely on documents produced by Amgen “to demonstrate Amgen’s prior work”). There is no excuse for Alvotech’s belated and generic citation to “Amgen’s prior work.” Nor should Alvotech be permitted to inject even more belated invalidity theories into its case based on its decision to delay seeking documents from Amgen.

The case schedule *that Alvotech demanded* is far faster than is typical. Alvotech’s delay significantly prejudices AbbVie’s ability to try its case. The Court should strike each newly identified invalidity ground and reference for the ’619, ’030, and ’686 Patents.

C. The Court Should Strike Alvotech’s Unpleaded Unenforceability Contentions

Alvotech’s Final Contentions seek to inject new unenforceability theories: (1) inequitable conduct allegations against the ’559 and ’216 Patents and (2) additional patent misuse and unclean hands allegations relating to its new inequitable conduct assertions and vague assertions against the ’619 and ’030 Patents never tied to any specific unenforceability claim. *See, e.g.*, Ex. 16 at 16 (new ’559 and ’216 Patent inequitable conduct assertions), 30-32 (vague allegations against the



'619 and '030 Patents). But Alvotech never made those allegations in its pleadings.⁶ Indeed, Alvotech admits that it would need to amend its pleadings to add them. Ex. 18. Alvotech's last-minute theories are an impermissible end run around the heightened pleading burden for such allegations. They should be stricken.

Inequitable conduct and unclean hands allegations must be pleaded with particularity. *Exergen*, 575 F.3d at 1326-27, 1328; *Manly*, 2016 WL 1213731, at *4; Fed. R. Civ. P. 9(b). The Federal Circuit requires accused infringers to “identify *which claims, and which limitations in those claims*” are the subject of intentional fraud. *Id.* at 1329. Anything short of this fails as a matter of law under Rule 9(b). Where a party does “not properly plead inequitable conduct[.] . . . [it] is not part of [the] case.” *Cent. Admixture Pharmacy Servs, Inc. v. Advanced Cardiac Sols., P.C.*, 482 F.3d 1347, 1357 (Fed. Cir. 2007); *Apotex Inc. v. Cephalon, Inc.*, 500 Fed. App'x 959, at *1 (Fed. Cir. 2013) (affirming a finding of no inequitable conduct as to an individual where no pleading asserted that an individual committed inequitable conduct). Such unpled contentions are routinely stricken. *RTC Indus., Inc. v. Fasteners For Retail*, C.A. No. 17-cv-03595, Dkt. 47 at 2 (N.D. Ill., May 7, 2018) (Ex. 33) (striking contentions that tried to “add additional patent claims to this case without first amending the operative pleadings”).

And so here. There are *no* inequitable conduct allegations against the '559 and '216 Patents in Alvotech's pleadings. *See* Dkt. 60 (2258); Dkt. 143 (2899); *supra* at n.6. Alvotech attempts to sweep these allegations in as “related” to its pleadings regarding the '973 Patent that “apply equally” because the '559 and '216 Patents are in the same family. Ex. 18. But this disregards the

⁶ *See* Dkt. 60 (2258) at ¶ 136 (Seventh Affirmative Defense), ¶ 139 (Tenth Affirmative Defense), ¶ 140 (Eleventh Affirmative Defense), Counterclaims at ¶¶ 57-62 (unclean hands), ¶¶ 63-65 (patent misuse), ¶¶ 96-112 (inequitable conduct against '973); Dkt. 143 (2899) at ¶ 12 (Twelfth Affirmative Defense), Counterclaims at ¶¶ 62-67 (unclean hands), ¶¶ 68-70 (patent misuse), ¶¶ 131-51 (inequitable conduct against '792 Patent).

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required claim-level specificity for pleading inequitable conduct. *Exergen*, 575 F.3d at 1329. As the *RTC* court wrote, there is no authority that would “permit [contentions] that are not raised in its complaint.” C.A. No. 17-cv-03595, Dkt. 47 at 2 (Ex. 33). “Such a result *sidesteps Twombly and Iqbal’s* plausible requirements, up-ends notice pleading requirements . . . , subjects the [opposing party] to potentially unnecessary and unwarranted discovery, and wastes judicial resources by preventing Rule 12(b)(6) motions from narrowing the focus of the case” *Id.*

Alvotech cannot be allowed to sidestep the pleading requirement and expand the case at this late stage. Alvotech never included the ’559 and ’216 Patents in its inequitable conduct pleadings; it is too late to do so now. The same goes for Alvotech’s new—and unpleaded—unenforceability theories against the ’619 and ’030 Patents. AbbVie has already moved to strike and dismiss the inequitable conduct, unclean hands, and patent misuse allegations Alvotech did plead, which attempt to turn this 10-patent trial into a 60-patent sideshow. *See, e.g.*, Dkt. 69 (2258); Dkt. 214 (2899). Fact discovery closes in two weeks, and expert reports are due shortly thereafter. The Court should not permit Alvotech’s tactics to expand the scope of discovery and trial beyond its actual pleadings. The Court should strike these new unenforceability contentions.

V. CONCLUSION

AbbVie respectfully requests that the Court strike Alvotech’s untimely and improper invalidity and unenforceability contentions and require Alvotech to serve revised contentions that comply with the 25-reference limit of Local Patent Rule 3.1(b) and delete the new invalidity arguments and references for the ’686, ’619, and ’030 Patents and unpleaded unenforceability contentions. AbbVie further requests that its responsive contentions be due three weeks after Alvotech serves compliant contentions. Finally, AbbVie requests that briefing and consideration of this motion be expedited in light of the rapidly approaching deadlines.

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Respectfully submitted

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CERTIFICATE OF SERVICE

I do hereby certify that a true and correct copy of Plaintiffs' Unredacted Motion to Strike Defendant's Final Invalidity and Unenforceability Contentions, Memorandum in Support and Exhibits submitted on February 18, 2022 were served by electronic mail to all counsel of record:

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