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PURSUANT TO THE PROTECTIVE ORDER AND/OR 42 U.S.C. § 262(l)

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ABBVIE INC. and ABBVIE BIOTECHNOLOGY LTD Plaintiffs, v. ALVOTECH HF. Defendant.	No. 1:21-cv-02258 No. 1:21-cv-02899 Hon. John Z. Lee Magistrate Judge M. David Weisman

JOINT STATUS REPORT

Pursuant to the Court's Minute Entries issued on September 20, 2021 (Dkt. 62 (Case No. 1:21-cv-02258); Dkt. 52 (Case No. 1:21-cv-02899)), Plaintiffs AbbVie Inc. and AbbVie Biotechnology Ltd (collectively, "AbbVie") and Defendant Alvotech hf. (collectively, the "Parties") submit the following Joint Status Report for Case Nos. 1:21-cv-02258 and 1:21-cv-02899 ("Cases").

I. Current Deadlines

On September 20, 2021, this Court issued a Scheduling and Discovery Order with respect to ten patents that will be subject to a first trial ("Ten Patents").[1] Dkt. 63 (Case No. 1:21-cv-02258); Dkt. 53 (Case No. 1:21-cv-02899). The current deadlines ordered by the Court for the Ten Patents are as follows:

[1] U.S. Patent Nos. 6,805,686, 8,926,975, 8,961,973, 8,999,337, 9,067,992, 9,085,619, 9,187,559, 9,512,216, 11,083,792, and 11,167,030.

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Event	Deadline
Technology Tutorial and Hearing on Claim Construction (LPR 4.3)	Thursday, 1/13/2022
Plaintiffs' List of Asserted Claims (LPR 3.1(a)(1))	Friday, 1/14/2022
Plaintiffs' Final Infringement Contentions (LPR 3.1(a)(2))	Friday, 1/28/2022
Defendant's Final Unenforceability and Invalidity Contentions (LPR 3.1(b), 3.3)	Friday, 1/28/2022
Defendant's Final Non-Infringement Contentions (LPR 3.2(a))	Friday, 2/18/2022
Plaintiffs' Final Enforceability and Validity Contentions (LPR 3.2(b))	Friday, 2/18/2022
Fact Discovery Closes (LPR 1.3)	Wednesday, 3/2/2022
Opening Expert Reports by burden of proof (including arguments on secondary considerations by both parties)	Thursday, 3/17/2022
Rebuttal Expert Reports (including responses to secondary considerations by both parties) (LPR 5.1(c))	Wednesday, 4/27/2022
Expert Discovery Closes (LPR 5.2)	Tuesday, 6/14/2022
Serve Pretrial Disclosures; File Motions *in Limine*	Tuesday, 6/28/2022
Serve Objections to Pretrial Disclosures; Serve Rebuttal Pretrial Disclosures	Monday, 7/11/2022
Serve Objections to Rebuttal Pretrial Disclosures	Monday, 7/18/2022
File Joint Pretrial Order, Responses to Motions *in Limine*, Updated Exhibit Lists, Updated Witness Lists, and Updated Deposition Designations	Monday, 7/18/2022
Pretrial Conference	Monday, 7/25/2022
Trial	Monday, 8/1/2022 to Friday, 8/19/2022
Opening Post-Trial Briefs/Proposed Findings of Fact and Conclusions of Law	Friday, 9/9/2022
Rebuttal Post-Trial Briefs/Proposed Findings of Fact and Conclusions of Law	Friday, 9/23/2022

The Cases have been referred to Magistrate Judge Weisman for general discovery supervision. Dkt. 113 (Case No. 1:21-cv-02258); Dkt. 87 (Case No. 1:21-cv-02899).

II. Progress of Discovery

The deadline for substantial completion of document production was December 1, 2021, and while the Parties were substantially complete by that time, they have continued to produce documents since then, including in response to additional requests or to resolve disputes without troubling the court.

The Parties have served and responded to interrogatories, requests for production, and requests for admission, and additional written discovery remains outstanding.

Fact depositions are to begin in January 2022.

III. Status of Briefing on Unresolved Motions

As of November 19, 2021, briefing was completed for AbbVie's Motion to Dismiss and Strike Defendant's Counterclaims and Affirmative Defenses of Inequitable Conduct, Unclean Hands, and Patent Misuse (Dkt. 69 (Case No. 1:21-cv-02258)). The Parties would appreciate the Court taking up that motion at its earliest convenience, as it affects the scope of the case.

Alvotech hf. filed a motion to dismiss AbbVie's complaint in Case No. 1:21-cv-02899 on July 29, 2021. Dkt. 28 (Case No. 1:21-cv-02899). Briefing on that motion was completed on August 18, 2021. AbbVie has filed two amended complaints in the -2899 case, on November 12, 2021 and December 21, 2021, respectively. Alvotech hf. filed renewed motions to dismiss following the filing AbbVie's amended complaints. Dkt. 91 (Case No. 1:21-cv-02899); Dkt. 138 (Case No. 1:21-cv-02899). Most recently, Alvotech hf. filed a motion to dismiss AbbVie's second amended complaint in Case No. 1:21-cv-02899 on December 29, 2021. Dkt. 138 (Case No. 1:21-cv-02899). AbbVie filed a response on January 3, 2022. Dkt. 140 (Case No. 1:21-cv-02899). Those papers merely incorporate by reference the memorandum in support of the motion (Dkt. 29) and opposition to the motion (Dkt. 39) filed with respect to the original complaint. That motion is now fully briefed.

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IV. Settlement Discussions

There have been some settlement discussions between the principals. Both Parties agree that any settlement discussions should proceed in this fashion, rather than with a mediator.

V. Requests for Any Agreed Action that the Court Can Take Without a Hearing

The Parties have no agreed action that the Court can take without a hearing.

VI. Agreed-Upon Claim Constructions

The Parties submitted a joint claim construction statement pursuant to LPR 4.2(f) on December 22, 2021 setting out the terms addressed in the claim construction briefs. The Parties are in agreement with regard to the following claim terms, not included in that joint claim construction statement:

Claim Term	Meaning
"treating" U.S. Patent No. 8,926,975, claim 1 (from which asserted claims 2 and 3 depend) U.S. Patent No. 8,999,337, claim 1 (from which asserted claim 18 depends) U.S. Patent No. 9,512,216, claims 1 (from which asserted claim 3 depends) and 9 (from which asserted claim 11 depends) U.S. Patent No. 9,187,559, claim 1 (from which asserted claims 9, 10, 15, and 17-20 depend)	Plain and ordinary meaning, i.e., "giving for the purpose of addressing signs, symptoms or other clinical parameters of"
"[a] multiple-variable dose method" U.S. Patent No. 8,961,973, claims 1 (from which asserted claims 4 and 12 depend) and 15 (from which asserted claims 26, 27, and 30 depend) U.S. Patent No. 9,187,559, claim 1 (from which asserted claims 9, 10, 15, and 17-20 depend)	"[a] method where the drug is administered to a subject in different amounts at various time points"

VII. Necessity of Hearing:

The parties request a hearing on January 13, 2022—the same day as the Technology Tutorial and Hearing on Claim Construction to discuss the following matters.

A. Matters to Be Discussed at Hearing

1. Potential Future Request for Case Deadline Extension

Plaintiffs' Position: While AbbVie is not yet requesting to extend the case schedule, it wants to give the Court advance notice that it may need to make such a request in the future.

The Parties have less than eight weeks to complete 120 hours of depositions per side, serve final contentions, argue claim construction, and resolve any outstanding discovery disputes with the opposing party or third parties, such as the exchange of samples and availability of deponents. While this already would have required a Herculean effort, several intervening events have compounded the difficulty.

First, Alvotech waited more than seven months—until January 5, 2022 (two days before the filing of this status report)—to answer the complaint in Case No. 1:21-cv-02899. Based on an initial review of the answer, it appears that Alvotech's answer repeats the same infirmities as its answer in the first case that are the subject of AbbVie's pending motion to dismiss (Dkt. 69 (Case No. 1:21-cv-02258)) as well as additional allegations. Briefing and resolution of another motion to dismiss will take time.

Second, recent events may interfere with the ability to complete depositions on the current schedule. To start, the recent COVID-19 spike may interfere with witness scheduling, even with virtual depositions, especially given the number of witnesses, the advanced age of several of the witnesses, which puts them at higher risk, and the fact that many are in foreign countries. In addition, securing witness testimony may present challenges. For example, just this week,

Alvotech notified AbbVie for the first time that it no longer employs one of the witnesses it identified and produced documents for, and cannot accept service. Compelling the attendance of foreign witnesses can take considerable time.

Third, [redacted]

Fourth, Teva (Alvotech's US commercialization partner) has refused to produce multiple categories of discovery that are relevant to issues such as direct and induced infringement and safe harbor. This will likely require a motion to compel, and AbbVie will need to secure these documents before taking Teva's deposition.

In the event that an adjustment to the schedule is necessary, Alvotech will not suffer any prejudice. The current super-accelerated case deadlines were set in view of Alvotech's alleged urgency it represented to the Court (7/21/2021 Hearing Transcript at 18:17-24; 8/12/2021 Hearing Transcript at 44:22-45:2), but it turns out that such urgency no longer exists—if it ever did. [redacted]. Also, the FDA has yet to inspect any of the three different foreign facilities involved in the manufacture of AVT02, a prerequisite to approval Alvotech's aBLA. Dkt. 158 at 1 (Case No. 1:21-02258) ("BLA No. 761205 has not yet been approved due to a COVID-19 related delay in the inspection of facilities."); Dkt. 137 at 1 (Case No. 1:21-02258) (same). It is uncertain when such inspections may occur as Alvotech provided no evidence that

any of the three inspections will take place this spring. In fact, the FDA, as of January 4, 2022, will only be doing "mission-critical foreign inspections" and has "postpone[ed] the planning of prioritized surveillance foreign inspection assignments that were scheduled to begin in February 2022." *FDA Roundup: January 4, 2022* (Jan. 4, 2022), https://www.fda.gov/news-events/press-announcements/fda-roundup-january-4-2022.

Defendant's Position: Alvotech hf. opposes any request to expand the case schedule.

First, AbbVie does not explain how the -2899 answer will cause a delay in the case beyond saying that it intends to file a motion to dismiss. Indeed, AbbVie itself says that the -2899 answer "repeats the infirmities" of the -2258 answer (filed September 14, 2021). If that is the case, then it is not clear how the -2899 answer changes the calculus. As for the timing of the filing of the -2899 answer, AbbVie has amended the -2899 complaint twice to add new patents, most recently on December 21, 2021. Although no answer was due because of a still-pending jurisdictional challenge to the -2899 complaint, Alvotech hf. agreed to file the answer before the upcoming depositions so AbbVie would have whatever additional information the -2899 answer provides about Alvotech hf.'s defenses. Again, those defenses were disclosed, both in the patent dance and in the filings in the -2258 case. Though Alvotech hf. has answered the second amended complaint in the -2899 case, it preserves its jurisdictional challenge, as set forth in its motions to dismiss.

Alvotech hf. has fully participated in all aspects of the litigation in accordance with the Court's schedule, including Claim Construction and Discovery, on all of the Ten Patents. To date, Alvotech hf. has produced over 8 million pages of documents; including the operative BLA, which AbbVie received in November 2020. Alvotech hf. has also provided deposition dates for all Alvotech-entity employee deponents noticed by AbbVie, with the last date more than two weeks prior to the scheduled close of fact discovery.

AbbVie has long been aware of Alvotech hf.'s positions on the asserted patents included within the -2899 complaint and addressed in Alvotech hf.'s answer. All but two of the asserted patents were part of the BPCIA patent dance. The remaining two had not yet issued at the time of the patent dance but are related to patents that were part of the dance, and the parties have since exchanged contentions on those patents in the litigation.

Second, AbbVie's fears regarding potential disruptions to deposition scheduling are, right now, hypothetical and, if anything, problems of AbbVie's own making. At AbbVie's request, the parties have agreed to virtual depositions. AbbVie noticed depositions for fifteen Alvotech hf. witnesses. Thirteen are current employees. Alvotech hf. has provided dates for each of the thirteen. Three of the current employees reside in countries (Switzerland and Germany) where video depositions are difficult. Alvotech hf. is going to have the witnesses travel to countries where AbbVie will be able to proceed on time. For the two former employees, Alvotech hf. is in contact with one and is hopeful to procure that person's appearance by notice. Alvotech hf. continues to reach out to the other. If it proves to be the case that AbbVie must obtain testimony by subpoena, Alvotech hf. has no objection to the testimony being taken outside the discovery period, should that be necessary.

Alvotech hf. noticed AbbVie's witnesses for depositions in December 2021. AbbVie has provided potential deposition dates for four of fifteen witnesses. AbbVie says some of its witnesses are in Germany (Alvotech hf. does not know how many), where, as discussed above, virtual depositions under oath are difficult. Of course, depositions for witnesses not in Germany should proceed, and AbbVie should provide dates as soon as possible. As far as any German-based witness, AbbVie is the plaintiff, and has vast resources. The witnesses can travel, as Alvotech hf. witnesses are. If travel is required for a particular witness to avoid restrictions in

Germany, and there is too great a health risk, the deposition can happen later in the schedule, when hopefully COVID cases are declining. Also, as an alternative to having witnesses leave Germany, Alvotech hf. is considering AbbVie's proposal to take depositions of AbbVie German-based witnesses without putting them under oath. While COVID presents challenges, it should not bring the case to a grinding halt.

Third, as described in Alvotech hf.'s regulatory update, [redacted]

Fourth, this status update is the first Alvotech hf. has heard of AbbVie's complaints with regard to Teva's third party document production. While it is possible that Teva may have some information relevant to the issues in this case, it is important to keep in mind that Teva is a distribution partner for a drug that is not yet being distributed. Alvotech entities were responsible for developing AVT02. The key facts related to infringement, validity and enforceability are in the possession of the parties.

A change in case schedule would prejudice Alvotech hf. Alvotech hf.'s subsidiary applied for regulatory approval of AVT02 in September 2020 in order to put itself in a position to launch AVT02 upon resolution of litigation. Alvotech entities and its vendors are in communication with

FDA regarding pre-approval inspections, and Alvotech hf. expects such inspections to take place in Spring 2022. *See* Dkt. 157 (Case No. 1:21-02258). The trial date in this case was set for the ten lodestar patents following discussions among the parties and the Court. AbbVie agreed "Plaintiffs will not seek a preliminary injunction on any patents other than the Ten Patents. Plaintiffs shall not seek a preliminary injunction on any patent before the Court's decision." Dkt. 63 at ¶ 1. The Court set a trial for August 2022 and said it "plans to issue its trial decision by the end of October of 2022." Dkt. 63 at ¶ 13. In light of that, "Defendant agreed not to launch AVT02 in the United States prior to the issuance of the Court's decision." *Id*. Alvotech hf.'s agreement not to launch prior to the end of October 2022 is not required by the BPCIA.

AbbVie has not asked to move the trial. If it does at some point in the future, Alvotech hf. can discuss those launch plans with the Court and AbbVie as needed.

2. Additional Prior Art Grounds in Final Invalidity Contentions

Defendant's Position: Defendant requests a limited increase in the number of prior art invalidity grounds it may include within its Final Invalidity Contentions under Local Patent Rule 3.1(b). The request for additional prior art invalidity grounds does not impact the maximum of 4 non-prior art grounds or the maximum of 25 prior art references allowed per patent. The present stage of the case involves ten patents with seven different specifications. At least five of the patents at issue have claims that are subject to priority disputes in the contentions. For example, the '619 and '030 patents were filed on October 3, 2014 and December 9, 2020, respectively, based on a provisional application filed on November 30, 2007. AbbVie has additionally claimed a conception date of December 1, 2005 and reduction to practice date of December 22, 2005. The 2005, 2007, and 2014 priority dates allow for significantly different prior art, and AbbVie has argued that several of Alvotech hf.'s cited prior art references do not qualify as prior art based on these dates. As another example, the '992 and '975 patents are continuations of multiple different

provisional and utility patent applications, resulting in claims that can have up to 10 and 3 different priority dates, respectively. AbbVie has not identified which it will ultimately rely on, and has argued that multiple references do not qualify as prior art based on their undefined priority dates. Particular art relied upon by Alvotech hf. qualifies as prior art for certain of the priority dates but either does not for some earlier dates, or was not published a year before some earlier dates that AbbVie may try to swear behind. Likewise, there exists a priority issue for all asserted claims of the '792 patent, which contains a limitation that was added very late in prosecution. Until the issue of priority is resolved for these five patents, Alvotech hf. requests the ability to preserve an additional two prior art invalidity grounds for each of the claims that have priority date issues.

Plaintiffs' Position: The Court should deny Alvotech's request. First, Alvotech is asking to enlarge the case when it should be narrowing its case given the ultra-compressed trial schedule it requested and received. Second, there are priority disputes in many, if not most, patent cases, and the LPR require the narrowing of prior art grounds to four regardless of any such disputes. LPR 3.1(b). If the Court would adopt Alvotech's proposal, parties would dispute priority in every case to evade the LPR limits and increase the number of prior art grounds. Alvotech should follow the LPR. Four grounds of invalidity per patent claim is more than adequate.

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Date: January 7, 2022

Respectively submitted,

/s/ Michael A. Morin

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EXHIBIT 1

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