UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

BIONTECH SE, BIONTECH MANUFACTURING GMBH, and PFIZER, INC.,

Plaintiffs/Counterclaim Defendants,

v. **Civil Action No. 2:23cv222**

CUREVAC SE (f/ka/a CUREVAC AG)

Defendant/Counterclaimant.
and

CUREVAC MANUFACTURING GMBH,
Counterclaimant
and

ACUITAS THERAPEUTIC, INC.,
Intervenor.

REVISED REPORT AND RECOMMENDATION ON SEVERANCE AND STAY

In this patent case related to COVID-19 vaccines, Acuitas Therapeutics sought to intervene, sever, and stay matters related to some of the patents in suit. (ECF No. 138). The combined motion and related filings were referred to the undersigned United States Magistrate Judge pursuant to 28 U.S.C. § 636(b)(1)(A). Referral Order (ECF No. 227). On April 12, 2024, in a written Opinion, Order, and Recommendation, I concluded that intervention was proper, but instead of severance, recommended a stay of the entire infringement action pending resolution of the inventorship questions also filed in this court. (ECF No. 258, at 1).

Thereafter, on April 25, 2024, CureVac filed a Notice of Settlement and stated that "all disputes between CureVac and Intervenor Acuitas Therapeutics, Inc. have been settled." (ECF No. 262, at 1). The following day, April 26, 2024, CureVac filed an objection to the Opinion and

Order Granting Intervention and Recommendation on Severance and Stay. (ECF No. 265). CureVac expressed that the settlement "(1) completely resolved the separate inventorship action in this Court and the arbitration proceeding in London; (2) will cause CureVac to withdraw three of the four patents in the '493 Patent Family from this litigation; and (3) will allow CureVac to proceed on one patent in the '493 Patent Family in this litigation (the '686 Patent)."[1] Id. at ¶ 4. CureVac relayed its expectation that "[t]he Settlement will result in Acuitas being dismissed from this case under Fed R. Civ. P. 41." Id. at ¶ 6. Because of the settlement, CureVac asked the District Judge to "'return the matter to the magistrate judge with instructions' to reconsider the Order and Recommendations with respect to the motion(s) to sever and stay." Id. at ¶ 10 (quoting Fed. R. Civ. P. 72(b)(3)).

The Court held a hearing with all parties on April 29, 2024. During the hearing, BioNTech did not oppose the Court modifying its Recommendation on Stay, but asked for additional time to seek discovery from Acuitas before it is dismissed from this action. The Court recommended that the parties submit a Joint Recommendation to Modify the Scheduling Order. Following the hearing, BioNTech and Pfizer filed a memorandum in response to CureVac's objections to the Opinion, Order, and Recommendation, and attached a proposed scheduling order (Exhibit A).[2] BioNTech & Pfizer's Response to CureVac's Objections ("BioNTech & Pfizer's Response") (ECF No. 285 (sealed version)). As stated in the Response, BioNTech and Pfizer met and conferred

[1] Although the '686 Patent is within the '493 Patent Family, CureVac stated during the hearing that it agreed to disclaim some of the claims in the '686 Patent, and as a result asserted that Acuitas has no rights to the remaining '686 claims. Transcript of Proceedings, Apr. 29, 2024 (ECF No. 272, at 7:22-25, 8:1-3). Acuitas agreed with CureVac and acknowledged that the claims disclaimed would eliminate any suggested licensing defense for Pfizer and BioNTech. The remaining claims in the '686 Patent remain as modified. Id. at 7:23-24.

[2] Exhibit A is attached to BioNTech and Pfizer's redacted, publicly filed version of the Response, (ECF No. 284).

with CureVac on May 7, 2024, and the parties agreed on a proposed schedule which includes a mid-March 2025 trial date, subject to the court's availability. Id. at 4. In light of the settlement and the parties' scheduling-related briefing, the District Judge recommitted the Recommendation to the undersigned in a written Order. (ECF No. 302).

While the parties disagree about the finality of the settlement stipulation, they agree that more time is needed to adjust their litigation strategy to conform to the absence of three of the four patents in the '493 Patent Family. Specifically, BioNTech and Pfizer identified experts, narrowed prior art selections, and made litigation decisions based on the fact that, at the time, they needed to defend against asserted claims of the '493 Patent Family that recited Acuitas' lipid nanoparticles ("LNPs"). Because the settlement removed issues related to Acuitas' lipids from this case, and ultimately changes the character of the case, BioNTech and Pfizer need time to adjust their litigation position to conform to the case after settlement.

BioNTech and Pfizer characterize the Acuitas settlement as a "complex development," observing that the terms leave certain claims related to the '686 Patent in the case. BioNTech & Pfizer Resp. (ECF No. 285 at 3). The settlement also precludes any claim that Acuitas shared confidential information with BioNTech and Pfizer during the development of the Comirnaty vaccine. Id. at 8. In addition, removing certain claims from the '686 Patent may raise new questions of enforceability and infringement that the companies need time to explore. Complicating matters further, Acuitas and CureVac have continued to finalize the terms of the Settlement Framework, which is now set to be confirmed by Final Order on June 11, 2024. (ECF No. 300).

Notwithstanding the foregoing, BioNTech, Pfizer, and CureVac all agree that the settlement resolves ownership questions which formerly animated the recommendation to sever

and stay. With Acuitas removed as a party, and the '686 Patent modified to clarify the limits of BioNTech's license of Acuitas technology, all parties agree that the request for severance will be rendered moot when the settlement is finally concluded. The remaining logistical challenges can be accommodated by slightly modifying the trial schedule on terms that the parties negotiated and agreed to, subject to the court's approval. I therefore VACATE the prior recommendation (ECF No. 258), and RECOMMEND that Acuitas's Motion to Stay and Sever (ECF No. 138) be DENIED AS MOOT. I further RECOMMEND the court adopt the schedule attached as Exhibit A to this Revised Report and Recommendation outlining a modified schedule for discovery, expert disclosure, and an estimated trial date, subject to the court's availability.

By copy of this Report and Recommendation, the parties are notified that pursuant to 28 U.S.C. § 636(b)(1)(C):

1. Any party may serve upon the other party and file with the Clerk written objections to the foregoing findings and recommendations within fourteen (14) days from the date this report is forwarded to the objecting party by Notice of Electronic Filing or mail, see 28 U.S.C. § 636(b)(1), computed pursuant to Rule 6(a) of the Federal Rules of Civil Procedure. Rule 6(d) of the Federal Rules of Civil Procedure permits an extra three (3) days, if service occurs by mail. A party may respond to any other party's objections within fourteen (14) days after being served with a copy thereof. See Fed. R. Civ. P. 72(b)(2) (also computed pursuant to Rule 6(a) and (d) of the Federal Rules of Civil Procedure).

2. A district judge shall make a *de novo* determination of those portions of this report or specified findings or recommendations to which objection is made.

The parties are further notified that failure to file timely objections to the findings and recommendations set forth above will result in a waiver of appeal from a judgment of this court

based on such findings and recommendations. Thomas v. Arn, 474 U.S. 140 (1985); Carr v. Hutto, 737 F.2d 433 (4th Cir. 1984); United States v. Schronce, 727 F.2d 91 (4th Cir. 1984).

/s/
Douglas E. Miller
United States Magistrate Judge

DOUGLAS E. MILLER
UNITED STATES MAGISTRATE JUDGE

Norfolk, Virginia

June 11, 2024

EXHIBIT A

BioNTech-Pfizer v. CureVac – Current Case Schedule and Plaintiffs' Amended Schedule Proposal

Event	Current Deadline	New Deadline
Fact discovery closes, including all fact depositions	**May 31, 2024**	**July 26, 2024[1]**
Identification of Proposed Expert Witnesses	June 14, 2024	August 9, 2024
Opening Expert Reports	July 3, 2024	August 28, 2024
Rebuttal Expert Reports	August 6, 2024	October 1, 2024
Sur-Rebuttal Expert Reports	August 27, 2024	October 22, 2024
Completion of all discovery, including depositions taken for presentation in evidence in lieu of the appearance of a witness at trial	**October 4, 2024**	**November 27, 2024**
Dispositive and Daubert Motions	October 18, 2024	December 20, 2024
Response to Dispositive and Daubert Motions	November 1, 2024	January 6, 2025
Pretrial Disclosures	November 6, 2024	January 6, 2025
Reply to Dispositive and Daubert Motions	**November 11, 2024**	**January 17, 2025**
All Non-Dispositive Motions Filed	November 18, 2024	January 17, 2025
Objections to Pretrial Disclosures and Plaintiff to distribute proposed final draft of proposed Final Pretrial Order	November 27, 2024	January 22, 2025
Opposition Brief to Non-Dispositive Motions Filed	December 4, 2024	January 29, 2025
Attorney's Conference	December 4, 2024	January 29, 2025
Settlement Conference	Before December 6, 2024	Before January 31, 2025
File Final Pretrial Order	December 6, 2024	January 31, 2025
Voir Dire and Jury Instructions	December 12, 2024	February 6, 2025
Deadline to oppose proposed jury instructions	December 17, 2024	February 11, 2025
Final Pre-Trial Conference	December 20, 2024 at 11:00 a.m.	February 14, 2025
Pretrial Briefs	January 6, 2025 (must be filed not later than five business days before trial)	Not later than five business days before trial
Submit three sets of pre-marked, indexed copies of that party's exhibits for use by the Court during trial proceedings and by the jury	January 10, 2025 (Not later than one business day before trial)	Not later than one business day before trial
3-Week Jury Trial	**Starts January 13, 2025 at 10:00 a.m.**	**Mid-March subject to the Court's availability**

[1]By prior Order, the fact discovery cutoff was already extended to July 26, 2024 (ECF No. 304).