

**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/k/a CUREVAC AG)

Defendant/Counterclaimant.

and

CUREVAC MANUFACTURING GMBH,

Counterclaimant,

and

ACUITAS THERAPEUTICS, INC.,

Intervenor.

**OPINION AND ORDER GRANTING INTERVENTION
AND RECOMMENDATION ON SEVERANCE AND STAY**

In this patent case related to COVID-19 vaccines, putative inventor, Acuitas Therapeutics seeks to intervene, sever, and stay matters related to some of the patents in suit. Acuitas claims ownership rights which it alleges would impair standing for the other patent owners. Because Acuitas licensed related patents to the vaccine makers BioNTech and Pfizer, those parties favor intervention and a stay. As explained below, I conclude that intervention is proper, but instead of severance, recommend a stay of the entire infringement action pending resolution of the inventorship questions also filed in this court.

I. Procedural History

Plaintiffs BioNTech SE and BioNTech Manufacturing GmbH (collectively, “BioNTech”) and Pfizer, Inc. (“Pfizer”) (and together, “Plaintiffs”), initially sought declaratory judgment against CureVac AG (“CureVac” or “Defendant”) that certain patents—denominated as the ’493 family¹ are not infringed by the COVID-19 vaccine, COMIRNATY[®] which BioNTech created and produced with Pfizer. CureVac answered and filed various counterclaims for infringement related to the ’493 patent family and additional patents, (ECF No. 56). This led to additional counterclaims and responsive pleadings related to the validity, enforceability, and alleged infringement of the other patents. (ECF Nos. 104, 106, 107, 116, 119). CureVac’s Answer and Counterclaim’s (ECF No. 56, at 66). The case was originally filed in Massachusetts, but eventually transferred here for jurisdictional reasons. Mem. Order (ECF No. 53). Thereafter, a non-party, Acuitas Therapeutics, Inc. (“Acuitas”), moved to intervene in this action and to sever and stay claims and defenses that relate to the ’493 patent family. BioNTech and Pfizer filed a joint brief supporting intervention and arguing to stay the entire case. (ECF No. 150). But CureVac opposed intervention, (ECF No. 156). Acuitas replied, noting Plaintiffs’ support for its request and reiterating arguments supporting intervention, severance, and a stay. (ECF Nos. 157, 170). The combined motion and the 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). As explained below, this opinion GRANTS Acuitas’ Motion to Intervene, (ECF No. 138), recommends DENYING

¹ The ’493 patent family includes U.S. Patent Nos. 11,241,493 (the “’493 Patent”), 11,471,525 (the “’525 Patent”), 11,576,966 (the “’966 Patent”), and 11,596,686 (the “’686 Patent”). Acuitas’ Mem. Supp. Mot. Intervene, Sever, & Stay (“Acuitas’ Mem. Supp. Combined Motion”) (ECF No. 137, at 6).

Acuitas’ Motion to Sever, and recommends GRANTING Acuitas’ Motion to Stay. (ECF No. 138).²

II. Factual Background

The following relevant facts taken from the pleadings summarize the underlying patent infringement dispute and Acuitas’ relationship to the claims asserted.

A. **The Dispute Between BioNTech, Pfizer, and CureVac**

BioNTech and Pfizer filed the instant suit against CureVac seeking only a declaratory judgment that CureVac’s patents—the ’312 Patent, ’278 Patent, and the ’493 Patent³—are not infringed by the COVID-19 vaccine (COMIRNATY[®]) that BioNTech created and produced with Pfizer. Compl (ECF No. 1, at ¶ 5, 17–19). In January of 2020, BioNTech initiated “Project Lightspeed”—an accelerated COVID-19 vaccine development program. *Id.* at ¶ 46. BioNTech partnered with Pfizer “on the development, manufacturing, distribution, and regulatory approval of the Pfizer-BioNTech COVID-19 vaccine.” *Id.* at ¶ 48. Both companies shared the costs of developing the vaccine, and Pfizer “activated its extensive manufacturing network and invested at risk in an effort to produce an approved COVID-19 vaccine as quickly as possible.” *Id.* at ¶¶ 49, 51.

After completing Phase 3 of the vaccine’s clinical trial, “[o]n November 20, 2020, Pfizer, on behalf of itself and BioNTech, submitted clinical trial data as part of an Emergency Use Authorization (“EUA”) request to the FDA for administering the Pfizer-BioNTech COVID-19 vaccine [COMIRNATY[®]].” *Id.* at ¶ 55. On December 11, 2020, the FDA granted the request. *Id.*

² United States Magistrate Judges may hear and decide motions to intervene which are non-dispositive. See *N. Am Specialty Ins. Co. v. Caves*, Case No. 3:22cv00050, 2023 WL 6931721, 2023, U.S. Dist. LEXIS 188383, at *n.1 (W.D.N.C. Oct. 19, 2023). The related requests to sever and stay are also non-dispositive but because they necessarily implicate trial before the District Judge, I have only recommended disposition as outlined below.

³ The following are the full names for the cited U.S. Patents: Nos. 11,135,312 (the “’312 Patent”); 11,149,278 (the “’278 Patent”), and 11,241,493 (the “’493 Patent”). Compl. (ECF No. 1, at 17–20).

at ¶ 56. COMIRNATY® “was the first mRNA drug product, and the first vaccine to target COVID-19, authorized for emergency use in the United States.” Id. at ¶ 57.

Pfizer and BioNTech allege that CureVac also attempted to develop a COVID-19 vaccine candidate (“CVnCoV”). Id. at ¶¶ 69, 70. CureVac also licensed lipid nanoparticle (“LNP”) technology from Acuitas and used the licensed technology in its COVID-19 vaccine candidate. Compl. (ECF No. 1, at ¶¶ 78, 80). Plaintiffs also contend that CureVac was aware that BioNTech had licensed LNPs from Acuitas for use with its mRNA therapeutic products. Id. at ¶ 79. However, on June 16, 2021, CureVac’s Phase 2b/3 clinical trial showed that its vaccine’s efficacy “did not meet the pre-specified statistical success criteria.” Id. at ¶ 70. In October 2021, according to Plaintiffs, CureVac withdrew its vaccine candidate from the European Medicines Agency approval process. Id. at ¶ 72.

Plaintiffs allege that CureVac N.V. first contacted BioNTech in February 2022, “seeking to initiate discussion between [the] IP counsel . . . regarding the potential licensing of certain IP rights from CureVac.” Id. at ¶ 81. CureVac also contacted Senior Patent Counsel of BioNTech, US Inc., “regarding the licensing of certain IP rights from CureVac in connection with COMIRNATY® vaccine.” Id. at ¶ 83. Although CureVac only contacted BioNTech, Plaintiffs allege that CureVac was aware “at all relevant times since the initial contact,” that Pfizer manufactured and was responsible for the distribution and sale of COMIRNATY® in the U.S. Id. at ¶ 84.

On March 29, 2022, CureVac sent BioNTech a document identifying its “purported IP portfolio,” which “included the patents-in-suit and related patents, of which the patents-in-suit are representative family members.” Id. at ¶ 87. In response, in April 2022, CureVac and BioNTech SE held a video conference and an in-person meeting. Id. at ¶ 86. Two months later, on June 9,

2022, CureVac and BioNTech SE held a meeting to discuss “CureVac’s threat to assert its patents in connection with the COMIRNATY[®] vaccine.” Id. at ¶ 88. The parties were unable to reach a resolution. Id. at ¶ 90.

On June 29, 2022, CureVac submitted an infringement complaint to the German Regional Court in Düsseldorf against BioNTech SE, BioNTech Manufacturing GmbH, and BioNTech Manufacturing Marburg GmbH, alleging that the manufacture and sale of the COMIRNATY[®] vaccine infringes European counterparts to the patents-in-suit. Id. at ¶¶ 90, 92.⁴ Plaintiffs allege that based on “CureVac’s assertion of the patents-in-suit and commencement of litigation with respect to European counterparts of such patents in connection with COMIRNATY[®] vaccine, an actual, immediate, substantial, and justiciable controversy exists between BioNTech, Pfizer, and CureVac as to whether COMIRNATY[®] vaccine has infringed or will infringe the patents in the ’493 family. Id. at ¶ 96. “CureVac’s assertion of the patents-in-suit in connection with COMIRNATY[®] vaccine has created a cloud of uncertainty ... with respect to what portion of the revenues from COMIRNATY[®] vaccine Plaintiffs may invest into [] research and development.” Id. at ¶ 97.

To address this uncertainty, Plaintiffs filed this action seeking a declaratory judgment that these patents denominated as the ’493 patent family and including U.S. Patent Nos. 11,135,312; 11,149,278, and 11,241,492—“are not infringed by the manufacture, use, offer to sell, and sale in the United States, of the mRNA vaccine against COVID-19 [COMIRNATY[®]] that BioNTech created and made available to doctors and patients with Pfizer.” Id. at ¶ 5. CureVac answered,

⁴ Although Pfizer was not named in the German infringement complaint, “when asked in a media call, CureVac’s chief executive said that he was not ruling out further legal action against BioNTech partner Pfizer.” Compl. (ECF No. 1, at ¶ 95). Plaintiffs contend that CureVac was aware of the relationship between BioNTech and Pfizer in developing and manufacturing COMIRNATY[®], and during their out-of-court discussion, “CureVac was aware that BioNTech SE was acting in the discussions with the knowledge of both BioNTech and Pfizer.”. See id. at ¶¶ 84, 85, 89.

and filed counterclaims for infringement related to the '493 patent family and additional patents, (ECF No. 56), which led BioNTech and Pfizer to assert additional counterclaims for invalidity, unenforceability, and non-infringement. (ECF Nos. 104, 106, 107, 116, 119). The additional patents—which involve other CureVac technology—do not involve Acuitas, or its LNP claims.

B. Acuitas' Relationship to the Instant Action

Acuitas is “a world leader in lipid and lipid nanoparticle (“LNP”) technologies.” Acuitas' Mem. in Supp. Mot. Intervene, Stay, Sever (“Acuitas' Mem. Supp. Combined Mot.”) (ECF No 137, at 6). LNPs “are used as a vehicle to deliver messenger RNA (“mRNA”) into a cell,” which was a key technology used in the development of COVID-19 vaccines. Id. Acuitas develops mRNA-LNP therapeutics and works with business partners who specialize in mRNA technology. Id. As relevant here, Acuitas and CureVac have a long-standing business relationship largely directed to vaccine development. Id. at 7.

Acuitas alleges that at the beginning of the COVID-19 pandemic, around January 2020, it approached CureVac and proposed working together “under their existing contractual framework to develop an mRNA vaccine for COVID-19.”⁵ Id. The two companies had previously collaborated on a successful vaccine for rabies. The company alleges that CureVac agreed to work together on the COVID-19 vaccine as well, but later “violated Acuitas' trust” by improperly taking credit for inventions the two companies jointly created. Id. at 7, 15. Specifically, Acuitas alleges that CureVac “applied for and subsequently obtained the '493 Patent Family based on Acuitas and CureVac's joint work.” Id. at 7. Acuitas alleges that “[e]ach member of the '493 patent family describes and claims inventive contributions from Acuitas' scientists,” and thus Acuitas is a co-owner of the '493 patent family. Id. at 8.

⁵ Acuitas and CureVac's partnership is governed by their jointly executed Development and Operation Agreement (“D&O”). See Acuitas and CureVac's D&O (“D&O Agreement”) (ECF No. 155-3).

In a related case also pending in this court, Acuitas contests inventorship of the '493 patent family which involves lipid nanoparticles—a critical component of the COMIRNATY® vaccine. See Acuitas Therapeutics, Inc. v. CureVac SE, No. 2:23-cv-610-JKW-DEM (E.D. Va. filed Nov. 13, 2023) (“Inventorship Action”). Because the '493 patent family is at issue in this action, Acuitas simultaneously filed its Combined Motion to Intervene, Sever, and Stay in this action to assert its inventorship interest in the '493 family.⁶ (ECF No. 136).

As a putative co-owner, Acuitas first argues that CoreVac lacks standing to assert the '493 patents because its Complaint does not include all owners of the patent as plaintiffs. It also contends that—regardless of the standing issues—it has a protectable interest in the subject matter of this litigation—namely its rights to the '493 patent family—and its interests would be impaired absent intervention, and are not adequately represented by the existing parties to the litigation. Acuitas' Mem. Supp. Combined Motion (ECF No. 137, at 8, 10–16). Acuitas also alleges that under its contractual agreements with CureVac, it has co-ownership rights, and alternatively licensing rights (with a right to sublicense), in the '493 patent family. Id. at 7. Acuitas claims that it granted BioNTech “a non-exclusive license to any and all Acuitas-controlled LNP technology, including any patents that Acuitas jointly owns and will own during the term of the license agreement.” Id. at 11. Under this agreement, Acuitas alleges that its ownership of the '493 patent family would confer a license on BioNTech, and thus CureVac's claims for infringement against BioNTech and Pfizer related to the '493 Family would fail. To preserve its ability to enforce its licensing model, Acuitas also argues that any claims raised in this action which related to the '493

⁶ One month before filing its' Combined Motion, on October 21, 2023, Acuitas requested an international arbitration to resolve its contract-based ownership claims for the '493 patent family against CureVac. CureVac's Mem. Opp'n Mot. Intervene, Sever, & Stay (“CureVac's Opp'n”) (ECF No. 155, at 11). Specifically, Acuitas seeks a declaration that the provisions of its contracts with CureVac grant it co-ownership and/or licensing rights (with a right to sublicense) in the '493 patent family. Acuitas' Mem. Supp. Combined Mot. (ECF No. 137, at 7). As explained to the court during a hearing on March 27, 2024, this arbitration proceeding is highly confidential, and the resolution timeline is unknown.

patent family should be severed and stayed, pending the resolution of the Inventorship Action and/or Acuitas' international arbitration action.

III. ANALYSIS

As explained below, the court will GRANT Acuitas' Motion to Intervene, recommend DENYING Acuitas' Motion to Sever, and recommend GRANTING Acuitas' Motion to Stay.

A. **CureVac Presently has Standing to Assert its Claims**

Acuitas first argues that intervention is required because CureVac lacks standing to assert its claims related to the '493 patent family. Because it claims to be co-owner of those patents, Acuitas argues “[a]bsent the voluntary joinder of all co-owners of a patent, a co-owner acting alone will lack standing.” Acuitas' Mem. Supp. Combined Mot. (ECF No. 137, at 12) (quoting Israel Bio-Eng'g Project v. Amgen, Inc., 475 F.3d 1256, 1264–65 (Fed. Cir. 2007)). But as CureVac observed, standing is determined at the time of filing, when Acuitas' claimed interest was only alleged. No party contests CureVac's separate status as an owner by virtue of assignments from the named inventors. CureVac's Mem. Opp'n. (ECF No. 155, at 33) (citing Sky Techs, LLC v. SAP AG, 576 F.3d 1374, 1379 (Fed. Cir. 2009)). CureVac also argues that the D&O Agreement, which governs the parties' partnership, provides each party with the unilateral right to sue. Specifically, CureVac argues that even if Acuitas were an inventor, the D&O Agreement “grants CureVac the right to bring this infringement action, and in any such action Acuitas agreed to be joined as a co-plaintiff,” and thus Acuitas “waived its right to refuse to join in this litigation.” Id. (emphasis removed); see Ethicon, Inc. v. United States Surgical Corp., 135 F.3d 1456, 1468 (Fed. Cir. 1998) (“[W]hen co-owners have granted each other a unilateral right to sue, each has waived his right not to join an infringement suit, and either of them can force the other to join a suit to collect accrued infringement damages.”). Without resolving any contract right to pursue the claim

over Acuitas' objection, the court nonetheless concludes that CureVac, as the present owner of the '493 patent family, has demonstrated that standing is proper. See Int'l Gamco, Inc. v. Multimedia Games, Inc., 504 F.3d 1273, 1276 ("Prudential standing to sue for patent infringement derives from 35 U.S.C. § 281: 'A patentee shall have remedy by civil action for infringement of his patent.');

Ethicon, Inc., 135 F.3d at 1460 ("Patent issuance creates a presumption that the named inventors are the true and only inventors.").

In general, all co-owners of a patent must be joined as plaintiffs to establish standing for an infringement suit involving that patent. See Ethicon, 135 F.3d at 1468. In this case all owners are joined. Acuitas asks the court to assume it is a co-owner, and accordingly find that "CureVac lacks standing to assert claims of the '493 Patent Family without joining Acuitas as a necessary party." Acuitas' Reply to Pl.'s Brief in Resp. to Combined Mot. (ECF No. 157, at 1). However, as of today, and when this declaratory judgment action began, Acuitas was not a co-owner of the '493 patent family. CureVac was, and still is, the sole owner of the '493 patent family and enjoys full rights of ownership—including the power to bring infringement actions. See Int'l Gamco, Inc., 504F. 3d at 1276. However, because Acuitas' claims to ownership may implicate important licensing issues that limit CureVac's assertion of the '493 family, the appropriate course of action for this court is to proceed sequentially. See Polyzen, Inc. v. Radiadyne, L.L.C., No. 5:11-cv-662-D, 2012 WL 4049841, U.S. Dist. LEXIS 131112, at *15 (E.D. N.C. Aug. 31, 2012) (rejecting a standing challenge where putative owner sought "first, correction of the '497 patent, and then dismissal"). Accordingly, as explained below, this report finds intervention is proper despite CureVac's standing to assert its claims.

B. Acuitas' Intervention of Right is Proper

Although Acuitas' claims do not presently diminish CureVac's standing, they do present a protectable interest best preserved by permitting intervention.

1. Legal Standard

Under Federal Rule of Civil Procedure 24(a), the Court must permit a party to intervene on timely motion as a matter of right who:

(1) is given unconditional right to intervene by federal statute; or (2) claims an interest relating to the property or transaction that is the subject of the action, and is so situated that disposing of the action may as a practical matter impair or impede the movant's ability to protect its interest, unless existing parties adequately represent that interest.

Fed. R. Civ. P. 24(a). To intervene as of right, the intervenor must show that it (1) filed a timely request; (2) has an interest in the subject matter of the action; (3) disposition of the action without its presence would impair or impede its ability to protect that interest; and (4) the interest is not adequately represented by the existing parties to the action. Houston Gen. Ins. Co. v. Moore, 193 F.3d 838, 839 (4th Cir. 1999); Teague v. Bakker, 931 F.2d 259, 260—61 (4th Cir. 1991). A party seeking to intervene as of right must satisfy all four requirements. Com. of Va. v. Westinghouse Elec. Corp., 542 F.2d 214, 216 (4th Cir. 1976). The intervenor's motion must state "the grounds for intervention and be accompanied by a pleading that sets out the claim or defense for which intervention is sought." Fed. R. Civ. P. 24(c) The Fourth Circuit has explained, that "[l]iberal intervention is desirable to dispose of as much of the controversy involving as many apparently concerned persons as is compatible with efficiency and due process." Feller v. Brock, 802 F.2d 722, 729 (4th Cir. 1986) (internal quotations omitted). A district court is "entitled to the full range of reasonable discretion" to determine whether the requirements of intervention as a matter of right

have been met. Westinghouse, 542 F.2d at 216 (4th Cir. 1976) (quoting Rios v. Enter. Ass'n Steamfitters Local U. # 638 of U.A., 520 F.2d 352, 355 (2d Cir. 1975)).

2. Discussion

Acuitas' motion to intervene is premised on both protecting its interest in licensing its LNP technology, and preventing CureVac from asserting the '493 family of patents against its licensee. CureVac opposes the motion, first claiming it does not meet the procedural requirements of Rule 24. CureVac's Mem. Opp'n Combined Mot. (ECF No. 155). Specifically, CureVac alleges that Acuitas failed to "set forth the claim or defense for which intervention is sought," and there is no defense based on a "license or incorrect inventorship. CureVac's Mem. Opp'n Combined Mot. (quoting Fed. R. Civ. P. 24(c)). (ECF No. 155, at 9, 15—16). Although Acuitas did not lodge a pleading with its motion to intervene, Acuitas referred to its contemporaneously filed Inventorship Action, and explains that it "is intervening to adjudicate all claims related to the '493 Patent Family because, if Acuitas prevails in either its Inventorship or Arbitration Complaints, CureVac will have no claim (e.g., infringement) related to those patents in this action." Acuitas' Reply in Supp. Combined Mot. (ECF No. 169, at 11). The Inventorship Complaint clearly informs the parties and the court of Acuitas' claims.

a. CureVac is not unduly prejudiced by Acuitas' delay in filing.

"Timeliness is a central consideration when deciding a motion to intervene, and a movant's failure to seek intervention in a timely manner is sufficient to justify denial of such motion." Scott v. Bond, 734 F. App'x 188, 191–92 (4th Cir. 2018). When assessing the timeliness of a motion to intervene, courts in this Circuit consider three factors: (1) how far the underlying case has progressed, (2) the prejudice any resulting delay might cause the other parties, and (3) the reason for any tardiness in filing the motion. Bumgardner v. Boothe, 798 F. App'x 770, 771 (4th Cir.

2020); Scott, 734 F. App'x at 191 (quoting Alt v. EPA, 758 F.3d 588, 591 (4th Cir. 2014)). The second factor is the most important when considering a motion to intervene—whether the existing parties will suffer prejudice if the motion is granted. Scott, 734 F. App'x at 191.

Acuitas argues that its motion to intervene is timely, and does not prejudice the parties because it filed the request when the case was just beginning. Responsive pleadings were completed on August 8, 2023, initial disclosures were exchanged on November 8, 2023, the court held a Rule 16(b) scheduling conference on October 31, 2023, and Acuitas' motion to intervene was filed in November one day before the Scheduling Order deadline for any motion for joinder of additional parties. Acuitas' Mem. Supp. Combined Mot. (ECF No. 137, at 5, 10). Acuitas also explained that its delay was, in part, caused by its attempt “to reach a business resolution with CureVac on a number of issues, including the dispute of the '493 Patent Family and the inventorship of the '493 Patent Family raised in Acuitas' Inventorship Complaint.” Id. at 10. Almost immediately after these negotiations failed, Acuitas initiated arbitration proceedings in the United Kingdom, filed the Inventorship Complaint, and filed the instant motion to intervene, stay, and sever. Id.

CureVac argues that Acuitas filed the motion fifteen months after BioNTech and Pfizer initiated this declaratory judgment action in Massachusetts. Despite this significant delay, the court finds that the existing parties will not be unduly prejudiced if Acuitas' motion to intervene is granted. Here, only CureVac alleges that Acuitas' delay has caused it prejudice, contending that “Acuitas could have brought its arbitration and inventorship claims long ago.” CureVac's Mem. Opp'n Combined Mot. (ECF No. 155, at 18). But its claim that the delay could prevent CureVac from ever collecting damages for infringement of the '493 patent family by the doctrine that bars double recovery for the same acts of infringement, is unrelated to any delay in seeking intervention,

and can be avoided by a comprehensive stay. Moreover, CureVac also had notice all along that Acuitas was challenging the inventorship of the '493 patent family; that it had license agreements with BioNTech; and that it believed CureVac lacked any ability to assert these patents against the COMIRNATY® vaccine. Thus, the arguments raised by Acuitas should not come as a surprise. Once the issue of inventorship is resolved, CureVac will have the opportunity to pursue or reexamine its claims.

b. Acuitas has a significantly protectable interest in the subject matter of the action.

“While Rule 24(a) does not specify the nature of the interest required for a party to intervene as a matter of right, the Supreme Court has recognized that ‘what is obviously meant . . . is a significantly protectable interest.’” Teague, 931 F.2d at 261 (quoting Donaldson v. United States, 400 U.S. 517, 531, 27 L. Ed. 580, 91 S. Ct. 534 (1971)). Where the proposed intervenors “stand to gain or lose by the direct legal operation of the district court’s judgement,” such intervenors have a significantly protected interest.” Id. The Fourth Circuit held that a proposed intervenor must demonstrate a “direct” interest in the proposed action that “bear[s] a close relationship to the dispute between the existing litigants.” Dairy Maid Dairy v. United States, 147 F.R.D. 109, 111 (E.D. Va. 1993). The Fourth Circuit has also ruled that “an interest contingent on the outcome of other pending litigation qualifies as ‘significantly protectable interest.’” Teague, 931 F.2d at 261.

Here, Acuitas has demonstrated a significantly protectable interest in this action. Acuitas contends that it is a co-owner of the '493 patent family, and that CureVac’s infringement claims against BioNTech and Pfizer would harm its interests because (1) Acuitas did not consent to CureVac’s infringement actions, and (2) Acuitas already licensed its patents—including any ownership it may acquire in the '493 patent family—to BioNTech. Thus, Acuitas stands to “gain

or lose by the direct legal operation of [this Court's] determination" as to whom CureVac is entitled to sue and if Acuitas' licensees (including BioNTech and Pfizer) hold a valid license to the '493 patent family. See Teague, 931 F.2d at 261. Acuitas thus has a protectable interest in preserving control over its LNP innovations and protecting its partner, BioNTech, from infringement actions based on that technology. Acuitas' Mem. Supp. Combined Mot. (ECF No. 137, at 11–12) (explaining that Acuitas has a "need to protect its business interests, including by preventing CureVac from using patents that Acuitas rightfully co-owns to threaten and sue Acuitas' other partners [i.e., BioNTech]."). Acuitas' interest in this action is therefore direct, and not "remote or contingent." Dairy Maid Dairy, 147 F.R.D. at 111.

c. Acuitas' interests may be impaired by trial before resolving its inventorship claims.

"The third requirement for intervention of right requires a showing that 'disposition of the action may practically impair or impede the movant's ability to protect [its] interest.'" Maxum Indem. Co. v. Biddle Law Firm, PA, 329 F.R.D. 550, 555 (D.S.C. Jan. 17, 2019) (quoting Newport News Shipbuilding & Drydock Co. v. Peninsula Shipbuilders' Ass'n, 646 F.2d 117, 120 (4th Cir. 1981)).

Acuitas contends that it has a "property interest in the '493 Patent Family, and exclusion from this case would impair Acuitas' ability to protect that interest." Acuitas' Mem. Supp. Combined Mot. (ECF No. 137, at 13) ("For example, Acuitas, as the rightful co-owner of the '493 Patent Family, has an interest in licensing those patents and deciding who is accused of patent infringement."). Acuitas also alleges that its "interests in receiving credit for its jointly developed inventions will be impaired if Acuitas is excluded from participating in this case in which the Court is asked to decide the validity and infringement of patents covering Acuitas' joint inventions." Id. Acuitas finally alleges that it has a "business interest in preventing litigations between two of its

partners,” and its “business model is based on licensing its technology to partners free and clear from patent infringement threats.” Id. at 14.

Here, a decision in favor of or against BioNTech and Pfizer on CureVac’s claims related to the ’493 family could impair Acuitas’ interests in protecting and profiting from its innovations in the subject matter of this litigation. If Acuitas is correct that its scientists made inventive contributions to the ’493 patent family that require recognition as owners, then a decision in favor of CureVac would have serious implications for Acuitas’ licensing model of innovation. But a decision in favor of Plaintiffs against CureVac could also impair Acuitas’ interest, given the invalidity defenses raised in the pleadings. Accordingly, Acuitas’ interests may be impaired by resolution of the claims pending in this case.

d. BioNTech, Pfizer, and CureVac do not adequately represent Acuitas’ interests.

Finally, a party seeking to intervene as of right must demonstrate inadequate representation of its interests by the existing parties in the litigation. United Guaranty Residential Ins. Co. v. Phila. Sav. Fund Soc’y, 819 F.2d 473, 475 (4th Cir. 1987). The “burden of showing an inadequacy of representation is minimal.” Va. v. Westinghouse Elec. Corp., 542 F.2d 214, 216 (4th Cir. 1976) (citing Trbovich v. UMWA, 404 U.S. 528, 538, 92 S. Ct. 630, 636, 30 L. Ed. 2d 686 (1972)). Many factors may suggest inadequate representation, including divergent interests. See In re Sierra Club, 945 F.2d 776, 780–81 (4th Cir. 1991) (finding an abuse of discretion in denying intervention of right due to the divergence of interests between the Sierra Club, which represented environmental activists, and a South Carolina environmental agency, which represented all state citizens). New legal arguments from the applicant may also suggest inadequate representation. JLS, Inc. v. Pub. Serv. Comm’n of W. Va., 321 F. App’x 286, 291 (4th Cir. 2009 March 20, 2009) (unpublished) (“Movants have also advanced some significant legal points that PSC did not present.”). Finally,

if the applicant has superior knowledge and stronger incentives, that may also suggest inadequate representation. *Id.* at 291 (“These factual challenges support Movants’ claims that their superior knowledge of railroad crew transportation and their greater incentive to defeat JLS gives them a significant advantage over PSC in their ability to litigate this case.”).

CureVac argues that BioNTech, and Pfizer are able to adequately represent Acuitas’ interests in this action to the extent they differ from CureVac’s, but this is only partially correct. Although BioNTech and Pfizer can assert the Acuitas’ license, and inventorship defenses, against CureVac’s infringement claims related to the ’493 family, they are not a party to the D&O Agreement between Acuitas and CureVac and cannot represent Acuitas’ rights under that agreement. Acuitas’ Mem. Supp. Combined Mot. (ECF No. 137, at 15). Acuitas and CureVac disagree as to what rights they each have under the D&O Agreement, and Pfizer/BioNTech are not parties to this agreement. Thus, absent intervention, Acuitas would be unable to protect its alleged rights as a co-owner and licensor under the D&O Agreement.

Acuitas also points out that BioNTech and Pfizer cannot fully represent its interests because they have “made no inventive contribution to, and do not co-own the ’493 Patent Family.” *Id.* Acuitas has a significantly protectable interest in defending its own right to license the ’493 family, to protect its innovative contributions and financial interest in licenses with all its partners—not just BioNTech and Pfizer. Accordingly, no other party to this action can adequately represent Acuitas’ interests as an alleged co-owner and licensor.

C. Motion to Sever

Having determined that intervention is proper, Acuitas next argues that the pending claims related to the ’493 family patents should be severed, and trial of those claims stayed until both the inventorship claims and international arbitration are resolved.

1. Legal Standard

Federal Rule of Civil Procedure 21 allows the Court to, “on motion or on its own . . . add or drop a party. The Court may also sever any claim against a party.” Fed. R. Civ. P. 21. The “court has virtually unfettered discretion in determining whether or not severance is appropriate.” 17th St. Assocs., LLP v. Markel Int’l Ins. Co., 373 F. Supp. 2d 584, 598 n.9 (E.D. Va. 2005). In applying this discretion, district courts within the Fourth Circuit consider the following eight factors:

(1) whether the issues sought to be tried separately are significantly different from one another; (2) whether the separable issues require different witnesses and different documentary proof; (3) whether the party opposing severance will be prejudiced if it is granted; . . . (4) whether the party requesting severance will be prejudiced if the claims are not severed[;] . . . (5) fundamental fairness[;] (6) judicial economy[;] (7) undue delay[;] and (8) the dual threat of duplicative litigation and inconsistent verdicts.

Moulvi v. Safety Holdings, Inc., No. 3:20cv595, 2021 U.S. Dist. LEXIS 189496, 2021 WL 4494191, at *6 (E.D. Va. Sept. 30, 2021) (quoting Rai Strategic Holdings, Inc. v. Altria Client Servs. LLC, No. 1:20cv393, 2020 U.S. Dist. LEXIS 221703, 2020 WL 6882646, at *2 (E.D. Va. Sept. 3, 2020) and Latson v. Clarke, No. 1:16cv447, 2016 U.S. Dist. LEXIS 195277, 2016 WL 11642365, at *3 (E.D. Va. Oct 14, 2016)).

2. Severance would create new obstacles to a complete, efficient resolution.

Acuitas contends that the claims related to the ’493 patent family should not proceed to trial with the other claims because if it obtains a favorable decision in either its international arbitration action or the Inventorship Complaint, the claims related to the ’493 Patent Family could be dismissed or rendered unnecessary. Acuitas’ Mem. Supp. Combined Mot. (ECF No. 137, at 18). Its request to sever makes sense in the context of its intervention pleadings. It only has an

interest in the '493 patent family, as described in its Inventorship Complaint, and thus seeks to sever solely those claims and defenses related to the '493 patent family.

But upon joining Acuitas as a party in this action, severing the '493 Patent Family would result in additional complications that can be avoided by staying the case altogether. First, if only the '493-related claims and defenses are severed and stayed, that may result in multiple trials to resolve the infringement questions presented in this action. These trials would necessarily involve exploring many of the same factual issues as they involve the same parties, the same accused product, and very similar technology. If litigation of the remaining patents continues now, and—if Acuitas is unsuccessful in its Inventorship Action—Pfizer, BioNTech, and CureVac would then have to resurrect litigation involving the '493 Patent Family and try all those issues again. Although “[m]ore than one trial on distinct patents is not uncommon,” this action concerns whether one vaccine—COMIRNATY®—infringes all of CureVac’s asserted patents-in-suit. See Pfizer & BioNTech’s Br. in Supp. Acuitas’ Combined Mot. (ECF No. 150, at 8).

Additionally, as discussed at oral argument, the prosecution history of the '493 Patent Family may complicate the resolution of inventorship question. See Hearing Transcript from March 27, 2024 (ECF No. 251, at 78–79). As described during oral argument, and presented in CureVac’s Answer to the Inventorship Complaint, CureVac raised the affirmative defense of equitable estoppel with respect to U.S. Patent Nos. 11,576,966 (the “’966 Patent) and 11,596,686 (the “’686 Patent”), both patents of the '493 Family. See Acuitas Therapeutics, Inc. v. CureVac SE, No. 2:23-cv-610-JKW-DEM (E.D. Va. filed Nov. 13, 2023), CureVac’s Answer to Inventorship Complaint (ECF No. 25, at 25–27). CureVac alleges that on September 14, 2022, it received a letter from Acuitas’ counsel—the “Groombridge Letter”—that “disavowed any claim by Acuitas to inventorship with respect to any patent claims that cite LNPs generically.” Id. at 25,

26 (internal citation and quotation omitted). CureVac contends that in the letter, and in communications prior to receiving the letter, “Acuitas represented that the issues could be resolved by reissuing the then issued ’493 Patent to remove reference to the specific lipids recited in the ’493 Patent claims and instead limit the claims to a generic LNP.” Id. CureVac alleges it relied on these representations, and on August 9, 2022, it filed a U.S. Patent Application with claims that recite a generic LNP, and on March 7, 2023, was issued as the ’686 Patent. Id. at 27. Then, on September 19, 2022, CureVac amended claims within a pending Patent Application, and replaced all references to specific LNPs with generic LNPs. Id. at 25. That patent was issued on February 14, 2023, as the ’966 Patent. Id. Both the ’686 and ’966 patents are part of the ’493 Family.

Despite CureVac’s changes, on November 13, 2023, Acuitas filed its Inventorship Complaint and contends that its employees should be named inventors of the ’686 and ’966 patents as well as the ’493 patent. Id. at 25–26. Because Acuitas could be estopped from claiming Inventorship of the two, amended patents, but granted inventorship over the ’493 which recites a specific LNP, the Inventorship Action could result in a finding of different inventors among those patents within the ’493 Patent Family. If that occurred, instructing the jury on these various claims would greatly complicate an already complicated case, and would not cure the problem that Acuitas seeks to resolve in severing the ’493 claims and allowing others to proceed. For these reasons, I recommend denying Acuitas’ motion to sever. However, the interests of judicial economy sought by Acuitas in its motion to sever can be met by staying the entire case until this court resolves the inventorship questions.

D. Motion To Stay

1. Legal Standard

"The power to stay proceedings is incidental to the power inherent in every court to control disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants." Landis v. N. Am. Co., 299 U.S. 248, 254, 57 S. Ct. 163, 81 L. Ed. 153 (1936). When considering a motion to stay, district courts generally consider three factors: "(1) judicial economy, (2) hardship and equity to the moving party if the action is not stayed, and (3) potential prejudice to the non-moving party." Brown v. Energy Servs. Grp. Int'l, Inc., Case No. 3:21-cv-611, 2022 WL 2161034, 2022 U.S. Dist. LEXIS 106481, at *8 (E.D. Va. June 14, 2022). This court has the discretion to grant a motion to stay under its general equity power. Williford v. Armstrong World Industries, Inc., 715 F.2d 124, 127 (4th Cir. 1983). In considering a discretionary stay, a court exercises its own judgment and "must weigh competing interests and maintain an even balance." Id. (quoting Landis v. North American Co., 299 U.S. 248, 254-55, 57 S. Ct. 163, 81 L. Ed. 153 (1936)).

2. Acuitas' Motion to Stay which both BioNTech & Pfizer joined, should be granted.

Acuitas seeks a stay of the claims and defenses raised in this action that relate to the '493 Patent Family—ECF No. 1, Count III; ECF No. No. 106, Counts VIII–XI; ECF No. No. 116, Count VII–X, XV–XVII, affirmative defenses seven to ten and seventeen to twenty. (ECF No. 137, at 15–16). BioNTech and Pfizer filed a brief supporting a stay, and arguing that a stay of the entire case was necessary. Pfizer & BioNTech's Br. in Supp. Acuitas' Combined Mot. (ECF No. 150, at 8). The court finds that the relevant factors weigh in favor of granting a stay of all claims and defenses, pending the outcome of Acuitas' inventorship claims. The Inventorship Action contests inventorship of the '493 Patent Family, which involve a critical component of the

COMIRNATY[®] vaccines—lipid nanoparticles. See *Acuitas Therapeutics, Inc. v. CureVac SE*, No. 2:23-cv-610-JKW-DEM (E.D. Va. Filed Nov. 13, 2023). Although BioNTech/Pfizer originally sought a declaratory judgment that CureVac’s ’493 patent family is not infringed by their COVID-19 vaccine, COMIRNATY[®], CureVac counterclaimed seeking a judgement that the COMIRNATY[®] vaccine infringed the ’493 patent family. Compl (ECF No. 1, at 2); CureVac’s Answer and Counterclaims (ECF No. 56). BioNTech also specifically alleges that it licensed LNP technology recited in the ’493 patent family from Acuitas. The resolution of these infringement claims therefore depends substantially on whether Acuitas becomes a named co-inventor of the ’493 Patent Family. If, for example, Acuitas loses the inventorship action, then CureVac remains the sole-owner of the ’493 Patent Family and BioNTech/Pfizer would have to defend against infringement without regard to Acuitas’ alleged license. Conversely, if Acuitas wins the Inventorship Action, that may implicate the D&O Agreement between Acuitas and CureVac. In that case, the court may require additional briefing to determine whether the pending international arbitration presents obstacles to the claims and defenses raised in this action.

Because the Inventorship Action implicates the resolution of this case, and it can be resolved relatively promptly,⁷ this report recommends staying this action pending the determination of the inventorship suit. Staying the entire action will save substantial judicial resources and avoid multiple trials between the same parties, concerning the same COVID-19 vaccine. Additionally, by staying this action until the issue of inventorship is resolved, the court will simplify the issues in this case that may be presented to a jury and will remove the risk of receiving a jury verdict that is subsequently vacated because of the court’s decision in the

⁷ The Inventorship Action was filed in this court and is before the same judges—United States District Judge Jamar K. Walker and United States Magistrate Judge Douglas E. Miller. It was recently set for trial, thus the schedule of both action’s remains within the court’s control. Inventorship Action, Scheduling Order (ECF No. 37).

Inventorship Action. Lastly, staying this action should avoid any issue related to the double recovery concerns raised by CureVac. See CureVac’s Mem. Opp’n Combined Mot. (ECF No. 155, at 18).

In Centripetal Networks, LLC v. Keysight Techs., Inc., the court considered a related issue on a motion to stay. No. 2:22-cv-2, 2023 WL 5127163, 2023 U.S. Dist. LEXIS 142014 (E.D. Va. Mar. 20, 2023). There, Centripetal asserted eleven of its patents against an accused infringer and filed a complaint with the International Trade Commission (“ITC”) concerning three of the same patents and the same accused infringing product. Id. Keysight sought a mandatory stay the claims related to the three ITC-Instituted Patents, and a discretionary stay of claims related to the remaining patents. Id. at *7. Centripetal opposed the stay and argued, among other things, that it would “inflict irreparable harm to [its’] business reputation.” Id. at *13. The court observed that “Centripetal [was] correct that the ITC investigation [would] not resolve all, or even most, of the issues between the parties in this action; however, a stay will still greatly simplify the matters before the Court.” Id. at *12. The court also noted that after the stay, the claims may need to proceed on “two different tracks,” but that it would be in a “better position to make that decision after the ITC’s initial determination.” Id. at *13–*14.

CureVac argues that this case is factually distinguishable from Centripetal, however, its central holding remains relevant—staying the proceeding significantly simplifies matters before the court, and the alleged prejudice to the non-moving party does not outweigh the other factors favoring a stay. Id. at *16–17; see CureVac’s Mem. Opp’n Combined Mot. (ECF No. 156, at 35). BioNTech and Pfizer initially brought this action to vindicate the COMIRNATY[®] vaccine against claims of infringement based on the ’493 patent family. These claims predominate in this suit, and

thus staying the proceeding and awaiting resolution of the '493 inventorship suit will greatly simplify the trial of the other claims.

For these reasons, the court recommends GRANTING Acuitas' Motion to Stay, and staying the entire proceeding until resolution of the Inventorship Action. Once the Inventorship Action is resolved, ~~the court may require additional~~ briefing as to whether a further stay is necessary pending the resolution of the international arbitration.

IV. CONCLUSION

For the foregoing reasons, the court GRANTS Acuitas' Motion to Intervene, (ECF No. 138), recommends DENYING Acuitas' Motion to Sever, and recommends GRANTING Acuitas' Motion to Stay. (ECF No. 138).

V. REVIEW PROCEDURE

By copy of this report and recommendation, the parties are notified that pursuant to 28 U.S.C. § 636(b)(1)(C), **with respect to the relief recommended in this report:**

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

April 12, 2024