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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

ACUITAS THERAPEUTICS INC.,

Plaintiffs,

v.

ARBUTUS BIOPHARMA CORP. and GENEVANT
SCIENCES GMBH,

Defendants.

Civil Action No. 3:23-4200-ZNQ-TJB

**DEFENDANTS' NOTICE OF
MOTION TO DISMISS PLAINTIFF
ACUITAS THERAPEUTICS INC.'S
COMPLAINT PURSUANT
TO RULE 12(b)(1)**

Motion Date: November 6, 2023

ORAL ARGUMENT REQUESTED

Document Filed Electronically

TO: All Counsel of Record

PLEASE TAKE NOTICE that on **Monday, November 6, 2023 at 10:00 a.m.**, or as soon thereafter as counsel may be heard, Defendants Arbutus Biopharma Corp. and Genevant Sciences GmbH (collectively, “Defendants”) shall appear before the Honorable Zahid N. Quraishi, U.S.D.J. at the Clarkson S. Fisher Building & U.S. Courthouse, 402 East State Street, Courtroom 4W, Trenton, New Jersey 08608, and shall move this Court for an Order dismissing Plaintiff Acuitas Therapeutics Inc.’s (“Plaintiff”) Complaint against them pursuant to Federal Rule of Civil Procedure 12(b)(1) for lack of subject matter jurisdiction.

PLEASE TAKE FURTHER NOTICE that in support of their Motion, the Defendants shall rely upon their Brief, the Declaration of Nicola R. Felice (with exhibits), submitted concurrently herewith, any Reply papers to be submitted, and oral argument, if any. A proposed form of Order is also submitted for the Court’s consideration.

Dated: October 13, 2023

Respectfully submitted,

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**BRIEF IN SUPPORT OF DEFENDANTS'
MOTION TO DISMISS THE COMPLAINT**

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TABLE OF CONTENTS

	Page
INTRODUCTION	1
BACKGROUND	4
A. The Defendants’ Patents And The Vaccine	4
B. Procedural History	6
LEGAL STANDARDS	8
ARGUMENT	9
I. THE COMPLAINT SHOULD BE DISMISSED FOR LACK OF SUBJECT MATTER JURISDICTION	9
A. The Complaint Does Not Allege A Reasonable Potential Of Indirect Infringement Liability	10
1. Contributory Infringement	10
2. Induced Infringement	13
B. The Complaint Does Not Allege A Reasonable Potential Of Indemnity Liability	15
C. The Complaint Does Not Allege Jurisdiction Based On Possible Economic Harm In Potential Future Business Dealings	19
D. The Complaint Does Not Even Allege A Controversy Between Defendants And Pfizer/BNT For Five Patents	21
II. THE COURT SHOULD EXERCISE ITS DISCRETION TO DECLINE TO HEAR THIS DECLARATORY JUDGMENT ACTION	22
CONCLUSION	25

TABLE OF AUTHORITIES

<u>Cases</u>	<u>Page</u>
<i>Acra Turf Club, LLC v. Zanzuccki</i> , 561 F. App'x 219 (3d Cir. 2014)	23
<i>Acuitas Therapeutics Inc. v. Genevant Scis. GmbH et al.</i> , No. 22-cv-02229-MKV (S.D.N.Y.)	3
<i>Adenta GmbH v. OrthoArm, Inc.</i> , 501 F.3d 1364 (Fed. Cir. 2007).....	9
<i>Allied Min. Prod., Inc. v. Osmi, Inc.</i> , 870 F.3d 1337 (Fed. Cir. 2017).....	20
<i>Alnylam Pharms., Inc. v. Pfizer, Inc.</i> , No. 22-336 (D. Del. Mar. 17, 2022), Dkt. 13	6
<i>Arbutus Biopharma Corp. et al. v. Pfizer Inc. et al.</i> , No. 3:23-cv-01876-ZNQ (D.N.J.).....	1
<i>Arris Grp., Inc. v. Brit. Telecommunications PLC</i> , 639 F.3d 1368 (Fed. Cir. 2011).....	11, 12, 20
<i>Asia Vital Components Co. v. Asetek Danmark A/S</i> , 837 F.3d 1249 (Fed. Cir. 2016).....	20
<i>Bio-Tech. Gen. Corp. v. Genentech, Inc.</i> , 80 F.3d 1553 (Fed. Cir. 1996).....	24
<i>In re Burlington Coat Factory Sec. Litig.</i> , 114 F.3d 1410 (3d Cir. 1997).....	5
<i>Commc'ns Test Design, Inc. v. Contec, LLC</i> , 952 F.3d 1356 (Fed. Cir. 2020).....	22
<i>Creative Compounds, LLC v. Starmark Lab'ys</i> , 651 F.3d 1303 (Fed. Cir. 2011).....	21
<i>Fiskars, Inc. v. Hunt Mfg. Co.</i> , 221 F.3d 1318 (Fed. Cir. 2000).....	24
<i>Gould Elec. Inc. v. United States</i> , 220 F.3d 169 (3d Cir. 2000).....	9, 15, 18

Hartig Drug Co. v. Senju Pharm. Co.,
836 F.3d 261 (3d Cir. 2016).....18

Hoots v. Commonwealth of Pa.,
672 F.2d 1133 (3d Cir. 1982).....24

Intel Corp. v. Future Link Sys., LLC,
No. CV 14-377-LPS, 2015 WL 649294 (D. Del. Feb. 12, 2015).....12

MedImmune, Inc. v. Genentech, Inc.,
549 U.S. 118 (2007).....8

Microchip Tech., Inc. v. Chamberlain Grp., Inc.,
441 F.3d 936 (Fed. Cir. 2006).....20

Microsoft Corp. v. DataTern, Inc.,
755 F.3d 899 (Fed. Cir. 2014)..... passim

Mitek Sys., Inc. v. United Servs. Auto. Ass’n,
34 F.4th 1334 (Fed. Cir. 2022) passim

Pension Ben. Guar. Corp. v. White Consol. Indus., Inc.,
998 F.2d 1192 (3d Cir. 1993).....5

Prasco, LLC v. Medicis Pharm. Corp.,
537 F.3d 1329 (Fed. Cir. 2008).....19

Priore v. Caravan Ingredients, Inc.,
No. CIV. 13-5229 KSH CLW, 2014 WL 2931182 (D.N.J. June 30, 2014).....18

Rules / Statutes

35 U.S.C. § 287(a)5

Fed. R. Civ. P. 12(b)(1).....1, 5

INTRODUCTION

Acuitas Therapeutics Inc. (“Acuitas”) filed this declaratory judgment action against Genevant Sciences GmbH (“Genevant”) and Arbutus Biopharma Corp. (“Arbutus” and, together with Genevant, “Defendants”) with respect to ten patents that Arbutus owns and licensed to Genevant (“Defendants’ Patents”). The Complaint seeks declarations that the manufacture, use, offer to sell, and sale of the COVID-19 vaccine COMIRNATY® (“Comirnaty”) does not infringe any claim of Defendants’ Patents and that the patents are invalid. Comirnaty is manufactured and sold by nonparties Pfizer, Inc. (“Pfizer”) and BioNTech SE (“BNT”). Defendants hereby move to dismiss the Complaint for lack of subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1) because Acuitas has not met its burden to allege an actual controversy between Acuitas and Defendants. In the alternative, the Court should exercise its discretion to decline to hear this declaratory judgment action.

The Complaint’s allegations do not establish a controversy between Acuitas and Defendants, because there is none. Acuitas does not make or sell Comirnaty, which is the sole product at issue, and Defendants have never accused Acuitas of infringing Defendants’ Patents or indicated an intent to sue Acuitas. Indeed, the Complaint does not allege that Defendants have ever accused Acuitas of infringing Defendants’ Patents (whether directly or indirectly), that Defendants have ever sent Acuitas any communication regarding Comirnaty whatsoever, or that Defendants have ever tried to stop Acuitas from licensing or supplying any lipid or LNP technology to Pfizer/BNT for use in Comirnaty. The only controversy is between Defendants and the nonparties Pfizer and BNT, which make and sell Comirnaty—a controversy that is currently being litigated in a separate action pending before this Court which does not involve Acuitas. *See Arbutus Biopharma Corp. et al. v. Pfizer Inc. et al.*, No. 3:23-cv-01876-ZNQ (D.N.J.) (the “Pfizer/BNT Action”). The Complaint should therefore be dismissed.

Acuitas argued three bases for subject matter jurisdiction in its recent letter to the Court (D.I. 9), but none of its theories withstands scrutiny. **First**, Acuitas asserts that there is a case or controversy between Defendants and Acuitas based on a potential claim of indirect infringement (*i.e.*, contributory or induced infringement). Acuitas does not allege that it indirectly infringes Defendants' Patents, unsurprisingly, and Defendants have made no assertions from which Acuitas can contend that it could be liable for contributory or induced infringement. Specifically, Defendants have never alleged that the lipids that Acuitas licenses to Pfizer and BNT are unsuitable for substantial noninfringing uses or that Acuitas encouraged Pfizer and BNT to infringe. Acuitas therefore has no basis to allege that it faces potential liability for indirect infringement.

Second, Acuitas alleges that it has received indemnity demands from BNT as to liability that BNT may incur in the Pfizer/BNT Action. Those allegations are insufficient because, under binding Federal Circuit authority, bare indemnity demands do not create subject matter jurisdiction. *Mitek Sys., Inc. v. United Servs. Auto. Ass'n*, 34 F.4th 1334, 1345-46 (Fed. Cir. 2022). A declaratory judgment plaintiff must instead allege *facts* showing a *reasonable potential* of indemnity liability. The Complaint here alleges nothing of the sort.

Notably, Acuitas's failure to allege facts concerning its purported indemnity liability is not an unintentional omission but rather evidence of the fundamental shortcoming of its jurisdictional theory. Acuitas has now had multiple opportunities to plead subject matter jurisdiction adequately, yet it has never provided any factual basis for its alleged reasonable potential of indemnity

liability.¹ Moreover, it has repeatedly resisted providing the alleged indemnity demands or an unredacted indemnity agreement to Defendants.²

Third, in its response to Defendants’ premotion letter, Acuitas argued that jurisdiction exists because of harm Acuitas may purportedly incur in its business dealings with other customers. That theory was not asserted as a basis for jurisdiction in the Complaint, which includes a specific section entitled “Jurisdiction and Venue” that never mentions this new ground. D.I. 1 at 16. But the theory fails in any event because it is based on a hypothetical future harm, rather than the concrete injury required to establish subject matter jurisdiction.

Moreover, even if one of Acuitas’s three foregoing arguments were correct (they are not), there is a separate, independent, and indisputable reason for dismissal of Acuitas’s declaratory judgment claims as to at least five of Defendants’ Patents. Specifically, Defendants have not asserted those patents in the Pfizer/BNT Action, nor have Pfizer and BNT asserted counterclaims on those patents against Defendants. Acuitas’s claims regarding those patents should be dismissed on that basis as well.

Finally, even if Acuitas could establish subject matter jurisdiction (it cannot), the Court should exercise its discretion to decline to hear this declaratory judgment action because

¹ Acuitas previously sued Defendants in the Southern District of New York, asserting claims substantively identical to those here based on equally threadbare jurisdictional allegations. *See Acuitas Therapeutics Inc. v. Genevant Scis. GmbH et al.*, No. 22-cv-02229-MKV (S.D.N.Y.) (the “SDNY Action”). When Defendants noted the lack of subject matter jurisdiction in a premotion letter there, Acuitas took the opportunity to amend its Complaint but chose not to disclose or meaningfully describe the scope and terms of any indemnity agreement or the basis or potential merits of any indemnity demands. When Acuitas then voluntarily dismissed the SDNY Action and refiled here, it again chose not to describe or disclose any factual basis for its purported potential of indemnity liability.

² On the afternoon before the present brief was due to be filed, Acuitas proposed to send a redacted version of the agreement subject to multiple unacceptable terms and conditions. Defendants rejected that belated and unreasonable proposal.

Pfizer/BNT are sufficiently representing Acuitas's interest in the Pfizer/BNT Action. Proceeding with this action would merely complicate the issues already pending before the Court by introducing patents not relevant to the Pfizer/BNT Action and needlessly create additional issues relating to damages and discovery. Those facts favor discretionary dismissal.

The Court should dismiss Acuitas's Complaint for lack of subject matter jurisdiction or, in the alternative, in the exercise of its discretion.

BACKGROUND

A. The Defendants' Patents And The Vaccine

Genevant is a technology-focused nucleic acid delivery company and a world leader in the lipid nanoparticle ("LNP") space, with the industry's most robust and expansive LNP patent portfolio and decades of expertise in nucleic acid drug delivery and development. Genevant has licensed LNP-related patents from Arbutus, which is a clinical-stage biopharmaceutical company with deep virology expertise and an unwavering focus on curing a variety of conditions. Defendants' Patents cover important aspects of LNP technology for delivering RNA to cells in the body for therapeutic effect and are generally directed to nucleic acid lipid particles comprising specific types of lipids, sometimes in required ratios. *See, e.g.*, Dkt. 1-1 (U.S. Patent No. 8,058,069, claim 1). All of Defendants' Patents require both a nucleic acid (*e.g.*, mRNA) and an LNP with specific lipid types.

Genevant and BNT have a long history of collaboration on LNP-related research and development programs. In 2018, BNT licensed Defendants' Patents from Genevant, among other patents, in connection with BNT's development of therapeutics in the oncology field. Pfizer/BNT Action, D.I. 1 ¶ 6. This 2018 license was limited, however, to the development of certain cancer or rare disease treatments and did not cover infectious diseases such as COVID-19. *Id.*

Accordingly, on November 23, 2020, Defendants sent a letter to Pfizer/BNT asking for the opportunity to discuss a partnering arrangement that would enable Pfizer/BNT to benefit from Genevant scientists' extensive expertise with the formulation and manufacture of LNP delivery systems and welcoming discussions of licensing Defendants' Patents. D.I. 1 ¶ 35. On October 12, 2021, Defendants sent a second letter identifying another Arbutus patent relevant to the proposed discussion. *Id.* ¶ 36. And on June 3, 2022, Defendants sent a third letter identifying two more newly issued patents. *Id.* ¶ 37. These letters also noted, under 35 U.S.C. § 287(a), that the making, using, selling, offering for sale, or importing into the United States of Comirnaty may infringe Defendants' Patents. *See* D.I. 1 ¶¶ 35-37; Exs. A, B, & C.³ The letters did not analyze potential infringement claims (*e.g.*, by attaching claim charts).

Defendants did not publicize the foregoing letters, nor did they send them to Acuitas. There was no reason to send them to Acuitas, whose only connection to Comirnaty is to license technology to Pfizer and BNT for use in Comirnaty. For example, although Pfizer/BNT have alleged that two of the lipids in Comirnaty implicate technology disclosed in Acuitas's patents, they have not alleged that Pfizer/BNT actually obtain those lipids (or any other component of Comirnaty) from Acuitas. Pfizer/BNT Action, D.I. 17 at 55. Likewise, Acuitas alleges here that its technology—the ALC-315 cationic lipid and the ALC-159 polyethylene glycol (PEG)-lipid conjugate—“is used, under license, in Pfizer and BioNTech's COVID-19 vaccine.” D.I. 1 ¶ 12; *see also id.* ¶¶ 6, 21. Furthermore, no one has ever suggested, much less alleged, that Acuitas's

³ References to “Ex. ___” are exhibits to the accompanying Declaration of Nicola R. Felice. On a Rule 12(b)(1) facial challenge, the Court may consider documents “explicitly relied upon in the complaint.” *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997)); *see also Pension Ben. Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993) (“[C]ourt may consider an undisputedly authentic document [attached] ... to a motion to dismiss if the plaintiffs['] claims are based on the document.”).

license agreement with Pfizer/BNT precludes Pfizer/BNT from licensing additional LNP-related technology from Genevant, Arbutus, or anyone else. To the contrary, Pfizer itself has alleged that BNT licensed technology used in the vaccine from “multiple partners,” of which Acuitas is only one. *Alnylam Pharms., Inc. v. Pfizer, Inc.*, No. 22-336 (D. Del. Mar. 17, 2022), D.I. 13 at 26-27. This is common, as there is no inherent conflict between licensors of LNP technology. Defendants have never told Acuitas to stop licensing or supplying any lipid or LNP technology to Pfizer/BNT.

B. Procedural History

On March 18, 2022, before discussions between Defendants and Pfizer/BNT had concluded, Acuitas filed a declaratory judgment action against Defendants in the Southern District of New York, as to nine of Defendants’ Patents. SDNY Action, D.I. 1 ¶ 14. The complaint sought declarations that Comirnaty did not infringe Defendants’ Patents and that those patents are invalid. Defendants promptly sought leave to move to dismiss the SDNY Action for lack of subject matter jurisdiction because Acuitas had failed to meet its burden to allege an actual controversy between it and Defendants. SDNY Action, D.I. 36-1. As Defendants explained, questions concerning Defendants’ Patents and Comirnaty should not be resolved in a litigation filed by Acuitas, with which Defendants had never even communicated regarding their patents or Comirnaty.

On September 6, 2022, at the SDNY Court’s invitation, Acuitas amended its complaint. SDNY Action, D.I. 42. The amended complaint did not allege any new information material to the existence of a case or controversy. Accordingly, on October 4, 2022, Defendants moved to dismiss that complaint, arguing among other things that Acuitas’s bare allegations of potential liability for indemnity and indirect infringement failed to demonstrate an actual controversy. SDNY Action, D.I. 44. Acuitas disagreed and, for the first time in its opposition brief, disclosed redacted excerpts of a purported indemnification agreement with BNT. As discussed in

Defendants' subsequent reply brief, those redacted excerpts remained insufficient to demonstrate subject matter jurisdiction. SDNY Action, D.I. 50, 54.

On April 4, 2023, after discussions between Defendants and Pfizer/BNT failed to result in a license agreement, Defendants sued Pfizer and BNT in this District, alleging that their manufacture, use, offer to sell, and sale of Comirnaty infringes five of Defendants' Patents. Pfizer/BNT Action, D.I. 1. Pfizer and BNT filed counterclaims of noninfringement and invalidity as to those patents. Pfizer/BNT Action, D.I. 17. Pfizer and BNT have never moved to add Acuitas as a party, nor has Acuitas tried to become a party to that case, which remains pending before this Court.⁴ On August 4, 2023, after Defendants' motion to dismiss the SDNY Action had been fully briefed, Acuitas voluntarily dismissed the SDNY Action and refiled here, again seeking declarations that Comirnaty does not infringe ten of Defendants' Patents and that those patents are invalid. D.I. 1.⁵ Acuitas's Complaint here is essentially identical to the one it had filed in the SDNY Action as to the alleged basis for subject matter jurisdiction.

Notably, although Acuitas's Complaint relies on its purported indemnity obligations as a basis for jurisdiction, it does not quote or include even the redacted excerpts of the purported indemnity agreement that Acuitas belatedly introduced in its briefing in the SDNY Action. On

⁴ Acuitas's pre-motion letter accuses Defendants of previously implying in the SDNY Action that they had no intention of ever suing Pfizer and BNT. D.I. 9 at 1. That is incorrect. As Acuitas knows, Defendants never stated that they had no intention of suing Pfizer and BNT. All Defendants said was that, given the then ongoing discussions between Genevant and Pfizer/BNT, there was "no compelling reason for judicial relief at th[at] time." SDNY Action, D.I. 44 at 25. Defendants also noted that "[s]hould those negotiations ultimately not succeed, any litigation regarding Comirnaty and the LNP technology it uses will flow from those discussions between the actual parties to the negotiation." *Id.* Defendants' action against Pfizer/BNT is entirely consistent with its prior statements.

⁵ The patents at issue here and in the SDNY Action are identical except that one of the patents there (U.S. Patent No. 9,404,127) is not at issue here, and two of the patents here (U.S. Patent Nos. 11,298,320 and 11,318,098) were not at issue there.

August 21, 25, and 29, 2023, Defendants asked Acuitas for the full unredacted agreement to enable the parties and Court to efficiently address any relevance it might have to subject matter jurisdiction. *See* D.I. 8 at 2. And on August 29, 2023, Defendants also asked Acuitas for the alleged indemnity demand letters from BNT and related correspondence. *Id.* On the same date, Defendants asked BNT for the same materials. In both cases, Defendants agreed to designate the requested materials as Outside Attorneys’ Eyes Only. BNT refused and Acuitas did not respond until the afternoon before the present brief was due to be filed.

On September 15, 2023, Defendants filed a letter with the Court seeking a promotion conference on the present motion to dismiss. In that letter, Defendants addressed Acuitas’s failure to provide the unredacted license agreement and indemnity demands and explained that Defendants sought those materials to “to assess the need for motion practice or to address fully [their] relevance to the jurisdictional issues in briefing to the Court.” D.I. 8 at 2. In response to Defendant’s letter, Acuitas again chose not to provide or offer to provide Defendants with the requested materials. D.I. 9. Moreover, as explained below, Acuitas should not be allowed to rely on these materials because they constitute evidence extrinsic to the Complaint are thus irrelevant to the analysis of Defendants’ facial challenge.

LEGAL STANDARDS

The threshold question for declaratory judgment jurisdiction is “whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007). It is Acuitas’s burden to plead facts sufficient to establish subject matter jurisdiction at the time of the complaint. *Microsoft Corp. v. DataTern, Inc.*, 755 F.3d 899, 903 (Fed. Cir. 2014). On a facial challenge to subject matter jurisdiction—*i.e.*, an argument that considers a complaint on its face and asserts that

it is insufficient to create subject matter jurisdiction—“the court must *only* consider the allegations of the complaint and documents referenced therein and attached thereto, in the light most favorable to the plaintiff.” *Gould Elec. Inc. v. United States*, 220 F.3d 169, 176 (3d Cir. 2000) (emphasis added). Where a declaratory judgment action concerns patent rights, Federal Circuit law controls the subject matter jurisdiction inquiry. *Adenta GmbH v. OrthoArm, Inc.*, 501 F.3d 1364, 1368 (Fed. Cir. 2007).

ARGUMENT

I. THE COMPLAINT SHOULD BE DISMISSED FOR LACK OF SUBJECT MATTER JURISDICTION

The Complaint does not allege that Defendants have ever accused Acuitas of direct or indirect infringement, that Defendants have ever threatened to sue Acuitas, or that Defendants have ever even *communicated* with Acuitas regarding Comirnaty or Defendants’ Patents. Instead, relying on a jurisdictional theory involving entities that supply product to an accused infringer, the Complaint asserts that subject matter jurisdiction exists based on Defendants’ infringement claims against Pfizer and BNT. *See, e.g.*, D.I. 1 ¶¶ 51-54. None of Acuitas’s articulated bases for subject matter jurisdiction withstands scrutiny. The Complaint does not allege that Defendants have ever asserted that Acuitas meets any of the numerous legal elements required for induced or contributory infringement (*see infra* § I(A)). Acuitas did not (and cannot) allege a reasonable potential of indemnity liability to BNT (*see infra* § I(B)). Acuitas’s vague suggestion that Defendants’ claims against Pfizer/BNT will cause it potential economic harm cannot, under the law, sustain subject matter jurisdiction (*see infra* § I(C)). Additionally, there is an indisputable absence of a case or controversy regarding the five patents included in this suit that Defendants have not asserted against Pfizer/BNT (*see infra* § I(D)). For these reasons, the Complaint must be dismissed.

A. The Complaint Does Not Allege A Reasonable Potential Of Indirect Infringement Liability

Acuitas has not met its burden to establish jurisdiction on theories of indirect infringement. Unsurprisingly, Acuitas does not allege that it indirectly infringes Defendants' Patents, which is, of course, what it would ultimately seek to disprove in this action. Instead, the Complaint relies on Defendants' letters to Pfizer (copying BNT) and Defendants' suit against Pfizer/BNT to support its allegation that jurisdiction exists here based on Acuitas's potential liability for indirect infringement. But to establish jurisdiction on theories of indirect infringement "there must be *allegations by the patentee* [i.e., Defendants] or other record evidence that establish at least a reasonable potential that [claims for indirect infringement] could be brought" against Acuitas. *Mitek*, 34 F.4th at 1343 (quoting *Microsoft*, 755 F.3d at 905) (emphasis added). This requires separate consideration of the different types of indirect infringement—induced and contributory—and the facts alleged in light of the elements of those two potential causes of action. *Microsoft*, 755 F.3d at 904–05; *Mitek*, 34 F.4th at 1343. The mere existence of litigation against a customer does not suffice to establish a supplier's reasonable potential of suit for indirect infringement. *Microsoft*, 755 F.3d at 904. Rather, there must be at least an "implied[] assert[ion]" by the patentee that the supplier committed acts meeting the elements required to establish a claim of contributory or induced infringement. *Id.* at 905.

Here, there has been no such assertion, implied or otherwise, creating a potential for indirect infringement liability. Neither Defendants' letters to Pfizer/BNT nor Defendants' suit against Pfizer/BNT mention Acuitas, let alone imply that Acuitas committed acts that would meet any of the elements of contributory or induced infringement.

1. Contributory Infringement

To state a claim for contributory infringement, a patent holder must allege, *inter alia*, that:

(a) the [component] supplier’s product was used to commit acts of direct infringement; (b) the product’s use constituted a “material part of the invention”; (c) the supplier knew its product was “especially made or especially adapted for use in an infringement” of the patent; and (d) the product is “not a staple article or commodity of commerce suitable for substantial noninfringing use.”

Arris Grp., Inc. v. Brit. Telecommunications PLC, 639 F.3d 1368, 1376 (Fed. Cir. 2011) (citation omitted). Accordingly, for a supplier to have a reasonable potential of suit for contributory infringement, the patentee must have at least “impliedly assert[ed]” both that the supplier’s product is “not a staple article or commodity of commerce suitable for substantial noninfringing use,” *see Microsoft*, 755 F.3d at 906, and that the supplier knew its product is especially made or especially adapted for use in infringing the relevant patent. *Id.* The inquiry thus necessarily focuses on the patentee’s communications concerning the supplier.

Here, Acuitas does not allege that Defendants’ communications—their letters to Pfizer/BNT and their Complaint in the Pfizer/BNT Action—even mentioned Acuitas, much less contended that (i) the lipids Acuitas allegedly licenses are unsuitable for substantial noninfringing uses, or (ii) Acuitas knew the lipids were especially made or adapted for use in infringing Defendants’ Patents. Those lacking allegations are dispositive.

For example, in *Microsoft*, the supplier/declaratory judgment plaintiff (Microsoft) argued that claim charts the patentee had served on Microsoft’s customers in a separate litigation were communications that created an actual controversy as to Microsoft’s contributory infringement of the relevant patent, the ’402 patent. *Id.* at 904–05. The Federal Circuit, however, found that the ’402 patent claim charts did not establish an actual controversy as to contributory infringement for two reasons: (i) the patentee’s claim charts did not include allegations that “imply or suggest that Microsoft’s [product] is not ‘a staple article or commodity of commerce suitable for substantial non-infringing use;’” and (ii) the patentee’s charts did not contain an allegation that “Microsoft knew that [its product] was ‘especially made or adapted for use in an infringement’ of

[defendant's] patents.” *Id.* at 906. Applying the Federal Circuit’s analysis in *Microsoft* here, Defendants’ letters and their complaint in the Pfizer/BNT Action fail to create an actual controversy for the same reasons. See *Intel Corp. v. Future Link Sys., LLC*, No. CV 14-377-LPS, 2015 WL 649294, *8 (D. Del. Feb. 12, 2015) (finding no actual controversy as to contributory infringement because there were no “allegations in [the patentees’ pre-suit] letters, nor in [the supplier’s] Complaint” that the supplier’s components were “‘good for nothing else’ but infringement, such that they ha[d] no substantial noninfringing use”). There has never been any communication by Defendants asserting that Acuitas engaged in acts that could constitute contributory infringement, and Acuitas does not allege otherwise.

The facts here are also markedly different than those in *Arris*, where the Federal Circuit found a controversy as to contributory infringement based on the patentee’s communications directed at the acts of Arris, the supplier/declaratory judgment plaintiff. There, the patentee sent Arris’s customer a 118-page presentation that: (1) “explicitly and repeatedly singled out Arris’ products used in [the customer’s] network to support its infringement contentions”]; (2) “identified Arris’ [] products as embodying numerous elements and performing [all or nearly all of] numerous method steps of the asserted claims” such that they were being used as a material part of the allegedly infringing invention; (3) specifically referenced Arris products or product literature on 26 pages of the presentation; and (4) alleged that Arris’ products were designed in such a way that they were especially made or adapted for a use that infringed the patents-in-suit, and were not staple articles or commodities of commerce suitable for substantial non-infringing use. *Id.* at 1376–78. This was all in addition to Arris’s receipt of “direct and repetitive” communications from the patentee as to the patentee’s infringement contentions. *Id.* at 1378–79.

The allegations here are very different. Defendants have never communicated with Acuitas

regarding the patents or Comirnaty, nor have Defendants identified Acuitas in their letters to Pfizer or their complaint against Pfizer/BNT—facts that Acuitas’s Complaint does not dispute. Acuitas’s Complaint likewise does not allege that Defendants have ever asserted, implied, or in any way suggested that Acuitas’s lipids were especially made or adapted for a use that infringed Defendants’ Patents or that are not suitable for substantial noninfringing uses. Indeed, Defendants have seen no evidence of either point. Acuitas has thus failed to plead an actual controversy as to contributory infringement.

2. Induced Infringement

Defendants’ letters to Pfizer/BNT and Defendants’ complaint in the Pfizer/BNT Action likewise do not create an actual controversy as to induced infringement. To state a claim for inducement, a patentee must allege that the accused inducer “took an affirmative act to encourage infringement with the knowledge that the induced acts constitute patent infringement.” *Microsoft*, 755 F.3d at 904 (citation omitted). Absent “knowledge and an affirmative act of encouragement, no party [can] be charged with inducement.” *Id.* Thus, to create an actual controversy as to inducement, the Complaint would have to allege that Defendants’ letters to Pfizer/BNT or its assertions in the Pfizer/BNT Action at least impliedly asserted that Acuitas encouraged Pfizer/BNT to take acts that would infringe the limitations of the claims in Defendants’ Patents. *See id.* at 905. Defendants have not made any such assertions of knowledge or encouragement by Acuitas, and there are no allegations in the Complaint to the contrary. The communications upon which Acuitas relies—*i.e.*, Defendants’ letters to Pfizer/BNT and complaint in the Pfizer/BNT Action—do not mention Acuitas or assert that Acuitas had encouraged Pfizer/BNT to infringe. Again, these pleading failures are dispositive under Federal Circuit precedent.

The Court’s contrasting holdings as to the two asserted patents in *Microsoft* are instructive. In *Microsoft*, the plaintiff-supplier (Microsoft) argued that the patentee’s claim charts served on

Microsoft’s customers in separate litigation created an actual controversy with Microsoft regarding induced infringement. *Id.* at 904–05. The patentee had served claim charts for two patents, the ’502 patent and the above-noted ’402 patent. *Id.* at 905. Addressing each patent in turn, the Federal Circuit found that the patentee’s allegations in its claim charts for the ’502 patent created an actual controversy as to Microsoft’s potential inducement of that patent because these claim charts *identified Microsoft* and *cited to Microsoft documentation*, including Microsoft’s instruction manuals, to show that every claim limitation was satisfied. *Id.* Thus, the court found that those claim charts “allege[d] that Microsoft is encouraging” direct infringement because “[p]roviding instructions to use a product in an infringing manner is evidence of the required mental state for inducing infringement.” *Id.* By contrast, the Federal Circuit found that there was *no* actual controversy as to inducement created by the ’402 patent claim charts because the claim charts for that patent did not identify Microsoft or cite to any Microsoft documents for several of the limitations of the asserted claims. As a result, the court found there was no assertion in the charts that Microsoft had encouraged the customer to infringe, and thus no actual controversy as to inducement created by the ’402 patent claim charts. *Id.*

Application of the Federal Circuit’s analysis to Defendants’ letters and the complaint in the Pfizer/BNT Action is straightforward. Neither cites to Acuitas’s documentation or otherwise accuses Acuitas of encouraging Pfizer/BNT to practice the limitations of the claims of Defendants’ Patents. Acuitas does not allege otherwise. There is thus no actual controversy as to inducement.

This result is not affected by Acuitas’s allegation that it was publicly known that Acuitas’s lipids and LNPs were used in Comirnaty or its allegation that Defendants’ Complaint in the Pfizer/BNT Action “explicitly identifies Acuitas’s lipids and LNPs while alleging that COMIRNATY® infringes their patents....” D.I. 1 ¶¶ 25, 51. “[S]imply selling a product capable

of being used in an infringing manner is not sufficient to create a substantial controversy regarding inducement.” *Microsoft*, 755 F.3d at 905; *see also id.* (“While these claim charts allege the customers’ direct infringement of the ’402 patent based on its use of Microsoft’s ADO.NET, they do not impliedly assert that Microsoft induced that infringement. Nothing in the record suggests that Microsoft encouraged the acts accused of direct infringement.”).

Here, there is likewise no actual controversy as to inducement because neither Defendants’ letters nor their complaint in the Pfizer/BNT Action asserts or implies that Acuitas encouraged Pfizer/BNT to infringe. Defendants have never cited to Acuitas’s documentation or instruction manuals in any communication with Pfizer/BNT like the patentee had done in the ’503 patent claim chart in *Microsoft*. Whether Defendants knew Pfizer/BNT were using Acuitas’s lipids does not alter that result. Acuitas has thus failed to demonstrate that it faces a potential of indirect infringement liability.

B. The Complaint Does Not Allege A Reasonable Potential Of Indemnity Liability

Acuitas’s Complaint falls well short of establishing subject matter jurisdiction based on indemnity liability. Acuitas’s indemnity theory for subject matter jurisdiction requires that it show a “reasonable potential” of liability, “beyond bare indemnity demands or requests.” *Mitek*, 34 F.4th at 1346. The “reasonable potential” of such liability creates “the required concrete stake in litigating the underlying customers’ freedom from infringement liability.” *Id.* Where, as here, the defendant’s motion presents a facial attack, the Court “must closely analyze the relevant indemnity allegations” to decide whether they suffice to demonstrate such a potential. *Id.*; *see also Gould*, 220 F.3d at 176 (facial attack is based only on “the allegations of the complaint and documents referenced therein and attached thereto”).

As the Federal Circuit explained in *Mitek*, although a plaintiff need not actually concede

the existence of a valid, applicable indemnity obligation to establish subject matter jurisdiction, it must do more than allege that it received a customer request for indemnity. Specifically, *Mitek* requires a showing that, “***beyond bare indemnity demands or requests***, there was actually a ‘***reasonable potential***’ of [plaintiff’s] indemnification liability.” 34 F.4th at 1346 (emphasis added). Consistent with this, *Mitek* also cited with approval the instruction in *Microsoft* that the “*merit* of the customer request” is relevant to determining whether a plaintiff has sufficiently pled an indemnity-based actual controversy. *Id.* (quoting *Microsoft*, 755 F.3d at 904) (emphasis added). This, of course, makes intuitive sense because, as the Federal Circuit explained in *Mitek*, “[t]he character of the indemnity demands received and the precise scope of the corresponding indemnity agreements may bear heavily on the sufficiency of [an] indemnity-based interest in obtaining the requested declaratory judgment that can be sought based on that interest.” *Id.* Thus, the question of whether a declaratory judgment plaintiff has a reasonable potential of indemnification liability turns on, at least in part, the merit of the customer request, which itself turns on the precise scope of the corresponding indemnity agreement.

Despite this precedent, Acuitas’s Complaint alleges only that “Acuitas’s license agreement with BioNTech contains indemnification provisions,” and “BioNTech gave notice to Acuitas, in January 2022, August 2022, and May 2023, of a claim for indemnification.” D.I. 1 ¶ 53. The Complaint is devoid of any allegation regarding the potential merit or character of BNT’s request. In fact, Acuitas takes the position that the merits of the customer demand are irrelevant—an allegation squarely at odds with the standard applied in *Mitek*. *Id.* (Acuitas alleges in its Complaint: “Whether or not Acuitas ultimately would have indemnification obligations, BioNTech’s assertion that it has indemnification rights is sufficient to create declaratory-judgment

jurisdiction . . .”).⁶ Likewise, Acuitas’s bare allegation that its agreement with BNT “contains an indemnity provision” fails to meet the required showing of a reasonable potential that the indemnity provision encompasses the indemnitee’s relevant conduct. *See Mitek*, 34 F.4th at 1346. Indeed, because Acuitas has not provided the alleged indemnity provision or pled anything about its scope, the Court has no basis on which to determine whether there is a reasonable potential of indemnity liability. Acuitas’s vague allegation that the license agreement “contains indemnification provisions” does not specify whether or how those provisions relate to Pfizer/BNT’s relevant conduct. And there can be no doubt that Acuitas’s alleged indemnity obligation, whatever it may be, is not applicable across all circumstances, and the Court has no way of evaluating whether it has a reasonable potential of being applicable here. Thus, Acuitas does not adequately plead a reasonable potential of indemnity liability.

Acuitas’s decision to rely on bare allegations of the existence of indemnity provisions and a demand from BNT is no accident but rather a tacit admission of the absence of a Rule 11 basis to allege that the indemnity provision at issue covers Defendants’ claims against Pfizer and BNT. Acuitas has had multiple opportunities to demonstrate the existence of subject matter jurisdiction over its claims (*see supra* at 7-8), yet it repeatedly refused to provide the indemnity demands and agreement that could support a factual basis for its alleged reasonable potential of indemnity liability. This Court should not allow Acuitas yet another attempt to replead a basis for jurisdiction

⁶ In its response to Defendants’ pre-motion letter, Acuitas mischaracterized Defendants’ argument as requiring Acuitas to concede the validity of an indemnity demand to establish jurisdiction. D.I. 9 at 2 (quoting *Mitek*, 34 F.4th at 1341). Defendants make no such argument and, in fact, expressly recognize that *Mitek* does not require such a concession. Rather, Defendants’ point is that, even though a concession of indemnity is not required, *Mitek* still expressly requires Acuitas to plead facts from which the court can infer a reasonable potential of indemnity liability. Pleading the existence of an indemnity demand does not suffice.

that clearly does not exist. And Acuitas should not be heard to argue otherwise when it could have long ago provided these documents to enable the parties and Court to efficiently assess their potential relevance to the existence of subject matter jurisdiction.

Moreover, Acuitas should not be allowed to rely in its forthcoming opposition on the terms of an alleged indemnity agreement for a separate reason: This motion presents a facial challenge that must be resolved based solely on the allegations in the Complaint. *Gould*, 220 F.3d at 176. Accordingly, the redacted excerpts from the license agreement, which Acuitas attached as an exhibit to its opposition brief in the SDNY Action but omitted from the Complaint here, may not be considered even putting aside the questions Defendants have repeatedly raised about their authenticity and reliability.⁷ *See Priore v. Caravan Ingredients, Inc.*, No. CIV. 13-5229 KSH CLW, 2014 WL 2931182, at *4 (D.N.J. June 30, 2014) (declining to consider documents attached to plaintiff's opposition brief that it failed to include in the complaint because plaintiff "may not cure the obvious deficiencies in his complaint with a stapler").

Moreover, even if considered, the redacted excerpts that Acuitas attached to its opposition brief in the SDNY Action are insufficient to demonstrate subject matter jurisdiction. Consideration of the excerpts would convert this motion to a factual challenge in which Acuitas would bear the burden of *proving* jurisdiction, rather than just plausibly alleging it. *See Hartig Drug Co. v. Senju Pharm. Co.*, 836 F.3d 261, 268 (3d Cir. 2016) ("[w]hen considering a factual challenge, the plaintiff [has] the burden of proof that jurisdiction does in fact exist.") (citations and

⁷ In its response to Defendants' pre-motion letter, Acuitas falsely asserted that it "provided a copy of the full indemnity provision [] to the Defendants [in the SDNY Action]" and that the provision is not questioned. D.I. 9 at 2. The only thing Acuitas provided (even under seal) was a heavily redacted excerpt, making the scope of the agreement unknown and unclear, and Defendants explained why it would not demonstrate a reasonable potential of indemnity liability even if it were considered. SDNY Action, D.I. 55 at 6-7.

quotation marks omitted). Acuitas cannot satisfy that standard, which requires analysis of both “[t]he character of the indemnity demands received” and “the precise scope of the corresponding indemnity agreement[,]” because (i) the redacted license agreement provided in the SDNY Action does not show a reasonable potential that the precise scope of the indemnity agreement covers the facts here, and (ii) Acuitas has never provided any documents in any form as to the nature of any indemnity demands. *Mitek*, 34 F.4th at 1346; *see id.* at 1338 (noting plaintiff’s failure to “attach any documents embodying ... a demand for indemnification”). Either of those facts would be dispositive.

C. The Complaint Does Not Allege Jurisdiction Based On Possible Economic Harm In Potential Future Business Dealings

In Acuitas’s response to Defendants’ pre-motion letter, Acuitas contends that a third basis for jurisdiction also exists that Defendants’ infringement allegations against Pfizer and BioNTech could harm Acuitas’s business dealings with other, unidentified customers. D. I. 9 at 3. As an initial matter, the absence of this “commercial harm” theory of subject matter jurisdiction in the section of Acuitas’s Complaint titled “Jurisdiction and Venue” seems to acknowledge its admitted weakness. That section of the Complaint includes only Acuitas’s alleged indirect infringement and indemnity liability as the bases for jurisdiction. D.I. 1 ¶ 54. The omission is for good reason because this new theory is not supported by Federal Circuit precedent.

As the Federal Circuit has instructed, to establish standing, a plaintiff must (1) “allege [] an injury-in-fact, i.e., a harm that is ‘concrete and actual or imminent, not conjectural or hypothetical.’” *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1338 (Fed. Cir. 2008) (citation omitted). Acuitas has alleged no such concrete, actual harm as to its alleged business dealings with other customers. There is no allegation of a specific lost licensing opportunity, lost business deal, lost royalty, lost revenue, or any other form of concrete injury. Instead, Acuitas

alleges that it has been “harm[ed]” (D.I. 1 ¶ 38) because it might lose hypothetical future business with unnamed “*potential* customers” or unidentified “*prospective* partners” due to those customers’ purported fear of hypothetical future suits by Defendants. D.I. 1 ¶ 6; *see also id.* (“[C]ustomers and potential customers of Acuitas must now contend with the risk of avaricious litigation by Arbutus and Genevant.”). But the Federal Circuit has instructed that neither a “fear of a future infringement suit” nor a “fear of future lost business because of infringement threats against a customer” establish standing:

[W]e have held that the *fear of a future infringement suit is insufficient to confer jurisdiction*. . . . And in *Arris*, we noted the *fear of future lost business because of infringement threats against a customer was, by itself, insufficient to create standing* for the manufacturer. [Plaintiff’s] fear alone does not give the district court jurisdiction.

Allied Min. Prod., Inc. v. Osmi, Inc., 870 F.3d 1337, 1341 (Fed. Cir. 2017) (internal citation omitted). This is consistent with the ““bedrock rule”” that the injury-in-fact requirement ““cannot be met by a purely subjective or speculative fear of future harm.”” *Asia Vital Components Co. v. Asetek Danmark A/S*, 837 F.3d 1249, 1253 (Fed. Cir. 2016) (citation omitted).

Nor can Acuitas rely on its purported economic interest in clarifying whether an unspecified number of unidentified “other” customers can practice Acuitas’s technology “free and clear of interference by threats of suit arising from third party patents.” D.I. 1 ¶ 6. This too runs contrary to Federal Circuit precedent:

At most, [plaintiff] had only an economic interest in clarifying its customers’ rights under [patentee’s] patents, which may have facilitated the sale of [plaintiff’s] products. [Plaintiff] *perhaps would economically have benefited if its customers had no fear of suit* by [patentee]. *Such an economic interest alone, however, cannot form the basis of an “actual controversy”*. . . .

Microchip Tech., Inc. v. Chamberlain Grp., Inc., 441 F.3d 936, 943 (Fed. Cir. 2006); *see also Arris*, 639 F.3d at 1374 (citing and quoting *Microchip* for the proposition that “where [the] sole injury alleged was economic harm to [the] declaratory plaintiff caused by patentee’s purported

threatening of its customers, “[s]uch an economic interest alone ... cannot form the basis of an actual controversy under the Declaratory Judgment Act.”); *Creative Compounds, LLC v. Starmark Lab’ys*, 651 F.3d 1303, 1316 (Fed. Cir. 2011) (affirming that district court lacked declaratory judgment jurisdiction because “Starmark has, at most, only an economic interest in clarifying its customers’ rights under Creative’s patents”).

Acuitas has thus failed to allege a concrete injury and a sufficient non-economic interest in pursuing this declaratory judgment action on behalf of its “other customers.” Acuitas’s generic allegations regarding its purported business dealings with other customers therefore also fail to demonstrate subject matter jurisdiction.

* * *

Acuitas has failed to allege facts demonstrating that it faces a reasonable potential of either indemnity or indirect infringement liability. It has also failed to allege jurisdiction based on possible economic harm in potential future business dealings with unspecified customers. The Court should therefore dismiss Acuitas’s Complaint in its entirety for lack of subject matter jurisdiction.

D. The Complaint Does Not Even Allege A Controversy Between Defendants And Pfizer/BNT For Five Patents

For the reasons discussed above, Acuitas’s complaint should be dismissed in its entirety as to all ten of Defendants’ Patents. Because five of Defendants’ Patents identified in the Complaint are not asserted in the action against Pfizer/BNT, it is indisputable that there is no controversy as to them and Acuitas’s declaratory judgment claims relating to those five patents should thus be dismissed for that independent reason.

A necessary element of Acuitas’s alleged indemnity-based interest in pursuing this declaratory judgment action is the existence of an actual infringement controversy between

Defendants and Pfizer/BNT “that would have sufficed for [Pfizer and BNT] to seek declaratory relief” themselves.” *Mitek*, 34 F.4th at 1345. The factual allegations in Acuitas’s Complaint do not demonstrate the existence of a controversy for the five patents that Defendants have not asserted against Pfizer/ BNT.

Acuitas’s only basis for this Court’s declaratory judgment jurisdiction over the five unasserted patents is that they were referenced in letters that Defendants sent to Pfizer and BNT. According to Acuitas, this purportedly demonstrates a controversy between Defendants and Pfizer/BNT as to those patents. Not so. Those five patents were listed in the first letter that Defendants sent to Pfizer *nearly three years ago* on November 23, 2020. Ex. A. Defendants have not filed any lawsuit against Pfizer/BNT on those patents in the time since, nor have Pfizer/BNT asserted counterclaims on those patents against Defendants in the Pfizer/BNT Action. Acuitas has thus failed to show a present controversy between Defendants and Pfizer/BNT with respect to at least the patents not asserted in the Pfizer/BNT Action.

II. THE COURT SHOULD EXERCISE ITS DISCRETION TO DECLINE TO HEAR THIS DECLARATORY JUDGMENT ACTION

Even if Acuitas could show subject matter jurisdiction (it cannot), the Court should exercise its discretion to decline to entertain this suit for at least two reasons: litigating Acuitas’s claims here serves no useful purpose and it would only complicate and needlessly expand the issues already before the Court. *See Commc ’ns Test Design, Inc. v. Contec, LLC*, 952 F.3d 1356, 1361 (Fed. Cir. 2020) (“[A] district court has ‘unique and substantial discretion in deciding whether to declare the rights of litigants.’”).

First, this litigation serves no useful purpose because the only legal right about which Acuitas seeks clarity in this action is whether Defendants’ Patents are valid and infringed. But there is already an action concerning the same vaccine and five of the same patents and that

litigation is between the real interested parties: the patent rights holders (Arbutus and Genevant) and the makers of the vaccine (Pfizer and BNT). Acuitas does not need this declaratory judgment action to provide it with relief from any alleged “uncertainty and delay regarding its legal rights,” which is the purpose of the Declaratory Judgment Act. *Id.* at 1361-62; *see also id.* (noting that a court has “broad discretion to refuse to entertain a declaratory judgment action” “[a]s long as the district court ‘acts in accordance with the purposes of the Declaratory Judgment Act and the principles of sound judicial administration’”) (citation omitted). The Pfizer/BNT Action will provide Acuitas with the clarity that it seeks.

Acuitas’s Complaint alleges that its primary interest here is as a purported indemnitor of BNT, but, even if that is true, that interest does not support maintaining this separate declaratory judgment action. Acuitas’s own conduct shows that its interests are aligned with those of Pfizer and BNT in the Pfizer/BNT Action and adequately represented by Pfizer/BNT. Despite being a purported indemnitor, Acuitas has chosen not to take over, or participate in, the defense in the Pfizer/BNT Action. Instead, it has stood by as BNT and Pfizer have mounted their own defense in the Pfizer/BNT Action, indicating that Acuitas believes its interests as a purported indemnitor are already adequately represented. Acuitas’s request for declaratory relief should therefore be dismissed for the same reason that an indemnitor third party is not permitted to intervene in a case where its interests are represented by the parties already involved. *See Acra Turf Club, LLC v. Zanzuccki*, 561 F. App’x 219, 222 (3d Cir. 2014) (“[W]here, as here, the interests of the applicant in every manner match those of an existing party and the party’s representation is deemed adequate, the district court is well within its discretion in deciding that the applicant’s contributions to the proceedings would be superfluous”) (quoting *Hoots v. Commonwealth of Pa.*, 672 F.2d

1133, 1136 (3d Cir. 1982)). Acuitas's declaratory judgment action is likewise superfluous to the Pfizer/BNT Action already underway.

Second, allowing Acuitas to maintain the present suit would complicate and needlessly expand the issues already before this Court. As discussed above (*supra* § I(D)), Acuitas seeks declaratory judgments of non-infringement and invalidity of five of Defendants' Patents that Defendants have not even asserted against Pfizer and BNT. Furthermore, Acuitas's Complaint makes clear that it intends to inject facts into this case regarding its purported "hard work and ingenuity," as well as its own patents and alleged "novel discoveries," none of which are relevant to whether Pfizer and BNT infringe Defendants' Patents or whether Defendants' Patents are valid. Indeed, Acuitas's Complaint contains more than a dozen allegations to this effect. D.I. 1 ¶¶ 1, 19; *see also id.* ¶¶ 6, 12-22, 25, 43-44. It is irrefutable that whether Comirnaty practices Acuitas's patents is irrelevant to whether it infringes Defendants' Patents. *See Bio-Tech. Gen. Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1559 (Fed. Cir. 1996) ("[T]he existence of one's own patent does not constitute a defense to infringement of someone else's patent."); *Fiskars, Inc. v. Hunt Mfg. Co.*, 221 F.3d 1318, 1324 (Fed. Cir. 2000) (holding that a defendant's own patent on its accused product is "evidence not material to the issue of infringement"). Acuitas's alleged "hard work and ingenuity" and "novel discoveries" do not bear on whether Pfizer/BNT use the technology disclosed and claimed in Defendants' asserted patents. Both can be true. Thus, the allegations raised by Acuitas in this action will only tend to complicate and confuse the actual issues.

The issues in this case should be resolved in the Pfizer/BNT Action that involves the parties between which an actual controversy exists. Even if the Court has jurisdiction over Acuitas's declaratory judgment claims, the Court should decline to hear them in favor of efficiently and expeditiously resolving that actual controversy. The Complaint should therefore be dismissed.

CONCLUSION

For the foregoing reasons, the Court should dismiss the Complaint.

Dated: October 13, 2023

Respectfully submitted,

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