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August 1, 2022

By ECF

The Honorable Mary Kay Vyskocil  
Daniel Patrick Moynihan U.S. Courthouse  
500 Pearl Street  
New York, NY 10007-1312

Re: *Acuitas Therapeutics Inc. v. Genevant Sciences GmbH*  
*and Arbutus Biopharma Corp.*, Case No. 1:22-cv-02229-MKV

Dear Judge Vyskocil:

I represent Plaintiff Acuitas Therapeutics Inc. and write pursuant to the Court's July 25, 2022 Order [D.I. 35] to submit this joint status letter on behalf of Acuitas and Defendants Genevant Sciences GmbH and Arbutus Biopharma Corp.

**1) A brief statement of the nature of the case, the principal claims and defenses, and the major legal and factual issues that are most important to resolving the case**

Acuitas seeks a declaratory judgment that patents owned by Arbutus and licensed to Genevant (the "Arbutus Patents") are not infringed by the manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of Comirnaty®, a COVID-19 vaccine made and sold by nonparties Pfizer and BioNTech, and that the Arbutus Patents are invalid under 35 U.S.C. §§ 102, 103, and/or 112.<sup>1</sup>

Before the case was re-assigned to Your Honor, the Defendants timely requested leave to move to dismiss the Complaint for lack of subject matter jurisdiction. [D.I. 31 (attached here as Exhibit A)]. Acuitas opposed that request. [D.I. 34 (attached here as Exhibit B)]. As such, Defendants have not answered the Complaint. The Defendants contend that the principal claims

<sup>1</sup> The Arbutus Patents are U.S. Patent Nos. 8,058,069, 8,492,359, 8,822,668, 9,006,417, 9,364,435, 9,404,127, 9,504,651, 9,518,272, and 11,141,378.

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and defenses and the major legal and factual issues will involve whether an actual controversy and injury-in-fact exists as necessary for a declaratory judgment. Beyond that, the Parties agree that the principal claims and defenses and the major legal and factual issues will involve whether making, using, selling, offering for sale, or importing into the United States the Comirnaty® vaccine infringes any valid and enforceable claim of any of the Arbutus Patents (including patent-law issues such as claim construction, novelty, obviousness, and sufficiency of the patents' disclosures).

### Plaintiff's Statement of the Nature of the Case

Acuitas is a private Canadian biotechnology company and global leader in the development of delivery systems for nucleic acid therapeutics, including messenger RNA ("mRNA") vaccines, based on lipid nanoparticles ("LNPs"). Acuitas partners with companies that market, or seek to market, such vaccines to address unmet clinical needs, including vaccines targeting COVID-19 and other viruses.

As relevant here, Acuitas invented an LNP delivery system that protects the mRNA in Comirnaty®, the vaccine for COVID-19 from Pfizer/BioNTech, effectively delivering that mRNA within a patient's body, allowing the patient to mount an immune response that will then protect against COVID-19 infection. Acuitas expects that there will be no dispute that Comirnaty® employs the lipid technology it provided to Pfizer/BioNTech. In part due to its use of Acuitas's LNP delivery system, Comirnaty® has been a global success in fighting COVID-19.

Defendants Arbutus and Genevant had nothing to do with that success. They did not invent any part of Comirnaty®, or even participate in that invention. But after Comirnaty® achieved worldwide success, Defendants sent demand letters to both BioNTech and Pfizer, identifying specific patents that they allege cover mRNA-LNP delivery systems such as those in Comirnaty® and demanding payment under those patents. They also sent apparently similar demand letters to Moderna, Inc., the manufacturer of the other mRNA vaccine against COVID-19, and followed up this threat with an infringement lawsuit against Moderna in the District of Delaware in which they assert several of the same patents that are the subject of this action.

Acuitas then brought this action, joining a long history of product suppliers who partner with others, and under circumstances like these, respond to threats of patent infringement against their partners and customers by bringing a declaratory-judgment action against the party making the threats. Acuitas will demonstrate that the Arbutus patents are invalid, and also that they are not infringed by Comirnaty® or by Acuitas's LNP delivery system incorporated in Comirnaty®.

As described below, Defendants have raised a threshold issue in the case: They contend that there is no actual controversy between them and Acuitas, that Acuitas has suffered no injury-in-fact, and that this is merely a "shadow litigation" that the Court should dismiss. As further described below, Defendants are wrong. A product supplier like Acuitas may bring a declaratory judgment action like this one against Defendants like these, who threaten the supplier's partners and customers, where there is a possibility either that the supplier might have to indemnify its partners or customers for damages owed to the Defendants or where the supplier itself might be

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liable for induced or contributory infringement. And, as Acuitas alleges in its Complaint [D.I. 1], Defendants' actions have caused concerns with Acuitas's ability to license its LNP technology freely without the possibility of litigation—a very real possibility given Defendants' recent litigious conduct. This is not a request, as Defendants suggest, for an advisory opinion: this is a request for a declaratory judgment to adjudicate an actual patent-infringement controversy that poses real harm to Acuitas. No more is required for this Court to have subject-matter jurisdiction.

#### Defendants' Statement of the Nature of the Case

Acuitas has no factual or legal basis for bringing this suit, which seeks to adjudicate whether a product Acuitas admittedly does not make or sell infringes Defendants' patents. Acuitas's alleged concerns about whether nonparties might or might not be infringing Defendants' patents do not create an actual controversy between Acuitas and Defendants. The Complaint fails to establish, or even plead, any enforcement threat by Defendants against Acuitas or any cognizable injury-in-fact. Simply put, Acuitas is seeking an advisory opinion regarding Pfizer and BioNTech's product and those nonparties' need for a license. The Court should not endorse Acuitas's shadow litigation, which seeks to resolve the rights of nonparties who have not sought judicial intervention.

Genevant is a technology-focused nucleic acid delivery company and a world leader in the LNP space, with world-class platforms, 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.

In 2018, Genevant and BioNTech entered a co-development and license agreement in which BioNTech licensed Defendants' LNP technology, but the license was limited to the development of certain cancer or rare disease treatments. In November 2020, Genevant and Arbutus sent a letter to Pfizer and BioNTech offering to discuss a nonexclusive license for Covid-19 vaccine applications and a partnering agreement that would enable Pfizer and BioNTech to benefit from Genevant scientists' extensive experience and expertise. Defendants' letter also identified Arbutus patents that the Comirnaty® vaccine may infringe. In October 2021, Genevant and Arbutus sent a second letter identifying another Arbutus patent and noting ongoing licensing discussions between Defendants and BioNTech (acting also on behalf of Pfizer).

There is no actual controversy between Defendants and Acuitas. Defendants have never communicated with Acuitas concerning the Arbutus Patents or the Comirnaty® vaccine at all, much less accuse Acuitas of infringement. Moreover, licensing discussions between Defendants and BioNTech regarding Comirnaty® have not concluded—Acuitas has no role in these discussions and is prohibited under confidentiality restrictions from even being privy to them.

Although Acuitas asserts above that jurisdiction exists because Acuitas “might have to indemnify its partners or customers,” *the Complaint does not even mention the word “indemnity,”* much less include a clear, direct allegation that Acuitas is actually obligated to indemnify anyone as the case law requires. Moreover, although Acuitas asserts above that jurisdiction exists because

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Acuitas “might be liable for induced or contributory infringement,” the Complaint does not and cannot allege that Defendants accused Acuitas of such infringement. Unlike cases in which the patentee accuses the declaratory judgment plaintiff of induced or contributory infringement, Defendants’ letters here did not even mention Acuitas or refer to any of its acts.

Furthermore, Acuitas has not alleged injury-in-fact, such as the loss of specific business deals or royalties, resulting from the letters Defendants sent to Pfizer and BioNTech. Acuitas instead seeks to rely on its speculative and otherwise non-cognizable subjective fear of potential litigation against unspecified potential licensees. Any such alleged harm would not only fail as a matter of law but also be self-inflicted—Defendants’ private letters to Pfizer and BioNTech were not known to the public until *Acuitas itself* chose to disclose them in its Complaint.

**2) A brief statement by the plaintiff as to the basis of subject matter jurisdiction and venue, and a brief statement by each other party as to the presence or absence of subject matter jurisdiction and venue.**

Plaintiff Acuitas’s Jurisdictional Statement

This Court has federal-question subject-matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), and 2201 because this is a declaratory-judgment action addressing an actual controversy between the parties regarding the validity and infringement of United States patents. Acuitas further alleges that venue is proper under 28 U.S.C. §§ 1391(b)–(c) and 1400(b) because Defendants purposefully availed themselves of this jurisdiction by sending demand letters into this District, e.g., to Pfizer’s headquarters in Manhattan, alleging potential patent infringement, affecting Acuitas’s ability to license its LNPs to companies headquartered and incorporated within this District.

Acuitas recognizes that the Defendants dispute the existence of subject-matter jurisdiction and propose that the Court exercise its discretion to dismiss this case even if there is jurisdiction. For the reasons set forth in Acuitas’s pre-motion letter [D.I. 34], the Defendants’ jurisdictional concerns are baseless. In brief: Where patent owners threaten a product-supplier’s partners or customers with patent infringement suits based on the partners’ or customers’ use of the supplier’s product—as Defendants did to BioNTech and Pfizer here, alleging infringement of the Arbutus Patents based in part on Comirnaty®’s use of Acuitas’s LNP technology—the product supplier itself may bring a declaratory-judgment action seeking a declaration that the patents are invalid and/or not infringed—as Acuitas did here with respect to the Arbutus Patents. Such declaratory-judgment actions are cognizable in either of two circumstances: where the supplier might have to indemnify its partners or customers for damages owed to the patent owners, or where the supplier itself might face liability for indirect patent infringement for selling the component of the accused product. Both are true here. BioNTech, Acuitas’s customer, has notified Acuitas of a claim for indemnification if BioNTech were found to owe damages to Arbutus and Genevant for infringement of the Arbutus Patents. And the possibility of a claim of indirect-infringement against Acuitas itself is not so remote or speculative as to moot any case or controversy between Acuitas and the Defendants. This is exactly the circumstance in which courts decide declaratory-judgment cases exactly like this one.

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Defendants' Jurisdictional Statement

Acuitas has not satisfied its burden to establish subject matter jurisdiction because it has not alleged and cannot allege an actual controversy or injury-in-fact, both of which are prerequisites to jurisdiction.

The issues are detailed in Defendants' pre-motion letter [D.I. 31]. In brief, the Complaint: (i) does not allege that Defendants ever contacted Acuitas regarding the vaccine, accused Acuitas of infringement, or sought to enforce the Arbutus Patents against Acuitas; (ii) relies on private communications, the first of which was sent over a year and a half ago without any subsequent legal action, from Defendants to Pfizer and BioNTech (not Acuitas); and (iii) does not allege objective concrete injury to Acuitas. Moreover, as discussed above, Acuitas's efforts to ground jurisdiction in a potential indemnification obligation fail, not only because a potential obligation is legally insufficient but also because the Complaint does not mention indemnity at all. Likewise, Acuitas's arguments regarding indirect infringement fail because unlike cases in which the patentee specifically accused the declaratory judgment plaintiff of induced or contributory infringement, Defendants here have never asserted that Acuitas induced Pfizer or BioNTech to infringe and Defendants' letters to nonparties, on which Acuitas relies, did not even mention Acuitas.

Moreover, even if subject matter jurisdiction existed (it does not), the Court should use its discretion to decline to exercise declaratory judgment jurisdiction because (i) licensing discussions regarding Comirnaty® have not concluded and a licensing deal between Defendants and Pfizer/BioNTech would moot Acuitas's claims at any time, and (ii) if Defendants prevail in this suit, either or both of Pfizer and BioNTech could render this Court's judgment a nullity by filing a new suit in their own names the next day, arguing that they are not bound by or estopped from challenging this Court's judgment.

**3) A statement of procedural posture**

Acuitas filed the Complaint on March 18, 2022 [D.I. 1], and the parties stipulated to extend Defendants' time to respond to the Complaint to June 24, 2022 [D.I. 20]. On that day, pursuant to the Individual Practices of Judge Edgardo Ramos, Defendants filed a letter seeking a pre-motion conference regarding their intended motion to dismiss the case for lack of subject-matter jurisdiction or in the Court's discretion [D.I. 31]. The filing of the pre-motion letter stayed the deadline for Defendants to respond to the Complaint. Acuitas responded to the pre-motion letter on July 8, 2022 [D.I. 34]. Judge Ramos recused himself at the start of the pre-motion conference on July 15, 2022, and the case was re-assigned to Your Honor. Defendants' request to move to dismiss the case remains pending. Given that posture, Defendants have not answered the Complaint, and no scheduling order has been implemented.

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