EXHIBIT B

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July 8, 2022

By ECF

The Honorable Edgardo Ramos
Thurgood Marshall U.S. Courthouse
40 Foley Square
New York, NY 10007

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

Your Honor:

Pursuant to this Court's Individual Practice Rule 2.A.ii and its June 27, 2022 Order [D.I. 33], I write on behalf of Plaintiff Acuitas Therapeutics Inc. in response to Defendants' June 24, 2022 letter [D.I. 31], which sought permission to move to dismiss the Complaint.

Defendants intend to argue that there is no subject-matter jurisdiction here, and that even if there were jurisdiction the Court should exercise its discretion to dismiss the case. Because each argument lacks merit, and because the motion would unnecessarily delay resolution of the important issues raised here, the Court should reject Defendants' request to move to dismiss.

1. Declaratory Judgment Actions Are Common In Precisely This Circumstance

This case is about the messenger RNA ("mRNA") vaccines used to create immunity to the COVID-19 virus. Acuitas invented a key component of such mRNA vaccines: the delivery system based on lipid nanoparticles ("LNPs") that functions to protect the mRNA and effectively deliver it within a patient's body. Acuitas partners with companies who are marketing or seeking to market therapeutics, including vaccines targeting COVID-19 and other viruses, to address unmet clinical needs. One well-known partner is BioNTech, which, together with Pfizer, is marketing the vaccine against COVID-19, Comirnaty®, which uses Acuitas's LNP technology.

The Defendants own patents that, they claim, cover Comirnaty®. They specifically contend that Comirnaty® includes a lipid nanoparticle that uses lipids that Acuitas invented and licensed to BioNTech. Defendants proclaim that they, not Acuitas, are the rightful inventors of that LNP. Defendants sent letters to BioNTech and Pfizer identifying specific patents and demanding that BioNTech and Pfizer pay them royalties because of Defendants' patents.

Acuitas then brought this action, seeking a declaratory judgment that Defendants' patents are invalid and/or not infringed by Comirnaty®. In doing so, Acuitas joined a long history of product suppliers who, under circumstances like these, respond to threats of patent infringement against their customers by bringing a declaratory-judgment action against the party making the threats. *See*, *e.g.*, *Arris Grp., Inc.* v. *Brit. Telecomms. PLC*, 639 F.3d 1368 (Fed. Cir. 2011); *Microsoft Corp.* v. *DataTern, Inc.*, 755 F.3d 899 (Fed. Cir. 2014).

2. The Court Has Subject Matter Jurisdiction Over This Action

A district court has subject-matter jurisdiction over a declaratory-judgment action by a supplier against a patentee that has threatened the supplier's customers either (i) where the supplier faces the possibility of liability under 35 U.S.C. § 271(b) for inducing its customers' infringement or under § 271(c) for contributing to it, or (ii) where the supplier may have to indemnify its customers under their contracts. *See Microsoft*, 755 F.3d at 903–04. Both are true here.

Indirect infringement: Defendants do not and cannot deny that they sent demand letters to Acuitas's partner (BioNTech), and its collaborator (Pfizer), identifying specific patents that they say cover BioNTech and Pfizer's COVID-19 vaccine. Inherent in the letters is Defendants' belief that an Acuitas LNP used in Comirnaty® infringes an element of their patent claims. Liability against Acuitas for induced or contributory infringement is not so speculative or remote as to defeat subject-matter jurisdiction; while Acuitas would have defenses to such a claim, it is sufficient here that Acuitas is "potentially an inducer of infringement." *Microchip Tech., Inc.* v. *Chamberlain Grp., Inc.*, 441 F.3d 936, 943 (Fed. Cir. 2006) (citing *Arrowhead Indus. Water, Inc.* v. *Ecolochem, Inc.*, 846 F.2d 731, 739 (Fed. Cir. 1988)). *Microchip*, on which Defendants rely, is distinguishable for two reasons: first, Microchip disclaimed any possibility of itself being sued by the patent-holder, from which it claimed to have a license, *see* 441 F.3d at 942; second, in *Microchip* the Federal Circuit assessed whether Microchip had a "reasonable apprehension of being sued," *id.*, a test that the Supreme Court later invalidated as too narrow in *MedImmune, Inc.* v. *Genentech, Inc.*, 549 U.S. 118, 127 (2007).

Defendants also contend that there is no injury-in-fact because their letters to Pfizer and BioNTech were not really threats to sue those companies, but were instead merely offers of collaboration. The letters themselves—both of them, the November 23, 2020 and October 12, 2021 letters to Pfizer and BioNTech—state that they are 35 U.S.C. § 287(a) notices of infringement, which is a predicate for recovery of damages in a patent-infringement action. *See* Compl. [D.I. 1] ¶¶ 13, 22, 45–47. The basis of this lawsuit, then, is not (as Defendants' letter asserts) Acuitas's "subjective worries" and "speculative fear" [D.I. 31] at 2–3; the basis of this lawsuit is Defendants' explicit threat to file suit. There is no reason to think that is hollow: Defendants sent a demand letter to Moderna about its COVID-19 vaccine on the same day that they sent a letter to Pfizer and BioNTech, and Defendants have since actually sued Moderna. *See Arbutus Biopharma Corp.* v. *Moderna, Inc.*, 1:22-cv-00252-MSG (D. Del. Feb. 28, 2022). Such "[p]rior litigious conduct is one circumstance to be considered in assessing whether the totality of circumstances creates an actual controversy." *Hewlett-Packard Co.* v. *Acceleron LLC*, 587 F.3d 1358, 1364 n.1 (Fed. Cir. 2009) (internal quotations omitted).

Indemnification: Acuitas's license agreement with BioNTech contains indemnification provisions. BioNTech has given notice to Acuitas of a claim for indemnification if BioNTech were found liable to Defendants for patent infringement. Whether or not Acuitas ultimately would have indemnification obligations, BioNTech's assertion that it has indemnification rights is sufficient to create declaratory-judgment jurisdiction. *Arris*, 639 F.3d 1375. That fact also distinguishes *Microsoft*, in which there were no contractual indemnity provisions and the supplier conceded that "no such obligation exists." *Microsoft*, 755 F.3d at 904.

Importantly, this is not a case where the supplier is a bystander to a dispute between its customers and the patent-owner. Rather, "the declaratory plaintiff and the patentee[s] [a]re competitors in the" LNP "industry." *Microchip*, 441 F.3d at 943 (citing *Arrowhead*, 846 F.2d at 733). Defendants are claiming credit for the lipids and LNPs that Acuitas itself invented and licensed. And this is not the first fight between Defendants and Acuitas about the inventorship of LNP technology. As detailed in the Complaint, Defendants and Acuitas, as corporations, arose from common ancestors, and—by agreement in 2012—spent the last decade pursuing different scientific pathways: Acuitas sought to develop LNPs that could deliver mRNA, while Defendants Arbutus sought to develop LNPs for an entirely different kind of nucleic acid called short-interfering RNA. *See* Compl. [D.I. 1] ¶¶ 5–14. Now that Acuitas's LNPs have been used in mRNA vaccines that have helped save the world from a pandemic, Defendants—which have no mRNA and no anti-COVID product—have shown up, falsely claiming to have invented that lifesaving technology, sending a notice of infringement to BioNTech and Pfizer and suing Moderna.

3. The Court Should Not Use Its Discretion To Dismiss The Complaint

Defendants also assert that the Court should decline jurisdiction as an act of discretion. That would be unwarranted: "there is an actual controversy and a declaratory judgment would settle the legal relations in dispute and afford relief from uncertainty or insecurity." *SanDisk Corp.* v. *STMicroelectronics, Inc.*, 480 F.3d 1372, 1383 (Fed. Cir. 2007) (internal quotations omitted). Discretion to decline jurisdiction "must be supported by a sound basis for refusing to adjudicate an actual controversy." *Id.* There is no sound basis to dismiss this case. While Defendants assert that a settlement with Pfizer/BioNTech could moot this dispute, that is always true. *See id.* at 1381 ("It is quite possible for two parties to simultaneously consider … settlement of a dispute, while at the same time maintaining an awareness that either settlement is improbable or that litigation is equally likely.") (internal quotations omitted).

* * * *

Acuitas looks forward to discussing these issues at the July 15, 2022 conference.

Respectfully submitted,

/s/Nicholas Groombridge
Nicholas Groombridge