quinn emanuel trial lawyers | new york
51 Madison Avenue, 22nd Floor, New York, New York 10010-1601 | TEL (212) 849-7000 FAX (212) 849-7100

WRITER'S DIRECT DIAL & EMAIL
(212) 849-7412

raymondnimrod@quinnemanuel.com

June 24, 2022

VIA ECF

The Honorable Edgardo Ramos
Thurgood Marshall U.S. Courthouse
40 Foley Square
New York, NY 1007

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

Your Honor:

I am writing on behalf of both Defendants pursuant to this Court's Individual Practice Rule 2.A.ii, to request a pre-motion conference concerning Defendants' anticipated motion to dismiss the Complaint. The anticipated motion would seek dismissal on the basis that Plaintiff has not satisfied and cannot satisfy its burden to demonstrate federal subject matter jurisdiction in this declaratory judgment action.

Background

Plaintiff ("Acuitas") filed this action on March 18, 2022. The Complaint names two Defendants: Genevant Sciences GmbH ("Genevant") and Arbutus Biopharma Corporation ("Arbutus"), each of which is a biotechnology company. The Complaint does not seek damages. Rather, it seeks declaratory judgments concerning nine patents that Arbutus owns and has licensed to Genevant (the "Patents"). Specifically, the Complaint seeks declarations that the Covid-19 vaccine made and sold by Pfizer and BioNTech (the "Vaccine") does not infringe the Patents and that the Patents are invalid. Acuitas's only connection to the Vaccine is as one of multiple companies that has licensed or supplied technology to Pfizer and BioNTech for use in the Vaccine.

Acuitas's claims are incurably defective. *Defendants have never accused Acuitas of infringing*. They have never communicated with Acuitas concerning the Patents or the Vaccine *at all*. The Complaint does not allege otherwise. Moreover, Pfizer and BioNTech are large and sophisticated public companies; if either deems it necessary or appropriate to clarify whether their Vaccine infringes Defendants' Patents, it is fully capable of initiating litigation to do so (provided of course that the claims are otherwise permissible). There is no reason why questions concerning

Defendants' Patents and Pfizer/BioNTech's Vaccine can or should be resolved in a litigation filed by *Acuitas* and to which Pfizer and BioNTech are not parties.

If permitted to proceed, this case will either be (i) a shadow litigation in which Acuitas is attempting to adjudicate the relationship between the Defendants and nonparties Pfizer and BioNTech in connection with a Vaccine that Acuitas does not make or sell, or (ii) a proxy litigation in which Pfizer and BioNTech are seeking to resolve those issues without appearing, while reserving the ability to seek a second bite at the apple by filing a case in their own names, later. The law does not permit either effort.

Argument

Defendants' anticipated motion would seek dismissal of the Complaint on the basis that Acuitas has failed to demonstrate an actual controversy between itself and Defendants, or injury-in-fact, both of which are prerequisites of federal subject matter jurisdiction. Defendants' anticipated motion would also argue that, even if there were subject matter jurisdiction, the Court should exercise its discretion not to entertain Acuitas's claims.

1. No Actual Controversy

There is no actual controversy between Acuitas and Defendants because, as noted above, the Complaint does not allege that Defendants ever contacted Acuitas regarding the matters at issue in this suit, does not allege that Defendants ever accused Acuitas of infringing the Patents, and does not allege that Defendants ever attempted to enforce the Patents against Acuitas. Although the Complaint attempts to distract from those glaring pleading failures by citing two letters that Defendants sent to *nonparties* Pfizer and BioNTech beginning more than a year and a half ago, the letters were not sent to Acuitas, do not mention Acuitas, and do not accuse Acuitas of infringement. They do not create an actual controversy between Defendants and Acuitas. Indeed, the letters do not even create an actual controversy with *Pfizer or BioNTech*. They merely propose a collaboration in which Pfizer and BioNTech would gain the benefit of Genevant scientists' experience and expertise (similar to a preexisting license agreement currently in effect between Genevant and BioNTech for applications other than Covid), noting that the Vaccine may infringe absent a license. Because the letters do not create a controversy with Pfizer and BioNTech, they do not create a controversy with Acuitas *a fortiori*.

2. No Injury-In-Fact

Acuitas has also failed to allege injury-in-fact. The Complaint does not allege that Acuitas has lost Vaccine royalties or any other specific revenues because of the two letters Defendants sent to Pfizer and BioNTech, nor does the Complaint identify even a single business deal that Acuitas has lost. Rather, the Complaint relies on Acuitas's subjective worries—for example, that "the ***prospect*** of future claims against other Acuitas licensees … ***threaten[s]*** to cause serious harm to Acuitas's business," and that "Acuitas's ability to enter into new relationships with other ***potential*** partners" may be impacted. Compl. ¶¶ 13, 48; *see id.* ¶ 47 (speculating that Defendants' letters might "hinder" Acuitas's ability to "freely research, develop, and commercialize therapeutics").

The Complaint's allegations do not approach the type of concrete harm required to plead injury-in-fact. First, injury-in-fact is assessed using "an objective standard that ***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). Second, a company's "***economic interest in clarifying its customers' rights ... cannot form the basis of an actual controversy***"—even if the company would "benefit[] if its customers had no fear of suit by [patentee]," and even if clarity might "facilitate[] the sale of [the company's] products." *Microchip Tech., Inc. v. Chamberlain Grp., Inc.*, 441 F.3d 936, 943 (Fed. Cir. 2006).

Third, various specific allegations in the Complaint, and other facts that the Court can consider in ruling on the anticipated motion, confirm the absence of cognizable injury. Far from lost revenues, the Complaint touts the ongoing "amazing success story" of the Vaccine and alleges that "Acuitas is researching and will continue to research and collaborate with partners to develop drugs utilizing" the relevant technology. See Compl., ¶¶ 1, 29, 38, 42. Far from "prospect[ive] … threat[s]" to new licensing deals, Acuitas has publicly touted two licensing deals that it just recently inked, including one with Pfizer (an actual recipient of a Defendants' letters). Far from "prospect[ive] future [litigation] claims" by Defendants against Acuitas's customers, the Complaint does not identify even one such claim in the more than a year and a half since Defendants sent their first letter to Pfizer and BioNTech. And it was *Acuitas itself* that publicly disclosed the existence and substance of the previously private letters in its Complaint—those letters could not have been impacting potential deals with "other potential partners" because they were not public until Acuitas chose to make them so in its Complaint.

3. Discretionary Assessment

Finally, even if the Complaint established subject matter jurisdiction (it did not), the Court should exercise its discretion not to entertain Acuitas's claims. A licensing deal among Defendants, Pfizer, and BioNTech would moot Acuitas's claims at any time—a relevant consideration because one of the very letters Acuitas relies on in its Complaint references licensing discussions and the Complaint does not allege anything to suggest the discussions have concluded. On the other hand, if there is no licensing deal and this Court determines that the Vaccine infringes or the Patents are not invalid, Pfizer and BioNTech could the very next day file an action for non-infringement and invalidity arguing that they are not bound by or estopped from challenging this Court's judgment. It is improper to use the Declaratory Judgment Act as a contrivance for facilitating a second bite at the apple in this fashion.

Defendants thank the Court for its attention to this matter.

Respectfully submitted,

/s/ Raymond Nimrod

Raymond Nimrod

Counsel for Genevant Sciences GmbH

Joined by:

/s/ Daralyn Durie

Daralyn Durie (*pro hac vice* application pending) (Counsel for Arbutus Biopharma Corp.)