

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

ACUITAS THERAPEUTICS INC.,

*Plaintiff,*

vs.

GENEVANT SCIENCES GMBH, and  
ARBUTUS BIOPHARMA CORP.,

*Defendants.*

Case No. 1:22-cv-02229-MKV

**REPLY IN FURTHER SUPPORT OF DEFENDANTS'  
MOTION TO DISMISS THE FIRST AMENDED COMPLAINT**

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The Court should dismiss this case because Acuitas has not met its burden to show subject matter jurisdiction. Alternatively, the Court should exercise its discretion to decline jurisdiction.

## **I. ACUITAS’S INDEMNITY THEORY FAILS**

Acuitas’s indemnity theory requires that it show both (a) an “actual infringement controversy” between Defendants and Pfizer/BNT and (b) a reasonable potential of indemnity liability, “beyond bare indemnity demands or requests.” *Mitek Sys., Inc. v. United Servs. Auto. Ass’n*, 34 F.4th 1334, 1345-46 (Fed. Cir. 2022). Acuitas has not met either requirement. That the Federal Circuit in *Mitek* recently relieved Acuitas of the need to *also* show a concession of indemnification does not change this result.<sup>1</sup> *Mitek* only confirms that dismissal is appropriate.

### **A. Acuitas Has Not Shown A Controversy Between Defendants And Pfizer/BNT**

Acuitas admits (at 12) that it must show an actual controversy between Defendants and Pfizer/BNT. Facts that Acuitas concedes demonstrate that it failed to meet its burden. Specifically, Acuitas does not dispute that: (i) Defendants’ letters to Pfizer/BNT lack any infringement analysis or claim charts; (ii) the letters offered a collaboration as well as discussion of a license; and (iii) Genevant and BNT (Pfizer’s Covid-19 vaccine partner) have a history of collaboration and prior licensing without litigation. Moreover, Acuitas admits (at 20) that it is not privy to and does not know the status of discussions between Genevant and Pfizer/BNT—making it impossible for Acuitas to show a present controversy between Defendants and Pfizer/BNT.

Because it cannot dispute these facts, Acuitas resorts to misdirection. For example, Acuitas argues that because Defendants sued non-party Moderna after having previously sent Moderna letters, an actual controversy between Defendants and Pfizer/BNT must exist as well. But Moderna is situated very differently vis-à-vis Defendants than is Pfizer/BNT. While Defendants’ letters to

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<sup>1</sup> Given *Mitek*’s instruction, Defendants no longer contend that a complaint requires a concession of an indemnity obligation, as had been previously stated in other cases.

Pfizer/BNT were sent with the historical backdrop of prior *collaboration*, Defendants' letters to Moderna were sent during an ongoing *years-long litigation battle* in which Moderna is seeking to invalidate several of Defendants' Patents. Acuitas further ignores that (i) Defendants have not sued Pfizer/BNT despite having sued Moderna more than eight months ago and (ii) discussions between Pfizer/BNT and Genevant have not been terminated. Dkt. 44 at 24 n.9. Acuitas also erroneously relies (at 9) on Defendants' mention of Acuitas in their complaint against Moderna as supposedly "showing that Defendants do allege that Acuitas's technology violates their patents." This is false. Moderna is not an Acuitas customer, and the complaint only mentions Acuitas to provide the full factual context of Moderna's licensing history, not as an accused infringer.

Acuitas also attacks Defendants' collaboration offer to Pfizer/BNT as somehow not sincere because it was sent after "the vaccine" had already been used in clinical trials. But, it was well-known that Pfizer/BNT were facing challenges related to formulation, such as stability and storage issues, and there was the possibility for next-generation vaccines (*e.g.*, booster shots). The letters offered access to "Genevant scientists' extensive experience and expertise with the formulation and manufacture of LNP delivery systems." Dkt. 45-2.<sup>2</sup> Acuitas's contention that Defendants' Patents do not relate to storage, transport, or manufacturing only highlights that Defendants offered a genuine collaboration in which Pfizer/BNT could gain access to Genevant scientists' expertise regarding formulation matters beyond those allegedly addressed in the patents.

Acuitas's resort to misdirection extends even further to the three cases it cites on this issue: *Mitek*; *3M Co. v. Avery Dennison Corp.*, 673 F.3d 1372 (Fed. Cir. 2012); and *Hewlett-Packard*

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<sup>2</sup> Contrary to Acuitas's suggestion (at 5) that Defendants have not commercialized relevant LNP technology, Defendants' technology is used in the only commercial siRNA-LNP product (ONPATTRO®), and multiple companies have licensed the technology for use with mRNA, including vaccines. *See, e.g.*, [www.genevant.com/our-technology](http://www.genevant.com/our-technology); [www.genevant.com/gritstone-and-genevant-sciences-announce-license-agreement-for-covid-19-vaccine/](http://www.genevant.com/gritstone-and-genevant-sciences-announce-license-agreement-for-covid-19-vaccine/).

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