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April 5, 2023

The Honorable Mary Kay Vyskocil
United States District Court
Southern District of New York
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. 22-cv-02229-MKV

Dear Judge Vyskocil:

I write on behalf of Plaintiff Acuitas Therapeutics Inc. in response to yesterday's letter from Defendants Genevant Sciences GmbH and Arbutus Biopharma Corp. Acuitas respectfully submits that Defendants' letter confirms why the Court should deny their pending motion to dismiss this action.

Acuitas brought this declaratory-judgment action over a year ago in March 2022 because Defendants were threatening Acuitas's customers (BioNTech and Pfizer) with patent-infringement lawsuits based on their sale of the COVID-19 vaccine Comirnaty®, which uses Acuitas's lipid nanoparticles. Those threats could expose Acuitas itself to infringement claims by Defendants or expose Acuitas to claims for indemnification by Acuitas's customers, or both.

In support of its motion to dismiss, Defendants protested that the Court either has no jurisdiction or should decline jurisdiction in part because Defendants were supposedly just engaging in business collaborations with BioNTech and Pfizer, not threatening patent infringement actions. (*See* D.I. 44 at 1–2, 22; D.I. 54 at 10.) For example, Defendants argued, "[t]here is no need to burden the Court with Acuitas's premature side-show action when the actual parties to the discussions have not sought judicial intervention and a license could moot this case at any time." (D.I. 44 at 4).

Defendants have now sued Pfizer and BioNTech in New Jersey. *See Arbutus Biopharma Corp. et al* v. *Pfizer Inc. et al.*, No. 2:23-cv-01876-ZNQ (D.N.J.) ("NJ Complaint"). Their NJ Complaint confirms that there is, and has been, an actual controversy between Defendants and Acuitas as to whether

Comirnaty® infringes Defendants' patents (*compare* D.I. 42 ¶¶ 114, 153, 179, *with* D.I. 63-1 ¶¶ 63–115), that this litigation is not, and never was, "premature"—it simply began sooner than Defendants would have liked—and that Defendants' motion to dismiss in this Court was just a delay tactic to buy time to sue elsewhere. Indeed, three of the patents that the Defendants assert in New Jersey are among the ones Acuitas challenged in this Court first, and the other two New Jersey-case patents are from the same patent family as one of the ones at issue here in this case, U.S. Patent No. 9,504,651. (D.I. 63-1 at *225, *255; D.I. 1-7 at 2.) Genevant had these two additional patents issue from the same families after Acuitas filed this action. Both patents expire in a matter of months, on June 30, 2023, and the timing of each appears to be a deliberate attempt by Defendants to try to ensnare Comirnaty®, as the applications for both patents were filed on May 25, 2021, after Comirnaty® was already being widely used throughout the world, and after information cited in the NJ Complaint as the ostensible basis for the infringement allegations had already been made public.

Defendants tout that their New Jersey lawsuit does not mention Acuitas. (D.I. 63 at 1.) That proves too much. Defendants wrote that complaint long after Acuitas had filed this case and Defendants had moved to dismiss it, and thus their omission of the name "Acuitas" in New Jersey was tactical. The entire theory of the NJ Complaint is that Defendants invented the "LNP technologies needed to deliver messenger ribonucleic acid ('mRNA') therapeutics" used in Pfizer and BioNTech's Comirnaty® (D.I. 63-1 ¶ 1) and that this technology is allegedly "key" (*id.* ¶¶ 3–5, 34–36), while the central allegation of Acuitas's first-filed case before this Court is that Acuitas invented that technology and Defendants' threats of infringement against Pfizer and BioNTech were meritless (*see, e.g.*, D.I. 42 ¶¶ 5–13). The NJ Complaint does not allege that Pfizer and BioNTech are Defendants' customers with respect to the LNP in the Comirnaty® vaccine, nor could it because Pfizer and BioNTech received their LNP technology for Comirnaty® from Acuitas. Furthermore, Defendants have not given Acuitas a covenant not to sue, or any other protection against suing Acuitas for induced infringement in the future. They just omitted the name "Acuitas" from their NJ Complaint so they could write a letter telling this Court they had done so.

Regarding the second basis of jurisdiction here—a risk of indemnification liability—Defendants' New Jersey lawsuit does nothing to reduce the risk that Acuitas might have to indemnify BioNTech; if anything, the filing of an actual lawsuit against BioNTech makes such a risk more acute.

To the extent the NJ Complaint has any bearing on Defendants' motion to dismiss this action, it favors denying that motion. Defendants previously told this Court that they had no controversy with Pfizer and BioNTech (D.I. 54 at 1), that they "have not sued" Pfizer or BioNTech even after having sued Moderna (*id.* at 2), and that Acuitas's lawsuit could be mooted "at any time" by "pending discussions" between Genevant and Pfizer and BioNTech. (D.I. 44 at 1.) But Defendants

have now sued Pfizer and BioNTech, and report in their complaint that the then-pending "discussions" have failed. (*See* D.I. 63-1 ¶ 7.)

The allegations in Defendants' NJ Complaint undercut the assertions they made to this Court, in their motion to dismiss, that they had not threatened Pfizer or BioNTech with patent-infringement suits before Acuitas filed this action. In their NJ Complaint, Defendants now admit that their letters to Pfizer and BioNTech—the very letters on which Acuitas relied—were, in fact, 35 U.S.C. § 287(a) notices of infringement. (*See* D.I. 63-1 ¶¶ 42, 46, 57–59, 75, 92, 102.) Defendants also admit that they "reached out orally and in writing multiple times in the second half of 2021" to Pfizer and BioNTech, and that Pfizer and BioNTech refused to provide samples, implicitly admitting that Defendants requested samples. (*See* D.I. 63-1 ¶¶ 54–61.) A reasonable person would view these actions as a threat of patent infringement. Indeed, Defendants go so far as to allege willful infringement based on BioNTech and Pfizer having not acquiesced to their threats, meaning that—according to Defendants—Pfizer and BioNTech could not reasonably have concluded anything other than that there was an allegation of infringement. (*See* D.I. 63-1 ¶¶ 78, 96, 114.)

Defendants nevertheless argue that this Court should exercise its discretion to dismiss this case because the New Jersey lawsuit creates a risk of duplicative litigation. (D.I. 63 at 1; D.I. 44 at 24–25.) If that is true, it is a problem of Defendants' own making. More than a year after Acuitas filed this lawsuit (D.I. 1 (filed March 18, 2022)), Defendants silently created—and were the sole entrants in—the slowest race to the courthouse ever, filing suit in New Jersey and thus creating the second, duplicative lawsuit. Notably, Pfizer is headquartered in New York and incorporated in Delaware; BioNTech is based in Germany with North American headquarters in Cambridge, Massachusetts. Defendants' trip to Trenton appears to be nothing more than an effort to avoid filing in this Court.

Acuitas respectfully submits that Defendants' belated opening of a second front in this controversy confirms that this Court had subject-matter jurisdiction to decide the issues raised by the first front—Acuitas's request for a declaratory judgment—and that the Court should deny Defendants' motion to dismiss.

Respectfully submitted,

/s/ Nicholas Groombridge

Nicholas Groombridge

CC: All Counsel of Record (via ECF)