IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

ACUITAS THERAPEUTICS INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 22-_____
	)	
GENEVANT SCIENCES GMBH, AND ARBUTUS BIOPHARMA CORP.	)	
	)	
Defendants.	)	
	)	

COMPLAINT FOR DECLARATORY JUDGMENT OF NON-INFRINGEMENT AND INVALIDITY

Acuitas Therapeutics Inc. ("Acuitas"), for its Complaint against Genevant Sciences GmbH ("Genevant") and Arbutus Biopharma Corp. ("Arbutus"), alleges as follows:

NATURE OF THE ACTION

1. COVID-19 has presented the worst public health crisis in a century. Two years later, however, the pandemic is receding. That is in large part due to the amazing success story of the mRNA vaccines against the virus that causes COVID-19. Those vaccines exist only because of decades of hard work and ingenuity by the Plaintiff, Acuitas, and others, to develop the technology that allowed the rapid development of a vaccine to combat the pandemic.

2. Traditional vaccines create immunity by injecting a patient with pieces of the virus, or an inactive form of that virus. The vaccines that Acuitas helped to develop utilize messenger RNA ("mRNA") technology, do not require injection of the virus, and were developed much more quickly than traditional vaccines. All living organisms, including both humans and viruses, make proteins, which are the workhorses that complete the tasks needed by that organism. In humans

the "blueprint" for these proteins is carried in genes (i.e., DNA), but that blueprint needs to be converted into an mRNA message that tells the body to make a particular protein.

3. mRNA vaccines work by introducing into a person the mRNA message that instructs the body to make a foreign protein that is itself a piece of a virus. When that viral protein is made, or "expressed," by the person's cells, that person's immune system then recognizes that the protein is foreign and develops an immune response to it. If that person is later infected with the virus itself, his or her immune system is primed to protect against or minimize the significance of the viral infection. Because the mRNA contained in the vaccine represents a protein that is only a piece of the virus, the entire virus is never introduced into the body and there is thus no risk of infection from the vaccine.

4. For all of its advantages, however, working with mRNA presents prodigious challenges. First, mRNA is exceptionally fragile and, when injected into the body, breaks down extremely quickly. Second, mRNA is too large a molecule to enter into human cells on its own. An mRNA vaccine therefore requires a delivery system that protects the mRNA after it is injected into the person and transports the mRNA into the person's cells.

5. In the decade before COVID-19 emerged, Acuitas worked to solve that delivery-system problem: it painstakingly engineered a microscopic sphere of fats called a Lipid Nanoparticle, or "LNP," that can envelop and protect the mRNA. These mRNA-LNPs protect the fragile mRNA, allow it to cross the membrane of a human cell, and then release the mRNA so that it can be used to create the proteins that will in turn generate an immune response. One of Acuitas's mRNA-LNPs is used, under license, in Pfizer and BioNTech's COVID-19 vaccine, COMIRNATY®, which has been a global success in protecting people from COVID-19. To date, over 320 million doses of COMIRNATY® have been administered in the United States.

6. The defendants here, Arbutus and Genevant, had nothing to do with that success. Neither has a COVID-19 vaccine, neither has created any component of such a vaccine, and neither has commercialized an LNP that can effectively wrap and protect any mRNA molecule. On the contrary, only after COMIRNATY® achieved worldwide commercial success did Arbutus and Genevant emerge to make the spurious claim that COMIRNATY® may infringe Arbutus's patents, and, on information and belief, to demand hundreds of millions, if not billions, of dollars in wholly unjustified payments. Arbutus and Genevant seek the benefits flowing from COMIRNATY® without having borne any of the burden of developing it. Their claim to rights in—and payment for—COMIRNATY® is baseless.

7. What is now Arbutus was originally founded as Inex Pharmaceuticals Inc. in the early 1990s, by leading LNP scientists Dr. Pieter Cullis, Dr. Thomas Madden, and Dr. Michael Hope, to develop therapeutics incorporating lipid-based nanomaterials. This research led to the development of anticancer therapeutics that provided greater potency in fighting tumors while reducing the side effects often seen with such drugs. Subsequently, Inex (later known as Tekmira Pharmaceuticals Corp.) developed lipid nanoparticles to deliver new classes of drugs based on a type of nucleic acid called small interfering RNA, or "siRNA," which are short pieces of RNA that interfere with the body's ability to make certain proteins that may cause disease. Some of this research led to the development of an siRNA therapeutic called ONPATTRO®.

8. By 2008 the company that is now Arbutus was no longer interested in supporting the work that Dr. Madden and Dr. Hope were pursuing, and terminated their employment. Together with Dr. Cullis, Drs. Madden and Hope founded Acuitas Therapeutics Inc. (originally called AlCana Technologies Inc.) to develop LNP technology, and, by 2012, Acuitas had decided to focus on the development of LNP technology for the delivery of mRNA. Conversely, Arbutus

chose to focus its business on the much less challenging problem of developing LNP carriers to encapsulate siRNA.

9. There were good scientific reasons for Arbutus to have bet on siRNA therapeutics rather than mRNA therapeutics. Despite the similarity in their names, siRNA and mRNA are fundamentally different in ways that may frustrate the design of LNPs to encapsulate mRNA. For starters, there is the size difference: mRNA molecules are much larger than siRNA molecules, with the mRNA in COMIRNATY® some 200 times longer than an average siRNA molecule. Then there is the rigidity difference: siRNA molecules are akin to short, sturdy rods, while the longer mRNA molecules can fold and wind into complex shapes. The technology needed to wrap an siRNA molecule in a lipid nanoparticle is thus vastly different (and simpler) than what is needed to wrap an mRNA molecule. Importantly, mRNA is also much less stable than siRNA, significantly complicating mRNA's formulation and encapsulation in LNP and the manufacture of mRNA vaccines.

10. While the hope for an mRNA therapeutic is over thirty years old, mRNA's inherent instability and its inability to enter cells presented major barriers to its clinical use. In addition, previously known ways to package and deliver mRNA were either ineffective or toxic.

11. Acuitas's scientists solved those problems. They identified appropriate formulation conditions to allow efficient encapsulation of mRNA into LNPs and, importantly, to protect the mRNA from degradation during the formulation process. They tested hundreds of different LNPs with mRNA in order to determine the characteristics for successful encapsulation. And Acuitas's scientists, in collaborations with its partners, evaluated different LNPs for use in a variety of different vaccines. This research has been published in leading scientific journals, including in *Nature*.

12. Acuitas's research has also focused on the design and synthesis of novel lipids that provide more efficient and safe delivery of mRNA. This research has resulted in the identification of hundreds of novel lipids with improved activity and safety. Acuitas has also patented its novel discoveries, which include the ionizable cationic lipid known as ALC-0315, which is used in the LNP in COMIRNATY®. Acuitas and its researchers have received global praise, recognition, and awards for their role in developing the LNP technology required for mRNA vaccines, including the critical LNP component of COMIRNATY®. These awards include the 2021 Global Impact Award by Life Sciences British Columbia, the Prince Mahidol Award, the VinFuture Grand Prize, the BIAL Award in Biomedicine, and the admission of Dr. Pieter Cullis to the Order of Canada.

13. When Arbutus saw the tremendous success of the mRNA vaccines for COVID-19, it realized that having chosen to pursue siRNA therapeutics instead of mRNA was a bad decision, both scientifically and financially. Upon information and belief, Arbutus and Genevant sent a demand letter to Pfizer threatening to assert nine patents against the sale and use of the COMIRNATY® vaccine. That demand, and the prospect of future claims against other Acuitas licensees seeking to use Acuitas's LNPs for other mRNA vaccines and therapeutics, threaten to cause serious harm to Acuitas's business.

14. Acuitas therefore brings this action pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201 for a declaratory judgment that the following nine Arbutus patents are not infringed by the manufacture, use, offer for sale, sale, or importation into the United States of COMIRNATY® and are, in any event, invalid: U.S. Patent Nos. 8,058,069 (the "'069 patent"); 8,492,359 (the "'359 patent"); 8,822,668 (the "'668 patent"); 9,006,417 (the "'417 patent"); 9,364,435 (the "'435 patent"); 9,404,127 (the "'127 patent"); 9,504,651 (the "'651 patent");

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