

Exhibit A

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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

ARBUTUS BIOPHARMA CORP. and
GENEVANT SCIENCES GMBH,

Plaintiffs,

v.

PFIZER INC. and BIONTECH SE,

Defendants.

PFIZER INC. and BIONTECH SE,

Counterclaimants,

v.

ARBUTUS BIOPHARMA CORP. and
GENEVANT SCIENCES GMBH,

Counterclaim-Defendants.

Civil Action No. 3:23-cv-1876-ZNQ-TJB

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JURY TRIAL DEMANDED

PFIZER INC. AND BIONTECH SE'S
ANSWER, AFFIRMATIVE
DEFENSES, AND
COUNTERCLAIMS IN RESPONSE
TO COMPLAINT FOR PATENT
INFRINGEMENT

Defendants Pfizer Inc. ("Pfizer") and BioNTech SE ("BioNTech") (collectively, "Defendants") hereby answer the Complaint for Patent Infringement ("Complaint") filed by

Plaintiffs Arbutus Biopharma Corp. (“Arbutus”) and Genevant Sciences GmbH (“Genevant”) (collectively, “Plaintiffs”). Any allegations not expressly admitted are denied. This answer follows the numbering provided in Plaintiffs’ Complaint. To the extent that the section headings of Plaintiffs’ Complaint contain allegations, those allegations are denied. To the extent Plaintiffs’ footnotes contain allegations, those allegations are denied.

INTRODUCTION

1. Arbutus invented and was awarded numerous patents on the breakthrough lipid nanoparticle (“LNP”) technologies needed to deliver messenger ribonucleic acid (“mRNA”) therapeutics to human cells. Genevant, a world leader in nucleic acid drug delivery and development, licenses these patents from Arbutus.

RESPONSE: Defendants admit that the Patent and Trademark Office issued United States Patent Nos. 9,504,651; 8,492,359; 11,141,378; 11,298,320; and 11,318,098 (collectively, the “Asserted Patents”), but deny that the Asserted Patents are valid or infringed by Defendants. Defendants otherwise lack the knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 1 and therefore deny the allegations.

2. When the world was thrust into a devastating pandemic and urgently needed LNP technologies to deliver an mRNA-based COVID-19 vaccine to cells in the body, the necessary LNP technologies had, fortunately, already been invented by Arbutus’s scientists years before and stood ready for use. Defendants could not have accomplished the feat of creating and manufacturing a vaccine at a speed unprecedented in the history of medicine but for their use of Plaintiffs’ existing and proven LNP technologies. Yet Defendants never paid Plaintiffs to use those technologies. And Defendants continue to knowingly use the technologies to make and sell the vaccine, amassing tens of billions of dollars in revenues. Plaintiffs have thus filed this case to obtain fair compensation for their inventions, without which the vaccine would not exist.

RESPONSE: Defendants deny infringement of any valid claim of the Asserted Patents and that Plaintiffs are entitled to damages. At least because of the scope, breadth, and vagueness of this allegation, Defendants otherwise lack the knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 2 and therefore deny the allegations.

3. Defendants’ vaccine works by delivering a synthetic mRNA to the body’s cells. The biggest technological barrier to mRNA-based medicines is not the mRNA itself—BioNTech’s

CEO designed the mRNA over a weekend. The biggest barrier is instead how to *deliver* the mRNA to cells safely and effectively. As Pfizer’s CEO Albert Bourla has explained, “[t]he whole mRNA [vaccine] platform is not how to build an mRNA molecule; *that’s the easy thing*.” The hard thing is “*how to make sure the mRNA molecule will go into your cells* and give the instructions.”¹ A Nobel Prize-winner has similarly explained that the key to RNA therapeutics was “*delivery, delivery, delivery*.”²

RESPONSE: To the extent the allegations of Paragraph 3 purport to rely on public statements, those statements speak for themselves. Defendants admit that Defendants’ vaccine (referred to herein by its trade name Comirnaty[®]) contains synthetic mRNA. At least because of the scope, breadth, and vagueness of this allegation, Defendants otherwise lack the knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 3 and therefore deny the allegations.

4. The delivery problem had persisted for decades until a team of Arbutus scientists, many now at Genevant companies, developed and refined technologies that solved the problem, for which they were awarded many patents. Their solution involved microscopic particles, built from four carefully-selected types of fat-like molecules, that are stable enough to shelter and protect fragile ribonucleic acid (“RNA”) molecules on a voyage through the human body to a target cell, and then through the target cell’s membrane, before finally releasing the RNA. These particles are called lipid nanoparticles and their invention was widely recognized as a major achievement that is essential for mRNA vaccines.

RESPONSE: Defendants admit that the Asserted Patents were issued, but deny that the Asserted Patents are valid or infringed by Defendants. At least because of the scope, breadth, and vagueness of this allegation, Defendants lack the knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 4 and therefore deny the allegations.

5. Arbutus also developed the technologies needed to manufacture these LNPs. Before Arbutus’s scientists tackled the manufacturing challenges, methods of manufacturing LNPs for RNA employed harsh conditions that would damage the RNA that the LNPs were supposed to protect. Arbutus’s scientists developed new, elegant manufacturing methods that preserved the

¹ Nathan Vardi, *Covid’s Forgotten Hero: The Untold Story Of The Scientist Whose Breakthrough Made The Vaccines Possible*, Forbes, Aug. 17, 2021 (<https://tinyurl.com/86ud83kj>).

² Erika Check, *RNA to the Rescue?*, Nature, 425:10-12 (2003) (www.nature.com/articles/425010a).

RNA and allowed for it to reach target cells in an undamaged state. Their solution used what is called a T-connector to mix together flows of lipids and dissolved RNAs in a process that ensures the RNA is both encapsulated and protected during the formulation process.

RESPONSE: At least because of the scope, breadth, and vagueness of this allegation, Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 5 and therefore deny the allegations.

6. Defendants have long recognized the value of Plaintiffs' LNP technologies and patent rights. For example, in 2018, BioNTech paid for a license to use the technologies in a contract that described Genevant's platform as "the best lipid nanoparticle technology." The license only permitted BioNTech to use the technology in specific cancer and rare liver disease treatments and did not extend to uses for infectious diseases like COVID-19. Pfizer, on information and belief, has long known about that license and Plaintiffs' patents. Yet neither BioNTech nor Pfizer asked for a license to use Plaintiffs' LNP technologies in a COVID-19 vaccine. They just used the technologies without paying for them—keeping for themselves tens of billions in revenue that would never have existed were it not for Plaintiffs' innovation.

RESPONSE: Defendants admit that there is a license agreement between BioNTech and Genevant, which speaks for itself. Defendants deny infringement of any valid claim of the Asserted Patents and that Plaintiffs are entitled to damages. Defendants deny the remaining allegations of Paragraph 6.

7. Plaintiffs have licensed their technologies to many companies and would have granted a license to Defendants on reasonable terms for use in a COVID-19 vaccine. Indeed, the parties engaged in licensing discussions that unfortunately failed to result in a settlement. Plaintiffs have therefore been left no choice but to file this lawsuit to seek fair compensation in the form of a reasonable royalty for Defendants' unlicensed use of Plaintiffs' patents.

RESPONSE: Defendants admit that Plaintiffs sent a letter to Pfizer copying BioNTech on November 23, 2020, and that Defendants have not entered into a license with Plaintiffs. Defendants deny infringement of any valid claim of the Asserted Patents and that Plaintiffs are entitled to damages. At least because of the scope, breadth, and vagueness of this allegation, Defendants otherwise lack the knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 7 and therefore deny the allegations.

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