IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

BioNTech SE, BioNTech Manufacturing GmbH, and Pfizer Inc.,

Plaintiffs and Counter Defendants,

v.

CureVac SE (*f/k/a* CureVac AG),

Defendant and Counter Claimant,

and

CureVac Manufacturing GmbH,

Counter Claimant.

Civil Action No. 2:23-cv-0222 (JKW-DEM)

JURY TRIAL DEMANDED

BIONTECH AND PFIZER'S SECOND AMENDED COUNTERCLAIMS AND ANSWER TO CUREVAC'S FIRST AMENDED COUNTERCLAIMS

COUNTERCLAIMS

Pursuant to this Court's Order (ECF No. 240), without admitting any of the allegations of CureVac SE and CureVac Manufacturing GmbH (collectively, "CureVac" or "Defendants") other than those expressly admitted herein, and without prejudice to the right of BioNTech SE and BioNTech Manufacturing GmbH (collectively, "BioNTech") and Pfizer Inc. ("Pfizer" and, together with BioNTech, "Plaintiffs") to plead additional counterclaims as the facts of the matter warrant, BioNTech and Pfizer assert the following counterclaims against CureVac.

INTRODUCTION

1. This action involves Plaintiffs' and Defendants' respective independent efforts to develop vaccines to combat the COVID-19 pandemic. Plaintiffs' Comirnaty® was the world's first mRNA vaccine approved for public use, deployed in record time, and proved to be effective in preventing severe disease, hospitalization, and death from the COVID-19 pandemic. BioNTech

worked tirelessly to create the mRNA vaccine after years of research and development of mRNA technology, collaborating with Pfizer to bring the vaccine through regulatory approval and distribution to combat this global pandemic. All of the investment and work paid off—BioNTech and Pfizer successfully developed an mRNA vaccine, proved its efficacy, established global manufacturing and supply chains, and gained regulatory approval. Their efforts played a vital role in managing the global COVID-19 crisis.

2. CureVac also tried to develop a vaccine to help the fight against COVID-19. Unlike BioNTech and Pfizer, CureVac was unsuccessful. Presumably using its alleged patented technology, CureVac's vaccine was an unsuccessful treatment and lacked sufficient efficacy for regulatory approval.

3. Failing to supply a useful vaccine, CureVac now attempts to profit from BioNTech and Pfizer's success through allegations of patent infringement. BioNTech and Pfizer, however, developed their Comirnaty® vaccine without any contribution from CureVac's alleged mRNA technology—which is why BioNTech and Pfizer brought this declaratory judgment action—instead relying on innovations from their own scientists and coordination with the global scientific community. CureVac played no part in Comirnaty®'s stunning success.

COMIRNATY® WAS BUILT ON DECADES OF PLAINTIFFS' AND THEIR PARTNERS' FOUNDATIONAL RESEARCH—NOT CUREVAC'S

4. Comirnaty® was the first-approved vaccine utilizing messenger RNA ("mRNA") technology. If efficacious, an mRNA vaccine works by introducing into a person mRNA that instructs the body to make a certain protein, such as a piece of a virus that the vaccine seeks to protect against. When that protein is made, or "expressed," by a person's cells, that person's immune system can recognize the protein as foreign and develop an immune response to it. If that person is later infected with the actual virus itself, his or her immune system is ready to protect

against or minimize the severity of the viral infection. This is unlike previously approved non-mRNA vaccines, developed before the COVID-19 pandemic, such as weakened or inactivated viruses injected into the patient.

5. Scientists have known since the 1970s that mRNA has the potential to be administered as a therapeutic to translate a protein that may treat or prevent disease in humans. By the 1990s, researchers demonstrated that mRNA administered as a therapeutic could be used to elicit antiviral immune responses in animal models, *e.g.*, encoding proteins expressed by cancer cells to induce an immune response.

6. One vexing problem encountered by researchers, however, was that synthetic mRNA can trigger proteins that result in a non-antigen-specific immune response, such as activation of toll-like receptors. This can lead to an undesirable reaction in the body, such as inflammation. Despite this, Dr. Katalin Karikó (a BioNTech scientist and professor at the University of Pennsylvania), was convinced that mRNA structures could be used to instruct cells to make their own therapeutic proteins.[1]

7. In the mid-2000s, after years of painstaking research, Dr. Karikó and Dr. Drew Weissman made a key breakthrough while they were both at the University of Pennsylvania: they discovered that certain chemical modifications to RNA nucleosides could reduce or eliminate the inflammatory reaction. They showed that the unmodified mRNA that they expressed induced an

[1] As Dr. Anthony Fauci acknowledged, Dr. Karikó "was, in a positive sense, kind of obsessed with the concept of messenger RNA." (D.I. 104, Ex. 1 at 1.) Despite her tenacity, Dr. Karikó struggled to stay afloat in academia, as she sought—and was denied—grant after grant to pursue ideas that seemed wild and fanciful to many in the academic community. (*Id.* at 1-2.) As one of her colleagues explained, "[w]hen your idea is against the conventional wisdom that makes sense to the star chamber, it is very hard to break out." (*Id.* at 1.) Yet, Dr. Karikó's focus and drive never wavered. Her genius was a "willingness to accept failure and keep trying, and her ability to answer questions people were not smart enough to ask." (*Id.* at 3.)

immune response, while the control—called transfer RNA ("tRNA"), an intermediary molecule used during protein translation that links the mRNA and the amino acid sequence of proteins—did not. In particular, they discovered that a class of nucleotides called pseudouridines found in tRNA allowed it to evade the cell's internal immune response.

8. This led Drs. Karikó and Weissman to investigate the idea of modifying uridines in mRNA with naturally occurring pseudouridines found in tRNA, including 1-methylpseudouridine. They discovered that the uridine modification helped synthetic mRNA evade the body's innate immune system. Drs. Karikó and Weissman published their insights in a series of research papers, including a seminal 2005 paper titled "Suppression of RNA Recognition by Toll-like Receptors: The Impact of Nucleoside Modification and the Evolutionary Origin of RNA." (D.I. 104, Ex. 2.)[2]

9. Drs. Karikó and Weissman presented their ideas to pharmaceutical companies and venture capitalists. At first, no one was interested. As Dr. Weissman later recounted, "[w]e were screaming a lot, but no one would listen." (D.I. 104, Ex. 1 at 4.) BioNTech, however, took notice of Drs. Karikó and Weissman's work and began funding Dr. Karikó's laboratory. (*Id.*) In 2013, Dr. Karikó joined BioNTech full-time as a senior vice president.

10. Drs. Karikó and Weissman's discovery that modified mRNA nucleosides could evade the cell's internal immune response was the critical innovation behind the only fully

[2] Drs. Karikó and Weissman patented their groundbreaking discovery by submitting, in 2005, Provisional Patent Application No. 60/710,164 titled "RNA Containing Modified Nucleosides and Methods of Use Thereof." (D.I. 104, Ex. 3.) The '164 application describes how "[t]his invention provides RNA . . . comprising pseudouridine or a modified nucleoside" and expressly identifies N1-methyl-pseudouridine. (D.I. 104, Ex. 3 at 1, 14.) The '164 application further "provides methods of reducing the immunogenicity of RNA" by using mRNA with pseudouridine nucleotides. (*Id.* at 1.) The U.S. Patent Office eventually granted U.S. Patent No. 8,691,966 ("the '966 patent") to Drs. Karikó and Weissman, which claims priority to the '164 application. (D.I. 104, Ex. 4.) The '966 patent expressly claims mRNA comprising "a modified nucleoside selected from the group consisting of (i) 1-methypseudouridine ($m^1\Psi$) and (ii) pseudouridine (Ψ)." (D.I. 104, Ex. 4 at claim 1.)

approved mRNA COVID-19 vaccines, BioNTech and Pfizer's Comirnaty® and Moderna's Spikevax®. Moderna's co-founder, Derrick Rossi, recognized this discovery as "fundamental to this entire field" of mRNA vaccines and therapeutics. (D.I. 104, Ex. 5 at 2.) In Dr. Rossi's estimation, Drs. Karikó and Weissman's work will "earn them a Nobel Prize because it really is what allows these mRNA vaccines and any mRNA therapeutic down the road" (*id.*), and Moderna's co-founder reiterated that, "[i]f anyone asks [him] whom to vote for some day down the line, [he] would put them front and center" (D.I. 104, Ex. 6 at 7). According to Dr. Rossi, Drs. Karikó and Weissman's "fundamental discovery is going to go into medicines that help the world." (*Id.*) In fact, Moderna backed up Dr. Rossi's belief with its pocketbook by taking a license from the University of Pennsylvania's successor-in-interest, Cellscript, LLC so it could practice patents embodying Drs. Karikó and Weissman's "fundamental discovery," including patents disclosing the modified uridine that Moderna's mRNA vaccine uses. (*Id.*; D.I. 104, Ex. 7.)

11. For their discovery, Drs. Karikó and Weissman have been honored on several occasions by institutions such as the Columbia University Irving Medical Center and the European Patent Office for their "trailblazing" work, which "laid the foundation for the creation of [an] incredibly effective COVID-19 vaccine[.]" (Exs. 8, 9; *see also* Exs. 10 and 11.) Drs. Karikó and Weissman have also been presented with many other awards, such as the Princess of Asturias Award, the Albany Medical Center Prize in Medicine and Biomedical Research, the 2022 Breakthrough Prize in Life Sciences, and the 2021 Lasker Award—America's top biomedical research prize. (D.I. 104, Exs. 10, 12, 13, 14, 15, and 16.)

12. Dr. Karikó's continued research on modified mRNA at BioNTech included determining that an mRNA vaccine could elicit antibodies against the Zika virus. In 2017, Dr. Karikó co-authored a paper in *Nature* (the "2017 *Nature* Paper") demonstrating that "a single low-

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