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

BIONTECH SE, BIONTECH MANUFACTURING GMBH, and PFIZER, INC., Plaintiffs/Counterclaim Defendants, v. CUREVAC SE (f/k/a CUREVAC AG), Defendant/Counterclaimant, and CUREVAC MANUFACTURING GMBH, Counterclaimant.	C.A. No. 2:23-cv-222-JKW-DEM **JURY TRIAL DEMANDED**

CUREVAC SE AND CUREVAC MANUFACTURING GMBH'S ANSWER TO BIONTECH SE, BIONTECH MANUFACTURING GMBH, AND PFIZER, INC.'S SECOND AMENDED COUNTERCLAIMS

INTRODUCTION

1. The COVID-19 pandemic was an unprecedented public-health crisis that required an unprecedented response, and BioNTech and Pfizer's Comirnaty® vaccine was, and continues to be, an essential part of that response. But the story that BioNTech and Pfizer are telling this Court about their development of Comirnaty® is, at best, incomplete. They say their success was based on their own work (though they don't say what that was), and that of scientists at the University of Pennsylvania, the National Institutes of Health, and Acuitas Therapeutics.

2. As will become evident in this case, the real story is that Comirnaty® is an effective vaccine, and that BioNTech and Pfizer were able to quickly develop and bring it to market, because it incorporates the extensive family of technologies claimed in CureVac's patents-in-suit: the same mRNA, manufactured by the same process, administered to patients in the same way, and delivered to those patients' cells using the same delivery system.

3. But instead of respecting CureVac's intellectual property rights (by taking a license to CureVac's COVID-19 patent portfolio), BioNTech and Pfizer filed this lawsuit, in which they argue that Comirnaty® does not infringe those patents. And instead of addressing the indisputable evidence of infringement in the documents discussed in and submitted with CureVac's Counterclaims, or providing any other evidence to support their assertions of non-infringement, they are trying to distract the Court from the real issues by instead focusing on the work of the Penn, NIH, and Acuitas scientists. To be clear, CureVac respects the work that others have done in the field of mRNA therapeutics, and does not seek to detract from or diminish others' prior contributions. As history makes clear, inventors do not work in a vacuum: advances in science and medicine can result from multiple scientists working to advance the field over the prior contributions of other scientists.

4. The inventions claimed in CureVac's patents are no different: they resulted from the creative and persevering work of the CureVac scientists listed as inventors on each patent, and they constituted additions to, and advances over, the contributions of others. BioNTech and Pfizer argue that the claims of the patents-in-suit are invalid because those contributions of other scientists were disclosed in prior-art patent applications and/or scientific publications. But they fail to tell the Court that CureVac submitted prior art disclosing those prior contributions to the expert examiners in the Patent Office during prosecution of the patents-in-suit, and that the Patent Office issued the patents-in-suit to CureVac only after thorough consideration of that prior art.

5. BioNTech and Pfizer also ignore the indisputable fact (discussed in CureVac's Counterclaims) that their success in rapidly developing Comirnaty® resulted in large part from Acuitas having improperly given them CureVac's confidential, proprietary clinical trial data proving that the Acuitas ALC-315 lipid could be used to safely and effectively deliver an mRNA vaccine to humans. With that information in hand, BioNTech and Pfizer were able to rapidly pivot to use that ALC-315 lipid (instead of the other Acuitas lipids they were testing) in Comirnaty®, which allowed them to bring Comirnaty® to market many months before they otherwise could have done so.

6. Finally, BioNTech and Pfizer try to contrast the success of Comirnaty® against the purported "failure" of CureVac's mRNA vaccine candidate, called "CVnCoV," in a clinical trial (the "HERALD" trial). But the real story is that, contrary to BioNTech and Pfizer's assertions that it was a "failure," CureVac's vaccine actually met the prespecified success criteria for efficacy against symptomatic COVID-19 of any severity, and for efficacy against moderate-to-severe COVID-19, as defined in the protocol: it was 48% effective in preventing infection of any severity, was 77% effective at preventing moderate and severe disease, and was 100% effective at

preventing death. This, despite the fact that it was tested when there were at least 13 different variants of the SARS-CoV-2 virus circulating in the population. Given these facts, BioNTech and Pfizer's attempt to disparage CureVac's inventions by contrasting the results of the successful clinical trials of Comirnaty® (which were conducted when the original SARS-CoV-2 virus was causing nearly all infections) against the results of CureVac's successful clinical trial of its COVID-19 vaccine (which were conducted much later, when at least 13 different variants of the virus were causing infections) is, to say the least, both factually wrong and disingenuous.

7. Simply put, the fact that others made contributions to this field, or that CureVac's vaccine candidate, while successful, was not brought to market, does not render the claims in the patents-in-suit invalid, and it does not excuse BioNTech and Pfizer's infringing use of CureVac's patented inventions to develop Comirnaty®.

8. As noted above, Comirnaty continues to be an essential part of the response to the COVID-19 threat. Accordingly, CureVac is not seeking an injunction that would prevent or impede the production, sale, or distribution of Comirnaty®: rather, CureVac seeks only to have its intellectual property rights acknowledged and respected in the form of fair compensation so that CureVac can continue to invest in the further advancement of mRNA technology and the ongoing development of new life-saving medicines.

ANSWERS TO SPECIFIC ALLEGATIONS[1]

Without admitting any of the allegations of BioNTech SE and BioNTech Manufacturing GmbH (collectively, "BioNTech") and Pfizer Inc. ("Pfizer") (and, together with BioNTech, "Plaintiffs/Counterclaim Defendants") other than those expressly admitted herein, and without

[1] CureVac does not reproduce the headings or footnotes from Pfizer and BioNTech's Counterclaims and denies any allegations contained in those headings or footnotes.

prejudice to their right to plead additional claims and defenses as the facts of the matter warrant, CureVac SE and CureVac Manufacturing GmbH (collectively "CureVac") respond to the counterclaims against CureVac as follows:

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.

ANSWER: CureVac admits that Comirnaty® was approved for public use under an Emergency Use Authorization on December 11, 2020, and avers that one reason it was able to be developed and deployed so quickly is because it incorporates the inventions claimed in CureVac's patents-in-suit, which resulted from the decades of pioneering research and development work at CureVac. CureVac denies the remaining allegations in Paragraph 1.

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.

ANSWER: CureVac admits that it developed an mRNA vaccine, called "CVnCoV," to help in the fight against COVID-19. CureVac avers that CVnCoV was tested in the "HERALD" clinical trial; that CVnCoV was 48% effective in preventing infection of any severity across the unprecedented 13 strains of the virus active at that time, was 77% effective at preventing moderate and severe disease, and was 100% effective at preventing death. CureVac avers that the HERALD trial met the prespecified success criteria for efficacy against symptomatic COVID-19 of any severity, and for efficacy against moderate-to-severe COVID-19, as defined in the protocol. CureVac denies the remaining allegations in Paragraph 2.

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