NO (MORE) BITES AT THE MRNA APPLE: PFIZER AND BIONTECH SEEK DECLARATORY JUDGMENT OF NONINFRINGEMENT RELATING TO THEIR COVID-19 VACCINE IN NEW SUIT

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U.S. Intellectual Property Alert

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On 25 July 2022, BioNTech SE and BioNTech Manufacturing GmbH (collectively, BioNTech) and Pfizer Inc. (Pfizer) (collectively, Plaintiffs) filed suit[1] in the District of Massachusetts against CureVac AG (CureVac or Defendant). Plaintiffs seek declaratory judgment of noninfringement of the patents-in-suit, U.S. Pat. Nos. 11,135,312 ("Pharmaceutical composition containing a stabilised mRNA optimised for translation in its coding regions"), 11,149,278 (Artificial nucleic acid molecules for improved protein expression), and 11,241,493 ("Coronavirus vaccine").

This suit comes as a response to a June 2022 complaint filed by CureVac against BioNTech SE and two of its subsidiaries in the German Regional Court in Düsseldorf, alleging infringement of mRNA-related intellectual property rights and seeking just compensation for the same.

BioNTech SE and BioNTech Manufacturing GmbH are German companies with their principal places of business in Germany. The latter is a wholly owned subsidiary of BioNTech SE. BioNTech specializes in vaccine development, including research and development of messenger ribonucleic acid (mRNA)-based technologies.[2] According to Plaintiffs, BioNTech “earn[ed] itself a reputation as an industry leader in mRNA technology” and has “partnered with several companies and research institutes to develop mRNA-based vaccines.”[3] Plaintiff Pfizer is an American corporation with its principal place of business in New York City. Pfizer is a research-based biopharmaceutical company.[4] Defendant is a German biopharmaceutical company with its principal place of business in Germany. It develops therapies based on mRNA and officially dubs itself “the RNA people.”[5]

In the early stages of the COVID-19 outbreak, Plaintiffs joined forces to design and manufacture one of the mRNA-based COVID-19 vaccines. Plaintiffs claim they developed their COVID-19 vaccine “at great risk to their companies,” as well as “by investing considerable sums of money and countless hours” in the endeavor.[6] Plaintiffs further claim that their accomplishment of developing, manufacturing, and securing regulatory approval for the vaccine “help[ed] the United States and the world begin to move past the COVID-19 public health crisis.”[7] Plaintiffs allege that, as a result of their vaccine efforts, now they “must also face threats of a groundless patent infringement suit by a company, CureVac, who has been unable to bring to market any product to help in the fight against COVID-19.”[8]

According to Plaintiffs' complaint, unlike them, CureVac failed and was unable to develop a COVID-19 vaccine product,”[9] which, in turn, caused CureVac to focus its attention on “an attempt to profit from the success of

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BioNTech and Pfizer through threats of patent infringement." As a result, Plaintiffs claim to have brought this action to "resolve CureVac's meritless allegations."[10]

Plaintiffs state that by early January 2020, BioNTech initiated "Project Lightspeed," an accelerated vaccine development program aimed at attacking the virus that causes COVID-19: SARS-CoV-2.[11] BioNTech claims it "rapidly developed and performed numerous toxicological and pharmacological studies to determine the safety and efficacy of the COVID-19 vaccine" and was able to quickly move into Phase 1 clinical studies.[12] Plaintiffs partnered to spearhead the development, clinical testing, manufacturing, distribution, and gaining regulatory approval of their COVID-19 vaccine.[13] The two companies shared costs of their endeavor, with Pfizer increasing its yearly research and development budget by US$500 million to reflect the COVID-19 vaccine investments.[14] "On December 11, 2020, the FDA granted EUA [Emergency Use Authorization] for the Pfizer-BioNTech COVID-19 vaccine to be used in individuals 16 years of age and older."[15] Subsequently, additional EUA approvals to include younger age cohorts quickly followed, with an EUA for children as young as 6 months old granted on 17 June 2022.[16]

Plaintiffs claim that CureVac has attempted to develop at least one COVID-19 vaccine.[17] Plaintiffs state that on or about 16 June 2021, a key clinical trial showed that CureVac's COVID-19 vaccine had an efficacy of about 47% against any severity of COVID-19 infection and that, the day after those results were published, CureVac's stock fell by about 50%.[18] A few months later, CureVac withdrew its COVID-19 vaccine candidate from the approval process with the European Medicines Agency and, according to Plaintiffs, as of the end of 2021, CureVac's accumulated deficit was approximately €1.06 billion.[19] This was followed by, in short order, the resignation of CureVac's chief technology officer in January 2022 and reports of "an expectation of continued losses in the future."[20]

According to Plaintiffs, around February 2022, CureVac contacted BioNTech seeking to initiate intellectual property (IP) licensing discussions in relation to the Plaintiffs' COVID-19 vaccine.[21] As part of the discussions, on 29 March 2022, CureVac sent BioNTech a "document identifying CureVac's purported IP portfolio. This document included the patents-in-suit and related patents, of which the patents-in-suit are representative family members."[22] Plaintiffs state that "on June 9, 2022, CureVac and BioNTech SE conducted a meeting relating to CureVac's threat to assert its patents in connection with the Plaintiffs' COVID-19 vaccine" and that the alleged threat included both U.S. patents and their European counterparts.[23] Plaintiffs allege that, at the time, CureVac was aware of Pfizer's partnership with BioNTech.[24] The parties were unable reach an agreement and, on 29 June 2022, CureVac filed, before the German Regional Court in Düsseldorf, a patent infringement complaint pertaining to the European counterparts to the patents-in-suit against BioNTech (specifically, BioNTech SE, BioNTech Manufacturing GmbH, and BioNTech Manufacturing Marburg GmbH). While this Germany-based complaint does not name Pfizer, Plaintiffs state that, according to news reports, CureVac's chief executive said that he was not ruling out further legal action against Pfizer.[25]

Depending on what the Massachusetts district court decides regarding infringement of the patents-in suit, this developing matter has the potential for broad impact on COVID-19 vaccine as well as mRNA vaccine and treatment efforts generally. With a favorable outcome of this action, Plaintiffs could potentially gain a certain level of "safety" in their utilization of the patents-in-suit in their mRNA-based vaccine development. However, if the court decides that Plaintiffs do infringe the patents-in-suit, that could increase their vulnerability to infringement suits related to mRNA-based vaccines and treatments in the future. This could, in turn, embolden competitors and

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would-be-licensees to launch legal attacks against certain parties, including against Plaintiffs, with whom their business negotiations did not reach the desired goals. Lastly, this case could open the door to an interesting and potentially difficult question of how courts approach damages for quickly developed pharmaceutical products that ultimately end up playing key, very public, worldwide roles in ongoing health care crises.

As of 24 August, 2022, CureVac has not responded to the instant complaint.

FOOTNOTES

[1] *BioNTech SE v. CureVac AG*, 1:22-cv-11202 (D. Mass. 2022).

[2] Pfizer/BioNTech Complaint at 6.

[3] *Id.*

[4] *Id.*

[5] CUREVAC, https://www.curevac.com/en/ (last visited Aug. 24, 2022).

[6] Pfizer/BioNTech Complaint at 2.

[7] *Id.*

[8] *Id.* at 1.

[9] *Id.* at 2.

[10] *Id.*

[11] *Id.* at 8.

[12] *Id.*

[13] *Id.*

[14] *Id.*

[15] *Id.* at 10.

[16] *Id.*

[17] *Id.* at 11.

[18] *Id.*

[19] *Id.* at 11–12.

[20] *Id.* at 12.

[21] *Id.* at 12–13.

[22] *Id.* at 13.

[23] *Id.*

[24] *Id.*

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[25] *Id.* at 14.

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