Modernatx, Inc. v. Pfizer Limited, Pfizer Manufacturing Belgium NV, Pfizer Inc., BioNTech Manufacturing GmbH and BioNTech SE (HP-2022-000022)

Pfizer Inc. and BioNTech SE v. Modernatx, Inc. (HP-2022-000027)

HP-2022-000022 & HP-2022-000027: Mr Justice Meade

[References in square brackets are to paragraphs in the judgment of the Court. Definitions used in this summary are the same as used in the judgment of the Court]

1. The Court handed down judgment ("the Judgment") on 2nd July 2024 following the trial of two actions concerning a pair of European Patents, EP949 and EP565, in the name of Moderna. The Patents relate to mRNA and its use in vaccines. Both Patents were asserted against Pfizer/BioNTech's SARS-CoV-2 vaccines.

2. Infringement was admitted by Pfizer/BioNTech if the Patents were found to be valid. Moderna did not seek injunctive relief, only financial remedies. Pfizer/BioNTech relied on public statements made by Moderna during the Covid-19 pandemic as at least a partial defence to financial remedies. These "pledge" issues were determined in a separate trial before Jonathan Richards J. The judgment concerning the pledge issues was also handed down on 2nd July 2024.

3. Both parties relied on evidence from several experts:

    a) For EP949, both Moderna and Pfizer/BioNTech called an expert in the field of nucleic acid biology i.e. an RNA biologist.

    b) For EP565, Moderna relied on evidence from a nucleic acid vaccinologist and a coronavirus virologist, and Pfizer/BioNTech relied on evidence from a nucleic acid vaccinologist, a coronavirus virologist and a drug delivery chemist (specifically LNP formulation and manufacture).

4. Both parties attacked the credibility and/or quality of the evidence given by each other's experts. The Judge dealt with each expert individually, but key findings included:

    a) The Judge found that knowledge of the importance of $m^1\Psi$ (which is the subject of the invention in EP949) had crept into the written evidence of the RNA Biologist relied upon by Pfizer/BioNTech, Dr Enright, and that there was some material hindsight in his overall approach.

    b) The Judge found that the nucleic acid vaccinologist relied upon by Moderna, Dr Ulmer, was an 'exceptionally cautious scientist' ([80]).

    c) The Judge found that he needed to scrutinise the evidence of Prof Dougan, the nucleic acid vaccinologist relied upon by Pfizer/BioNTech, for hindsight and that Prof Dougan's objectivity was reduced, but that he remained a better guide as to how a pragmatic vaccinologist who wanted to carry things forward would behave compared to Dr Ulmer (and from the perspective of a virologist, Dr Sola), with their deep negativity.

5. At trial, the key issues and findings for EP949 were:

    a) The identity of the skilled person.

Moderna was wrong in seeking to define the skilled person as someone working on, specifically, transcript therapy. They could be working in any number of fields including cellular reprogramming studies, immunotherapy and direct vaccination. Moderna's definition of the skilled person was too narrow. The Judge identified the skilled person at [263]:

> *I therefore identify the skilled person as being someone with a knowledge of RNA biology, with a practical interest in improving the use of mRNA in relation to translation and immunogenicity in any of the fields above.*

b) The scope of the CGK.

Moderna conceded that the skilled person would know that the RNAMD, a database containing modified nucleotides, existed, its purpose, the nature of its contents, and that it was searchable. On the remaining disputed points, the Judge summarised the position at [251]:

> *On points (i), (ii) and (iv) Moderna agreed with the following (with a minor deletion) as CGK as stated in Pfizer/BioNTech's closing skeleton:*
>
> *i) The skilled person would take away from Karikó 2005, and it would be CGK, that certain naturally occurring modified nucleotides suppress the capacity of RNA to activate the innate immune response, and suppression is proportional to the number of modifications.*
>
> *ii) It was known that some nucleotides which were methylated had reduced immunogenicity, like m7G of the 5' cap and m5C. This knowledge came from Karikó 2005 and also from earlier knowledge about m7G.*
>
> *iv) The skilled person would recall that it was not just Ψ that was tested in Karikó 2005, other nucleotides were also tested and it would be very easy to go back to the paper and look up which nucleotides had been tested.*

c) Anticipation by International Patent Application WO 2007/024708 A2 ("UPenn").

To succeed, Pfizer/BioNTech needed to show that claim 3 and claim 5 of EP949 were both anticipated. Pfizer/BioNTech set out three routes to anticipation in its closing submissions. The Judge found that there was no anticipation by Route 1 or Route 2. Route 3 was found to be more persuasive but was nevertheless rejected by the Judge. This finding aligns with the EPO's preliminary opinion that the novelty attack on EP49 over UPenn was not convincing. The Judge acknowledged that this finding was inconsistent with a decision of the Court of the Hague which found EP949 to be invalid for lack of novelty over UPenn.

d) Obviousness over:

i. UPenn

The main disputes related to whether the success seen with Ψ in UPenn would lead to progressing it alone or to making other modifications, and if other modifications

were explored, whether the ones of interest would be the "Ψ-like" ones. At [415] the Judge found that Pfizer/BioNTech's attack of obviousness failed.

ii. Or Karikó et al, "*Incorporation of Pseudouridine Into mRNA Yields Superior Nonimmunogenic Vector With Increased Translational Capacity and Biological Stability*" Molecular Therapy 2008; 16(11):1833-1840 ("Karikó 2008")

At [446] the Judge found that Karikó 2008 was weaker than UPenn for Pfizer/BioNTech, so the obviousness attack on Karikó 2008 also failed.

e) Insufficiency as an enablement squeeze expressed in the following form: the disclosure of EP949 is no more enabling than that of the common general knowledge and prior art.

Whilst this squeeze was never formally abandoned, it was not suggested that Moderna was taking inconsistent positions between enablement by the prior art and by the Patent.

6. At trial, the issues and findings for EP565 were:

a) The identity of the skilled person.

The Judge found that the problem EP565 claims to solve is an effective/improved nucleic acid vaccine for betacoronaviruses, in an LNP formulation. He stated as follows at [460] and [461]

460. The problem therefore resided in the fairly broad field of vaccine development, which included both identifying and choosing pathogens to work on, and then designing, making and testing vaccines. Different commercial organisations had different vaccine platforms to deploy, but that does not bear on this facet of identifying the skilled team.

461. This all means that the skilled team would include persons with the knowledge and skill to select among the various pathogens which were the most appropriate targets. They would not know or need to know every obscure pathogen but they would know the main ones of interest, and especially viral pathogens. The virology expertise in the team would not be specifically a coronavirus expert since the established field was broader, but it would cover coronaviruses to the extent that vaccines for them were of significant interest. Since, when I come to CGK, I conclude that coronaviruses were of very significant interest, the skilled team would include someone who knew about them, among other pathogens.

b) Two disputes over CGK. These were:

a) the skilled team's view as to whether, and if so to what extent, betacoronaviruses were considered a vaccine development target at the EP565 Priority Date; and

e) the skilled team's view as to the relevant factors for an antigen-specific immune response by a nucleic acid vaccine.

With regards to disputed issue (a), Pfizer/BioNTech relied on a several materials which the Judge found painted an "*extremely clear picture that coronaviruses were widely regarded as important vaccine targets*" ([559]). On disputed issue (e) the Judge accepted Pfizer/BioNTech's submission that the skilled team would know from information they had about other vaccine candidates that the S protein was being properly folded,

processed and glycosylated where those candidates were shown to have a protective effect.

c) Anticipation by and obviousness over a Moderna application WO 2015/164674 ("WO674").

The issue for novelty was whether the functional feature and the physical (non-functional) features of the claim were all clearly and unambiguously disclosed together in WO674. The Judge found that choices are needed to combine selected, different parts of the teachings in specific ways which are not taught at [705], so no combination of all the physical features was disclosed in WO674.

The Judge addressed the submissions on obviousness in the order of the factors to be considered as set out in *ICOS v Actavis* at [715] to [731]. He concludes in [732] that EP565 is obvious over WO674:

> *732. Taking all these together, I reach the clear conclusion that EP565 is obvious over WO674. Example 20 gives a clear pointer towards a goal that would be attractive, offering very good prospects of an effective vaccine, using a platform with attractive features that showed good results against flu and thus "proof of concept", against an important and well known target. The availability of other targets and platforms would be known to the skilled team but does not undermine my conclusion.*

d) Obviousness over Pardi et al, "*Expression kinetics of nucleoside-modified mRNA delivered in lipid nanoparticles to mice by various routes*" Journal of Controlled Release; 217(2015): 345-351 ("Pardi").

The Judge found at [737] that Pardi did not add anything over WO674.

e) Added matter.

The Judge found that the application as filed did not adequately disclose all the physical features together, so EP565 is invalid for added matter (see [675] to [682]).

7. The conclusions set out in [746] are:

i) EP949 is valid.

ii) EP949 is infringed, given that Pfizer/BioNTech conceded that it would be infringed if valid.

iii) EP565 is obvious over WO674.

iv) EP565 is not anticipated by WO674.

v) EP565 is invalid for added matter.

vi) None of the proposed claim amendments to EP565 makes any difference to these conclusions.