EIP

Incomplete secondary evidence pleaded late in proceedings has no chance against prima facie obviousness in High Court decision

A 163-page judgment for Pfizer Limited v. GlaxoSmithKline Biologicals S.A. & Anor [2024] EWHC 2523 was handed down on 7 October 2024 by Mr Justice Mellor. The decision concerns the requirements of secondary evidence with respect to obviousness, particularly when assessing the skilled team and the common general knowledge (CGK), including what can be used as supporting secondary evidence and how the need for such evidence should be pleaded when defending an obviousness attack. Another decision point concerned the behaviour of experts had they been part of a real-world research team without any subjective motivations when considering the prior art in light of the CGK.

The case concerned two UK patents owned by GSK, each claiming vaccination strategies, including the use of the F subunit vaccine in its prefusion form (Pre-F) and the construction of a stabilised F antigen in Pre-F, against respiratory syncytial virus (RSV), a condition causing bronchiolitis and pneumonia particularly in vulnerable people by infecting the lower respiratory tract.[1] Pfizer sought revocation of both patents and GSK counterclaimed for infringement.

~~Infringement~~

The parties each construed the expression 'a soluble F protein polypeptide comprising an F2 domain and an F1 domain' in different ways, in particular the meaning of 'polypeptide'. The Judge accepted the Claimant's construction that a polypeptide consisted of a single

chain of amino acids linked by amido bonds. As the Claimant's RSVpreF product consisted of two polypeptides linked by covalent disulphide bonds, it fell outside of the
p2 scope of normal infringement.[2] The judge further considered that what the patents disclose and what they claim are distinct, and that the patents clearly disclosed more than was claimed which subsequently formed the basis of Pfizer's claim for Arrow relief.[3]

Mellor J applied the Actavis[4] questions to assess infringement by equivalence, determining that the Claimant's product achieved the result of stabilisation in a substantially different way than the claimed method. As the patents described other methods of stabilisation, the judge determined that the claimed method of stabilisation was intended by the patentee to be strictly applied.[5]

~~The Skilled Team~~

The judge noted the different approaches taken by the parties in instructing their respective technical experts, with the Defendant's experts kept completely separate and with no line of communication between them, and found that this would have been too narrow an approach to the prior art and CGK.[6] The judge agreed with the Claimant's evidence of real-world teams led by a vaccinologist, and that a structural biologist would have, at the priority date, advised on structural issues of the F-proteins being investigated.[7]

~~The CGK~~

There was much discussion in the judgment on the areas of CGK in dispute, namely whether the F as well as the G protein was part of the CGK at the priority date. While Mellor J accepted Pfizer's case that the F protein was part of the CGK, he reserved his decision until he considered the secondary evidence in case GSK was right about hindsight of the experts affecting the make-up of the CGK.

~~Obviousness~~

The prior art consisted of extracts from an RSV symposium as a related paper from the same presenter on the structure of the parainfluenza virus type 5 F protein (PIV 5)[8], classified in the same viral family as RSV. The prior art teaches the use of a C-terminal trimerization domain to stabilise the F protein of the PIV F protein in its prefusion conformation. Mellor J considered that if the skilled team had made a prefusion F construct and had added a trimerization domain to further stabilise the protein, then it would be "obvious and routine" for the skilled team to assess its immunogenicity using the techniques such as those described in the patent, and that they would be reasonably

confident in its success. The judge, again, reserved his conclusion until he had considered the secondary evidence.[9]

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~~Secondary evidence~~

Regarding the development and utility of secondary evidence in litigation, Mellor J pointed out that secondary evidence "must be kept in its place", that "[i]ts usefulness must depend in significant part on how complete and how testable it is", and the importance of supporting it with oral evidence "from real-world participants on what was going on".[10] The judge further considered that secondary evidence can serve a useful purpose provided that it is pleaded earlier in the proceedings (rather than in closing submissions) giving opposing parties and their expert/s the opportunity to respond to it, as well as providing for more appropriate case management directions and cross-examination.[11]

~~Conclusions~~

Overall, Mellor J noted there was a prima facie case on obviousness over the prior art on the primary evidence for both the GSK patents, and that the secondary evidence was not "complete enough or anywhere near persuasive enough to displace that prima facie evidence." As such, the patents were found invalid.[12] Further, the Claimant was granted an Arrow declaration on the basis that it would provide a useful purpose[13] in giving the Claimant commercial certainty in the UK, citing the principles set out in Fujifilm[14].

The judgment can be found here.

[1] [1]-[4].

[2] [513]-[517].

[3] [491].

[4] [2017] UKSC 48.

[5] [547]-[553].

[6] [310].

[7] [45], [74].

[8] [638]-[647].

[9] [669]-[681]

[10] [783].

p4 [11] [39], [800]-[801].

[12] [799].

[13] [840]-[843].

[14] [2017] EWHC 395, [365]-[371].