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MSD v Wyeth – The Crucial Role of the Common General Knowledge and Experts in English Patent Litigation

Emma Irwin (Bristows) · Monday, November 2nd, 2020

On 15 October 2020 Meade J. handed down his first ever written judgment in his new role as a Judge of the High Court in *MSD v Wyeth*. The neutral citation for the case is [2020] EWHC 2636 (Pat) and a link to the judgment is found [here](#).

The Judge had heard the case back in the summer as a Deputy Judge but by the time of handing down the decision had assumed a permanent position on the High Court Bench.

Merck Sharp & Dohme Limited (**MSD**) sought to invalidate Wyeth LLC's (**Wyeth**) patent, EP (UK) 2 676 679 (the '**Patent**'), with Wyeth maintaining that the Patent was valid and counterclaiming for infringement on a *quia timet* basis in relation to MSD's V114 product. Interestingly Wyeth confirmed from an early stage that they would not seek an injunction on any infringement finding, rather an order for compensation. Meade J. was asked to assess the validity and infringement of the Patent in a proposed unconditionally amended form. The Patent covers Wyeth's pneumococcal bacteria vaccination product, Prenvar 13® and claimed a formulation which inhibited silicone-induced aggregation of a polysaccharide-protein conjugate in siliconised containers for a vaccine with polysaccharides of 13 specified serotypes. The claimed formulation involved the use of an aluminium salt adjuvant, a buffer and a surfactant.

With the issues in the case having been narrowed since its inception Meade J. was left to decide on MSD's invalidity arguments which included anticipation, obviousness and insufficiency primarily as a squeeze against obviousness. There was also an issue of claim construction for claim 1 in relation to infringement, as well as a claim for infringement by equivalents.

Both MSD and Wyeth called two expert witnesses a-piece, a vaccinologist and a formulator. Meade J. was, in his judgment, complimentary of both of the vaccinologists, describing both as excellent witnesses. However, Meade J. described himself as having real reservations about both formulator expert witnesses, stating that he had a general preference for MSD's expert over Wyeth's. This is an important factor, especially given that Meade J. explained this general preference on the experts as being one of the central issues leading to his overall conclusion. Meade J. did however agree with Wyeth's definition of the skilled team in that it would include a vaccinologist alongside a formulator. MSD had contended that a vaccinologist should not form part of the skilled team.

It is clear from the fact that well over half of the judgment addressed the common general

knowledge ('CGK') that this was a key issue in the case. The obviousness attacks involved an assessment by Meade J. on the heavily disputed aspects of the CGK. Of the two citations for obviousness, MSD pleaded a prior art document (Pena) which referred to the use of 9-, 11- and 13-serotype formulations in the production of conjugate vaccines. The only feature lacking from Pena was to identify and solve the problem of aggregation using an aluminium salt adjuvant.

Wyeth referred Meade J. to the *Idenix v Gilead* and *KCI v Smith & Nephew* cases when making its submissions on the principles of the law on CGK. Taking issue with the fact that MSD had, in support of its obviousness case, relied on documents such as syringe manufacturers' commercial literature about reducing silicone. Meade J. found no reason why these documents could not form part of the picture in assessing whether the issues around silicones were widely discussed, which in turn could support a conclusion that those issues were in fact CGK. Meade J. appeared to have found the technical primer for this case helpful, as he used relevant sections of the primer to set out the CGK in his judgment. Of central dispute between the parties was the use of surfactants to prevent aggregation, with Meade J. agreeing with MSD that it was CGK to vaccine formulator that surfactants could potentially be used where aggregation was encountered. The use of silicone pre-filled syringes as a lubricant was accepted by Wyeth's expert however he did not accept that it was CGK that it could cause problems and that in particular it could cause aggregation. Again, Meade J. found that the materials provided to him showed it was CGK that silicone presented a hydrophobic interference and that the materials showed that this would be expected to cause aggregation specifically. Therefore, Meade J. held that "standing back, as I consider I should, I think that the claims of the Patent are about taking forward a very attractive proposal (the 13v vaccine in de la Pena) by routine means, including solving a modest CGK problem (aggregation caused by silicone) in a way which was CGK (a surfactant)." The Patent was found to be invalid for lack of inventive step.

Meade J. then tackled the claim construction relevant to infringement. Of importance was whether an integer of claim 1 required precisely the 13 identified *S. pneumoniae* serotype polysaccharides or whether it required those 13 but permitted more. This decision was said to hinge on the use of the word "are" in the integer. Wyeth submitted that the effect of the word "comprising" in claim 1 was that other polysaccharides were also allowed and that a later inclusion of the word "comprises" in the claim was to avoid any limitation to the 13 identified serotypes. Meade J. did not agree, and stated that it was hard to see how else Wyeth would have phrased the claim if it has intended to specify precisely the 13 serotypes. It was therefore held that on this narrow construction of the claim there was no infringement by MSD's product of claim 1 or dependent claims. Infringement by equivalents was said to be irrelevant to Meade J.'s overall conclusions of non-infringement and invalidity and so he declined to decide on this point.

This decision reaffirms the importance in English Patents Court proceedings of the role of experts and the characterisation of the CGK. It also contains a clear statement of the difference between CGK on the one hand and information that would be found by routine means as the skilled person set about a problem, on the other. Both may be taken into account by the Court in its assessment of inventive step and therefore putting such materials in evidence, and more importantly, adducing credible evidence as to the status of such materials, will often be of central importance in English proceedings.

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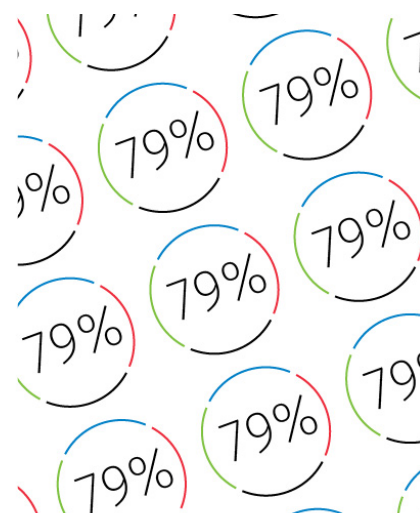
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