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Lessons in expert selection

Hannah Rigby (Bristows) · Tuesday, July 9th, 2024

In his *Abbott v Dexcom* ([2024] EWHC 1664 (Pat)) judgment, published on 28 June 2024, Mr Justice Mellor was faced with the rather unenviable task of determining the approach of the Skilled Team when “*due to their differing experiences and expertise*” it was unclear if any of the experts were in a position to comment with authority on the views expressed by each other. The case provides a helpful reminder of the key considerations for expert selection and the potential utility of facilitating interactions between experts from different fields.

Summary of the Judgment

This judgment is just one of multiple ongoing cases in a global dispute between Dexcom and Abbott in respect of continuous glucose monitoring (“CGM”) device technology. Mr Justice Mellor’s latest judgment relates specifically to the sensor and the sensor electronics unit of CGM devices. The sensor detects blood glucose levels of the user. The signal from this sensor is processed by the sensor electronics unit and transmitted to a reader device. Abbott alleged that its patent protecting an integrated sensor and sensor electronics unit and its application to the user (EP (UK) 3 730 044) was infringed by Dexcom’s device, the Dexcom G7. Dexcom counterclaimed on the basis of obviousness and added matter, including two further insufficiency attacks as squeezes on obviousness.

The Patent was ultimately found invalid for lack of inventive step on the basis of one of the three pieces of prior art considered (“**Heller**”). Heller describes a subcutaneous sensor inserted through a needle using an insertion device. One embodiment describes a ‘single unit’ device containing a sensor, transmitting/processing electronics and battery and includes details of how to attach this device to a user.

Establishing mind-set

Abbott called a single expert: Dr Schoemaker. Dr Schoemaker’s career appears to have focussed on the development of CGM systems, and he was characterised by Abbott as the representative leader of the Skilled Team. Dexcom called two experts: an electronics engineer and a mechanical engineer with experience in medical device design. However, neither were involved in the design of CGM devices at the priority date.

As the decision of the UK Supreme Court *Actavis v ICOS* reaffirmed, the absence of a motivation makes lack of inventive step harder to establish. Therefore, Abbott pressed Dr Schoemaker’s evidence as to mindset and sought to characterise him as the only authority on CGM product

development.

Abbott submitted that one of the key prejudices of the Skilled Team concerned sensor accuracy: the Skilled Team would be motivated to improve sensor accuracy and may not have bothered to develop a new device unless it met this aim. Further, the devices on the market at the priority date consisted of two parts: the sensor and the electronics unit, which were manually attached after the sensor was inserted into the skin. This ‘two-part’ construction had a clear commercial rationale, and was therefore a key feature of devices at the priority date.

Mr Justice Mellor accepted that a commercially driven mindset is a relevant aspect of the common general knowledge of the Skilled Person, but if it prevents the skilled person from implementing a technically obvious idea it must be strong (see *Koninklijke Philips NV v Asustek Computer Corp* [2019] EWCA Civ 2230). He went further still, and noted that prejudices might need to be stronger still if they are to prevent the Skilled Person from taking forward an explicit disclosure in the prior art.

Unfortunately for Abbott, the prejudices proposed by Dr Schoemaker did not appear to gain sufficient traction, largely because they had not been borne out in practice. Multiple teams progressed the development of CGM devices without a focus on sensor accuracy and the reasons for the two-part construction of existing CGM devices would be known to the Skilled Person and given relatively little weight.

The importance of relevant experience

An issue underlying many of Mr Justice Mellor’s findings was Dr Schoemaker’s lack of experience in issues of mechanical engineering. This deficit in knowledge meant that Dr Schoemaker was (quite understandably) unable to interpret the prior art like a mechanical engineer who might consider the necessary modifications to the prior art routine and propose a device consisting a single unit with an appropriate insertion mechanism. Further, the senior specialist leading the team would not be “*impervious to the ideas from team members*” (such as design and electronics engineers).

One can understand why Abbott adopted its approach. By limiting the Skilled Person’s ability to implement the prior art and lumbering them with prejudices, one might conceivably limit the damage caused by an obviousness attack. Unfortunately, this approach failed to make its mark in light of the strength of Heller and the marked differences between Dr Schoemaker’s sole expertise and the disclosures of the prior art. The result was that Dr Schoemaker was unable to comment with great authority on issues of mechanical engineering, which was central to much of the inventive step analysis.

This issue of relevant experience may have also hampered Abbott’s ability to effectively deploy its mind-set arguments. Whilst Dr Schoemaker presented several issues that would prejudice the Skilled Team against modifying the prior art, the Patent did not address nor resolve these prejudicial issues. As addressed by Richard Meade QC (as he then was) in *Fisher & Paykel v Flexicare* ([2020] EWHC 3282 (Pat)): if the skilled person is to be derived from the contents of the patent, one cannot create a motivation from a perceived problem in implementing the prior art unless the patent shows how to overcome it. The Court was unconvinced by Abbott’s argument that the lack of knowledge and experience of inserting integrated CGM devices meant that modifying insertion devices in the prior art so as to insert sensor and sensor electronics together

would not come readily to mind without hindsight (see *Unilever v Chefaro* ([1994] R.P.C. 567)). The mechanical engineer evidence submitted by Dexcom undermined this argument, particularly in light of Mr Justice Mellor’s characterisation of the Skilled Team (in which “*Each member was bringing their own ideas for different areas of the CGM device*”).

The impact of hindsight

Abbott levied the criticism of hindsight at Dexcom’s experts, noting that Dr Schoemaker was the only expert able to ‘anchor’ himself at the priority date. Dexcom’s experts were aware of integrated single unit CGM devices in the context of the technical field post-priority, and brought this hindsight to their obviousness analysis. These criticisms do appear to have gained some purchase with Mr Justice Mellor in respect of two pieces of prior art. However, the differences between Heller and the Patent were ultimately deemed “*minimal and merely required some necessary but routine design implementation*” such that general hindsight criticisms failed to land a ‘knock-out’ blow.

Further, while the lack of experience of Dexcom’s experts in CGM devices may have limited their authority to speak to the mind-set of the Skilled Team, Mr Justice Mellor ultimately did not accept Dr Schoemaker’s specialist evidence in its entirety either.

The balancing act

Achieving an effective balance between the mind-set, hindsight and experience of an expert is by no means an easy task. It is hardest in cases concerning specialist technology in which appropriately qualified experts may be few and far between. The success of any combination of these features will of course be impacted by the strength of the prior art and patent. However, this latest judgment demonstrates that if neither party uses experts with comparable expertise they risk losing control over key aspects of the narrative they wish to present to the Court. In this instance, Abbott was left unable to provide material assistance to the Court in respect of the prior art, resulting in Mr Justice Mellor characterising their choice of a single expert “*strange*”.

Dr Schoemaker did not have the benefit of a mechanical engineer’s expertise before preparing his evidence, and thus formed conclusions in respect of the prior art that may have not been reached otherwise. In recent years, UK Patent judges have provided more guidance on how to approach interactions between members of the hypothetical Skilled Team and are actively encouraging parties to facilitate comparable interactions between experts. As noted by His Honour Judge Hacon in *Sandoz v Bayer* ([2024] EWHC 796 (Pat)): “*It has become established that where real life experts would collaborate in the pursuit of a project, corresponding expert witnesses should consult one another in a broadly similar way*”. This follows his earlier judgment in *Teva v Novartis* ([2022] EWHC 2847 (Pat)). Further, in his recent judgment in *Moderna v Pfizer and BioNTech* ([2024] EWHC 1695 (Pat)), Mr Justice Meade emphasised that interactions between members of the notional Skilled Team can be critical, and may require a dialogue between experts. Such a dialogue may have been of material assistance to Dr Schoemaker.

The third trial in the Abbott/ Dexcom litigation (and first judgment, delivered in October 2023) concerned Abbott’s patent protecting the apparatus for inserting a sensor beneath the skin of a user. The same experts presented evidence in this trial, and similar arguments relating to commercial viability and the prejudices of the Skilled Team were raised. They were dealt with in a similar way by Mr Justice Richards (see [2023] EWHC 2591 (Ch)).

Few UK patent practitioners would disagree with the statement that expert witnesses can make or break proceedings in the English Patents Court. The selection of appropriate experts and the preparation of their evidence is often the most important part of any case. At the end of the day, the Court needs to be able to reach a view as to how the notional skilled addressee of the patent in suit, imbued with the relevant common general knowledge (including any relevant technical prejudices or other “mindset” issues), would react to the teaching of the patent and what steps they would take after reading the prior art. Getting this right is not easy, but it is crucial. Where, as is so often the case, the skilled addressee is a team and experts from more than one technical discipline are required, it is clear that interaction between such experts, at a relatively early stage of the preparation of their evidence, may be appropriate. However, exactly when that “Goldilocks” moment is arrived at is not yet settled and guidance from the Court of Appeal in this regard would be welcome.

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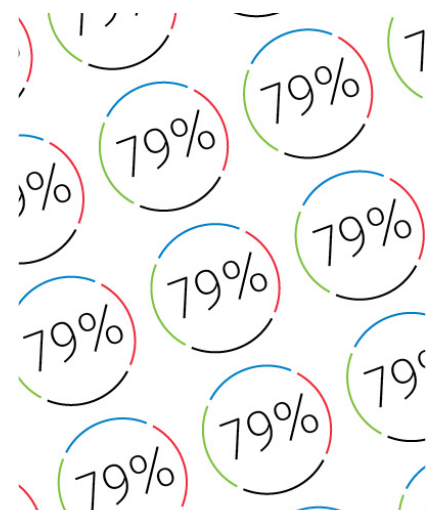
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