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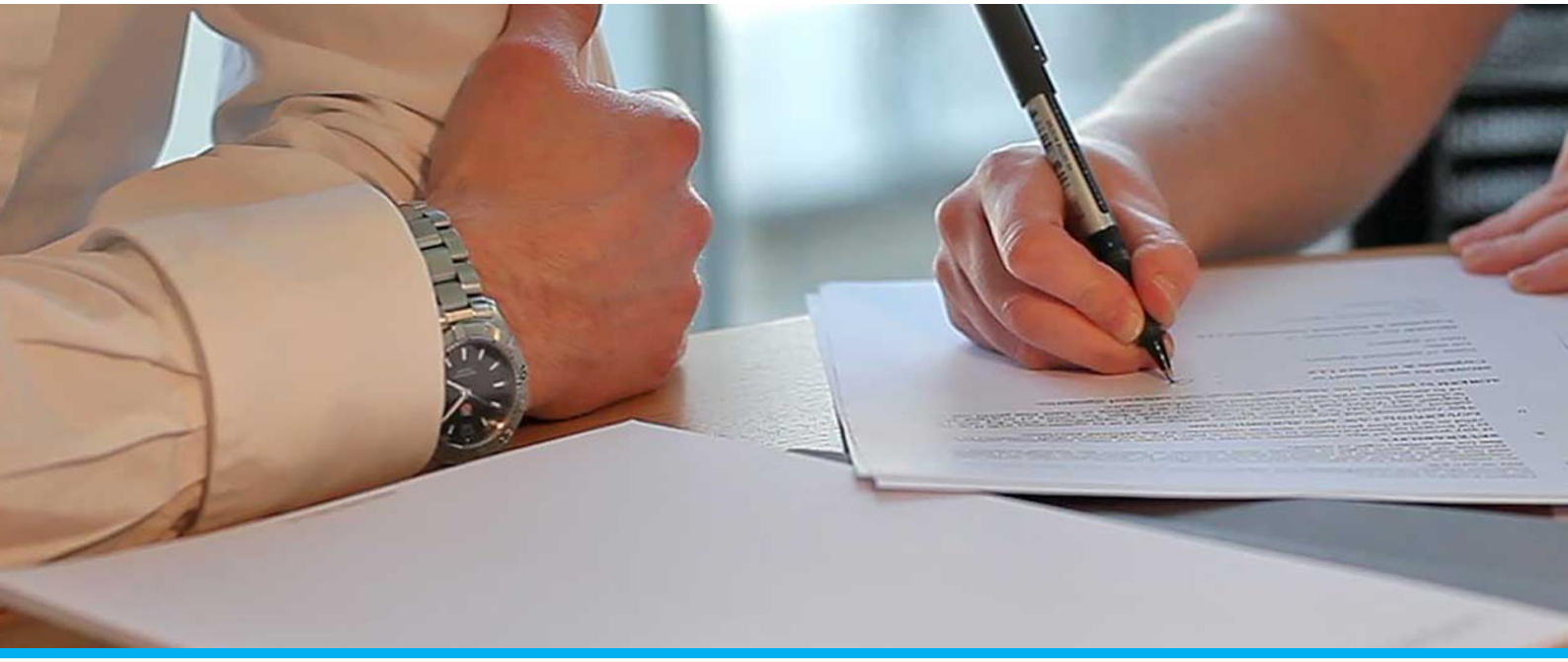


Expert instructions for instructing experts

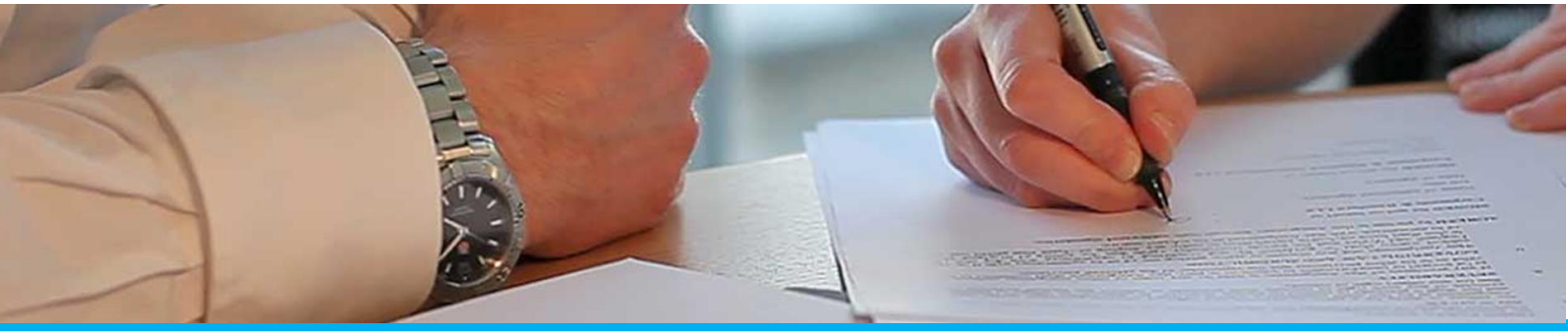
Unmasking the sequential approach – analysing recent judicial guidance

Expert evidence is key to a UK patent case. Ordinarily the role of an expert witness is to provide an independent, impartial and objective opinion on technical matters within their expertise, with the dual objective of helping the court understand the technical issues and to educate the court as to what people working in the relevant field were doing and thinking at the relevant time (usually the priority date of the patent in suit, which may be many years prior to the litigation). However, the nature of a typical patent action means that the expert will also likely be required to consider concepts from patent law that are unlikely to be familiar, such as the identity of the skilled person, the state of the common general knowledge, and the legal tests for obviousness and sufficiency (although ultimately these are matters for the court to decide). As Mr Justice Arnold (as he then was) put it in *MedImmune Ltd v Novartis Pharmaceuticals UK Ltd & Anor*[1]:

"*For these reasons expert witnesses in patent actions require a high level of instruction by the lawyers. Furthermore, even if they are experienced authors, they need considerable assistance from the lawyers in drafting their report. In practice, most expert reports in patent cases are drafted by the lawyers on the basis of what the expert has told them and the draft is then amended by the expert. This, of course, requires the lawyers to understand what the expert is saying. It follows that the drafting of an expert's report in a patent action involves a steep learning curve for both the expert and the lawyers. The lawyers are learning the technology and the expert is learning enough of the law to understand the questions he must address. It follows that a high degree of consultation between the expert and the lawyers is required. Frequently, the preparation of the report will involve an iterative process through a number of drafts.*"

While experts in a UK case are instructed by the lawyers, ultimately their overriding duty is to the court and to assist the court on matters within their expertise. Experts are used to help educate the court when the subject matter being litigated is outside the court's own expertise or experience, and hence the court is reliant on their input as independent experts, informed by their opinions on the matters in dispute, but unbiased in terms of the parties and the parties' ultimate interests.

[1][2011] EWHC 1669 (Pat), at [110]



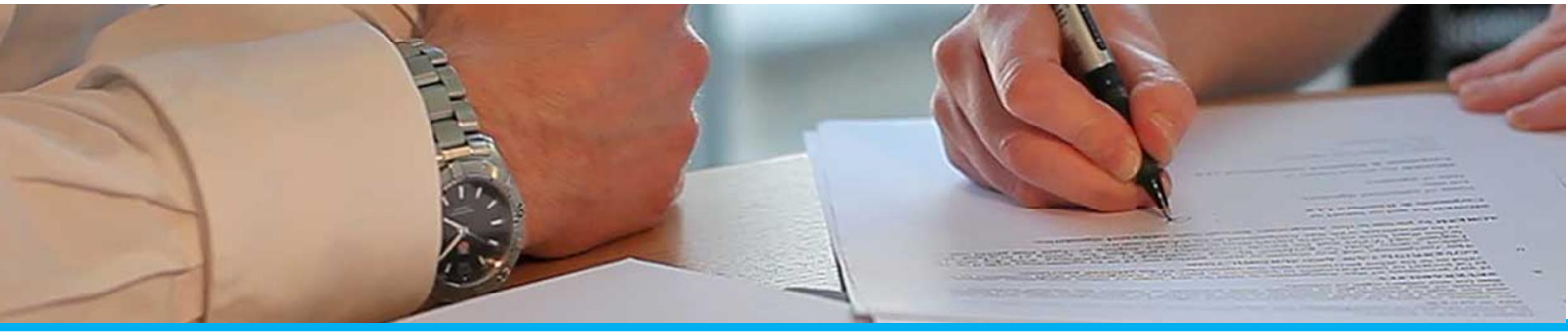
The court's dependence on, or trust in, the expert means their independence is central to their role, and hence the rules of procedure are designed to safeguard that independence as far as possible in the context of an adversarial system of litigation. The underlying rules governing instruction of experts in civil litigation in general are set out in CPR 35, Practice Direction 35 and the Civil Justice Council Guidance for the Instruction of Experts in Civil Claims. However in patent cases some additional considerations arise, one of which is the risk of hindsight. In short, the concern is that if an expert in a patent case knows too much about the case and the parties' arguments at the outset then this has the potential to taint or distort their views (or even just how those views are presented), even subconsciously, on key issues, such as whether a certain product or process would have been obvious at the relevant date, given what was already known. There can be a difference, sometimes very subtle but still important, in the answer given to the questions "in the light of the prior art, do you think X would be obvious?" and "having read the prior art, what do you think the obvious next step would be?". The practical implications of this are that, if the court feels that an expert's evidence has been influenced by hindsight, it will take this into account and place less weight on this evidence as a result. Equally, and perhaps more seriously, this also exposes the expert to potentially embarrassing cross-examination and risks the expert becoming (through no fault of their own other than being human) defensive or, worse, appearing to descend into advocacy in order to justify their position. In either case credibility can be lost because the expert was put in a difficult position in court by those instructing them (see below). Therefore, assuming it is not possible for an expert to disregard this foreknowledge (e.g. of the arguments, or the alleged invention) in order to maintain their objectivity, it follows that the safer course in order to minimise the risk of hindsight is for the lawyers to effectively "blind" the expert and reveal information in a controlled manner so that the expert can form their own unbiased view.

Over the past decade several cases have dealt with this peculiarity of the instruction of experts in patent cases, and recently in *Fisher & Paykel Healthcare Ltd v Flexicare Medical Lt & Anor*[2] and even more recently in *Promptu Systems Corporation v Sky UK Ltd & Ors*[3] Mr Justice Meade (one of the new generation of High Court Judges in the Patents Court following the elevation of Arnold and Birss LLJ to the Court of Appeal) gave his own views on the subject. Before discussing Meade J's comments in *Flexicare* and *Promptu Systems*, we briefly review below some of the key cases that have addressed this topic in the past.

Key cases

In *MedImmune*, Arnold J gave his views on the instruction of experts and the preparation of expert reports, emphasising (see above) that in patent cases the drafting of an expert report required considerable assistance from the lawyers and that a high degree of consultation between the expert and the lawyers is required. As a result of this substantial involvement there is a risk that the expert loses his or her objectivity. Accordingly, Arnold J counselled lawyers that they should always hold the expert's need to be objective at the forefront of their minds and not put the expert in a position where he or she appears to have failed in his or her duty to the court. Arnold J highlighted two examples of situations where this might arise, both of which are related to the hindsight risk. The first is in circumstances where an expert has been shown the prior art and has already formed a view on obviousness. When drafting the expert report, the natural tendency is to focus on passages from the prior art document supporting the expert's opinion, but this risks failing to present a fair view. Arnold J was clear that the lawyers should emphasise to the expert the need to provide a balanced account of the prior art document in question irrespective of the expert's ultimate conclusion.

[2][2020] EWHC 3282 (Pat)
[3][2021] EWHC 2021 (Pat)
[4][2011] EWHC 1669 (Pat), at [99]-[114]



The second arises where the expert has had some prior involvement with the invention at issue (or a similar invention), for example having published a paper commenting on the invention. Failing to disclose this fact would put the expert in an uncomfortable position, and so Arnold J explained that the lawyers should ensure that the expert discloses and, where necessary, explains such facts in their report.

Arnold J's views as set out in *MedImmune* (summarised above) have become so well known that they are frequently provided to experts in patent cases to read, and indeed it is common for experts to refer in their expert reports to the fact that they have read and understood them. However, Arnold J also went on to express a view on the order in which experts should properly be shown particular documents, and made the following observations at [118] of *MedImmune*:

"*...he [the expert] was first asked to consider the prior art, then the priority documents and then the Patents. That was the correct way for those instructing him to proceed, since it was calculated to enable Professor Brammar to form and express his opinions on the prior art without knowledge of the invention and on the priority documents without knowledge of the Patents*."

This structured approach, in which the expert is first asked to consider the skilled person or team, then the common general knowledge, then the prior art, then the priority documents and finally the patent(s), has become known as "sequential unmasking" (see *Akebia Therapeutics Inc v FibroGen, Inc*[5], discussed in more detail below).

While sequential unmasking is intended to reduce the risk of hindsight, it is not possible to eliminate the risk altogether: for example in a later case (*American Science & Engineering Inc v Rapiscan Systems Ltd*[6]), Arnold J acknowledged that in order to properly apply the established *Windsurfing/Pozzoli* test for obviousness it was necessary for the expert to identify differences between the prior art and the patent and then consider whether, viewed without any knowledge of the claimed invention, these differences constituted steps that would have been obvious to the skilled person. Therefore, even following the sequential unmasking approach, at the culmination of the process after the expert has seen the patent in order to be able to establish the differences between it and the prior art, they will then still need to factor out their knowledge of the patent in order to then be able to apply the *Windsurfing/Pozzoli* test correctly, and so to an extent the hindsight risk remains.

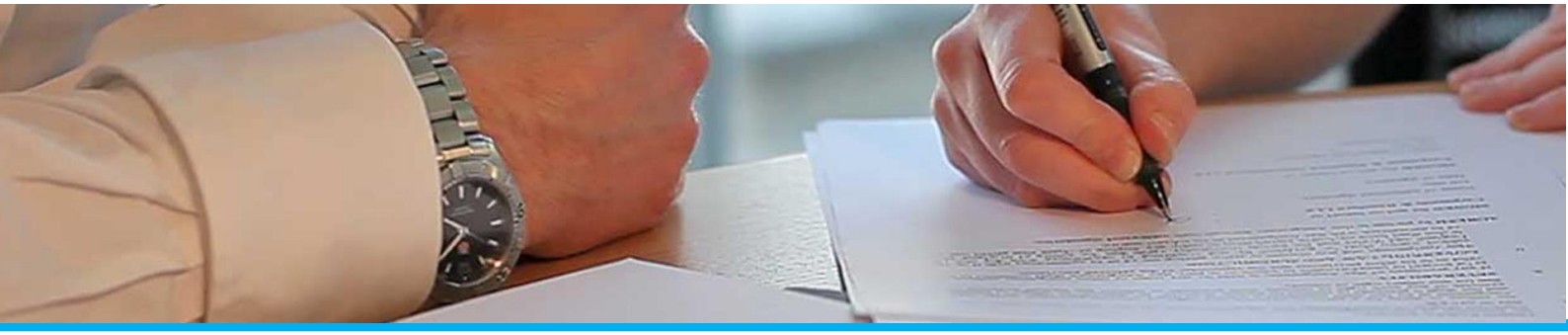
When Mr Justice Birss (as he then was) came to consider the instruction of experts in *HTC Corporation v Gemalto S.A.*[7] he agreed with what Arnold J had said in *MedImmune* in paragraphs [99]-[114]. However, so far as sequential unmasking was concerned, Birss J expressed the following view at [273]:

"*In paragraph 118 of the same judgment Arnold J indicated that the way in which an expert had been instructed in that case, by providing him with the prior art, then the priority documents and then patents, was useful in the context of that case. Plainly experts need to be aware of the risk of hindsight reasoning and of allowing ideas in the patent to influence their views about what the skilled person would do but I do not read Arnold J's judgment as seeking to lay down a rule that this is how experts must be instructed in all patent cases.*"

[5][2020] EWHC 866 (Pat), at [36]

[6][2016] EWHC 756 (Pat), at [109]-[111]

[7][2013] EWHC 1876 (Pat), in particular at [273]-[275]



Birss J went on to say at [274-275] that:

"*…I believe it is important to emphasise that approaches like this are servants and should not become elevated into masters. The approach can risk creating a number of potential difficulties. First the expert naturally may think there is a legal requirement that this be done and that somehow a breach of this protocol is wrong or is his or her fault. There is no legal requirement that expert evidence in patent cases must be given this way. It will not always be fair on the expert to place this burden on them. Second, many patent lawyers are highly skilled at presenting information to the expert which, consciously or subconsciously, has the effect of leading the expert to the conclusion sought. Neither the expert nor the legal team may be aware of it at all. The expert may genuinely think they have formed views without knowledge of the contents of the patent when in fact they may have been led there. Thus the approach may not in fact eliminate hindsight and is capable of giving a false impression. The exercise in this case caused much more trouble than it could ever have been worth*.

Therefore, Birss J took the view that while sequential unmasking could be useful in certain circumstances depending on the context of the case, it should not be considered compulsory to adopt this approach when instructing experts in patent cases and indeed it could not guarantee that hindsight would be avoided – one therefore must always keep in mind the problem one is seeking to avoid rather than simply following a procedure offered as one potential solution.

Arnold LJ returned to the topic of instruction of experts in *Akebia*. Arnold LJ himself acknowledged[8] that while it was "*…desirable to try to minimise hindsight on the part of expert witnesses where possible…*" there was "*…no rule or principle that experts must be instructed sequentially…*" and that "*…there are often real practical problems in doing so.*"

As examples of such practical issues, Arnold LJ noted that "*…problems can be caused by the pre-existing knowledge of the expert and by amendments to the parties' cases (such as the introduction of new prior art after the expert has read the patent)*" and also highlighted the fact that: "*any discussion about the common general knowledge must start by identifying the skilled person or team",* questioning "*[h]ow is this to be done if the expert cannot be shown the patent?*" Arnold LJ suggested that the expert could be asked to make an assumption about the identity of the skilled person or team, which they could check later, but acknowledged that this was not necessarily a perfect solution. Arnold LJ also observed that "*…instructing experts in this way can make their task even more burdensome, particularly when it comes to cross-examination, because they may find it difficult to recall what they knew when unless it is clearly documented."*

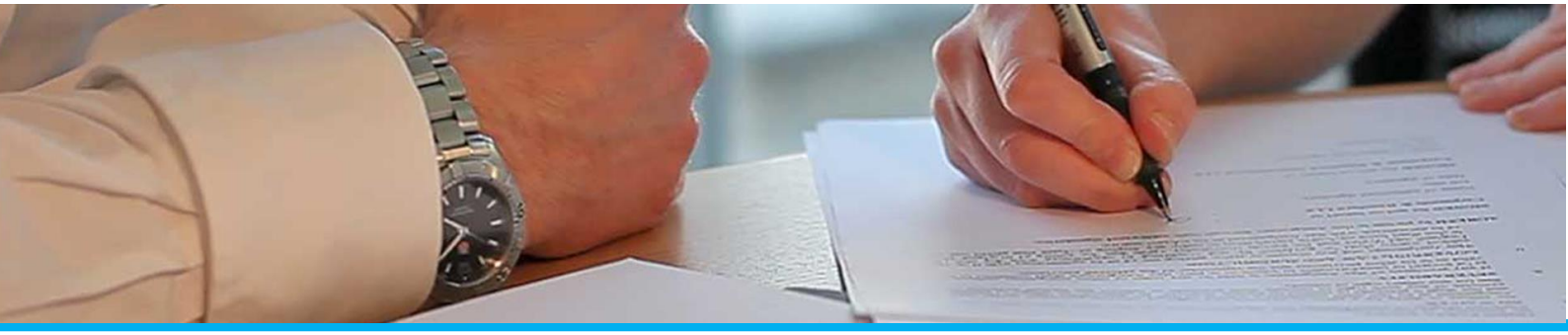
Taking *HTC* and *Akebia* together, it seems clear that the sequential unmasking approach should not be considered compulsory. What is important, however, is ensuring that the expert (and those instructing him/her) is aware of the risk of hindsight reasoning and trying to minimise this risk wherever possible. While sequential unmasking is one way of achieving this, it may not be appropriate in every case.

Flexicare

In *Flexicare*, Meade J gave his views on sequential unmasking[9], explaining that while it was "*…preferable for experts to be asked about the CGK, then shown the prior art, and only then shown the patent in suit…*" this was *"…a counsel of perfection since the expert may well already know what the invention of the patent in suit is, for example from the patentee's commercial embodiment of it…*"

[8][2020] EWHC 866 (Pat), at [36]

[9][2020] EWHC 3282 (Pat), at [20]-[22]



Despite this, Meade J considered that even where the expert knows about the invention there may still be value in sequencing the documents they review, in order to try to avoid hindsight, but he acknowledged that it was not possible for them to give a completely hindsight-free view of the prior art. Ultimately it was down to the expert to discipline themselves carefully to avoid hindsight and, provided they are able to do so, they should still be able to give evidence on obviousness. It goes without saying that it is incumbent on those instructing the expert to ensure that the expert is aware of the need for this discipline and is exercising it.

In common with *HTC* and *Akebia*, in *Flexicare* it was acknowledged that while in an ideal world the sequential unmasking approach may be desirable, it can be difficult to apply in practice. While Meade J noted that the sequential unmasking approach has its merits even where the expert has knowledge of the invention, he emphasised again the overriding importance of making the expert aware of the hindsight risk.

In a similar vein, Meade J also cautioned that in such a situation it was important for the expert to identify how and when they knew about the invention and to reflect carefully on how this might have influenced them. This recalls the comments made by Arnold J in *MedImmune* at [113], where he said:

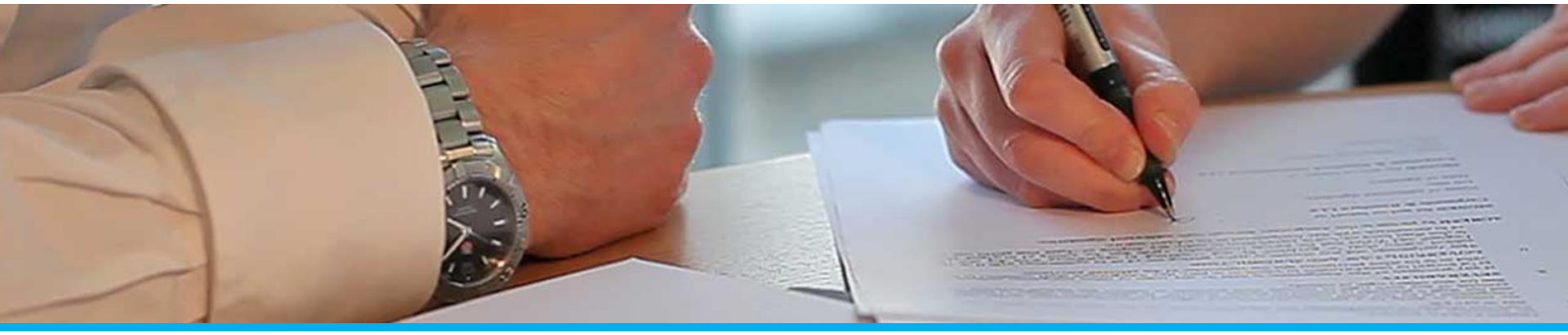
"*The second example arises out of the fact that it is not uncommon for an expert witness to have some involvement with the invention in issue, or a similar invention, in the past. For example, he may have published a paper commenting on the invention or have been a named inventor on a patent application claiming a similar invention filed before or after the one in suit or he may even have given evidence in some form (such as a declaration filed with a patent office). The lawyers who are instructing the expert should make sure that the expert discloses such contributions and, where appropriate, explains them in his report*."

Promptu Systems

Meade J made some further comments on sequential unmasking very recently in *Promptu Systems*[10]. Here the expert's instructing lawyers had been criticised by the other side's lawyers for referring the expert to a particular key passage of a prior art document. It was argued that this sort of directed reading was not consistent with sequential unmasking owing to the hindsight risk. Meade J held that it was "*...sometimes necessary for purely practical reasons to ask a witness to look at a particular part of a prior art citation, otherwise if they are asked to give all their thoughts about many different passages the task is too big and too diffuse. If it presents a risk of hindsight the Court may have to take it into account, but it is not necessarily fatal or even serious, especially if, as in this case, the witness acknowledges the pointer and gives evidence about why that part of the prior art would be of interest ... A similar issue arises when experts are given, as they often have to be, guidance about what aspects of CGK to explain.*" Meade J also noted that sequential unmasking ceases to be relevant once the experts know the patent claims in issue (as by this point they are aware of what the product or process is and what the case is about), however even once the expert has seen the patent claims (at which point sequential unmasking has become effectively impossible) there is still the risk of hindsight if he or she is asked to consider other documents or additional arguments with the benefit of this knowledge.

Taking all of this together, a consistent theme emerges, with judges emphasising that whichever approach is used to instruct the expert witness, they should (with assistance from the lawyers) recognise and acknowledge the hindsight risk, remain vigilant and take steps to minimise this risk affecting their opinions wherever possible.

[10][2021] EWHC 2021 (Pat), at [14]-[16]



Practical considerations

As Arnold J observed in *MedImmune*, working on a complex patent case is often a steep learning curve for both the expert and the lawyers, and a high degree of consultation between them is required. Indeed, as noted above, experts are expected to become conversant with certain concepts in patent law, and if it becomes clear that an expert cannot demonstrate the requisite understanding of these concepts then this will impact their credibility and expose them to criticism. For example in *Neurim Pharmaceuticals (1991) Ltd & Anor v Generics UK Ltd (t\a Mylan)*[11], Mr Justice Marcus Smith criticised one of the expert witnesses for lacking the necessary understanding of the "nuts and bolts" of patent law, which rendered the expert's evidence unreliable with the result that parts of it were rejected by the judge. The difficulty for practitioners has been that the sequential unmasking approach can often make these crucial interactions between the expert and the lawyers more challenging for all concerned as for example it can be difficult to build a rapport and learn from one another within the confines of this process. Following the sequential unmasking approach can also be time-consuming, which has implications when it comes to costs, and if the approach is used then depending on procedural timelines and the amount of prior art involved it is potentially the case that the expert is not shown the patent(s) in suit until relatively close to the trial date. All of this can be somewhat alarming for clients with little or no experience of UK patent litigation, particularly if the expert's views on, for example, obviousness or sufficiency of the patent(s) are not known until a fairly late stage of the proceedings. There is also the difficulty that sometimes the lawyers will want to discuss aspects of the proceedings with the expert, for example the possible merits of amending the claims of the patent in suit, to help them take a view on the best course of action but are prevented from doing so by adhering to the sequential unmasking approach.

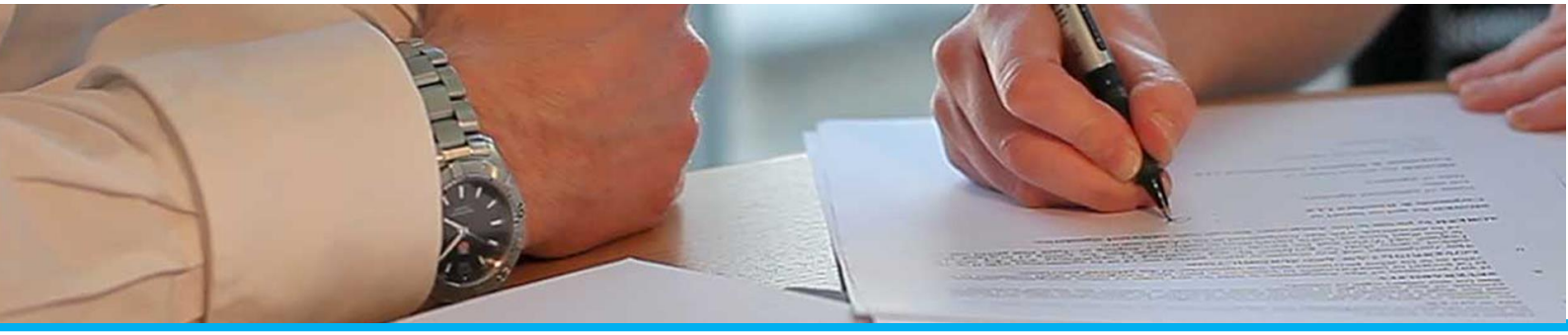
The lawyers must therefore either proceed without the benefit of expert input or engage non-testifying experts on a consultancy basis with whom to discuss these issues, thereby insulating the testifying expert. The former approach deprives lawyers and clients of key insights that often only experts can provide, whereas the latter approach results in duplication and drives up costs.

Another way in which the perceived need to follow the sequential unmasking approach strictly can cause practical difficulties is when dealing with multi-jurisdictional patent disputes, in particular in an area of technology where there are few candidates with the required expertise who are not in some way connected to either party such that they can be said to be properly independent. If parties hope, or are forced by circumstances, to use the same expert in multiple jurisdictions, then unless the UK advisers have got there first an expert may have been instructed in a manner which makes following a sequential masking approach impossible. Indeed the expert may have spent significant time with lawyers who, quite properly as per local practice, have instructed the expert in a way that makes it very difficult for the expert to fully "reset" for UK purposes. If this has not yet happened then often the instruction of an expert according to the approach outlined above can result in the UK proceedings becoming the rate-limiting step for the global litigation project.

Conclusion

Where does this leave us? It seems clear from the comments in *HTC*, *Akebia, Flexicare* and *Promptu Systems* that the sequential unmasking approach should not be considered mandatory as there are circumstances in which its use might be less appropriate, for example, where the expert has pre-existing knowledge of the invention (*Akebia*, *Flexicare*)).

[11][2020] EWHC 3270 (Pat)



It may also be impractical to use the sequential unmasking approach where new prior art is cited during proceedings and the expert has to give their opinion on it despite having already seen the patent(s) in suit (*Akebia*) or where the expert is asked for their views in relation to specific issues and/or documents after having seen the patent claims (*Promptu Systems*), although even in these situations there may still be value in sequencing the documents an expert is shown (*Flexicare*). However in this scenario the lawyers and the expert should be able to demonstrate that they have made every effort to minimise the hindsight risk at every stage. In practice, this will not only involve the lawyers ensuring at the outset of the case that the expert is aware of this risk, but also frequent reminders throughout the proceedings and challenging the expert to consider the hindsight risk whenever they are shown a new document. For example in *Flexicare*, one of the experts acknowledged in their expert report that they had seen the patent in suit before. However the judge felt that the passing reference to this in the expert's report was not adequate, as it did not demonstrate that the expert had thought about how the extent of their previous knowledge, which only became apparent during cross-examination, might have influenced their views on obviousness. In general, it is crucially important for an expert not only to disclose any pre-existing knowledge in their expert report, but also to reflect on what they knew at every stage and the hindsight risk that this might pose, and to explain how they have tried to mitigate the risk. It is also important to record what documents an expert has seen, when they were shown these documents and in what order. Not doing so can lead to difficulties, for example in *Flexicare* where as part of the discussion of the common general knowledge of the skilled team in an expert's report there was a reference to the patent in suit, despite the fact that the expert was not supposed to have seen the patent at this stage. Whether or not the sequential unmasking approach is used, the ultimate aim remains the same, which is for the expert to assist the court by giving an independent, impartial and objective opinion on technical matters within their expertise that is untainted (so far as possible) by hindsight.

Finally, despite the proper instruction of experts for UK litigation often affecting the management of a global or pan-European litigation project (see above), it is easy to think of this as a "UK-only problem", in particular since, as the cases discussed herein show, the problems of hindsight are often exposed only during the cross-examination of the expert at trial. Across Europe cross-examination is less common and is usually much more limited in scope, with other European jurisdictions typically (but not exclusively) preferring to conduct a patent trial using documentary evidence (e.g. expert reports) only. However, with the rejuvenation of the UPC project following Germany recently taking steps to enable ratification and the provision in the rules of procedure for the cross-examination of witnesses where appropriate, it may well be that the issues described above, and the learning and experience of the UK courts and practitioners, will be relevant in this system too, despite the UK no longer forming part of the jurisdiction of this new court.

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