

Plausibility and the role of post-published evidence in UK litigation

The Court of Appeal has dismissed Mylan's appeal against the High Court's decision upholding the European patent (UK) protecting Teva's largest branded drug, the multiple sclerosis treatment Copaxone®.

The Court of Appeal upheld the first instance decision despite a different conclusion being reached on the admissibility of evidence published after the priority date. The focus of this article is not the outcome itself, but the precedent of allowing evidence published after the priority date to be employed in an obviousness challenge against a UK patent. The decision further highlights the importance of including experimental data, if possible, when filing new applications to inventions based on unexpected technical effects and the risks associated with filing applications prematurely before experimental support for the pleaded technical effects can be obtained.

The legal principles

The inventive step arguments before both instances centred around two principles which have emerged from European Patent Office (EPO) Board of Appeal case law. The first of these is the "AgrEvo" principle, based on decision T939/92, that it is the patentee's burden of proof to demonstrate (e.g. by reference to experimental evidence) that the technical effect alleged is indeed credibly achieved across substantially the entire scope claimed. This determination is considered necessary by the EPO because it ensures that the invention is properly judged by reference to the technical contribution actually made, rather than the effects simply alleged. It is often used when assessing

the appropriate breadth of claims. If the technical effects relied upon for inventive step are not, in fact, achieved across substantially the entire scope claimed then the EPO holds that those effects should not be taken into account for the assessment of inventive step. In that case, the technical contribution must be reassessed as the achievement of other, usually more modest, technical effects.

The second principle at issue was that of the technical "plausibility" of the invention when the application was filed, as first articulated in EPO decision T1329/04. This decision dealt with whether the technical effects relied upon to establish an inventive step need to be supported by evidence in the specification as filed, and to what extent, or whether it is permissible for those technical effects to be proven by later "post-published" evidence. The principle established by the decision was that later "post-published" evidence could be relied upon only when the invention was made "plausible" by the specification as originally filed.

The first instance decision

The patent in question covers a particular fraction of copolymer-1, a synthetic random copolymer of four amino acids, having a high proportion of low molecular weight species. The technical effects put forward in support of the invention were the lower toxicity and lower injection site inflammation shown by

the claimed fraction when compared to the known copolymer-1 fractions. Mylan argued that the technical effects in the patent were not plausibly disclosed and, consequently, following T1329/04 that Teva should not be able to rely on post-published data to support them. After reviewing a number of earlier UK decisions, the court concluded that UK law supported the plausibility principle and agreed that post-published data could not be the sole basis to establish a technical effect. However, on the facts, the data in the patent were held to establish that the pleaded effects were plausibly achieved and so further evidence from Teva to support these effects was admitted by the court.

In a contingent argument, Mylan sought to apply the AgrEvo principle and file its own post-published evidence to show that the technical effects plausibly established in the patent were not in fact achieved by the claimed copolymer-1 fraction. However, the court held that it was not possible to use post-published evidence in this way, because to do so would violate the fundamental principle that obviousness must be judged at the priority date.

Accordingly, the first instance decision set an interesting precedent in the UK that an AgrEvo type attack based on post-published data cannot be used if a patent satisfies the plausibility requirement.

Of interest is the Court's reliance on EPO case law and the use of the problem and solution approach which could be seen as reflecting an increasing tendency for the UK courts to align themselves with the EPO in preparation for the commencement of the Unified Patents Court in the years to come.

The appeal

The plausibility principle was not in issue on appeal. Instead, the appeal focussed on the High Court's decision to reject Mylan's AgrEvo attack based on its post-published evidence. The Court of Appeal started from the general proposition that evidence may be deployed if it is relevant to a matter in issue between the parties. Referring to AgrEvo, the judge noted that the monopoly claimed by the patentee must be justified by its contribution to the art. Accordingly, it was justified to call into question the technical contribution alleged by the patentee. The judge commented that it was correct to allow the technical effects relied upon by the patentee to be challenged, because this is the standard by which the patentee is asking the court to assess inventive step. The use of evidence to call into question the technical effects achieved by an invention was fully in line with the AgrEvo principle and the established requirement of the problem and solution approach that the invention does in fact provide a solution to a problem.

The fundamental principle that obviousness must be judged at the priority date, referred to in the first instance decision, was not disputed on appeal. The Court of Appeal stated:

"The evidence which is relied on to show that the invention was an obvious step for the skilled person to take must, plainly, be evidence which would have been available to the skilled person at the time. But in order to determine whether an invention is obvious at the priority date one needs to decide an anterior and purely factual question: what is the invention?"

Despite disagreeing with the first instance decision and allowing the AgrEvo attack, the Court of Appeal held that Mylan's post-published evidence was in fact inadequate to contradict the technical effects made plausible by the patent specification. Mylan were unable to prove on the facts that there was no difference between the claimed fraction of copolymer-1 and the prior art fractions having a higher molecular weight. According to the judge: "no evidence of a difference is not the same thing as evidence of no difference". On this basis, the decision from the first instance was maintained, the Court of Appeal agreeing with the High Court that the claimed copolymer-1 fraction displayed a non-obvious technical advance over the copolymer-1 fractions known in the art.

Summary

The Court of Appeal has confirmed that both the AgrEvo and plausibility principles derived from EPO case law should be taken into account for the assessment of inventive step in the UK. The decision sets a clear precedent for using external evidence to challenge UK patents for lack of inventive step and highlights the important role of post-published data both in defence and attack in UK proceedings. The decision also serves as a reminder to include as much supporting data as possible when drafting applications relying on technical effects which are not apparent prima facie from the definition of the invention.

Aside from the detailed legal principles discussed, of further interest is the courts' reliance on EPO case law and the use of the problem and solution approach for the assessment of inventive step. This

could be seen as reflecting an increasing tendency for the UK courts to align themselves with the EPO in preparation for the commencement of the Unified Patents Court in the years to come.

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