EIP

Needles in the UK Patents County Court

Liversidge v (1) Owen Mumford Limited (2) Abbott Laboratories Limited

In April 2011, the claimant commenced patent infringement proceedings in the UK Patents County Court ("PCC") against the defendants in respect of European Patent No. 2067496 entitled "Medical Injector". The defendants denied infringement and counterclaimed invalidity.

Background

The claimant filed a patent application for a safety arrangement for a medical needle in June 2003. It was for a normal (non-autoinjector) syringe and all of the disclosure and claims related to the safety arrangement. In 2006, the second defendant launched the Humira Pen in the UK (an autoinjector delivery syringe containing the Humira drug). In March 2009, the claimant filed a divisional application which cut out almost all of the application as filed apart from one part of the disclosure relating to one of the embodiments which had "protuberances". New text was also introduced addressing the "sequencing problem" (inserting the needle to the correct depth before expelling the medicament).

Summary of the Judgment

HHJ Birss QC held that the patent was not infringed and was invalid through lack of novelty and inventive step, and by added matter. An argument of insufficiency did not succeed.

Of most interest are the discussions on experiments in the PCC and added matter. These are focused on in the rest of this report.

Experiments in the PCC

p2

A major issue in contention at the Case Management Conference was whether the defendants would be permitted to rely on experiments in order to support their non-infringement defence. The claimant fought hard to prevent the use of experiments arguing that he would still have to spend time and money on his own side to deal with them, they were complex and costly, and moreover, he did not want to be forced to litigate as if the case was being conducted in the High Court.

HHJ Birss QC held that the experiments went directly to the question of how the product alleged to infringe actually worked, and having satisfied the cost-benefit test, the experiments would be admitted into the proceedings. However, there were to be no repeats without permission of the court. HHJ Birss QC fixed the proceedings to two days to ensure the issue of how the product worked could be addressed properly using the experimental results (ordinarily a case like this would be accommodated in one day, he said).

At trial the burden of proof to prove infringement rested with the claimant, which he subsequently discharged by providing prima facie evidence that the Humira Pen did infringe. The (heavy) onus then shifted to the defendants to rebut that inference of infringement, which they succeeded in doing based on their experiments. HHJ Birss QC held in favour of the defendants that there was no infringement, based on their demonstration of the Humira Pen's mechanism by the experiments.

Added Matter

The originally filed application focused on a syringe safety arrangement incorporating protuberances to solve the problem of needle stick injury. It made no reference to autoinjector syringes. In contrast, the granted patent included extensive amendments, and gave clear disclosure of the protuberances as a solution to the sequencing problem (and also autoinjectors) – thus being very different from the first filing.

In considering added matter, HHJ Birss QC held that the re-focus of the granted patent was to the protuberances solving the sequencing problem, whilst relegating the safety arrangement of the original parent application to a mere optional extra. This gave rise to added matter and a finding of invalidity.

The Judge highlighted this case as a paradigm example of the kind of unwarranted advantage to an applicant and damage to legal security of third parties that extension of subject matter can give (citing European Patent Office decision G1/93 of the Enlarged Board).

Conclusion

p3

This case gives valuable insight into the permissibility of experiments in the PCC, namely when they go directly to the central issue being tried, and providing the cost-benefit test is satisfied. This is welcomed as experiments can be pivotal to the decision, as clearly demonstrated by the defendants.

Moreover, the Judge's analysis on added matter gives useful insight on the limits to which an applicant may stretch their original disclosure.

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