United Kingdom
Developing patent law: the courts lead the way

This year has seen several interesting developments in UK patent law. The law relating to obviousness, which has been a recurrent topic in Court of Appeal decisions over the past few years, made a reappearance this year in a case relating to a drug patent. In *Merck Sharp & Dohme Corp v Teva Ltd* the Court of Appeal dismissed an appeal against an earlier High Court decision granting Teva UK Limited's application for revocation of Merck Sharpe's patent relating to ophthalmic compositions for the treatment of glaucoma on the basis of a prior art document published just six days before the priority date of the patent. In a rare outing, the issue of reconditioning a product and whether this constitutes 'making' and therefore infringement under the Patents Act 1977 was examined by the Court of Appeal (*Schütz (UK) Ltd v Werit (UK) Ltd*). In the same case, the court went on to clarify the effect of Section 68 of the act relating to the recovery of damages and costs where a registrable transaction on which proceedings are based is not registered in a timely manner. Finally, the Supreme Court is due to rule soon on whether English courts are bound by decisions of the European Patent Office (EPO) (*Human Genome Sciences Inc v Eli Lilly and Company*). Outside the courts, the long-awaited Hargreaves Report on intellectual property was published and, among other things, provided support for the ever-elusive European patent system.

Obviousness

On April 11 1991 the Association for Research in Vision and Opthalmology published a paper related to the additive effect in reducing intraocular pressure of administering an eye drop including 2% of a drug then known as MK507 10 minutes after administering an eye drop containing 0.5% of a drug called timolol. The paper suggested that such consecutive administration improved intraocular pressure by about 17%. On April 14 1992 Merck filed its application for a European patent in respect of "ophthalmic compositions comprising combinations of MK507 and timolol" for the treatment of glaucoma, claiming a priority date of April 17 1991 (six days after the paper was published).

Teva issued proceedings in the Patents Court seeking a declaration that the patent was invalid and should be revoked on the grounds of lack of novelty, lack of inventive step, insufficiency and added matter. Merck sought to meet these objections by applying to amend the patent. The judge concluded that the patent, both as originally granted and as proposed to be amended, was invalid for lack of an inventive step. The Court of Appeal granted Merck permission to appeal.

On appeal, the court had to consider whether Teva had established that the outcome of its step-by-step approach would be a formulation of timolol and dorzolamide in the proportions specified in the relevant claim at a pH range of 5.5 to 6, as required by the proposed amended claim. Counsel for Merck said that the conclusion on this issue was in the negative and offered the following propositions:

- As the paper did not say how to suspend or dissolve both timolol and dorzolamide in water so as to constitute a co-formulation, the skilled team would have had to find that out in the six days which had elapsed between the publication of the paper and the priority date.
- Notwithstanding his correct self-direction on the law, the trial judge had wrongly applied hindsight in concluding that the skilled team starting with the paper would end up with a co-formulation within the amended claim.

The appeal court agreed with Teva that the test of obviousness did not have an additional time requirement. If an invention was obvious, it could not have been rendered inventive because of some supervening publications. On the second point raised by Merck, the court held that there was nothing in the trial judge's decision to suggest that impermissible hindsight had a bearing on his conclusions. The court then considered the issue of solubility and pH adjustments of the formulation, and stated that the trial judge's conclusion was based firmly on his evaluation of the evidence adduced before him.

Merck was unsuccessful in this case, given that it was obvious to attempt to create a co-formulation of the two drugs. Fine-tuning an experiment by adjusting pH, concentration or other parameters was a common trial-and-error approach in the drug research field, and unfortunately in this case the result was obvious and not patentable.

Reconditioning

In *Schütz (UK) Ltd v Werit (UK) Ltd* the key issue before the Court of Appeal was whether reconditioning a product amounted to 'making' the product within the meaning of Section 60(1) of the Patents Act 1977, and was therefore infringement. The patent at issue, of which Schütz was the exclusive licensee, was for an intermediate bulk container used for transporting large quantities of liquid. It consisted of a square plastic bottle housed within a square cage. If the bottle transported toxic liquids, it could not be reused. However, the cage could be repaired or reconditioned and reused several times over. Defendant Werit made its own bottles and sold them to Delta Containers Limited, which would then install the fresh bottles in the reused square cages and place the reconditioned intermediate bulk containers on the market.

Both sides had relied on the House of Lords decision in *United Wire v Screen Repair Services*, in which it was established that the correct approach was to ask whether, when the part in question is removed, what was left embodied "the whole of the inventive concept of the claim". In this case, the trial judge had held that it was the cage which embodied the whole of the inventive concept of the claim, and had reasoned that putting a new bottle into a cage was not 'making' the patented article. However, the appeal court disagreed and held that what Delta had done was to recondition or repair a cage made by Schütz and re-use it to make an assembly as claimed in the patent at issue. Delta was therefore making intermediate bulk containers when it inserted Werit bottles into Schütz cages. Therefore, by supplying plastic bottles to Delta to fit into the Schütz cages, Werit was liable for contributory patent infringement.

Effects of registrable transactions

In the same case the court issued a further decision which has provided much-needed clarification of the effects of Section 68 of the Patents Act 1977 relating to the recovery of damages and costs where a registrable transaction on which proceedings are based is not registered in time.

Schütz was the exclusive licensee of the patent by virtue of a 1994 licence agreement with Swiss company Protechna, but had not registered the licence at the Patent Office until July 21 2008, shortly before it commenced the patent action on August 7 2008. The period for which compensation was sought by Schütz was from the date of the licence agreement (1994) to the time of the proceedings. Once the parties learned of the judgment on the patent issue, counsel for Werit informed counsel for Schütz that a point under Section 68 would be taken. That point was that although Schütz had been successful in its claim, because Schütz's exclusive licence had not been registered in time at the Patent Office the effect of Section 68 was that the court was precluded from awarding costs against Werit. Furthermore, Werit claimed that the court could not award Schütz damages for the period prior to the amendment of Section 68.

Section 68 was amended on April 26 2006 to allow the courts to award damages and account of profits to patentees and exclusive licensees for infringements committed after the registration of the transaction, even if the registration was made after the expiry of the six-month time limit. The amendment also provided that a claimant would not be awarded costs and expenses in cases where the transaction was registered after the six-month time limit. In this case, Werit claimed that Schütz was not entitled to costs since it had registered outside the six-month time limit.

As to whether it was too late for Werit to raise the Section 68 issue, the court stated that the purpose of the section was to: "make people register relevant transactions timeously. Any benefit to a defendant is a happenstance. The section is not framed in terms of a defence which is there to be taken: the section says 'the court shall not'." The court therefore considered that it was unnecessary to consider whether Section 68 had been properly raised.

The court noted that Werit's acts of infringement fell into three distinct periods:

- the period before the amendment of Section 68;
- the period following amendment of Section 68 until registration of the licence; and
- the period after the licence had been registered.

Counsel for Werit suggested that if compensation was claimed for a period when the licence was not registered but should have been, then no costs could be awarded even for the later period when the licence was registered. The court disagreed, stating: "if and insofar as a claim covers a period for which a relevant transaction was not registered when it should have been (a 'non-registration period') then any costs incurred during that period cannot be recovered. Costs for periods outside a non-registration period are recoverable in the usual way." The court added that it was clear that Parliament did not intend to say that once a party had failed to register a document in time, it could never recover costs even if all the infringements complained of occurred only after registration.

In this case, most of the costs were incurred as a result of Werit resisting the proceedings during the period when the transaction was registered, and it was only fair to make Werit pay those costs. The court noted that before the amendment, the penalty for non-registration was no compensation – rather than no costs – for infringements carried out during the non-registration period, and that after the amendment of Section 68, costs could be awarded for infringing acts done after late registration. Werit went on to argue that this construction meant that the exclusive licensee could get its full costs for the period after registration and this fact rendered Section 68 largely ineffective, since discovery of infringement usually triggered registration before an action started. On this point, the court agreed, saying that Section 68 was "not a well thought-out piece of legislation in either its original or amended form". On costs, it was agreed that given the fact that the amendment was not retrospective, Schütz could not claim compensation for the pre-amendment period.

Binding effect of EPO decisions

In its forthcoming hearing of *Human Genome Sciences Inc v Eli Lilly and Company* the Supreme Court must consider whether English courts are bound by decisions of the EPO. The Court of Appeal upheld the High Court's decision that the patent at issue in this case was invalid for lack of industrial applicability. However, in concurrent opposition proceedings, the EPO Technical Board of Appeal had found the patent valid. The appeal court described the importance of the board's case law as follows: "We follow any principle of law clearly laid down by them, only reserving the right to differ if we are sure that the commodore is steering the fleet on to the rocks." The judge added: "I do not see why the English court's intense fact finding and evaluation process should give deference to the findings or evaluations of fact by the [board] in other cases – cases which, as we shall see, the [board] itself regards as fact-sensitive. The English Courts have never, for instance, given deference to the [board] in the case of the objection of obviousness. I do not see why the position should be different in the case of other fact-evaluation objections such as sufficiency or, here, susceptibility of industrial application". The Supreme Court's decision is eagerly awaited, as it will have bearing on the extent to which the English courts can differ from the Technical Board of Appeal.

Hargreaves Report

In May 2011 Professor Ian Hargreaves published his eagerly awaited report on intellectual property and growth in the United Kingdom. The independent report, entitled "Digital Opportunity, a Review of Intellectual Property and Growth", commissioned by Prime Minister David Cameron in November 2010, is the product of a five-month review of the UK IP framework and the consideration of evidence submitted by almost 300 individuals and organisations, undertaken by Hargreaves, – the chair of Digital Economy at the Cardiff School of Journalism, Media and Cultural Studies and Cardiff Business School – and a panel of five experts.

Although the report has no binding effect, opinion is that the government recognises that legislative reform is needed, and the proposals put forward in the report should provide a solid foundation for such reform. Two of the 10 recommendations in the report relate to patents. First, the report promotes the United Kingdom's role in the move to establish a European Patent Court and a unified European patent, stating that it should "attach the highest immediate priority" to this goal. Second, the report suggests ways in which barriers to innovation can be limited – for example, by:

- establishing fee structures with international partners;
- limiting the extension of patents into sectors such as business methods and non-technical computer programs without clear benefit; and
- cutting the application backlog by managing the pressures of the increased numbers of patent applications.

At this point, the report is conceptual in nature and contains scant detail of how the recommendations would work in practice.

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