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THE “EXPERIMENTAL USE” DEFENCE

JUDGMENT OF THE ENGLISH HIGH COURT

COREVALVE INC V EDWARDS LIFESCIENCES [2009] EWHC 6

s60(5)(b) of the UK Patents Act 1977 provides that an act which would otherwise infringe a patent shall not do so if “it is done for experimental purposes relating to the subject-matter of the invention”. This seldom-used defence was pleaded in the recent CoreValve case in the English High Court, and discussed in the Judgment of Mr Peter Prescott QC, delivered this week.

Edwards owns a European Patent for an artificial heart valve that is deliverable by a technique of catheterisation. It alleged infringement against its competitor CoreValve, which had been supplying its own percutaneously delivered replacement heart valve (the so-called “ReValving system”). CoreValve argued that the patent was invalid, and that in any case their own product was not covered by the claims of the patent. As an extra line of defence, CoreValve argued that it had been supplying the product for experimental purposes relating to the subject matter of the invention.

Peter Prescott QC (sitting as Deputy Judge of the English High Court) held that the patent was valid, but that CoreValve’s product did not infringe¹. Nevertheless the Judge went on to consider the experimental use defence.

FACTS RELATING TO THE “EXPERIMENTAL USE” DEFENCE

CoreValve supplied its product only to selected hospitals in Europe as part of a clinical programme referred to as the Registry. One of the key aims of the Registry was to “investigate and confirm the safety and efficacy of the procedure and valve function on a long-term basis and in a large number of patients”.

The Judge referred to the leading English case on experimental use – *Monsanto v Stauffer*² which established that mere field trials to establish efficacy of a product for regulatory approval do not qualify for the exception to patent infringement set out in section 60(5)(b) of the Act, and that the purpose of the defence is to “encourage scientific research while protecting the legitimate interests of the patentee”.

He noted that the defence is based on community law³, and also referred to the judgment of the Federal Supreme Court of Germany in *Klinische Versuche (Clinical Trials)*⁴, in which a patented pharmaceutically active substance for treating arthritis, was used in clinical trials with the aim of

¹ because, instead of having a stent with a ‘generally cylindrical shape’, as defined by the claims of the patent, it instead was bulbous at one end, which was potentially advantageous.

² [1985] RPC 515, C.A.

³ Article 27(b) of the Community Patent Convention

finding whether and in what form the active substance could be suitable for curing other diseases. That was held to fall within the exception.

CoreValve had argued that the data generated from the Registry was 'directly guiding CoreValve's decisions on future design generations'. However, citing the Ford Model T motor car as an example, the Judge opined that a defendant could always argue that by putting its product on the market it was gaining valuable information that might lead to improvements to the product in the future. This was clearly not the purpose of the defence. Furthermore, he noted that CoreValve did not supply the product free of charge; indeed they invoiced a substantial amount for each unit. While the mere fact that CoreValve's activities were commercial was not a rebuttal to the defence, the Judge identified that an immediate and present purpose of CoreValve's Registry programme was to generate revenue.

THE JUDGE'S FINDINGS

The Judge held that any statement of principle relating to this defence should involve the consideration whether the immediate purpose of the transaction in question is to generate revenue. CoreValve's purposes were threefold: (1) to establish confidence in their product; (2) to generate immediate revenue of a substantial character; and (3) to gain information about clinical indications, and, possibly, future modifications to be made to the physical structure of the device in light of the experience. However, he found that purpose (3) was not their "preponderant purpose".

Whilst he noted that he had not found this point easy, he ultimately found that CoreValve's information gathering under purpose (3) was not sufficient to constitute a defence under s60(5)(b).

DISCUSSION

Consideration of whether a potentially infringing activity will fall within the exception to patent infringement set out in s.60(5)(b) requires an assessment of its "preponderant purpose". While the generation of revenue will not be an absolute rebuttal of the defence, it will clearly be a major factor in assessing whether the defence applies or not.

Nevertheless, having said that he did not find this point easy, if Edwards appeal the main finding of non-infringement, there is likely to be a cross-appeal of the Judge's findings on this point, and we can expect more guidance on this little used defence from the English Court of Appeal in due course.

⁴
[1997] RPC 623

FOR FURTHER INFORMATION:

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