CoreValve Inc v Edwards Lifesciences AG & Anor. EWHC 6 (Pat) (2009)
(In the High Court of Justice, Patent Court, London, 9 January 2009)

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Summary

It was held that the mere fact that the purpose of a use is commercial is no rebuttal of the statutory defence of experimental use. A more complete consideration of the defence requires consideration whether the immediate purpose of the transaction in question is to generate revenue. There is a need to consider the defendant's preponderant purposes.

The facts

In 1990, it was possible to replace a defective heart valve, but it required major chest surgery with a complex operation. Edwards secured European Patent No 0592410, with a priority date of 18 May 1990. The general idea of the patent is to implant a replacement valve remotely by catheterisation e.g. through a vein, without major interventional surgery, and to leave it in place, so that the patient may lead a normal life. This is to be achieved by mounting the valve on a stent (a supporting scaffold) of essentially cylindrical conformation. Both the valve and the stent are elastic and can collapse. On arriving at the correct site, the valve and stent can be re-expanded and left in place. By 1990 stents were well known to cardiologists, but their use was limited. The patent description contains a few practical instructions that are concerned with a prototype device used in experiments with pigs. The claim, however, covers a cardiac valve prosthesis that is in fact practically suitable for implantation in the human body, whether one knows it or not.

CoreValve Inc was a competitor of Edwards. It started supplying its ReValving system in 2007. In 2008, CoreValve requested for revocation of Edwards' patent for reasons of anticipation, obviousness and insufficiency. Edwards contended that, on the contrary, the patent was valid and that the claimant had been infringing it by supplying its ReValving system. During the consideration of the case, CoreValve did not supply its product to all clients, but only to selected hospital sites in Europe as part of a clinical trial programme.

The legal issues

Infringement of Edwards' patent by supply of CoreValves technology, the experimental use defence and the validity of the patent were the legal issues the patent court was requested to address. This summary of the case focuses on the findings of the court on the scope of the experimental use exception.

According to the Court, the device supplied by CoreValve uses bulbous at its end remote from its valve, instead having a stent with generally cylindrical shape as envisaged in Edwards' patent. Accordingly, the Patent Court concluded that claimant's product did not infringe Edwards' patent.

Section 60(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".

According to the Court, the relevance of the exception in this case is somewhat hypothetical, in that it has held that CoreValve is not using the patented invention. If it was, it would be supplying a product different from what it is using in reality. It would be cylindrical instead of bulbous. The statutory exception does not permit a patented invention to be used for experimental acts relating to a different invention.[1]

The supply of CoreValve's device as part of the regulatory approval is targeted at (1) investigating and confirming the safety and efficacy of the procedure and valve function on a long-term basis and in a large number of patients; (2) monitoring unwanted effects under expanded use, and (3) investigating and understanding the effectiveness of the training/certification program in anticipation of larger scale expansion of such a program. CoreValve do not supply its product gratis; on the contrary, it invoices a very substantial amount for each unit.

The Court reiterated that it is well settled that mere field trials which are intended to demonstrate the efficacy of the product for the purposes of regulatory approval do not qualify for the experimental use exception. In general, the purpose of this defence is to encourage scientific research while protecting the legitimate interests of the patentee. This involves a balance. The Patent Court sited the Federal Court of Justice of Germany that stated:

> An act for experimental purposes which is related to the subject-matter of the invention and therefore legitimate can exist if a patented pharmaceutically active substance is used in clinical trials with the aim of finding whether and, where appropriate, in what form the active substance is suitable for curing or alleviating certain other human diseases.[2]

However, the Court stated that there must be an outward limit to that principle. A defendant could always say, and with some truth, that by putting his product on the market (general or special) he was gaining valuable information that might even prompt him to modify his device in future. Although the mere fact that the purpose of the defendant is commercial is no rebuttal of the statutory defence – after all, most pharmaceutical research organisations are commercial –, in the present case it cannot be denied that an immediate and present purpose of CoreValve is to generate revenue - which was not so in the German case. The Court therefore expressed the view that a more complete statement of the principle - it did not arise in the German case - should involve the consideration whether the immediate purpose of the transaction in question is to generate revenue.[3]

The relevant statutory phrase is "acts done for experimental purposes". The difficulty arises where the defendant has mixed purposes. There is a need to consider the

[1] See paragraph 67 of the decision.

[2] German Federal Court of Justice, *Klinische Versuche* (Clinical Trials) I [1997] RPC 623, first page available at http://rpc.oxfordjournals.org/content/114/15/623.full.pdf+html.

[3] See paragraphs 72 – 80 of the decision.

defendant's preponderant purposes. On the evidence in this case, the Court held that CoreValve's purposes are threefold:

> (1) to establish confidence in their product within the relevant market;
>
> (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 the light of experience.

The Court did not find that purpose (3) was the preponderant purpose of CoreValve in supplying its devices. Hence, had it been the case that the CoreValve device falls within Edwards' patent claim, the experimental use exception would not have been a valid defence on the facts of this case.

Points of Significance

1. With respect to the validity of the patent, the Court extensively evaluated the standard of disclosure, novelty (not anticipated by prior art) and obviousness and rejected the counterclaims of CoreValve. The Court of Appeal for England and Wales upheld the decision of the Patent Court in 2010 on the question of patent infringement but did not re-examine the conclusions on the experimental use exception. (See Medtronic CoreValve LLC *vs* Edwards Lifesciences AG and Edwards Lifesciences PVT Inc, EWCA Civ 704).
2. The Patent Court in the case at hand reiterated that it is well settled that mere field trials which are intended to demonstrate the efficacy of the product for the purposes of regulatory approval do not qualify for the experimental use exception. Instead, they can benefit from the more specific regulatory review exception, which allows generic manufacturers of regulated product to undertake studies, such as bio-equivalence and bio-availability studies, and clinical trials in order to generate data necessary for marketing approval of their product by the drug regulatory authorities.
3. This case illustrates the broad leeway left by the TRIPS Agreement in Article 30 to determine the scope of the experimental use exception. The UK Patent Court adopts a much broader approach than the Court of Appeals for the Federal Circuit in the United States in *Madey v. Duke University* on the scope of the American experimental use exception. [4] The Patent Court's approach focuses on the preponderant purpose of the use. Even commercial uses may fall under the exception, provided commercial gains are not the preponderant objective. This approach shows that the traditional distinction between (authorized) non-commercial uses and (patent-infringing) commercial uses that we find in many developing countries' laws is an unnecessary restriction of experimental research and not mandated by the TRIPS Agreement.

Key words: experimental use, regulatory review, experimental purpose, and the preponderant purpose test.

Link: https://www.bailii.org/ew/cases/EWHC/Patents/2009/6.html.

[4] See the summary of that case in this database.