Applying the law of sufficiency to inventions disclosing a “principle of general application”

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by Steven Willis and Olivia Henry
On 28 March 2018, the Court of Appeal overturned Henry Carr J’s finding that two Regeneron patents (EP (UK) 1 360 287 and EP (UK) 2 264 163) were insufficient. The judgment is an important reminder of the importance of taking the nature of the invention into account when assessing sufficiency, particularly where that invention can be properly described as a “principle of general application”.

The patents in suit

The patents in suit concerned transgenic mice that produce hybrid antibodies containing human variable regions and mouse constant regions and the methods for making them. The invention disclosed primarily related to the concept of the “reverse chimeric locus” which involves the “*in situ* replacement” of mouse variable region immunoglobulin gene segments with human variable region immunoglobulin gene segments whilst maintaining the mouse constant regions.

The prior art use of transgenic mice to produce fully human antibodies resulted in immunologically sick mice. The patents in suit purported to overcome this problem. The Court of Appeal described the invention as being *“a striking, radical and highly original departure in the art*” and noted that Regeneron’s VelocImmune® mouse (which embodies the invention) is now the gold standard for in vivo antibody production.

Construction

The key question on construction was whether the term “*in situ* replacement” required the deletion or inactivation of the mouse genes or whether “positional displacement” was sufficient. Having held that deletion or inactivation was not required, the Court followed Henry Carr J in finding that Kymab’s transgenic mice would fall within the scope of the claims.

Interestingly, in light of the Supreme Court decision in **Actavis v Lilly** having been handed down after the first instance judgment in the present proceedings, Regeneron appears to have argued that even if Kymab was right on construction, there was still infringement under the newly-conceived English law doctrine of equivalents. Having found in Regeneron’s favour on construction, the Court did not need to resolve this question. However, the Court noted that it was troubled by the suggestion that it could approach the issue for the first time on appeal. Accordingly, had Kymab succeeded on construction, the case would have been remitted to the Patents Court on the doctrine of equivalents.

Sufficiency

At first instance, Henry Carr J found the patents in suit to be insufficient on the basis that the skilled team would not have been able to work the method provided in the key example of the specification at the priority date without a great deal of creative thinking. Moreover, having found that it was not a principle that enabled the method to be performed across the scope of the claim but rather the result of successfully carrying out the method, Henry Carr J did not consider the reverse chimeric locus to be a principle of general application which unified all embodiments within the claim.

The Court of Appeal disagreed with Henry Carr J’s characterisation of the nature of the invention, finding that the reverse chimeric locus was a principle of general application. The principles to be applied to such inventions have been summarised by the House of Lords in **Kirin-Amgen** and **Lundbeck**. A principle of general application is an element of a claim which is stated in general terms and a patent relating to such an invention will not be insufficient if it can be reasonably assumed that the invention will work with anything which falls within the general term. Furthermore, it is not necessary to enable inventive improvements which would fall within the scope of the claim.

Applying these principles and having found that the skilled person could make a transgenic mouse falling within the scope of the claim using his or her CGK and without undue effort (by making use of the “minigene” approach), the patents in suit were held to be sufficient. In the case of EP ‘163, the Court found that any transgenic mouse which falls within the scope of the claim 1 (and so produces hybrid antibodies containing the human variable region and the mouse constant region) will benefit from the technical contribution of the disclosure of the specification and will do so irrespective of the antigen which is used to challenge the mouse. Similarly, in the case of EP ‘287, any person carrying out a method falling within the scope of the claim 1 will benefit from the technical contribution of the disclosure of the specification. Accordingly, the Court found that the Judge had erred in failing to appreciate the nature and extent of the contribution to the art. In both cases, the Court was satisfied that the patent monopoly corresponded to the technical contribution to the art and that the claims were adequately enabled across their scope.

As a postscript, it is worthy of note that the Court of Appeal permitted Regeneron to advance an argument on appeal which was not addressed in the judgment (namely, that the use of “minigenes” as a way of implementing the teaching of the patents formed part of the CGK at the priority date). This was so despite Regeneron’s failure to draw this to the Judge’s attention on receipt of the draft judgment being described as “highly unsatisfactory”. The Court was satisfied that the argument did form part of Regeneron’s case at first instance. Accordingly, as there was no finding on the point to appeal, the parties were permitted to make fuller submissions than they may otherwise have been entitled to on appeal.