**24 June 2020**

**PRESS SUMMARY**

**Regeneron Pharmaceuticals Inc (Respondent) v Kymab Ltd (Appellant)**
**[2020] UKSC 27**
*On appeal from: [2018] EWCA Civ 671*

**JUSTICES**: Lord Reed (President), Lord Hodge, Lady Black, Lord Briggs, Lord Sales

## BACKGROUND TO THE APPEAL

In 2001 Regeneron Pharmaceuticals Inc filed patents for a new type of genetically modified mouse. Regeneron's breakthrough was a hybrid version of the gene that produces antibodies, combining a section of the mouse's genetic material (the "constant region" DNA) with a section of genetic material from a human (the "variable region" DNA). The resulting mouse can be used to produce antibodies which are suitable for medical treatment in humans, but are sufficiently similar to mouse antibodies that they do not cause immunological sickness in the mouse. The idea of combining a human variable region with a mouse constant region was a major contribution to science. At the hearing in February 2020 the court was told that hybrid mice incorporating this invention had a range of medical uses, including in the race to generate antibody therapies against coronavirus.

In 2013 Regeneron sued a British company, Kymab Ltd, for infringement of its patents. Kymab was producing its own genetically modified mice, branded Kymice, with a similar genetic structure to Regeneron's mice.

Kymab responded by arguing the patents filed by Regeneron in 2001 were invalid because they fell foul of a patent law rule called sufficiency. Sufficiency means documents filed with the patent must be detailed enough to enable scientifically skilled readers to make the invention for themselves.

The Court of Appeal found that Regeneron's patents contained enough information to enable a skilled reader to insert *some* of the human material into a mouse's genes. This would have created one type of hybrid mouse. However, the patents did not explain how to create a hybrid structure incorporating the *full* human variable region genes into the mouse's genome. That was a complicated feat of genetic engineering and no reliable method for doing it was invented until 2011. This meant an expert reading the patents in 2001 would be unable to make many types of hybrid mice which Regeneron had claimed to have invented.

The Court of Appeal upheld the patents, saying there was no need for the patents to explain how to make the full range of mice because Regeneron's idea was a "principle of general application". Kymab appealed to the Supreme Court.

## JUDGMENT

The Supreme Court allows Kymab's appeal by a majority of four to one, holding that the patents are invalid. Lord Briggs gives the majority judgment. Lady Black gives a dissenting judgment.

## REASONS FOR THE JUDGMENT

A patent reflects a bargain between the inventor and the public. The inventor gains a time-limited monopoly over the making and use of a product. In return, the public gains the ability to make the product after the expiry of the monopoly. As part of this bargain, the inventor must publish sufficient information to enable a skilled member of the public to make the product. This ensures that patent holders only gain legal protection which is proportional to their actual technical contribution to the art, and encourages inventors to conduct research for the benefit of society **[23]**.

The Court of Appeal was influenced by the fact that Regeneron's invention is a principle of general application. Its contribution to the field was present not only in mice which could be made in 2001, but also in mice with a larger amount of human genetic material which could be made using later scientific developments. The Court of Appeal thought it was unfair to limit Regeneron's monopoly to types of hybrid mice which could be made when the patent was filed **[27]**.

However, the authorities establish a number of principles in this area. Patentees must not make overly broad claims **[56(iii)]**. If they claim the right to make a range of products, sufficiency means they must disclose enough information to enable a skilled person to make the full range which is claimed **[56(iv)]**. This means a relevant range which affects the utility of the product **[56(vii)]**. So Regeneron was not required to explain how to make mice of varying colours, or with tails of varying length, because these features do not affect a mouse's ability to produce antibodies **[21]**.

Applying these principles, Regeneron's patents did not enable a skilled person to make mice containing more than a very small section of the human variable region. The amount of human material was an important factor which was thought to affect the diversity of useful antibodies which the mice would produce. Mice at the more valuable end of the range could not be made using Regeneron's patents. So Regeneron was claiming a monopoly which was far wider than its contribution to the art **[57]**.

The Court of Appeal upheld patents over a range of mice even though Regeneron could only make mice over a small part of the range, at the least beneficial end of the range with the smallest amount of human genetic material **[58]**. Its analysis watered down the sufficiency requirement which is a bedrock of patent law, tilting the balance of patent law in favour of patentees and against the public **[59]**. Therefore, the majority allows the appeal and holds that the patents are invalid for insufficiency.

Lady Black gives a dissenting judgment, in substance agreeing with the Court of Appeal. The application of the sufficiency requirement depends on the nature of the individual invention and the facts of the case. The Court of Appeal characterised Regeneron's invention as a principle of general application which solved the problem of immunological sickness **[83-84]**. Seen in this way, the sufficiency requirement was met since the invention was deployed in each mouse across the range, irrespective of the quantum of human material incorporated **[86]**.

*References in square brackets are to paragraphs in the judgment.*