

Top UK Court Invalidates Regeneron's Lab Mice Patents

By **Bonnie Eslinger**

Law360, London (June 24, 2020, 10:20 AM BST) -- The U.K.'s highest court has invalidated two of Regeneron's patents for genetically modifying research mice, ruling on Wednesday that patents must include enough detail for someone else to reproduce the full range of inventions that the patent would cover.



The court has said the biotech giant did not provide enough information on the invention and that the principle of sufficiency should not be "disregarded or watered down." (AP)

In a 4-1 split, the Supreme Court panel overturned a 2018 Court of Appeal ruling upholding the patents in the closely watched case. The court concluded that the American biotech giant did not provide enough information on the invention, warning that the principle that patents must disclose sufficient data to allow a skilled person to replicate the invention should not be "disregarded or watered down."

"The sufficiency requirement is a basic principle of U.K. and European patent law," Justice Michael Briggs said as he handed down the judgment. "It is too deeply established a principle now to be disregarded or watered down, even in the case of an important scientific invention like this one."

The litigation is over transgenic mice, which are modified to include sections of DNA identical to that of humans for medical research. Regeneron originally accused Kymab of infringing its U.K. patents, but the British pharma company hit back with counterclaims arguing the patents were invalid for lack of sufficiency.

The question at the heart of the appeal is whether a patent's description of the invention needs to be sufficiently broad to enable someone else to make the full range of products claimed by the patent, or only some of the relevant products. A majority of the Supreme Court concluded that the description must cover everything the patent seeks monopoly protection for.

Justice Briggs noted that Regeneron's patent laid claim to all mice fitted with a "hybrid genetic structure" but that the information provided in the patent would allow the creation only of a mouse containing a small amount of genetic material, not the broad range claimed.

Briggs said that although the Court of Appeal held that Regeneron's invention was important enough to uphold the validity of the patent he and three of his colleagues on the bench disagreed.

The amount of human DNA inserted into a transgenic mouse substantially affects its usefulness, Briggs said. Kymab's mice were found to carry "all of the necessary human genetic material" and were thought to be better for the development of antibodies for the treatment of humans.

Transgenic mice are being employed in the race to develop a treatment for COVID-19, among other uses, Briggs said.

Supreme Court Justices Robert Reed, Patrick Hodge, and Philip Sales also agreed with the majority decision. Justice Jill Black dissented, agreeing with the Court of Appeal.

Justice Black said in her written dissent that the majority focused their attention on products, specifically the amount of replaced genetic material, and not "ideas."

The invention disclosed in Regeneron's patent is used across the scope of transgenic mice, Justice Black said, "irrespective of the quantum of human material incorporated."

"Protection across the range coincides with the technical contribution of the patents which was to solve the problem of immunological sickness, or putting it (loosely) another way, to facilitate the making of immunologically efficient mice," Justice Black wrote.

At a February hearing before the High Court, a lawyer for Cambridge-based Kymab said that — at the time of Regeneron's 2001 application — the techniques disclosed covered only a part of the invention that would later be developed by the company, even though the patents made broader claims.

Regeneron had the underlying idea, but making the most of the genetically modified mice required further inventions that were never fully disclosed and patented, Kymab's lawyer, Iain Purvis QC of 11 South Square, said.

Purvis suggested that the lower court had been "seduced by later products by Regeneron" that were based upon the patents.

Regeneron's lawyer argued that companies would be deterred from investing the time and money needed to produce such products if they do not receive patent protection aligned with the value of their inventions.

The U.S. company said in a statement after the judgment that the decision invalidated the patents only in the U.K.

"Regeneron's rights concerning these patents in other European jurisdictions remain in full force and effect," it said.

Kirkland & Ellis LLP's Nicola Dagg, who represents Regeneron, warned that the result of the decision is that "patent protection for the underlying invention will be illusory" if others improve on the underlying patented invention.

"For a life sciences company with a groundbreaking invention like this one, this decision will incentivize them to rely on trade secret protection rather than the U.K. patent system," Dagg said in an email.

Simon Sturge, chief executive of Kymab, said the company was "grateful that the court has recognized the shortcomings of the Regeneron patents and reinforced the established law that requires that an invention is adequately enabled across its scope."

Powell Gilbert partner Penny Gilbert, who represents Kymab, said the case raised important questions of patent law over innovation in life sciences.

"Kymab has shown tremendous resilience in defending this case since Regeneron commenced proceedings in September 2013," Gilbert said.

The patents-in-suit are European Patent Nos. 1,360,287 and 2,264,163.

U.K. Supreme Court Justices Robert Reed, Patrick Hodge, Jill Black, Michael Briggs and Philip Sales sat on the panel that reached Wednesday's decision.

Regeneron is represented by David Pannick QC of Blackstone Chambers, Adrian Speck QC of 8 New Square and Justin Turner QC of Three New Square, instructed by Nicola Dagg, Katie Coltart and Jin Ooi of Kirkland & Ellis LLP.

Kymab is represented by Iain Purvis QC of 11 South Square and Michael Tappin QC of 8 New Square, instructed by Penny Gilbert, Siddharth Kusumakar and Joel Coles of Powell Gilbert LLP.

The case is Regeneron Pharmaceuticals Inc. v. Kymab Ltd., case number UKSC 2018/0131, in the Supreme Court of the United Kingdom.

--Editing by Ed Harris.

Update: This story has been updated with additional information about the decision.