UCL Institution Brand & Innovation Law

Regeneron: Good or Bad?
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Lord Hoffmann

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1. This appeal challenges the validity of two patents, which seek to confer a monopoly over the creation of a range of types of transgenic mouse.

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Claim 1 of the 163 patent:

"A transgenic mouse that produces hybrid antibodies containing human variable regions and mouse constant regions, wherein said mouse comprises an *in situ* replacement of mouse VDJ regions with human VDJ regions at a murine chromosomal immunoglobulin heavy chain locus and an *in situ* replacement of mouse VJ regions with human VJ regions at a murine chromosomal immunoglobulin light chain locus."

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10. A typical human heavy chain gene locus has around 125 V segments (each different from the others), 27 D segments and nine J segments in the variable region.

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16. Looking at the V segments, did [Claim 1] capture only a mouse with all 125 human V segments, or also a mouse with only one such segment, and therefore mice with any number of V segments between one and 125?

17. Both the judge and the Court of Appeal concluded that the quoted phrase meant both all and any.

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22. [Claim 1] is to mice which produce a stream of antibodies with human variable regions, and the disclosure more generally shows that this stream is for eventual use (after further engineering and mass production) in treating disease in humans. True it is that the particular ground-breaking contribution achieved by the invention of the Reverse Chimeric Locus is the delivery of a means of preventing (or greatly reducing) murine immunological sickness, to which the range of embedded human variable segments is irrelevant, but murine immunological health is not an end in itself. It is a means to a different end.

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57. The extent to which that variable region of the human antibody gene structure could be included in the hybrid antibody gene structure was, at that date, understood to be a very important factor affecting the diversity of useful antibodies capable of being "discovered" by the use of transgenic mice, so that the range thus denominated was a relevant range for sufficiency purposes, even though it did not affect the immunological health of the transgenic mouse. Thus the claim to a monopoly over the whole of that range went far beyond the contribution which the product made to the art at the priority date, precisely because mice at the more valuable end of the range could not be made, using the disclosure in the patents.

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