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Regeneron v Kymab
Decision of the Supreme Court

IBIL
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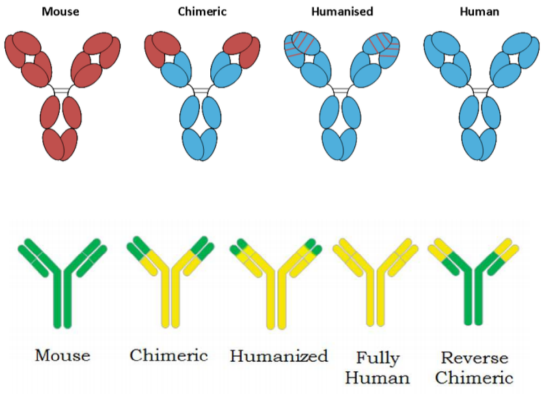
Technical background

The problem to be solved

- 'Gold standard' mice at priority date produced fully-human antibodies to avoid HAMA response
- Fully human mice had subnormal immune response
- Fully human mice were therefore 'immunologically sick'

Regeneron's contribution

- Mice expressing reverse chimaeric antibodies
- Retain the mouse constant region, insert VH regions
- Reverse chimaeric antibodies interact normally with the B-cell receptor, curing the 'immunological sickness'



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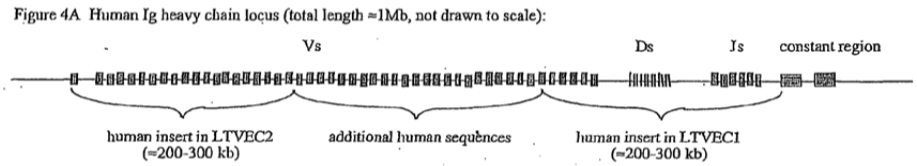
Regeneron's patents (1)

- Two patents in suit – EP 287 and its divisional, EP 163
- Examples 1 and 2 described a new generic engineering techniques involving vectors with 'long homology arms' = LTVECs for targeted insertion of large stretches of cloned DNA into the genome
- Example 3 described use of new genetic techniques to produce a mouse in which entire variable region was replaced by entire human variable region. Fig 4A proposed a 3 step replacement of ~ 1250KB



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Regeneron's patents

EP 287

- Claim 1: method claim for making a reverse chimaeric heavy chain locus involving genetic engineering techniques using LTVECs – **not infringed by Kymab**
- Claims 5 and 6: mice/cells obtainable by the method of claim 1

EP 163

- Claim 1: mice comprising reverse chimaeric loci
- Claims 2 and 3: method of making antibodies using a mouse of claim 1

- Claims extend to mice/cells in which the entire mouse variable locus has been replaced by the entire human variable locus
- These are the most commercially useful = antibody diversity

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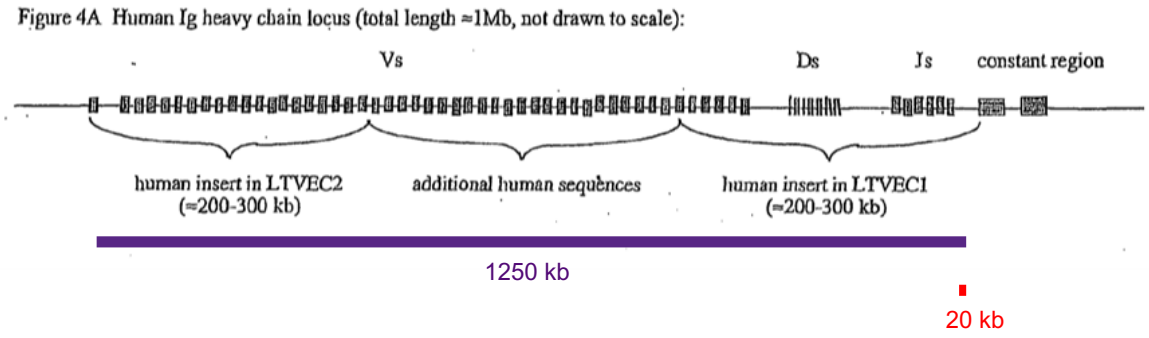
The Minigene Approach



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Supreme Court – the issue raised by the Appeal

"Is it a requirement for a valid patent under Article 83 EPC that the description enables the skilled reader (at the date of the Patent) to make products across the whole scope of the claim, or is it enough that they could make products within only a limited part of that range, provided that all the products within the scope of the claim (if and when they could be made) would use the invention?"

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Did anything change?