FORRESTERS
Clear direction

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A large pool of tadpoles is sufficient

The UK Court of Appeal has decided that patents to antibodies binding a specific target are sufficiently disclosed if those antibodies could have been made by the skilled person without undue effort at the filing date. The fact that the antibody binds to the specific target provides a utility to the antibody. It is not necessary to identify a practical utility for every antibody falling within the scope of the claim.

Background

HGS own a European (UK) patent that includes claims to antibodies which bind specifically to neutrokine-α. This is a very broad claim, which effectively could prevent anyone making neutrokine- α antibody products for any purpose. The patent also includes claims for pharmaceutical and diagnostic compositions.

Eli Lilly and Company (Lilly), who make neutrokine- α antibody products specifically for the treatment of rheumatoid arthritis and multiple myeloma, have attacked HGS's patent on several grounds.

The case has passed through several UK courts, including the Supreme Court (the highest court in the UK) and now the only question remaining is whether the subject-matter of the claims is sufficiently disclosed.

Lilly argued that the claims lack sufficiency because not all of the claimed antibodies have a utility.

The Court of Appeal has now decided on this issue.

The Decision

Neither party disputed that antibodies that bind to neutrokine-α could have been made by the skilled person without undue effort at the filing date, given the teaching in the application. HGS argued that this meant the claim was sufficient.

Lilly argued that the claim should be read as being confined to antibodies that specifically bind to neutrokine-α and have a practical use, because several antibodies would bind to neutrokine- α that will not turn out to be useful, for example as a pharmaceutical.

Lilly argued that it would take undue effort to find out which of the millions of antibodies that bind would actually be useful. They compared the problem to identifying which of a large pool of tadpoles was a tadpole that would develop into a frog which when kissed would turn into a prince.

The Court of Appeal rejected Lilly's argument and found that all the antibodies had a "use". All the wording of the claim requires is an antibody which specifically binds to neutrokine- α, and that in itself is a potential utility. Since such antibodies could be made, the claim was sufficient.

Lilly's argument would require reading into the claim a further limitation that the antibodies are "useful". The Court decided that words should not be read into claims unless the context compelled this, and the context here did not. Furthermore, the term "useful" does not have any precise meaning.

The pharmaceutical and diagnostic claims were also considered for sufficiency. The Court found that because the claims did not state any particular application, i.e. any particular disease to be treated or diagnosed, all that was required for the claims to be sufficient was for the skilled person to be able to make compositions which would be suitable for administration as a pharmaceutical, or suitable for a use as a diagnostic. As this could be done, the claims were considered sufficient.

The implications

This decision emphasises the UK stance on the importance of the actual wording of the claim. Since the claims were not limited to any particular use, disclosure of how to identify a specific use was not required for sufficiency.

Overall, the court allowed such general claims because the disclosure of the application as a whole was very general. This suggests that broad, general claims have a comparatively low threshold to overcome for sufficiency of disclosure.

The finding that because the antibody binds to a specific target this provides a utility to the antibody will be welcome news to patentees in the antibody field. Of course, claims to antibodies with no specific use will still need to satisfy the other patentability requirements, such as inventive step.

It is unlikely that the Court of Appeal will have the final say in this matter. Based on the lengthy legal battle between the parties, Lilly is likely to seek an appeal to the Supreme Court.