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Antibody claims held sufficient, but how valuable will they be?

In the latest Eli Lilly v HGS ruling, the Court of Appeal has found HGS antibody claims to be sufficient, given the Supreme Court has already held the claims to be capable of industrial applicability. Lord Justice Jacob has also confirmed (albeit obiter) that HGS could be subjected to a compulsory licence, should a licence not be agreed between the parties, and seemingly implied that the royalty rate for such a licence might be relatively low.

In a previous ruling [see EIP's Newsflash], the Supreme Court found that all claims of HGS' patent (EP 0 939 804) were capable of industrial application. It now fell to the Court of Appeal to determine whether claim 13, "An isolated antibody or portion thereof that binds specifically to [Neutrokine-α]", and claims 18 and 19, which claim respectively a pharmaceutical composition and a diagnostic composition comprising the antibody of claim 13, were sufficient (i.e. whether the inventions defined in those claims had been disclosed in a manner sufficiently clear and complete for them to be carried out).

Claim 13 had been held sufficient by the first instance judge, a finding appealed here by Lilly. However, given the Supreme Court's ruling of industrial applicability, and that the first instance judge had made a finding of fact that "it did not require undue effort to make and identify specific antibodies to Neutrokine-α at the priority date", Lilly faced an uphill task. They argued that most of the antibodies so made would not be of any use, and that a substantial research effort would be needed to identify any that were useful. However, the Court was not convinced. For Lilly to succeed, this would mean reading a limitation into the claim the further limitation that the antibody should be "useful" which was not there; further, this limitation would itself be imprecise. The Supreme Court had ruled that the claim was capable of industrial applicability, and, for the purpose of

assessing "usefulness", that was enough. This combined with the fact that the claimed antibodies could be readily made meant the claim was sufficient.

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Claims 18 and 19 had originally been held to be insufficient. HGS appealed this and succeeded. The first instance judge had found the claims insufficient as it would have taken a substantial research programme to obtain a candidate pharmaceutical or diagnostic composition. Whilst agreeing with this finding of fact, the Court of Appeal overturned the first instance finding on the basis that, given the general level of disclosure of the patent, the skilled reader would not expect the patentee to have intended these claims to be directed to compositions with immediate practical use as a pharmaceutical or diagnostic. The claims simply require compositions comprising an antibody of claim 13 that are formulated as being suitable for use as a pharmaceutical or diagnostic. This could be done based on the specification of the patent, and so the claims were sufficient.

In addition to these rulings, Lord Justice Jacob made several obiter remarks that imply an ongoing disagreement with the Supreme Court as to whether the claims are really susceptible of industrial application, and in one instance also raised the issue of compulsory licensing. This was addressed during the hearing, with counsel for HGS commenting that finding claim 13 as valid would not mean that patients would not be treated with Lilly's product, as in practice Lilly could avoid an injunction by means of a compulsory licence. This was on the basis that Lilly had obtained a patent for their own antibody, and was reflected in the judgment with Jacob LJ noting that "I say no more than that if [the royalty] were to be determined pursuant to an application for a compulsory licence pursuant to s. 47 of the Patents Act 1977 the question would be what is a 'reasonable term' fixing the amount payable and that the assessment of that might well include the degree of risk, expense and work incurred by the respective parties." Given that Jacob LJ makes reference earlier in the judgment to the further research conducted to actually develop the products as "expensive and risky", there does seem to be implication that even though HGS' patent is valid, they may only be able to obtain a relatively small royalty, in light of the possibility of the royalty rate to be decided by the courts under a compulsory licence.

By Andrew Sharples