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SPCs for Antibodies: A CJEU reference probably but not immediately

The Patents Court has issued another judgment expressing dissatisfaction with the CJEU's ruling in Medeva (C-322/10). In particular, the Court has held that in order to determine if a particular antibody which binds X is "specified" by a general claim "An antibody or portion thereof which binds specifically to X", then a reference to the CJEU will be necessary. However, no reference was made pending evidence from the parties. Additionally, although the Court considered the law to be reasonably clear, it is willing to additionally refer the question of whether a supplementary protection certificate ("SPC") can be obtained based on a third party's marketing authorisation for a medicinal product.

This case (Eli Lilly & Company v Human Genome Sciences Inc. [2012] EWHC 2290 (Pat)) is one in a series between the parties in respect of HGS' patent EP 0 939 804, Lilly having sought to invalidate the patent both at the EPO and via the UK Courts, including the Supreme Court [See EIP Newsflashes here and here]. Here Lilly are concerned with the prospect of HGS obtaining an SPC for the patent based on a Lilly marketing authorisation.

Lilly intends to apply for a marketing authorisation for an antibody product they currently have in clinical trials. However, if the marketing authorisation is granted before expiry of HGS' patent (and if the patent covers Lilly's product, which was not at issue in this case), then HGS could obtain an SPC based on the patent, extending its monopoly by up to five years. Lilly therefore brought a claim seeking a declaration that any such SPC would be invalid.

The present judgment relates to two interim applications in the case, the first by Lilly seeking an immediate reference to the CJEU, and the second by HGS seeking that Lilly's claim be struck out.

HGS' sought a strike-out on the basis that the claim is hypothetical, as no SPC has been applied for, and that the Court should not usurp the role of the Patent Office by making a declaratory judgment in relation to an application. However, Mr Justice Warren thought otherwise: as no application had been made, there was no usurpation of the Patent Office's function, and so the Court had the jurisdiction to grant declaratory relief. Further, the Court was prepared to exercise the jurisdiction in this case given the commercial uncertainty faced by Lilly. However, the judge did caution that this should not be seen as "an opening of the gates" as the commercial uncertainty was due to uncertainty in the law governing SPCs, and once the law was clear there is no reason the issue could not be dealt with by the Patent Office in due course.

Lilly had two grounds for seeking a reference to the CJEU. First, Lilly contended that an SPC should not be granted to a patent holder who has no connection with the party obtaining the marketing authorisation for the product. Mr Justice Warren dismissed this for a number of reasons: it would be contrary to the reasoning of the CJEU in Biogen (C-181/95); would require the reading of an additional condition into the statute, namely that there be a connection between the patent holder and the holder of the marketing authorisation; require guidance as to the nature of a requisite connection; and require Patent Offices to assess such a connection, contrary to the European Commission's express desire for a simple application procedure. Nevertheless, even though the judge considered the issue reasonably clear, he indicated that he would be prepared to put the question to the CJEU if a reference was required on Lilly's second point.

On the second ground, the CJEU in the Medeva judgment held that for an SPC to be granted for a patent, the authorised product must be "specified" by the claims of the patent. No further guidance has yet been given as to what "specified" means. Lilly's antibody, if and when approved, will be a specific and precisely defined antibody. Lilly therefore argued that a reference to the CJEU was needed to clarify whether HGS' claim "An isolated antibody or portion thereof that binds specifically to [Neutrokine-α]" could be held to specify Lilly's particular antibody. The Court agreed that a reference would be needed to answer this, but declined to make a reference. Instead the Court stayed this case, pending conclusion of Lilly's revocation action against the patent (at the time of writing, the Court of Appeal have found the patent valid, but there remains the possibility of Lilly seeking permission to appeal to the Supreme Court). Further, Mr Justice Warren wanted the parties to exchange evidence, so as to provide sufficient factual context for a reference to the CJEU to be made.

It seems inevitable that, absent a settlement by the parties, this case will result in a reference to the CJEU on the question of "specification". The fact that such a reference

is clearly necessary, despite the numerous references already made by the UK courts in relation to the underlying issue of when, for the purposes of an SPC, a patent protects a product, is indicative of the difficulty the CJEU has had in addressing this question, and the inadequacy of the CJEU's rulings to date.

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