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An important day for Supplementary Protection Certificates

On Friday 10th February, the UK High Court had a busy morning applying recent decisions of the Court of Justice of the European Union (CJEU) in *Medeva (C-322/10)* and related referrals, to real world situations involving Supplementary Protection Certificates (SPCs).

In doing so, the High Court has shed some much-needed light on the situations in which SPCs will be available to extend patent term. Although the Judge considered the CJEU's decisions unclear, and did not shy away from saying so, he still found it possible to hold that the terms of Medimmune's patent were not specific enough to allow it an SPC covering Lucentis, the treatment for wet AMD. On the other hand, in a separate case heard the same morning, CSL/University of Queensland's patents *were* considered specific enough, this time to cover components of the Gardasil HPV vaccine. We therefore now have the UK judiciary's first guidance as to how the CJEU's rulings should be interpreted.

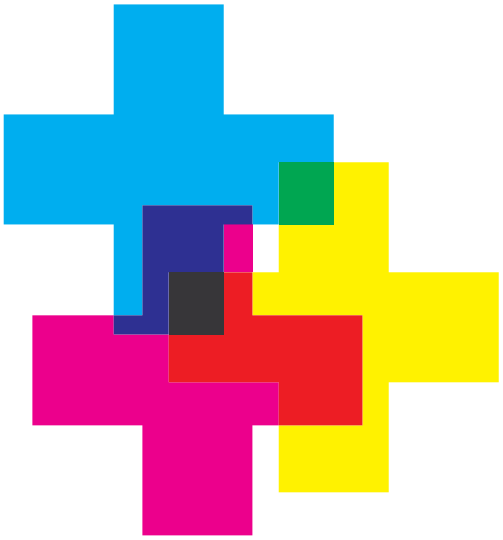
At 10:00 am, Mr. Justice Arnold handed down a decision in the second leg of the *MedImmune v. Novartis* Lucentis litigation. A key issue was whether MedImmune's patent to a method for producing "*a molecule with binding specificity for a particular target*" included within its claims adequate "specification" of the active ingredient in Lucentis (the ranibizumab monoclonal antibody) to obtain an SPC for this product. MedImmune had argued that the CJEU's requirement, set out in the Medeva judgment, for the active ingredient to be "*specified in the wording of the claims*" was unclear and required a further reference to the CJEU to determine how much "specification" was required. The Court had some sympathy for this argument, even saying that it was "*inevitable*" that there will have to be further references to the CJEU to obtain clarification of the test. The judgment's tone is quite strident, and backs up the despair of many industry commentators, who have found the CJEU judgment too vague for national courts to draw clear lines around what is, and what is not, allowable.

Despite expressing sympathy in those terms, the Court then found that the patent in any event certainly did not contain an adequate level of "specification" to cover Lucentis. The Court's principal reason was that there was "*nothing at all in the wording of the claim, or even the lengthy specification of the Patent, to identify ranibizumab as the product of the process in question.*"

MedImmune had argued that Mr. Justice Arnold should refer the matter in suit to the CJEU for further consideration but he declined to do so. The first leg of the litigation, in which MedImmune's patent was found to be invalid and not infringed, is already due to be heard by the UK Court of Appeal later this year, so the High Court felt that the higher court was better placed to order a reference should that become necessary to settle the dispute.

So although no referral was ordered in this case, many commentators have questioned the meaning of "*specified in the wording of the claims*" and time will tell whether the UK Court of Appeal or indeed another EU national court (e.g. the German court which will be considering the same facts soon) decides that the CJEU needs to explain what it meant by its test. The Court of Appeal in the Hague has already opined on the point in the *Lundbeck v. Tiefenbacher* escitalopram matter, holding that although escitalopram oxalate was not explicitly recited in the claims, the reference in the claims to non-toxic acid addition salts was adequate "specification" of escitalopram oxalate to support an SPC for this product.

Of further concern to some will be the Court's questioning of the now standard practice (following the *Biogen* decision, C-181/95) of patentees applying for SPCs based on unlicensed third party products. Although this point was not taken up by either party, Mr. Justice Arnold gave a good indication that he saw this practice diverging from the original purpose of the Regulation, so it may be that this point will in due course be taken up by someone, probably an innovator pharmaceutical company that does not benefit from this practice.



At 10:30 am, the same judge heard Queensland/CSL and the UK Intellectual Property Office in the *Queensland* case, which he had himself referred to the CJEU in late 2010. The CJEU issued its decision in this referral shortly after the *Medeva* judgment, so this marked the first time that any of the referred cases had been back before a UK judge to apply the CJEU's logic.

The parties agreed that the effect of the CJEU's decisions was that Queensland/CSL's four SPC applications for the individual active ingredients in the Gardasil combination vaccine were allowable based on Queensland/CSL's three basic patents, and so the Court granted an order for these applications to proceed to allowance. Interestingly, the IPO did not object to the grant of multiple SPC applications on a single patent, despite the controversial "one SPC per patent" objection that some commentators have derived from the CJEU's judgments. The judgment explicitly refers to the IPO's view that the CJEU was not intending to change the existing law, which is generally understood to mean that there can be one SPC per product per patent. It therefore seems that in the UK at least, this established practice will continue. It will be interesting to see whether other countries take the same approach: initial comments from the Dutch Patent Office suggest that things may be seen differently elsewhere. Moreover, counsel for the IPO suggested that this point will be raised by Medeva when its own referral gets back to the UK Court of Appeal later this year.

Of course, SPCs represent an extremely valuable form of intellectual property because they protect marketed medicinal products at the tail end of patent life, when sales volumes are likely to be high. Both these judgments should be welcomed in that they provide some useful guidance on how to apply the CJEU's decisions, which are typically terse. Whilst newly drafted patent applications can incorporate a selection of wording in the claims to maximise the chances of satisfying this branch of SPC law, it will be some time before these patent applications start to filter through the system. In the meantime, we suspect that many companies will continue to be vexed by this issue, and because of the value of these cases we can expect litigation to follow in this area for some considerable time.

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Need advice?

We hope that this initial analysis has been of interest to you. We will now review the decisions in detail. If you have any questions about these decisions, or SPCs more generally, please let us know. Carpmaels & Ransford has been at the forefront of SPC law and practice for many years and last year filed more national SPC applications than any other UK firm. It is also leading the Queensland and Neurim SPC referrals at the CJEU, which raise further fundamental questions of SPC law. For more information, please contact: email@carpmaels.com.

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