Kluwer Patent Blog

SPCs based on 3rd Party Marketing Authorisations – Finally a Question is Referred

Brian Cordery, Laura Reynolds (Bristows) · Monday, March 4th, 2019

On Friday 1 March 2019, Arnold J handed down his judgment in the patent dispute between Eli Lilly and Genentech regarding IL-17A/F antibodies*1. This lengthy judgment, which as the Judge observed: "*was one of most complex patent cases I have ever tried*", is littered with interesting legal points. However, to many life sciences patent lawyers, as, or equally as interesting, was the comparatively diminutive judgment relating to the corresponding SPC case which was handed down at the same time*2.

The SPC case revolved around two issues: first, was Lilly's IL-17 antibody called ixekizumab protected by Genentech's basic patent in force (EP (UK) 1 641 822) for the purposes of Article 3(a) of the SPC Regulation? And secondly, was it legitimate for Genentech to apply for an SPC based on the 822 patent using Lilly's Marketing Authorisation for ixekizumab?

It should be noted that Arnold J found that all claims of the 822 patent were invalid for differing reasons. Therefore the determination of the SPC issues was strictly *obiter*. However, as will be explained at the end of this post, the Judge considered that it was appropriate to make a CJEU reference nevertheless.

The 3(a) Issue

SPC enthusiasts will be well aware of the long history of the interpretation of Article 3(a) which requires that to obtain an SPC, the product must be "protected by a basic patent in force". The latest CJEU pronouncement on this issue came in summer 2018 in Gilead*3 when the Grand Chamber of the CJEU consisting of 13 judges held, in the context of an SPC for a product comprising two active ingredients, that:

"a product composed of several active ingredients with a combined effect is 'protected by a basic patent in force' within the meaning of that provision where, even if the combination of active ingredients of which that product is composed is not expressly mentioned in the claims of the basic patent, those claims relate necessarily and specifically to that combination. For that purpose, from the point of view of a person skilled in the art and on the basis of the prior art at the filing date or priority date of the basic patent:

– the combination of those active ingredients must necessarily, in the light of the description and drawings of that patent, fall under the invention covered by that patent, and

– each of those active ingredients must be specifically identifiable, in the light of all the information disclosed by that patent."

Whilst this decision arguably provided a degree of clarity especially in relation to combination product SPCs, the new test prescribed by the CJEU inevitably raised further questions. One question related to functional claims. Since the earlier decision of HGS*4, it had been clear that products could be protected for the purposes of the SPC Regulation by a patent with functional claims – for instance a claim to "antibodies which bind receptor X". However, one issue left unresolved by **Gilead** was whether an antibody developed after the patent application had been filed would be "specifically identifiable" for the purposes of the second limb of the new test set out by the CJEU.

Lilly v Genentech provided Arnold J will the opportunity to consider this issue in the context of two claims of Genentech's patent to IL-17A/F antibodies. The first claim (Claim 1) was in essence to IL-17A/F antibodies themselves and the second claim (Claim 12) was a Swiss-type second medical use claim to such antibodies in the treatment of rheumatoid arthritis or psoriasis. Ixekizumab was developed by Lilly after the priority date of the 822 patent and is authorised for the treatment of psoriasis.

In the patent judgment, Arnold J had concluded that under the correct construction of the 822 patent, ixekizumab fell within the scope of protection of amended claims 1 and 12. The question was whether the ixekizumab satisfied the additional criteria laid out in **Gilead**.

Arnold J considered that the **Gilead** tests were satisfied in respect of the antibody per se claim. The Judge considered that ixekizumab was an embodiment of the technical contribution of that claim and it did not matter that the antibody was developed after the priority date of the 822 patent. Thus, the first limb of the test was satisfied. As regards the second limb, the Judge considered that the functional definition in the claim was sufficient to render ixekizumab specifically identifiable and that, again, it did not matter that ixekizumab was developed after the priory date of the 822 patent.

It is interesting to note that Arnold J found that the position was different in respect of the second medical use claim. Having held in the patent judgment that the skilled team reading the 822 patent at the priority date would not have considered it plausible that IL-17A/F antibodies would have a discernible therapeutic effect on psoriasis, Arnold J considered that neither limb of the Gilead test was satisfied for this claim – the fact that ixekizumab had been shown after the priority date to be efficacious in the treatment of psoriasis could not be taken into account in this analysis.

SPCs based on Third Party MAs?

For almost all of the 25 years that the SPC Regulation has been in force, a question that has remained unresolved is whether it is possible for a patentee to seek an SPC based on another's MA e.g. where that MA is held by a competitor. The current practice in all national patent offices is currently to allow such SPCs but outside of Europe, by and large, equivalent patent term extension rights are not permitted. The issues have arisen indirectly from time to time in the case-law but this was the first time that the question was addressed head-on. Inevitably, Lilly pointed to the underlying rationale of the SPC Regulation – to provide a degree of compensation to research based organisations for the loss of market exclusivity due to the need to obtain regulatory approval – and contended that as Genentech had not experienced such loss of exclusivity, it should not obtain compensation. For its part Genentech pointed to the wording of the SPC Regulation and to

corresponding parts of the Plant Protection Products Regulation which, in Genentech's view encouraged all types of research and clearly permitted such SPCs.

In the circumstances, it came as no surprise that Arnold J elected to make reference to the CJEU along the lines of: *"Does the SPC Regulation preclude the grant of an SPC to the proprietor of a basic patent in respect of a product which is the subject of a marketing authorisation held by a third party without that party's consent?"*. Perhaps a bigger surprise was that the question had not been referred before.

In the final section of the judgment, Arnold J considered the need for a reference in light of his finding that the 822 patent was invalid. The Judge considered that all the factors pointed towards the need for a reference, the UK's seemingly imminent departure from the EU precipitating the need to make such a reference now whilst the UK court still had power to do so.

*1 [2019] EWHC 387 (Pat)
*2 [2019] EWHC 388 (Pat)
*3 C-121/17
*4 C-493/12

Kluwer IP Law

This entry was posted on Monday, March 4th, 2019 at 5:44 pm and is filed under European Union, Pharma, Pharmaceutical patent, Plausibility, Second Medical Use, SPC, United Kingdom
You can follow any responses to this entry through the Comments (RSS) feed. Both comments and pings are currently closed.