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Novartis Pharmaceuticals UK Ltd v Medimmune Ltd & Anor – Self-perpetuating references to the CJEU

Multiple rulings of the CJEU on the SPC Regulation fail to answer questions posed by the national courts, result in greater confusion and give rise to a need for yet more references.

Introduction

In Novartis Pharmaceuticals UK Ltd v Medimmune Ltd & Anor [2012] EWHC 181, Mr Justice Arnold was required to apply the recent decisions and reasoned opinions of the Court of Justice of the European Union ("CJEU") in the Medeva, Georgetown, Yeda, Daiichi and Queensland[1]references. The application of these references wasin the context of the validity of Medimmune's UK SPC for ranibizumab (SPC/GB09/053). The key question for the judge was whether ranibizumab was protected by a basic patent within the meaning of Article 3(a) of Regulation 469/2009 ("the Regulation").

While in no less than three of the aforementioned references the CJEU had been directly asked the question of:

"what is meant in Article 3(a) of the Regulation by 'the product is protected by a basic patent in force' and what are the criteria for deciding this?"

the judge was quite clear that this important question, central to the issue he was now required to rule upon, had not been answered. As one of the judges who referred the question, he did not hesitate to express his disappointment in the opportunity that had

been missed and the continued uncertainty that would result:

p2 "As a separate point, it will be noted that the Court did not actually answer question 1. I have to say that, as the national judge who made one of the references before the Court, I am disappointed by this. One of the reasons for the multiplicity of references was the need of the national courts for clear guidance as to the criteria to be applied in deciding whether a product is "protected by a basic patent" within the meaning of Article 3(a). As I shall discuss below, not only has the Court not answered the question referred, but also the guidance it has provided is not sufficiently clear to enable future disputes to be resolved."

Background

Ranibizumab is sold in the UK by Novartis Pharmaceuticals UK("Novartis") with the marketing authorisation being held a member of the same corporate group. However, the SPC in issue and the underlying patent ("the Patent") are owned by MedImmune and the Medical Research Council. In an earlier judgment (Medimmune Ltd v Novartis Pharmaceuticals UK Ltd & Anor [2011] EWHC 1669 (Pat)) Mr Justice Arnold had found the Patent invalid. Even if it was not invalid, Arnold J found that it would not have been infringed by ranibizumab.

As part of this wider action, Novartis had sought a declaration that the SPC based on the Patent was invalid, and as the earlier decision of Mr Justice Arnold was under appeal, this issue remained live. Novartis argued that even if the Patent was valid and even if ranibizumab was a product that was obtained directly by means of a process falling within claim 1 of the Patent, ranibizumab was not protected by the Patent within the meaning of Article 3(a) of the Regulation as Novartis said it was not specified or identified in the wording of the claims of the Patent.

The Decision

For the purposes of assessing whether the Patent protected ranibizumab, it was only necessary for the judge to consider claim 1 of the Patent. Ranibizumab was not named in the wording of the claim, and Mr Justice Arnold summed it up as being "directed to a method of producing a molecule with specificity for a particular target comprising two key steps: (i) producing a population of phage particles displaying at their surface binding molecules having a range of binding properties wherein each particle contains nucleic acid encoding the binding molecule; and (ii) selecting particles displaying a binding molecule with a desired binding property by contacting the population of particles with a target epitope or antigen to which the binding molecule of interest binds. In essence, what the Patent discloses and claims is a technique for screening a library of binding molecules (or, more specifically, antibodies or antibody fragments or derivatives) to identify one of interest."

Ultimately he did not consider it to be a patent for ranibizumab.

p3 Following a review of the UK's case law on Article 3(a) of the Regulation and of the questions more recently posed of the CJEU in Medeva, Georgetown, Yeda, Daiichi and Queensland, Mr Justice Arnold then sought to apply the CJEU's resultant answers to the language of the Patent.

In attempting to make this application, Mr Justice Arnold voiced several criticisms of the various CJEU rulings and reasoned orders. One such criticism was that the CJEU had not used the same language in its decisions. In some cases Article 3(a) was said to preclude the grant of a SPC relating to active ingredients which are not specified in the wording of the claims of the basic patent, and in other cases the question to ask was whether the active ingredients were identified in the wording of the claims. A second criticism was that some of the final conclusions and answers given did not, on his interpretation, follow from the logic and earlier case law that the CJEU relied upon. The overall result of these criticisms and shortcomings were summed up by the judge in his paragraph 53:

"it is unclear precisely what is meant by "specified (or identified) in the wording of the claims". Does this mean that it is sufficient for the product to fall within the scope of the claim on its true construction, or is something more required and if so what? For example, is it sufficient, say, for the claim to incorporate a Markush formula which covers a large number of compounds one of which is the product in respect of which an SPC is sought? Is it sufficient for the product to be defined in functional terms? Even in combination cases, it is not clear to me how the test enunciated by the Court should be applied in a case like Gilead. Regrettably, therefore, it is inevitable that there will have to be further references to the CJEU to obtain clarification of the test."

However, despite this finding, the judge was still able to rule on the validity of Medimmune's SPC and whatever it was that the CJEU required by specified or identified in the wording of a claim, Mr Justice Arnold concluded that ranibizumab did not fulfil the test.

He found support for this conclusion on several bases:

- He considered that the CJEU required a test that more than merely required the product to be within the scope of the claim; albeit that the judge could not determine from the CJEU's rulings and orders how much more demanding this test was to be.
- He found that the reasoned order handed down in Queensland imposed a more stringent test in the case of process claims in comparison with product claims.

- He further found that the Patent was not in any sense a patent for ranibizumab, and could find no reason to think that the patentees were delayed in reaping their rewards from the patent. As such the invalidity of the SPC was in accordance with the policy underlying the Regulation.

Comment

Mr Justice Arnold was clearly, and undoubtedly rightly, disappointed with the response of the CJEU to such numerous and direct questions on how to apply Article 3(a) of the Regulation. The CJEU had been presented with an excellent opportunity to answer this question, but instead of doing so has simply created further ambiguity and the need for yet another reference on this Regulation.

While the ambiguity that so often arises from CJEU judgments in this field acts to stimulate academic debate amongst patent practitioners and continues to push SPC law into its own specialist area of IP law, it can only cause further frustration for the pharmaceutical industry. The European Commission's 1990 proposal for the Regulation suggested it was to be a "simple, transparent system which can easily be applied by the parties concerned" but this is not a description of the system this industry now has to grapple with.

It should also be noted that the confusion underlying the application of EU SPC law is a shining example of why industry and practitioners are generally opposed to the idea of the CJEU's involvement in any Unitary Patent, a topic of recent debate in the UK following Baroness Wilcox's appearance before the House of Lords' EU Sub-Committee E on Justice and Institutions.

By Robert Lundie Smith

[1] Case C-322/10 Medeva BV v Comptroller General of Patents, Designs and Trade Marks; Case C-422/10 Georgetown University and Others v Comptroller General of Patents, Designs and Trade Marks; Case C-518/10 Yeda Research and Development Company Ltd and Aventis Holdings Inc. v Comptroller General of Patents, Designs and Trade Marks; Case C-6/11 Daiichi Sankyo Company v Comptroller General of Patents, Designs and Trade Marks; Case C-630/10 University of Queensland and CSL Ltd v Comptroller General of Patents, Designs and Trade Marks.