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When ‘Nature’ attacks the ‘Hill of Testimony’…

Thorsten Bausch (Hoffmann Eitle) · Tuesday, July 31st, 2018

…great forces are up against each other and a dispute arises. Fortunately, it is not a war of biblical dimensions, but only a lawsuit, a significant and legally interesting one though, about an Supplementary Protection Certificate. The parties were **Teva** (Hebrew word for nature) and **Gilead** (aka Hill of Testimony, a mountainous region east of the Jordan river). As such, it obviously had to be settled in Luxemburg.

Last week the Court of Justice of the European Union gave its eagerly awaited ruling in the Teva v Gilead case (C-121/17) on the criteria for determining whether the product of an SPC (active or combination of actives) is protected by the basic patent or not. Specifically, the case concerned Gilead’s SPC for the combination of tenofovir and emtricitabine. In order to obtain the same, Gilead had relied on a patent (EP 915894) which describes and claims tenofovir but also includes one broadly worded composition claim reading *“a pharmaceutical composition comprising a compound according to any one of claims 1-25 and optionally other therapeutic ingredients”*. Since emtricitabine was not mentioned in the patent and was in fact not even known at the priority date of the basic patent, the main issue of these proceedings was whether the expression “…optionally other therapeutic ingredients” is sufficient to protect emtricitabine in the sense of Article 3(a) of the SPC regulation No. 469/2009.

In the decision leading to the referral, Justice Arnold considered that the answers previously given by the CJEU on the interpretation of Article 3 (a) in Medeva, Actavis v Sanofi and Lilly were not sufficiently clear and therefore asked question 1 in Actavis v Sanofi again:

> “What are the criteria for deciding whether ‘the product is protected by a basic patent in force’ in Article 3(a) of the SPC Regulation?”

The case came before the Grand Chamber of the CJEU, which answered the referral question as follows:

> Article 3(a) of Regulation No 469/2009 of the European Parliament and of the Council of 6 May 2009, concerning the supplementary protection certificate for medicinal products, must be interpreted as meaning 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.

With this answer, the CJEU did not follow Justice Arnold who had suggested that a product should be considered to be "protected" only if it embodies the inventive advance of the basic patent, even though the final outcome might be the same in the case at stake.

Indeed, it is questionable whether the test proposed by Arnold J. would also be readily applicable and deliver just and fair results in the event that the basic patent is not a product patent but rather a formulation, process or use patent where the "inventive advance" does not lie in the substance itself but rather formulation details, process steps or the claimed use.

The CJEU also did not simply take over the proposal made by the Advocate General who had suggested that Art. 3(a) is fulfilled if "it would have been obvious to a person skilled in the art that the active ingredient in question was specifically and precisely identifiable in the wording of the claims of the basic patent". Even though the CJEU clearly recognized the skilled person's role in interpreting the claims of the patent under Art. 69 EPC (para 47) and in determining whether the product is 'specifically identifiable' in the light of the information provided in the patent and of the prior art at the effective date of the patent (para 51), it apparently felt that 'obviousness' is not the right yardstick for such an evaluation.

What does this mean for the future SPC practice?

It is now clear and settled that it is not sufficient for the purposes of Article 3(a) that a product would infringe a claim when applying national infringement rules. It is also clear that a prerequisite for Article 3(a) to be fulfilled is that the product falls within the "extent of the protection" conferred by a basic patent according to Article 69 EPC. For the determination of the extent of protection, Article 69 EPC is fully applicable and this includes that the claims of a patent are to be interpreted from the perspective of a person skilled in the art.

Thus, one might think that Gilead might have had an easy case, as a skilled person might readily be of the view that the extent of protection of a claim to a pharmaceutical composition comprising a compound according to any one of claims 1-25 (such as tenovofir) and optionally other therapeutic ingredients includes each and every other therapeutic ingredient, including such that had not been discovered/invented at the priority or filing date. The justification of such an interpretation might be that each of such combinations derives its value from the tenovofir component and its utility against retroviral diseases.

However, this is where the CJEU clearly wants to draw the line, which is also consistent with the Medeva and Georgetown decisions relating to combination vaccines. The Court explicitly states that it is not the purpose of the SPC to extend the protection conferred by the basic patent beyond the invention which the patent covers (paragraph 40):

> it is not the purpose of the SPC to extend the protection conferred by that patent beyond the invention which the patent covers. It would be contrary to the objective of Regulation No 469/2009 (…) to grant an SPC for a product which does not fall under the invention covered by the basic patent, inasmuch as such an SPC would not relate to the results of the research claimed under that patent.

The ruling of the CJEU brings to mind the test proposed by Warren J. in Eli Lilly v Human Genom Sciences [2014] EWHC 2404 (Pat) (18 July 2014)). Justice Warren found it helpful to examine "what the patent is really about" and suggested that a given product will be protected within Article 3(a), if it falls within the claims, subject to one proviso relating to circumstances where the claims contain some general word or words extending their extent beyond the principal scope of the claims, typically by the use of a word such as "comprises". Applying this test to the circumstances of the Teva case would produce meaningful results in line with the gist of the CJEU judgement since an expression like "…optionally other therapeutic ingredients" – without any description of these other therapeutic ingredients – does nothing else than extend the extent of protection beyond the principal scope of the claims.

Accordingly, it seems reasonable to interpret the Teva v. Gilead decision in the sense that the CJEU suggests applying a modified "extent of protection" test. In a first step, the extent of protection of the basic patent has to be determined under Article 69 EPC. This has to be accomplished from the perspective of a person skilled in the art, taking the description of the patent (including prior art mentioned therein), the drawings, if any, and the skilled person's common general knowledge into account. The Protocol on the Interpretation on Article 69 should also be given due regard.

If the product falls within the extent of protection thus determined, it is then to be evaluated in a second step whether the product also falls "under the invention covered by the basic patent" (para 38). In paragraph 43, the CJEU explicitly stated: *"Accordingly, having regard to the objectives pursued by Regulation No 469/2009, the claims cannot allow the holder of the basic patent to enjoy, by obtaining an SPC, protection which goes beyond that granted for the invention covered by that patent. Thus for the purposes of the application of Article 3(a) of that regulation, the claims of the basic patent must be construed in the light of the limits of that invention, as it appears from the description and the drawings of that patent."*

The evaluation of what has been the "invention" claimed by the basic patent also has to be made by the person skilled in the art, but the requirements are higher ("without any doubt") and require a problem-solution-analysis (para 48): To that end, it is necessary to ascertain whether a person skilled in the art can understand without any doubt, on the basis of their general knowledge and in the light of the description and drawings of the invention in the basic patent, that the product to which the claims of the basic patent relate is a specification required for the solution of the technical problem disclosed by that patent.

It is here where SPCs based on basic patents that include broad claims to unspecified "further ingredients or using "comprising" language will normally fail, as it should be difficult to formulate a meaningful problem which is to be solved by an ingredient that has neither been invented nor characterized at the effective date of the patent. In addition, the CJEU has made it crystal clear that it will not accept such SPCs (para 49, 50):

> … having regard to the objective of Regulation No 469/2009, recalled in paragraph 39 above, for the purposes of assessing whether a product falls under the invention covered by a basic patent, account must be taken exclusively of the prior art at the filing date or priority date of that patent, such that the product must be specifically identifiable by a person skilled in the art in the light of all the information disclosed by that patent.
> Were it to be accepted that such an assessment could be made taking into account results from research which took place after the filing date or priority date of the basic patent, an SPC could enable its holder unduly to enjoy protection for those results even though they were not yet known at the priority date or filing date of that patent, what is more outside any procedure for the grant of a new patent. That would, as pointed out in paragraphs 40 and 41 above, run counter to the objective of Regulation No 469/2009.

All Problems Solved?

On the whole, the Teva v. Gilead decision provides a welcome clarification of the existing case law of the CJEU and a test which can be applied with a reasonable degree of certainty to the majority of cases.
However, there may still be open questions in how to apply this case law in specific situations, such as in cases where a given product clearly falls under a broad Markush formula or a functional definition claimed in the basic patent and thus under its extent of protection, but where this product has not as such been identified in the specification. The problem may be even more acute if this product could only have been found as a result of a further (possibly dependent) invention.

The referral proceedings pending in Sandoz et al. v. G.D. Searle et. al [2018] EWCA Civ 49, UK Court of Appeal, Judgment of 25 January 2018, will offer an excellent opportunity for the CJEU to further develop its Case Law and to clarify the situation. The Sandoz referral concerns Searle's SPC for Darunavir which relies on a basic patent with a very broad Markush claim covering this active ingredient. Since, due to a specific pattern of substituents, the chemical structure of Darunavir is relatively far removed from the concrete compounds disclosed in this patent, the forthcoming judgement of the CJEU will hopefully show where the Court wants to draw the line between the extent of protection under Article 69 EPC and the requirement of "protected by the basic patent" pursuant to Article 3(a) of the SPC regulation. In other words, it will have to be determined what the CJEU meant by stating that "for the purposes of the application of Article 3(a) of that regulation, the claims of the basic patent must be construed in the light of the limits of that *invention*, as it appears from the description and the drawings of that patent."

Another interesting question is whether the CJEU's comments (between-the-lines) about patents arguably conferring protection beyond the invention which the patent covers, will have a bearing on the national case law on the extent of protection of patents under Art. 69 EPC. It may be appropriate to recall that the purpose of Art. 69 EPC and of the SPC regulation is not the same in all aspects, and that even under the CJEU's own case law (Actavis C-443/12, para 34) an SPC directed to Substance A confers its holder the right to proceed also against a combination of Substance A with Substance B.

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