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With Medeva on its journey through Europe

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Almost one year ago the European Court of Justice (CJEU) “clarified” the law on supplementary protection certificates. On November 24, 2011 it rendered its verdict in the “Medeva” case (C-322-10). One should not forget that “Georgetown” (C -422/10) was rendered on the same day and only one day later, the Yeda (C-518/10), Queensland (C-630/10) and Daiichi Sankyo (C-6/11) decisions came down.

In short, „Medeva“ has ruled that Article 3 (a) of the European Unions SPC Regulation 469/2009 requiring the product to be “protected by a basic patent” must be interpreted not according to the respective national law (no infringement test) but according to a uniformly applicable standard. According to this “new” criterion, SPCs may only be granted if the active ingredients “are specified (identified) in the wording of the claims” of the basic patent.

It is not surprising that “Medeva” has not been received as clarification. It rather seemed to have created confusion. Some (generic publications) have even suggested that the Medeva ruling may render one third of combo SPCs invalid. Why?
The question is, how specific must the claim be in specifying the active ingredient. Decently drafted patent claims should provide the broadest protection possible, which means they should and must generalize. Instead of referring to an individual compound they rather refer to a class of compounds or in case of combination claims to combinations with classes of compounds. What about Markush formulas or functional claims such as “beta blocker” or “diuretic”?

“Medeva” has created further uncertainty by repeating a rule which was formulated in a different factual setting in “Biogen” (C-181/95) years ago. Biogen ruled that “only one certificate may be granted for that basic patent”. Nevertheless it was common practice in virtually all member states to grant more than one SPC based on one basic patent, provided they referred to different products. The Biogen decision was considered to mean “one SPC per product per patent”. “Medeva” did nothing else but repeat Biogen. The uncertainty rests upon the previous opinion of the Advocate General Trstenjak. She explicitly suggested and justified a “one SPC per patent” rule.

Sooner or later there would be a generic company to give it a try…
The SPC under attack was Sanofi’s combination SPC. Sanofi has two SPCs, one for irbesartan (the mono SPC) and another for irbesartan in combination with hydrochlorothiazide HCT (the combination SPC). The SPCs were based on separate Marketing Authorizations (MA) for the mono product and the combination product respectively. Both SPCs were based on (different claims of) the same patent. The mono SPC expired in August 2012, but the combination SPC is

valid until October 2013. The combination SPC is based on claim 20 of the patent which claims irbesartan in combination with a diuretic. HCT is not mentioned explicitly as an example of a diuretic, neither in the claim nor in the description.

Several generics prepared a launch in France, Germany, the Netherlands and UK.
The first attempt was made in Germany. Shortly before the expiry of the mono SPC Actavis, a generic company from Island, announced that it will launch a generic combination of Irbesartan and HCT upon expiry of the mono SPC in Germany. The launch was prepared by filing a nullity action with the Federal Patent Court in Munich arguing invalidity of the SPC in view of Medeva.

Sanofi promptly filed a motion for a preliminary injunction with the District Court of Düsseldorf. The court scheduled an oral hearing to take place prior to the intended listing of the generic in the Lauer Taxe. Considering all arguments based on Medeva, the court issued a preliminary injunction which hindered the launch of the product. Actavis did not file an appeal and withdrew the nullity action.

The District Court of Düsseldorf considered the active ingredient hydrochlorothiazide ("HCT") to be "specified in the wording of the claims" because the claim of the basic patent referred to the general term "diuretic" which comprises HCT as the most prominent example. According to the court it is sufficient if active ingredients are only mentioned in the wording of the claims in a general manner – as long as the person skilled in the art considers a certain substance as encompassed by the claim or reads it into the claim. Such an interpretation does not contradict the relevance of the patent claims intended by the CJEU, as long as the active ingredient can be inferred based on a feature restricting the patent claim. The wording "diuretic" was therefore considered to be sufficient to "specify" the active ingredient HCT, which is the most commonly used diuretic worldwide, particularly when it comes to the high blood pressure therapy in question.

Secondly, the District Court of Düsseldorf decided that more than one SPC may be granted per basic patent, as it was the case here. It considered Biogen and "Medeva" to mean "one SPC per product per patent" as it was commonly understood before. Since the claims of the basic patent protected two different "products" in the sense of Art. 1(b) SPC-Regulation (irbesartan, and irbesartan + HCT), two SPCs could be granted based on this patent. Neither the wording of the SPC-Regulation nor its system or the recitals allow for the suggested limitation, which –by the way- could be circumvented quite easily. If the CJEU had intended to change the common practice it would have done so explicitly by referring to the opinion of the advocate general.

Following the German decision, the Dutch court also issued an interim decision prohibiting the launch of TEVA's generic combination product in the Netherlands.

In the UK again Actavis tried to clear the way and brought suit against Sanofi before the Patens Court for England and Wales to declare the SPC invalid. The Patents Court felt that the CJEU should have been clearer right away and thus took the opportunity to refer the case to the CJEU again to further clarify what "specified in the wording of the claims" ought to mean. From the reasoning it appears that the UK court rather tends to invalidate the SPC for that reason. The UK court also wants the Biogen question to be clarified by the CJEU.

As in Germany the Dutch court rendered a preliminary injunction against TEVA. It basically applied the same reasoning as the District Court of Düsseldorf whose decision was known by then already.

The first attempt of Sanofi to stop generic launch in France failed in first instance. The tribunal de grande instance de Paris dismissed Sanofi's request for a preliminary injunction against Mylan, Sandoz and Arrow Génériques because the validity of the SPC was "questionable" With regard to article 3(a) and Medeva the court held that the word "diuretic" in the was not precise enough to cover HCT. The same court, but another judge later ruled in favour of Sanofi and granted a preliminary injunction gainst another generic, TEVA Santé.

It seems that at least the courts on the continent tend to interpret "Medeva" not as restrictive as generic companies suggest. In fact the history of CJEU decisions relating to SPCs suggests that the CJEU is rather promoting the grant of SPCs than trying to restrict their grant. "Medeva" itself overturned the decision of the Comptroller of Patents to refuse the grant of an SPC.

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