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## The Next Referral on Article 3(a): CJEU Medeva – what does “specified in the wording of the claims” mean?

Peter Burgers (Brinkhof) · Friday, November 25th, 2011

On 24 November 2011 the CJEU passed judgment in the cases [C-322/10 \(Medeva\)](#) and [C-422/10 \(Georgetown\)](#). In the Medeva judgment, the Court answers six questions put to it by the UK Court of Appeal and the High Court respectively. The facts are deemed known by the reader – they can be conveniently reduced to:

- A basic patent claiming A+B;
- A market authorization (“MA”) for A+B+C (which are all active ingredients);
- SPCs requested for both A+B and A+B+C.

The questions boiled down to: can the SPC for A+B+C be granted based on the MA for A+B+C if the patent claims only A+B (Questions 1-5)? and can the SPC for A+B be granted if the MA is for A+B+C and the patent claims A+B (Question 6)? Obviously the UK Patent Office had answered both questions in the negative; the first for non-compliance with Article 3(a), the second for non-compliance with Article 3(b).

I will only address Questions 1-5 in this post.

In jointly answering questions 1-5 about the interpretation of “protected by a basic patent in force” as one of the requirements for the grant of an SPC (Article 3(a) of the SPC Regulation), the court held:

*“The answer to the first five questions is, therefore, that Article 3(a) of Regulation No 469/2009 must be interpreted as precluding the competent industrial property office of a Member State from granting a SPC relating to active ingredients which are not specified in the wording of the claims of the basic patent relied on in support of the SPC application”*

In various national decisions on the interpretation of Article 3(a), courts and national patent offices have answered this question in different ways. Certain courts (German) were of the opinion that the ‘infringement test’ should be used to determine whether the “product” which is the subject of the SPC is “protected by a basic patent”, i.e. if a third party would infringe the basic patent when it

would market (sell, deliver, offer etc.) the product, the latter would be “protected by” the basic patent. Other courts and a number of national patent offices (among which the Dutch Patent Office) used the ‘subject-matter’ test, i.e. the product for which the SPC was requested should form part of the claimed subject-matter, which is a narrower interpretation of the 3(a) requirement. Still others (some UK judges) used the ‘disclosure’ test. If an SPC were requested for a combination of compounds, this combination should at least be disclosed somewhere in the patent, but not necessarily in the claims. This disparity in the interpretation of Article 3(a) was one of the reasons for the current referrals to the CJEU.

By answering Questions 1-5 as it did, the CJEU seems at first sight to advocate a different, hitherto unknown interpretation of “protected by a basic patent” in Article 3(a). It does not discuss the ‘infringement-’, ‘subject-matter’ or ‘disclosure’ tests that have been used previously, and does not dwell on the pros and cons of each of these different tests. This makes the rule the Court has now formulated – “*specified in the wording of the claims*” – hard to understand. A few different interpretations can be examined.

- Does “*specified in the wording of the claims*” mean that the *name* of the active ingredient itself must be in the claim? This seems unlikely. If this were the case, then single ingredient SPCs could not be granted based on basic patents claiming *a group* of compounds (for instance as a Markush-formula) to which the active ingredient belongs, because the active ingredient was not mentioned *as such* in the claim. The latter taken together with the fact that many SPCs have been granted based on patents claiming groups of compounds makes this an improbable interpretation.
- Can it mean that the product for which the SPC is requested must be ‘disclosed’ in the claims? This could point to the “disclosure-test”, but then restricted to the claim language (because the Court specifically refers to “the claims”). This interpretation of the Court’s words would only allow an SPC for A+B to be granted if both A and B are *as such* ‘disclosed in’ the claim language. Here the question remains whether naming a group of compounds to which A or B belong is in effect a ‘disclosure’ of A or B. Certainly the way ‘disclosure’ is used in patent law does not allow for such interpretation; a disclosure of a group is not the disclosure of each of the individual members of that group.
- Does “*specified in the wording of the claims*” mean that the product is *comprised in* what is claimed? The words “specified in the wording of the claims” do not rule out such an interpretation, which is tantamount to the ‘subject-matter-test’. This interpretation permits granted SPCs based on basic patents that claim groups of compounds to remain alive and/or enforceable, and is concurrent with the way a number of national patent offices and courts have interpreted Article 3(a). What it does not permit is that an SPC is granted for a combination of ingredients A + B if the basic patent claims only A (or B), because the combination of A+B is obviously not ‘comprised in’ a claim to A (or B). It may be argued, however, that it allows an SPC for A+B if the claims say “composition of A and another active ingredient” or “composition comprising A” (which allows the presence of B), although disputes may arise as to what level of specificity is required.

- Can the Court's rule also be the 'infringement test' in disguise? That seems hard to reconcile with the wordings of the Court. The infringement test is arguably the lowest threshold compared to either the subject-matter test or the disclosure test, and from the rest of Court's judgment such a permissive approach does not seem likely.

As can be taken from the above, the Court's decision on the interpretation of Article 3(a) is all but clear and seems to give practitioners and SPC applicants little comfort. It seems a matter of time before a new referral on the 'interpretation of the interpretation' of Article 3(a) comes along.

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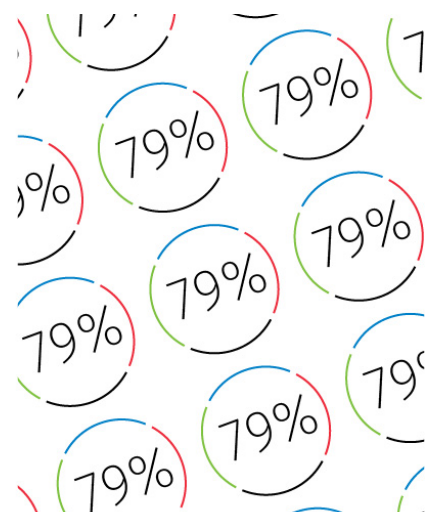
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