

CJEU rulings on SPC requirements raise



In a series of recent judgments and orders, the Court of Justice of the European Union has ruled on several requirements for grant of supplementary protection certificates. There appears to be general consensus that the rulings fall short of clarity as well as consistency with existing patent law and practice, thereby raising more questions than they answer.

Background

Article 3 of the SPC Regulation (Regulation EC no. 469/2009) stipulates that a supplementary protection certificate (SPC) can be granted to the holder of a basic patent protecting an authorized medicinal product subject to four requirements:

- (a) the product is 'protected' by a patent;
- (b) an authorization for placing the product on the market as a medicinal product has been granted;
- (c) the product has not been the subject of an SPC before; and
- (d) the authorization referred to in b) is the first authorization for the product.

In a number of cases the UK Court of Appeal referred questions to the CJEU concerning requirements (a) and (b). In a nutshell, these cases all concerned SPC applications where a 'mismatch' existed between the basic patent and the Marketing Authorization (MA) on which the SPC application was based, in that the authorized medicinal product contained multiple active ingredients while the basic patent claimed only a single one of them. Before the referral most national Intellectual property offices took the view that the combination was not the same product as a single ingredient, i.e. in the sense of article 1(b) of the Regulation¹, so that an SPC concerning only the single ingredient claimed by the basic patent would not comply with requirement (b). An SPC for the entire combination of active ingredients, on the other hand, by certain Intellectual property offices, would be held not to comply with requirement (a), as the basic patent only 'protected' one of the single ingredients. Without going into this 'peculiarity' in too much detail, it is to be

¹ Article 1(b) of Regulation no. 469/2009: "[...] 'product' means the active ingredient or combination of active ingredients of a medicinal product".

understood that over the years, on member state level, 3 different approaches to determine whether requirement (a) was fulfilled had evolved:

- (i) the product should (theoretically) infringe the basic patent ('infringement test');
- (ii) the product should be part of the claimed subject-matter ('subject-matter test'); or
- (iii) the product should be disclosed specifically in the basic patent and/or at least be implicitly derivable from the basic patent ('disclosure test').

Hence, in those member states where the disclosure test was applied, a mismatch between basic patent and MA in certain cases had the rather harsh result that no supplementary protection was available at all whereas the patent relied on would confer exclusive rights for authorized medicinal products.

The CJEU Rulings

In the 'Medeva' and 'Georgetown' judgments (C-322/10 and C-422/10), where such a mismatch had resulted in refusal of SPC applications, the CJEU answered the questions concerning the requirements of article 3(a) and 3(b) referred to it as follows:

"Article 3(a) [...] must be interpreted as precluding the competent industrial property office of a Member State from granting a supplementary protection certificate relating to active ingredients which are not specified in the wording of the claims of the basic patent relied on in support of the application for such a certificate."

"Article 3(b) [...] must be interpreted as meaning that, provided the other requirements laid down in Article 3 are also met, that provision does not preclude the competent industrial property office of a Member State from granting a supplementary

protection certificate for a combination of two active ingredients, corresponding to that specified in the wording of the claims of the basic patent relied on, where the medicinal product for which the marketing authorisation is submitted in support of the application for a special protection certificate contains not only that combination of the two active ingredients but also other active ingredients."

In relation to article 3(a), the CJEU has thus not chosen to follow any of the existing approaches but to devise yet a different test, requiring that the product is "specified in the wording of the claims". The approach with regard to article 3(b) also entails a rather drastic turn away from established views. The CJEU quite clearly intended to mitigate the harsh effects of the mismatch between basic patent and MA. As a matter of fact, the CJEU specifically emphasized that the fundamental objective of the Regulation, which is to ensure sufficient protection to encourage pharmaceutical research and play a decisive role in the continuing improvement in public health, could be undermined if the mismatch would prohibit a proprietor to enjoy supplementary protection altogether.

Quite remarkably, the CJEU, by way of obiter dictum, also noted in the decision that, under article 3(c) no more than one SPC per patent should be granted, contrary to the widely accepted view that article 3(c) only prohibits the grant of more than one certificate per patent (proprietor) for the same product.

Other pending referrals (C-518/10; C-630/10; and C-6/11) were concluded by 'order of the court', with the exact same answers on the main issues. Interestingly, referral C-630/10, also adds that:

"In the case of a basic patent relating to a process by which a product is obtained, Article 3(a) [...] precludes a supplementary protection certificate

being granted for a product other than that identified in the wording of the claims of that patent as the product deriving from the process in question. Whether it is possible to obtain the product directly as a result of that process is irrelevant in that regard."

Comments

At a first glance, these CJEU rulings may appear to be favorable for patent proprietors in general, in that the CJEU gave much weight to the objective of the Regulation of ensuring sufficient protection to encourage pharmaceutical research and, effectively, concluded that supplementary protection should be awarded in the cases brought before it. Upon closer consideration, however, one inevitably comes to realize that the approach chosen by the CJEU raises a number of serious concerns and may ultimately prove to limit rather than broaden the possibilities for patent proprietors to enjoy supplementary protection.

In relation to the article 3(a) requirement, it is yet to be clarified what is meant by 'specified in the wording of the claims'. In the combination product cases referred to the CJEU, it was always quite clear that any suggestions to combine the claimed active ingredient(s) with further active ingredients was lacking completely. Many cases exist, however, wherein the requirement will give rise to much uncertainty. This applies to certain 'combination product cases', wherein e.g. a new therapeutic compound has been claimed in combination with a compound that is only referred to in generic terms (as belonging to a certain therapeutic class), as well as to certain 'single ingredient cases', wherein e.g. a new therapeutic compound itself belongs to a group of compounds generically defined (in a Markush formula), without being claimed also specifically. The result of the CJEU referrals, for such cases, may prove to be quite unfavourable, depending on the precise meaning of the term 'specified in the wording of the claims'.

Given the CJEU's reasoning underlying the decisions at hand, especially the reference to the general objective of the Regulation, it would still seem logical if supplementary protection would be available also in case of these types of 'mismatches'. This logic, on the other hand, does not immediately seem to fit in with the final part of the answer in C-630/10 (supra).

The ruling on the article 3(b) requirement has obscured the meaning of the term 'product' in the sense of the Regulation. Article 1(b) of the Regulation defines the product as 'the active ingredient or combination of active ingredients of a medicinal product'. Notwithstanding the fact that said provision refers to 'the active ingredient' and not to 'an active ingredient', the CJEU has, effectively, decided that the product can be one of multiple active ingredients of an authorized combination product. Whether such a departure from the generally accepted approach (i.e. that the product, in case of a combination product, necessarily equates to the entire combination of active ingredients) is allowable only in case of a mismatch between basic patent and MA still remains to be seen. A precise meaning of the term product is, however, absolutely crucial for proper application of e.g. articles 3(c), 3(d), 4 and 13 of the Regulation and it is, as yet, difficult to comprehend the possible consequences of the CJEU rulings in this regard. Some further clarity will be shed on this issue by the CJEU in its anticipated judgment in case C-442/11.

Finally, the principle of 'only one certificate per patent' may give rise to quite a turmoil, if it would be held to prohibit further application of the existing and widely accepted approach of 'one certificate per product per patent (proprietor)' indeed.

In the cases presented to it, the CJEU intended to meet the demands of the patent proprietors. The

same result certainly could have been achieved in more elegant ways, by adopting either the infringement test (as, for instance, maintained by the UK Government in these proceedings) or the subject-matter test (as maintained in the opinion by the advocate-general). Either one of these approaches would have avoided, most, if not all, of the above issues. The matter, of course, is now acte éclairé and national Intellectual property offices and courts are likely to consider themselves bound by the decisions, in spite of the rather scarce substantiation, lack of clarity, and poor coherence with existing patent law and practice.

Future Recommendations

Although many issues still need further clarification, we hold the view that these CJEU rulings warrant careful consideration by those involved in patenting of pharmaceutical inventions, also at the stage of drafting and prosecution of patent application. The general aim should be to ascertain that claims are eventually derivable from an application that 'specify' the product receiving regulatory approval, many years of pharmaceutical development later. Whether this should involve anticipating future developments in the initial application as much as possible or the filing of later applications directed to specific further developments, will have to be evaluated on a case-by-case basis.

Our attorneys will continue to closely follow further developments in this area.



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New PCT feature for indicating the willingness to license inventions

In January 2012 WIPO is to introduce a register that will allow applicants interested in licensing the inventions contained in their international application, to make this information available on the PATENTSCOPE website (<http://www.wipo.int/patentscope/search/en/search.jsf>).

Applicants who are interested in licensing their inventions can request the International Bureau to indicate the availability for licensing purposes of the invention(s) claimed in the international application on the PATENTSCOPE website. In addition, applicants may state the licensing terms, such as the Contracting States for which they are willing to license the claimed invention(s) and/or whether the license will be for the licensee's exclusive or non-exclusive use. Applicants can also indicate a contact person who is to be addressed by whoever is interested in a licensing agreement.

The licensing indications will be provided in PATENTSCOPE in the bibliographic data relating to the particular application, but will not be part of the published international application itself. In addition, WIPO will add the existence of licensing indications to the search criteria list within PATENTSCOPE.

As from 1 January 2012 this PCT feature will be available for any international application for which the 30 months' period from the priority date has not yet expired.



Should you have any questions regarding the above, please contact Caroline 't Hoen-van der Hoogt (hoen@octrooibureau.nl); +31 70 3312507