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SPCs: clarity on claims with functional features?

A new referral asks for more clarity regarding the type of patent claim required for an SPC

The German Federal Patent Court has asked the CJEU how its “implicitly, but necessarily and specifically” test for assessing Article 3(a) of Regulation (EC) No.469/2009 (the “Regulation”) should be applied to functional features.

For an SPC to be granted, Article 3(a) requires that the product (active ingredient(s)) must be “protected by a basic patent in force”. Previous CJEU rulings have clarified that in the context of SPC applications “protection” is not as wide as patent protection in infringement proceedings. Instead, the CJEU decided that SPCs may be granted for an active ingredient falling within a functional definition provided that the claims relate “implicitly, but necessarily and specifically to the active ingredient in question” ([Eli Lilly \(C-493/12\)](#)). This test has led to much debate as to whether or not the specific active ingredient must be individually disclosed for an SPC to be granted.

The UK Courts have held that no individualised disclosure is necessary in the context of generic antibody claims and claims with Markush formulas ([\[2014\] EWHC 2404 \(Pat\)](#) and [\[2017\] EWHC 987 \(Pat\)](#)). The UK Courts have instead focussed on

whether the active ingredient in question falls within the claims and embodies the inventive contribution of the underlying basic patent. However other jurisdictions, such as Germany, have interpreted the CJEU ruling in *Eli Lilly* to require the active ingredient to be individually disclosed at least in the specification.

The different interpretations across European jurisdictions go against the objective of the Regulation to ensure a consistent approach to SPCs across the EU. In order to resolve the inconsistencies, the German Federal Patent Court referred three questions (set out in full below), which effectively ask:

1. Does an active ingredient need to be a specific embodiment in the claims to be “protected” for the purpose of Article 3(a)?
2. If so, does an active ingredient that falls within a general functional definition without being individualised fail this test?
3. Is an active ingredient “protected” if it falls within the functional definition but was developed only after the filing date by an independent inventive step?



A CJEU ruling on these questions will help clarify the position on granting SPCs based on claims with a functional feature. If the CJEU ruling aligns with the UK Court's approach, SPCs will be easier to obtain across additional jurisdictions because active ingredients will not need to be individually disclosed in the patent claims. If the CJEU ruling follows the German Court's approach, care will need to be taken to ensure potential active substances are individually disclosed in the claims of the basic patent to enable SPC protection. There are now two pending referrals regarding the meaning of the word "protected" in Article 3(a), following the referral in [\[2017\] EWHC 13 \(Pat\)](#), so perhaps these will finally settle how this key part of the Regulation should be implemented.

Questions referred

- "1. Is a product protected by a basic patent in force according to Article 3 (a) of Regulation (EC) No 469/2009 only if it belongs to the protected subject-matter as defined by the claims and is thus provided to the person skilled in the art as a specific embodiment?"*
- "2. Is it therefore not sufficient for the requirements of Article 3 (a) of Regulation (EC) No 469/2009 that the product in question meets the general functional definition of an active substance class as mentioned in the claims, but apart from that is not individualised as a specific embodiment of the teaching protected by the basic patent?"*
- "3. Is a product not protected according by Article 3 (a) of Regulation (EC) No 469/2009 by a basic patent in force if it is covered by the functional definition contained in the claims, but was developed only after the filing date of the basic patent based on independent inventive activity?"*

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