CJEU Confirms Strict Interpretation of Article 3(a) for SPCs

Background

The referral in Royalty Pharma was made by the German Bundespatentgericht (Federal Patent Court) in a case concerning the refusal by the DPMA (German Patent Office) of an application for an SPC for the diabetes product Januvia due to failure to comply with Article 3(a).

The product comprises the active ingredient sitagliptin, a DP IV inhibitor. The basic patent EP1084705 effectively claims DP IV inhibitors defined as a functional class, for the treatment of diabetes. However, sitagliptin is not disclosed in individualised form in EP1084705. It was developed after the filing date of the basic patent by a licensee. The licensee obtained a separate patent for sitagliptin, on the basis of which it was granted its own SPC.

The Bundespatentgericht considered that there were conflicting views regarding how to assess the requirements of Article 3(a), including the relevance of a so-called 'core inventive advance' test applied by the judge for a corresponding case in the UK.

Accordingly, it referred the following questions to the CJEU:

"1. Is a product protected by a basic patent in force pursuant to Article 3(a) of Regulation (EC) No 469/2009 only if it forms part of the subject matter of protection defined by the claims and is thus provided to the expert as a specific embodiment?

2. Is it not therefore sufficient for the requirements of Article 3(a) of Regulation (EC) No 469/2009 if the product in question satisfies the general functional definition of a class of active ingredients in the claims, but is not otherwise indicated in individualised form as a specific embodiment of the method protected by the basic patent?

3. Is a product not protected by a basic patent in force under Article 3(a) of Regulation (EC) No 469/2009 if it is covered by the functional definition in the claims, but was developed only after the filing date of the basic patent as a result of an independent inventive step?"

Following the July 2018 delivery of the judgment in C-121/17 (Teva), which also concerned Article 3(a), the CJEU invited the Bundespatentgericht to confirm whether it wished to maintain its referral and, if so, on what grounds.

The Bundespatentgericht maintained its referral on the grounds that the CJEU did not explicitly criticise the 'core inventive advance' test in their ruling in Teva, and thus it remained unclear the extent to which such a test may be relevant to Article 3(a).

The oral hearing took place in June 2019, with Advocate General Hogan's opinion issuing in September 2019. Royalty Pharma subsequently requested re-opening of the oral procedure on the grounds that the Advocate General's opinion contained errors. Specifically, they asserted that the patent relied upon for Royalty Pharma's SPC application was misidentified in the opinion (the wrong number was quoted), and also that the Advocate General had misinterpreted CJEU case law.

The CJEU denied the request. It is settled case-law that the Court may order the reopening of the oral procedure, but only if it considers that it is insufficiently informed, or that the case turns on the basis of an argument which has not been discussed between the parties, or that one of the parties has submitted a new development which could have a decisive influence. It does not provide for the parties to file observations in response to conclusions presented by the Advocate General. Royalty Pharma's criticism of the Advocate General's interpretation of the case law was considered to fall into this latter category, and so did not occasion re-opening the oral procedure. The factual error in identification of the patent number was held not to be material.

The Ruling

In its introductory remarks (paragraphs [30] – [32]), the CJEU state explicitly that the 'core inventive advance' test is **not** relevant for the interpretation of Article 3(a). Although it is acknowledged that this test was not explicitly excluded, the CJEU states that its ruling in Teva provides a test that relies solely on the interpretation of the claims of a basic patent in line with the Protocol on Interpretation of Article 69 EPC.

Having established this background, the CJEU turns to the first and second referred questions, which are considered together in a condensed form. This is paraphrased as:
"Must Article 3(a) of Regulation No 469/2009 be interpreted as meaning that a product is protected by a basic patent in force…, if the product meets a general functional definition in one of the claims and necessarily falls under the invention covered by the patent, but cannot be derived individually from the teaching of the patent as a specific embodiment?"

The CJEU goes on to explain that (in effect) it believes this question has already been answered in Teva. As such the court has broadly followed the reasoning of Advocate General Hogan. It is confirmed in paragraph [37] that, where a product is not explicitly recited in the claims, the two cumulative conditions set out in Teva must be met in order for Article 3(a) to be satisfied:

(1) The product must, from the point of view of a person skilled in the art and in the light of the description and drawings of the basic patent, necessarily fall under the invention covered by the basic patent.

(2) The person skilled in the art must be able to identify the product specifically in the light of all the information disclosed by that patent, on the basis of the prior art at the filing date or priority date of the patent concerned.

This conclusion is essentially repeated in paragraph [43] as the answer to referred questions 1 and 2. However, in paragraphs [38] – [42] the CJEU provides some additional guidance as to how the test should be applied, with a particular view to the facts before it for sitagliptin.

The CJEU considers it to be clear from the referral itself that sitagliptin is not explicitly recited in the claims, and that the referring court evidently find it to fall under the invention of the basic patent. Thus, although the CJEU notes that it is for the referring court to decide these matters, the CJEU considers both that the two part test must be applied and also that the first part of that test is satisfied.

However, the CJEU notes that the referring court appears to have doubts that sitagliptin satisfies the second part of the test and has (effectively) asked the CJEU to clarify the degree of specificity required.

In paragraph [40], the CJEU states that the referring court must satisfy itself that the subject matter of the SPC is within the limits of what the person skilled in the art, on the filing or priority date of the basic patent, is objectively able to deduce **directly and unambiguously** from the specification of the patent as filed, taking into account general knowledge and the state of the art considered at the filing or priority date.

In paragraph [41], the CJEU repeats that there is no requirement for the product to be explicitly disclosed as an individual embodiment. However, they go on to state in paragraph [42] that, when the product is not explicitly disclosed in the claims of the basic patent, but falls within a general functional definition (such as in the present case), the skilled person must be able to deduce **directly and unambiguously** from the specification of the patent as filed that the product falls under the invention covered by the basic patent.

The CJEU does not explicitly conclude that sitagliptin fails this test. However, they give a strong hint in their answer to the third question. The third question is interpreted by the CJEU as asking: whether Article 3(a) is not satisfied if a product that falls within a functional definition of the claims was developed after the filing date of the application for the basic patent, following an independent inventive step? The CJEU appears to conclude in paragraph [50] that it is impossible to grant an SPC under such circumstances.

Unfortunately, the CJEU's use of the term "independent inventive step" in this analysis is open to interpretation. Neither the degree of independence nor the degree of inventiveness required is specified. At one extreme, the CJEU's position could perhaps be interpreted as suggesting that the mere existence of a later patent protecting a product that falls within the scope of a functional definition in an earlier patent will automatically exclude the earlier patent as basis for an SPC for that product. However, there are reasons to believe that the CJEU must have intended a less extreme interpretation, not least because it cannot be assumed that there will always be a later patent for an authorised product that is developed after the filing date of an earlier patent.

Furthermore, even if there is a later patent, there is no single reason for it having been found inventive (including over the earlier patent) by a patent office. For example, it may claim the specific product as an inventive selection over the earlier patent, or it may claim the use of the product for treatment of a more specific indication or patient group, or it may claim a particularly effective dose regime or a particularly stable formulation of the product. Each of these concepts (and more) may be found to represent an "inventive step" for the purposes of grant of a later patent, and each can be viewed as a later development of a product, but each can also be characterised as being more or less "independent" of the original inventive concept of the earlier patent. It is not clear that the CJEU has considered the different forms that a later patentable invention may take, and hence the different degrees of "independence" that may exist. No guidance is provided as to how these differences may affect an assessment of Article 3(a) for an earlier patent. A further referral may be required to clarify the intention of the CJEU in this respect.

In addition to the unhelpful terminology discussed above, the CJEU also makes a number of other broad generalisations in reaching its answer to question 3. In particular, in paragraphs [45] and [46], the CJEU takes the position that the protection conferred by the basic patent must be assessed at the filing date or priority date of the patent, since otherwise the patentee could "unduly benefit" from the results of research that were not known at these dates. The CJEU appears to consider grant of an SPC in such circumstances to be contrary to the aim of the SPC regulation, which is to offer an additional period of exclusivity in order to incentivise research.

The CJEU appears to have interpreted "research" in this context to mean late-stage, clinical research into a specific product. This is consistent with a trend in recent CJEU case law, which does not appear to recognise value in also incentivising broader, early-stage research. This is particularly unfortunate, since the SPC regulation explicitly does not favour any specific type of research.

The Implications

The ruling can be interpreted as simply confirming that the two part test of Teva applies to products comprising single active ingredients as well as to combinations. However, the more significant implication is that it continues the general trend of CJEU case law from C-322/10 (Medeva), through C-493/12 (Eli Lilly), to C-121/17 (Teva) itself, which is towards a stricter interpretation of Article 3(a). This inevitably favours SPCs based on patents which protect late-stage inventions arising during clinical development of specific products, over early-stage research which may open up a new field without necessarily identifying (or needing to identify) a specific active ingredient.

Of particular concern to innovators holding broader, earlier patents to a general therapeutic concept will be the CJEU's use of the wording directly and unambiguously (highlighted above in paragraphs [40] and [42]). This echoes the so-called 'gold standard' applied by the EPO when assessing whether or not a feature is present in an application for the purposes of Article 123(2) EPC (prohibition against extending beyond the content of the application as filed). The same standard is applied by the EPO when assessing whether or not a feature is present in a prior art document for the purposes of Article 54(2) EPC (requirement for novelty). Readers familiar with the EPO will be aware that this standard is applied strictly.

Assuming that the CJEU's choice of words was deliberate, it

implies that if the product is not explicitly recited in the claims, it will nonetheless need to be disclosed to a high degree of specificity elsewhere in the patent. Indeed, applying the strictest possible interpretation, it may suggest that the disclosure in the underlying patent application as filed should be such that (if the application were hypothetically still pending at the EPO) it would be possible to amend the claims to recite the product without facing an objection under Article 123(2) EPC. Put another way, the implication is that whilst the claims of the patent may not expressly recite the product now, in order for an SPC to be granted it is necessary that they could have done so.

Even if this judgment is not interpreted as strictly as the **directly and unambiguously** language may imply, it nonetheless suggests there will be challenges to securing SPC protection based on a patent that does not individually disclose the active ingredient(s) of an authorised product.

This is more likely to be problematic in the field of complex biological molecules (e.g. antibodies), for which it may be more difficult to satisfy the two-part test in the absence of a literal disclosure of the individual molecule. By contrast, the small molecule field may be more forgiving. It could be argued, for example, that given a disclosure of C1-C6 alkyl and specific examples of “methyl” and “propyl”, the skilled person can directly derive “ethyl” even though it is not individually disclosed.

Prospective applicants should in any case continue to base their SPC applications on patents which claim the product as specifically as possible.

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