Supplementary Protection Certificates: the never-ending saga of Article 3(a)

Mike Snodin discusses the latest decisions on Article 3(a) of the EU SPC legislation and explains why the issues relating to this fundamental provision are still far from settled.

On 18 July 2014, the UK High Court issued a judgement refusing to grant pharmaceutical company Eli Lilly a declaration of non-infringement in respect of a prospective supplementary protection certificate (SPC) based upon a patent owned by Human Genome Sciences (HGS)[1].

The judgement of Warren J represents the latest development in two different, long-running sagas. The first saga is the dispute in the UK between Eli Lilly and HGS, which relates to the patent and SPC protection for antibodies to neutrokine alfa, such as Eli Lilly's tabalumab. The second saga, which is by far the longest-running of the two, relates to the judicial interpretation of Article 3(a), a key provision of the SPC legislation for medicinal products (Regulation 469/2009).

Whilst Warren J's judgement may well represent the beginning of the end of the Eli Lilly and HGS saga in the UK, it is highly unlikely to represent the last word in the saga relating to Article 3(a) of Regulation 469/2009.

This article therefore discusses the interpretation of Article 3(a) used by Warren J. It also discusses two examples of alternative (modified or more permissive) interpretations of Article 3(a), one of which presents a fundamental challenge to the conclusions reached by Warren J.

Fortunately, that most challenging alternative interpretation of Article 3(a) can probably be dismissed on the grounds that it is fundamentally inconsistent with not only the case law of the Court of Justice of the EU but also the primary purpose of the SPC legislation. Nevertheless, the alternative interpretations discussed in this article highlight the point that, even in the UK, still further challenges are likely to arise in connection with Warren J's interpretation of Article 3(a). Thus, the view of this author is that, whilst one chapter in the saga of Article 3(a) may well be drawing to a close, there are likely to be more chapters to come before a settled interpretation is reached across the whole of the EU.

Background

SPCs

SPCs represent the EU's answer to Hatch-Waxman Patent Term Extensions (PTEs) in the US. An important feature of SPCs is that they do not extend the patent. Instead, they represent stand-alone rights that protect only the authorised indications of a patent-protected product (active ingredient or combination of active ingredients).

Of the criteria that must be satisfied in order for a SPC to be granted, one of the most fundamental is that specified in Article 3(a) of Regulation 469/2009. This requires that, on the day of application in the territory where SPC protection is sought, "the product is protected by a basic patent in force".

The CJEU's interpretation of Article 3(a)

Because SPCs are governed by EU legislation, the CJEU is the final arbiter of how the legislation should be interpreted. Thus, where national courts are uncertain of the correct interpretation of the legislation, they can refer questions to the CJEU in order to obtain clarification.

The CJEU has already answered questions relating to Article 3(a) in connection with a total of seven different cases. The key points stemming from the judgements of the CJEU in those cases can be summarised as follows.

- The question of whether or not a patent "protects" a product cannot be (fully) answered by reference to the provisions of Regulation 469/2009. This is because that question must be answered by reference to the (national and/or European Patent Convention) rules that govern the patent concerned (see *Farmitalia*, C-392/97).
- The rules for determining what is protected by a basic patent for the purpose of Article 3(a) of Regulation No 469/2009 are those relating to the extent of the invention covered by such a patent. For example, for a UK patent, the relevant rules are those of Section 125 of the UK Patents Act 1977 and the Protocol on the Interpretation of Article 69 of the European Patent Convention (see paragraph 32 of *Eli Lilly*, C-493/12).
- Regulation 469/2009 nevertheless aims to prevent the separate development (and hence possible divergence) of national laws, as that would be likely to create obstacles to the free movement of medicinal products within the EU (see paragraph 24 of *Medeva*, C-322/10).
- For determining compliance with Article 3(a), recourse may not be had to the (national) rules governing infringement proceedings (see, for example, paragraph 33 of *Eli Lilly*).
- An active ingredient that is not identified in the claims of a basic patent by means of either a structural or a functional definition cannot be considered to be "protected" within the meaning of Article 3(a) of Regulation 469/2009 (see paragraph 38 of *Eli Lilly*).
- Conversely, the requirements of Article 3(a) are not satisfied if the active ingredient that is the subject of the SPC application is identified in the wording of the claims of the basic patent as an active ingredient forming part of a combination in conjunction with another active ingredient, but is not the subject of any claim relating to that active ingredient alone (see, for example, *Yeda*, C-518/10).
- The same criteria apply to claims in process format, wherein the product for the SPC application must be identified in the claims of the patent as the product deriving from the process in question (see *Queensland*, C-630/10).

The Judgement of Warren J

The issues in the dispute between Eli Lilly and HGS turned upon whether Claim 13 of HGS's patent (EP 0 939 804) protected Eli Lilly's antibody to neutrokine alfa (tabalumab). In particular, the parties disagreed upon whether or not the claim, which used purely functional terms to define antibodies to neutrokine alfa, "protected" tabalumab in the manner required by the case law of the CJEU.

The dispute was first heard before the UK High Court in June 2012. Having heard the arguments of the parties, Warren J decided to refer further questions to the CJEU in connection with Article 3(a). This was on the grounds that, at that time, it was unclear whether functional definitions of active ingredients were capable of "specifying" the product for the SPC in accordance with the test set out in *Medeva*.

In *Eli Lilly*, the CJEU's judgement on the questions referred by Warren J included the clear statement that:

> *"for an active ingredient to be regarded as 'protected by a basic patent in force' within the meaning of that provision, it is not necessary for the active ingredient to be identified in the claims of the patent by a structural formula".*

Regrettably, however, the CJEU modified the above statement by including the additional (and almost incomprehensible) requirement for claims using functional definitions to "relate, implicitly but necessarily and specifically, to the active ingredient in question".

This left Warren J with the unenviable task of resolving the dispute between the parties in the absence of any clear guidance from the CJEU as to how Article 3(a) should be interpreted. However, Warren J tackled this task admirably, by reaching conclusions based upon the whole of the CJEU's judgement in *Eli Lilly* (as opposed to from just isolated statements in the judgement), and by placing the judgement in the context of the CJEU's prior case law.

The conclusion reached by Warren J related to what was meant in the CJEU's prior case law (including *Medeva*) by "specified [or identified] in the wording of the claims". His view on this was that, subject to a proviso (discussed below):

> *"If the product falls within the claims, it will be protected within Article 3(a)".*

The proviso to this conclusion is explained in paragraph 66 of Warren J's judgement, which reads as follows.

> *"The proviso relates to products which are combinations of active ingredients and is necessary to reflect the Medeva approach where the claims contain some general word or words extending their extent beyond the principal scope of the claims, typically by the use of a word such as "comprises". In the absence of such an extending word, the claims have a focused scope and the question is simply whether the product falls within the scope of the claims. In the language of Medeva, the question is whether the product (ie the combination of active ingredients) is "specified" in the claims, a question which is answered by a close examination of the claims. If general words are included, the position is different. The product does not fall within the focus of the claims and is not within its scope apart from the general words. In such a case, the product is not "specified" any more than it is "specified" where the general words are absent".*

Further, with regard to the troublesome phrase "relate, implicitly but necessarily and specifically, to the active ingredient in question", Warren J's conclusion was that:

> *"the Court was saying that an active ingredient is "identified" so as to fall within the protection of a basic patent if the active ingredient is within the claims of the basic patent provided the claims relate, implicitly but necessarily and specifically, to the active ingredients. Those words reflect, in the context of a functional definition, no more and no less than the word "specified" in Medeva and "identified" in subsequent cases".*

Commentary on Warren J's Judgement

Piecing together the various conclusions reached by Warren J, it would appear that the test for compliance with Article 3(a) that he has proposed can be summarised as a requirement for the product for the SPC application to:

(i) fall within the extent of protection provided by the claims; and

(ii) represent the *focus* of the claims (as opposed to fall within the scope of the claims merely due to the use of extending, general words).

In Warren J's view, part (ii) of this test only becomes relevant to consider if the claims contain "some general word or words extending their extent beyond the principal scope of the claims". Thus, for many claims, it will only be relevant to consider part (i) of the test, ie whether the product for the SPC application falls within the extent of protection of the claims, as interpreted in the light of Article 69 of the European Patent Convention (and the Protocol to that Article) and/or the corresponding national provision, such as Section 125 of the UK Patents Act 1977.

Part (i) of the above two-part test finds ample support in the case law of the CJEU. For example:

- in cases such as *Farmitalia* and *Eli Lilly* it is emphasised by the CJEU that "protection" by the basic patent can only be decided by reference to non-Community rules (ie national and/or EPC rules that determine the extent of protection provided by the claims); and
- in *Yeda*, the CJEU ruled that there is a requirement for the active ingredient that is the product for the SPC application to not only be identified in the claim but to also be the subject of a claim relating to that ingredient alone (ie the product merely being identifiable as an integer of the claim is not enough, as there is a requirement for that product to also fall within the extent of protection of a claim of the basic patent).

The legal basis for part (ii) of the test is less obvious. Indeed, it is arguably inconsistent with conclusions leading to part (i) of the test. However, it is certainly required to make sense of the case law of the CJEU in connection with combination products, such as *Medeva*.

Thus, it would appear that Warren J has provided what the SPC community has been seeking for many years, namely a test for compliance with Article 3(a) that is not only simple and robust but that is also relatively straightforward to apply in a wide variety of cases.

To be continued...

In the light of the above, the casual observer could be forgiven for believing that Warren J's judgement in *Eli Lilly v HGS* represents the beginning of the end of the long-running saga relating to the interpretation of Article 3(a). Disappointingly, however, there is reason to believe that there will be further chapters to come in that saga.

Firstly, Eli Lilly were granted leave to appeal Warren J's judgement. This means that the Court of Appeal in the UK may well be tasked with reviewing that judgement.

Secondly, perhaps the most interesting challenges to Warren J's interpretation may well not come from enforcers of the SPC system (the patent offices and courts), but instead from the users of that system, namely SPC applicants and holders. This is because, as would be expected, the users of the system are unlikely to hold back from proposing either modified or more permissive interpretations of Article 3(a) in circumstances where acceptance of those alternative interpretations represents the only (or the most likely) route for the user to gain or maintain SPC protection.

In this regard, questions that have come to the attention of this author include:

(1) whether it is permissible to consider equivalents when interpreting the products that are "protected" by the basic patent; and

(2) whether it is even necessary for patent offices to determine whether the product for the SPC application falls within the extent of protection of the claims of the basic patent.

Equivalents

In principle, it would appear that considering equivalents could be achieved without fundamentally changing the basis of Warren J's conclusions regarding the interpretation of Article 3(a). This is because considering equivalents in connection with the extent of protection provided by the claims of a basic patent granted by the EPO can arguably be justified by Article 2 of Protocol on the Interpretation of Article 69 of the European Patent Convention, which states:

> *"For the purpose of determining the extent of protection conferred by a European patent, due account shall be taken of any element which is equivalent to an element specified in the claims".*

The author is aware of at least one case where this issue could be relevant, and so it will be very interesting to see what the national patent offices (or the courts) make of it.

Is the extent of protection test essential?

In contrast to the issue of equivalents, question (2) above represents a fundamental challenge to the conclusions reached by Warren J in connection with Article 3(a).

The question emerges from the CJEU's comments in *Queensland* that:

> *"The grant of a SPC is not conditional on whether it is possible to obtain a product directly as a result of the process by which the product is obtained, where that process has been the subject of a patent" (see paragraph 40); and*
>
> *"Whether it is possible to obtain the product directly as a result of that process is irrelevant in that regard" (see point 3 of the ruling).*

Some commentators have taken these comments to mean that it is not necessary for the patent office to delve into the issue of whether the product for the SPC application falls within the extent of protection provided by the claims of the basic patent. As a result, they have proposed a test for compliance with Article 3(a) that, for claims in process format, merely requires a patent office to establish:

- whether the product for the SPC application is what the claim describes as the product of the process; and
- whether that product is "commensurate" with the active ingredient(s) that is (are) authorised by way of the marketing authorisation relied upon.

Because this test does not require the product to fall within the extent of protection of the basic patent, its acceptance could give rise to the bizarre situation where the SPC "protection" granted has (and will always have) zero effective scope.

Using the proposed test would give rise to a (permanently) zero scope SPC when the specified product is not actually encompassed by the scope of protection provided by the basic patent. This is because a SPC is incapable of protecting anything that was not protected by the basic patent (see Article 4 of Regulation 469/2009, which indicates that the scope of protection provided by the SPC is "within the limits of the protection conferred by the basic patent").

This rather bizarre result is particularly troublesome because it appears to run contrary to one of the fundamental aims of the SPC system, which is to provide "sufficient protection" or "adequate effective protection" (see Recitals (3) and (9), respectively, of Regulation 469/2009) for marketed medicinal products. Thus, a SPC that does not actually protect any marketed medicinal products would appear to run contrary to the ethos of the SPC system. Moreover, because such a SPC would not protect the authorised active ingredients(s), it would be impossible for that SPC to satisfy Recital (10) of Regulation 469/2009, which requires that:

> *"The protection granted should furthermore be strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product".*

With this in mind, it is a relief to learn that even *Queensland* contains commentary from the CJEU that makes it clear that it is essential under Article 3(a) to ensure that the product for the SPC application falls within the scope of protection of the basic patent.

That is, paragraph 28 of *Queensland* reads as follows:

> *"Accordingly, in the absence of European Union harmonisation of patent law, the extent of patent protection can be determined only in the light of the non European Union rules which govern patents (see Farmitalia, paragraph 27, and Medeva, paragraph 23)".*

In terms of determining "protection" by a basic patent, the only relevant "non-European Union rules that govern patents" are those that govern the extent of protection provided by a patent. Indeed, this is explicitly acknowledged by the CJEU in *Queensland* by virtue of the fact that the sections entitled "The European Patent Convention" and "National Law" (paragraphs 9 to 12) discuss only those provisions that relate to either the extent of protection or to the acts that fall within the extent of protection, namely Article 69 of the EPC and the Protocol thereto, as well as Sections 60 (infringement) and 125 (extent of invention) of the UK Patents Act 1977.

Moreover, it is clear from the CJEU's ruling in *Yeda* that it is not enough for a claim to merely name (or describe) the active ingredient that is the product for the SPC application. Instead, the product must be "protected" by the claim in the sense that it represents (and therefore falls within) the subject matter of the claim. If this were not the case, then the CJEU would have seen no problem with granting a SPC to cetuximab alone upon the basis of a claim that "named" cetuximab, but that actually related to the combination of that active ingredient with another active (irinotecan). However, that is not what the CJEU decided.

In this respect, it would appear that Warren J's interpretation of Article 3(a) is likely to withstand the challenge posed by the above-mentioned alternative interpretation based upon *Queensland* – for the reason that that alternative interpretation can, at least in this author's view, be conclusively demonstrated to be incorrect.

Interestingly, if the alternative interpretation were to be accepted, that would not only lead to bizarre results regarding SPC scope (as discussed above), but it would also open up a completely new can of worms in connection with the interpretation of Article 3(a). In particular, it would beg the question of which claim integers can validly be taken into account and which can be ignored when assessing whether the claim defines the product specified in the SPC application.

However, in the light of the above analysis regarding the invalidity of the alternative interpretation based upon *Queensland*, it is hoped that the various patent offices and courts will only ever need to decide instead upon the much more clear-cut question of whether a product falls within the extent of protection provided by a patent.

A rational interpretation of Queensland

From the above commentary, it is clear that the above-mentioned, alternative Article 3(a) test is not the correct one. However, this conclusion does raise the question of what should be made of the CJEU's above-quoted comments from paragraph 40 and point 3 of *Queensland*.

In the view of this author, the answer to this question is simple. That is, the CJEU's comments mean nothing more than that, when interpreting Article 3(a) in connection with claims in process format, the correct approach is not to enquire as to the identity of the direct product of the process. Instead, the correct approach is to ascertain which active ingredient(s) is (are) "identified in the wording of the claims" of the basic patent.

In other words, the CJEU's comments mean that a claim in process format would not satisfy Article 3(a) in circumstances where the product for the SPC application is *inherently* produced by the process steps but is not otherwise *"identified"* in the wording of the claims.

This makes perfect sense in the context of the facts in *Queensland*, where, for example, the wording of the process claims of one of the basic patents (which referred to the production of "A method of production of papillomavirus virus-like particles (VLPs) of HPV11 or HPV6") did not identify as the product of the process the full combination of active ingredients defined as the product for one of the disputed SPC applications (the combination of VLPs of types HPV 6, HPV 11, HPV 16 and HPV 18).

Moreover, paragraph 40 of *Queensland* also contains the following commentary:

"However, just as Article 3(a) of Regulation No 469/2009 precludes the grant of a SPC relating to active ingredients which are not specified in the wording of the claims of the basic patent (Medeva, paragraph 25), where the basic patent relied on in support of a SPC application relates to the process by which a product is obtained, that provision also precludes a SPC being granted for a product other than that identified in the wording of the claims of that patent as the product deriving from that process".

These comments explicitly spell out the CJEU's belief that, for the interpretation of Article 3(a), the answer for claims in process format is no different in principle to the answer (eg as provided in *Medeva*) for claims in any other format.

Moreover, it is important to remember that Queensland was a case that the CJEU decided by way of a reasoned order. In this respect, Article 99 of the Rules of Procedure of CJEU indicate that, where the question referred is not identical to a question already answered, a decision by way of reasoned order may only be issued:

"where the reply to such a question may be clearly deduced from existing case-law or where the answer to the question referred for a preliminary ruling admits of no reasonable doubt".

Thus, the above considerations rule out the possibility that the CJEU's comments in *Queensland* could mean anything significantly different from their conclusions on Article 3(a) in earlier cases, such as *Medeva*. Further, as *Medeva* and its progeny (such as *Yeda*) very clearly require the product for the SPC application to fall within the extent of protection of the basic patent, then the CJEU's comments in *Queensland* simply cannot be taken to imply anything different.

Conclusions

Although Warren J's relatively patentee-friendly interpretation of Article 3(a) has provided welcome relief to many in the pharmaceutical industry, it may well take quite some time for a complete and consistent interpretation of Article 3(a) to be adopted in the UK (let alone in other territories of the EU).

That is, whilst it is possible that Warren J's interpretation of Article 3(a) may well end up forming the basis of a new position in the UK, there are likely to be many interesting and varied challenges posed by new cases, for example relating to issues such as equivalents and unusual interpretations of the legislation and the case law of the CJEU.

In this respect, whilst the above-described, alternative interpretation of *Queensland* can be readily dismissed as being incorrect, experience would suggest that it will not take long for other cases to pose issues that are more challenging for Warren J's interpretation of Article 3(a). Thus, there will almost certainly be further court cases – and perhaps even yet another reference to the CJEU – before we reach the final chapter in the saga of Article 3(a).

References

1. *Eli Lilly and Company v Human Genome Sciences Inc. [2014] EWHC 2404 (Pat). www.bailii.org/ew/cases/EWHC/Patents/2014/2404.html*

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