

Recent Decisions of the European Court of Justice of the European Union on SPCs: A few Answers – Many Questions

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25 September 2014

A discussion of the implications of the recent decisions of the Court of Justice of the European Union (CJEU) in the cases of *Actavis* (C-443/12), *Georgetown II* (C-484/12), and *Eli Lilly* (C-493/12).

Recent Decisions of the CJEU on SPCs: A few Answers – Many Questions

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Supplementary Protection Certificates (SPCs) were implemented in Europe in 1993 in order to compensate patentees in the pharmaceutical field for the loss of effective patent term caused by the delay in obtaining regulatory approval for medicinal products. The legal framework is presently codified in Regulation (EC) No. 469/2009 of the European Parliament and of the Council, dated May 6, 2009¹ (in the following termed ‘SPC Regulation’ or simply ‘Regulation’).

As with any EU-Law, the authority on interpreting EU-Law ultimately rests with the Court of Justice of the European Union (CJEU). Though SPCs are generally dealt with on the national level, as far as registration and enforcement of an SPC is concerned, the national courts may or, as the case may be, even must, request the CJEU to give advice when it comes to the interpretation of the Regulation.

The CJEU has been called on numerous times in recent years to answer questions regarding the interpretation of the SPC Regulation arising during national proceedings throughout Europe. Many of these questions centered on the substantive requirements for gaining supplementary protection as detailed in Article 3 of the Regulation which states:

A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:

(a) the product is protected by a basic patent in force;

(b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;

(c) the product has not already been

the subject of a certificate;

(d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product. (Emphases added)

The Regulation itself provides a definition of the term ‘product’ in that the ‘product’ is defined as “the active ingredient or combination of active ingredients of a medicinal product”, while the ‘medicinal product’ is defined as “any substance or combination of substances presented for treating or preventing disease in human beings or animals [...]”².

In particular, Articles 3(a) and 3(c) of the Regulation have been repeatedly interpreted by the CJEU in various rulings, yet some of these decisions have left us with more questions than answers.

As early as 1999, the CJEU commented for the first time on the question of when a “product is protected by a basic patent in force” (Article 3(a) of the Regulation) in its *Farmitalia* decision (C-392/97). The case was referred by the German Federal Court of Justice (BGH) and concerned an SPC application for “idarubicin and salt thereof including idarubicin hydrochloride”. The basic patent in this case was German patent No. 25 25 633, whose claims were directed *inter alia* to idarubicin as such, but not the salts of it. The Federal Court of Justice asked the CJEU whether, for the interpretation of Article 3(a) of the Regulation, it is necessary to consider the wording of the claims or the scope of protection of the claims. The CJEU decided that in the absence of patent law harmonization in the European Union, it is a question of the applicable national law whether a product is protected by a basic patent.

In the following years, the different European courts developed divergent practices with regard to what constitutes a product that is

¹ superseding EEC Regulation 1768/92 and the Regulations amending it

² Art. 1(a) and 1(b) of Regulation (EC) No. 469/2009

protected by a basic patent. Essentially, two different approaches were established: the “infringement test”, asking whether the product defined in the SPC application would, on manufacturing or selling, infringe the rights deriving from the basic patent, and the “disclosure test”, asking whether the product defined in the SPC application would be disclosed in the wording of the claims of the basic patent.

Recognizing the divergent practice, which stood in stark contrast to the Regulation’s objective of providing a “uniform solution” “under the same conditions” in each of the member states (recitals 7 and 8 of the Regulation), the Court of Appeal of England and Wales turned to the CJEU in the *Medeva* case (C-322/10) and asked how, in the absence of harmonization of national patent laws, Article 3(a) of the Regulation should be interpreted. *Medeva* BV had sought supplementary protection for different combination vaccines, each vaccine containing at least the antigens A and B in addition to further active ingredients. The SPC applications all referred to the same basic patent with claims directed to a method for preparing a vaccine comprising A and B. In its ruling, the CJEU stated that to be protected by a basic patent, the active ingredients according to the SPC request have to be “specified in the wording of the claims”. The court’s decision has been largely understood as rejecting the “infringement test” that had been applied by numerous European national courts. Yet, what the term “specified” means remained a mystery³. No further light was shed on this matter by additional decisions of the CJEU that were handed down at the same time, e.g. *Yeda* (C-518/10), *University of Queensland* (C-630/10), and *Daiichi-Sankyo* (C-6/11), all of which essentially agreed with *Medeva*. As a result, practitioners and patent/SPC proprietors were left with some uncertainties

³ The referring Court of Appeal in *Medeva* interpreted the CJEU’s decision in C-322/10 handed down to it as follows: “the ambit of ‘specified’ may range from express naming, through description, necessary implication to reasonable interpretation” ([2012] EWCA Civ 523)

as to the correct interpretation of Article 3(a) and worried that “specified in the wording of the claims” might actually mean, *literally disclosed in the claims*, which would significantly limit applicant’s options on gaining supplementary protection - in particular if the underlying patent claims are phrased broadly, e.g., if the claims are directed to a genus of compounds rather than to a particular species.

Another major battleground has been the interpretation of Article 3(c) of the Regulation, which requires that the “product has not already been the subject of a certificate” and essentially serves the purpose of preventing the patent holder from obtaining an unwarranted extension of protection for a given medicinal product⁴. Already in the 1990’s the CJEU held in its *Biogen* decision (C-181/95) that Article 3(c) should not be interpreted to prevent the grant of multiple SPCs for the same product, where this product is protected by several basic patents belonging to different owners. The CJEU held that under Article 3(c) only one certificate may be granted for each basic patent. In *Biogen*, the Court was exclusively concerned with a single product (but multiple patents). Therefore, the Court’s statement was generally understood to be limited to the individual product; and in the years following the *Biogen* decision, patent offices continued to allow multiple SPCs for different products based on the *same* underlying patent, effectively establishing a “one SPC per product per patent” practice throughout Europe.

Yet, recently, the CJEU’s 2011 *Medeva* decision (C-322/10) was interpreted to prohibit the grant of more than one SPC per patent even if the SPCs were directed to different products, based on a statement that essentially reiterated verbatim what had been said in *Biogen* (“where a patent protects a product, in accordance with Article 3(c) of Regulation No 469/2009, only one certificate may be granted for that basic patent (compare *Biogen*, paragraph 28 and

⁴ COM(90) 101 final, explanatory memorandum

paragraph 41 of *Medeva*) (emphasis added). This interpretation, which deviates from the established view, may be ascribed to the different facts underlying the *Medeva* case: whereas in *Biogen*, the entire case centered on one product covered by different patents, the case of *Medeva* centered on questions of whether different combination products may be eligible for multiple SPCs on the basis of one basic patent. As a result of the *Medeva* decision, some patent offices tightened the requirements to “one SPC per patent”, while others maintained the previous “one SPC per product per patent” practice. Given the ensuing divergent interpretation of Article 3(c), the question arose as to what the correct approach would be.

To seek clarification on the above matters, various national courts have referred additional questions to the CJEU regarding the interpretation of Article 3(a) and (c) of the Regulation, resulting in the three recent rulings that were handed down by the CJEU last year in cases of *Actavis* (C-443/12), *Georgetown II* (C-484/12), and *Eli Lilly* (C-493/12). These cases are discussed in the following.

I. Considerations of the CJEU in relation to Article 3(a) of the Regulation

1.1 *Eli Lilly* (C-493/12)

In the case underlying *Eli Lilly* (C-493/12), Human Genome Sciences Inc. (HGS) held a patent protecting an antibody against a specific protein. The antibody was defined only by its binding characteristics to said specific protein (an “antibody specifically binding to protein X” type of claim). *Eli Lilly* had a marketing authorization (MA) for a specific antibody (tabalumab) directed against said protein and intended to market tabalumab. *Eli Lilly* brought an action before the High Court of Justice (England and Wales) seeking a declaration that any SPC, relying on HGS’ patent and based on *Eli Lilly*’s MA for a medicinal product containing tabalumab should be invalid. The High Court decided to stay proceedings and referred the following questions to the CJEU:

(1) What are the criteria for deciding whether “the product is protected by a basic patent in force” in Article 3(a) of Regulation [No 469/2009]?

(2) Are the criteria different where the product is not a combination product, and if so, what are the criteria?

(3) In the case of a claim to an antibody or a class of antibodies, is it sufficient that the antibody or antibodies are defined in terms of their binding characteristics to a target protein, or is it necessary to provide a structural definition for the antibody or antibodies, and if so, in how much detail?

It is remarkable that the referring Court asked the same Question 1 that was also asked in *Actavis* (C-443/12, see below). In sum, the CJEU has now been asked this question three times⁵!

Although having been specifically asked about the criteria for deciding whether a product is protected by a basic patent in force, the CJEU, in *Eli Lilly* (C-493/12), decided to reformulate the referred questions, as follows:

[...] whether Article 3(a) of Regulation No 469/2009 must be interpreted as meaning that, in order for an active ingredient to be regarded as ‘protected by a basic patent in force’ within the meaning of that provision, the active ingredient must be identified in the claims of the patent by a structural formula, or whether the active ingredient may also be considered to be protected where it is covered by a functional formula in the patent claims.

In its reasoning, the CJEU emphasized that the rules for determining what is protected by a basic patent are to be sought in the national legislation or, for EP patents, also in the EPC (paragraph 32 of C-493/12). In this regard, the CJEU followed its previous decision in

⁵ Slightly differently phrased, the question was already referred to the CJEU in *Medeva* C-322/10.

Farmitalia (C-392/97)⁶. The CJEU also explicitly stated that in determining whether a product is protected by a basic patent in accordance with Article 3(a) of the Regulation, it is not decisive whether the product at issue would infringe the basic patent (paragraphs 33 and 37), thereby clearly rejecting the “infringement test”.

In short, the CJEU did not answer the questions referred to it, but rather answered the above-quoted reformulated question and ruled:

[...] in order 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. Where the active ingredient is covered by a functional formula in the claims of a patent issued by the [EPO], Article 3(a) of that regulation does not, in principle, preclude the grant of [an SPC] for that active ingredient, on condition that it is possible to reach the conclusion on the basis of those claims, interpreted *inter alia* in the light of the description of the invention, as required by Article 69 [EPC] and the Protocol on the interpretation of that provision, that the claims relate, implicitly but necessarily and specifically, to the active ingredient in question, which is a matter to be determined by the referring court. (*Emphasis added*)

This ruling at least clarifies that functional definitions directed to a genus do not *per se* preclude a specific product covered by the functional definition (a species) from being eligible for an SPC. Furthermore, not only the claims, but also the specification can be used as a source of interpretation in order to determine whether a specific product is protected by the basic patent within the sense

⁶ Judgment, second sentence: “In order to determine, in connection with the application of [the Regulation] and, in particular, Article 3(a) thereof, whether a product is protected by a basic patent, reference must be made to the rules which govern that patent.”

of Art 3(a) of the Regulation.

1.2 *Actavis* (C-443/12)

In the proceedings leading to the *Actavis* decision (C-443/12) Sanofi had been granted an SPC for irbesartan (an antihypertensive agent) based on a first MA for a product called Aprovel, which contains irbesartan as the only active ingredient. The SPC expired 14 August 2012. The claims of the basic patent were directed to irbesartan or one of its salts and one dependent claim was also directed to a pharmaceutical composition comprising irbesartan and a diuretic. No specific diuretic was disclosed in the claims or the description of the patent as granted. On the basis of the same patent, Sanofi obtained a further SPC for irbesartan-hydrochlorothiazide (irbesartan-HCTZ), based on a later MA for a product called Co-Aprovel. The second SPC expired 14 October 2013. Actavis, which intended to market generic versions of Aprovel and Co-Aprovel, brought invalidity proceedings against Sanofi’s second SPC. The referring Court asked two questions:

(1) What are the criteria for deciding whether “the product is protected by a basic patent in force” in Article 3(a) of ... Regulation No 469/2009?

(2) In a situation in which multiple products are protected by a basic patent in force, does Regulation [No 469/2009], and in particular Article 3(c), preclude the proprietor of the patent being issued a certificate for each of the products protected?’

Surprisingly, the CJEU did not deal with the issue whether the generic protection conferred by the term “diuretic” (genus) in fact is sufficient to regard HCTZ (the species) to be protected by that patent in the sense of Article 3(a). Paragraphs 28 and 30 of the *Actavis* decision (C-443/12) allow the interpretation that the CJEU was inclined to accept that the combination product fulfils the requirements of Article 3(a). However, in *Actavis*, the CJEU found it appropriate to first answer the second question, relating to

Article 3(c) (see point II.1 below). Because of its finding that obtaining a second SPC would not be possible under Article 3(c), the court did not answer the question of what criteria may apply for deciding whether a product is protected by a basic patent.

II. Considerations of the CJEU in relation to Article 3(c) of the Regulation

II.1 *Actavis (C-443/12)*

On the basis of the above fact pattern, the CJEU assessed whether Co-Aprovel would be eligible for an SPC, given that Sanofi had already obtained an SPC for Aprovel based on an earlier MA. In this respect, the CJEU argued that the SPC to the single active ingredient, irbesartan, may be enforced against a medicinal product comprising combinations of that active ingredient with other active ingredients (paragraph 33). Sanofi had thus already been rewarded for irbesartan by way of its first SPC. Therefore, a further, second, SPC could not be allowed. Another consideration of the CJEU was that under national jurisdictions providing “a degree of protection against indirect infringement,” an SPC for irbesartan-HCTZ may also permit the holder to oppose the marketing of medicinal products containing irbesartan also as a single active ingredient. Therefore, the granting of an SPC on the basis of a later MA to the combination product Co-Aprovel (irbesartan-HCTZ) would inadmissibly extend the period of protection for irbesartan, which would contravene Article 3(c) of the Regulation (paragraphs 37 and 38).

In addition to the above considerations, the CJEU also emphasized the objective of the SPC Regulation. On the one hand, the CJEU held that Sanofi had already been granted an SPC for irbesartan alone and had therefore been awarded enough in the sense of the objective of the Regulation (paragraph 40 of the ruling⁷). A further consideration was that

⁷ Paragraph 40: “Bearing in mind the objective of Regulation No 469/2009, [...] namely, to compensate the patent holder for the delay to the commercial exploitation of his invention by providing him with an

the diuretic (HCTZ) was not protected as such by the basic patent. On the other hand, the CJEU explained that the SPC Regulation’s objective is “to compensate for the delay to the marketing of what constitutes the core inventive advance that is the subject of the basic patent” (paragraph 41, emphasis added). According to the CJEU, referring to Recital 10 of the Regulation⁸, it would be contrary to the objective of the Regulation to allow an SPC for marketing forms of an active ingredient together with other active ingredients that are not protected *as such* in the basic patent because such a view would not appropriately balance the interests of the pharmaceutical industry and those of public health.

In view of the above considerations the CJEU ruled that

[...] where, on the basis of a patent protecting an innovative active ingredient and a [MA] for a medicinal product containing that ingredient as the single active ingredient, the holder of that patent has already obtained [an SPC] for that active ingredient entitling him to oppose the use of that active ingredient, either alone or in combination with other active ingredients, Article 3(c) of [the Regulation] must be interpreted as

additional period of exclusivity – first, the grant of the first SPC in respect of the single active ingredient irbesartan has already afforded the holder such compensation and, second, the objective of that regulation is not to compensate the holder fully for the delay to the marketing of his invention or to compensate for such delay in connection with the marketing of that invention in all its possible forms, including in the form of combinations based on that active ingredient.”

⁸ Recital 10 reads: “All the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector, should nevertheless be taken into account. For this purpose, the certificate cannot be granted for a period exceeding five years. The protection granted should furthermore be strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product.” (Emphasis added)

precluding that patent holder from obtaining – on the basis of that same patent but a subsequent [MA] for a different medicinal product containing that active ingredient in conjunction with another active ingredient which is not protected as such by the patent – a second [SPC] relating to that combination of active ingredients. (*Emphasis added.*)

One may speculate that as long as the SPC applications are all based on the earliest MA, a further SPC for a combination product may be granted on the basis of the same basic patent. In such a case, it may be irrelevant whether the further active ingredient would be protected *as such* by the basic patent.

II.2 *Georgetown II* (C-484/12)

In *Georgetown II* (C-484/12), the basic patent included claims directed to a vaccine for the prevention of papillomavirus infection, comprising at least an L1 protein, or a fragment thereof, *inter alia* HPV-16 and HPV-18 (subsequently C and D, respectively). The applicant relied on two third-party marketing authorizations:

- an earlier one (MA1) was directed to a papillomavirus vaccine composition comprising four components (A+B+C+D; A and B being further L1 proteins), and
- a later one (MA2) directed to another papillomavirus vaccine composition, comprising only two of these components (C+D).

Multiple SPC applications were filed; two of them concerned the combination of A+B+C+D and the combination of C+D. Two SPCs, directed to the combination of A+B+C+D, and to the combination of C+D had been granted already, prior to the *Medeva* (C-322/10) decision. Then, a number of other applications were filed for SPCs in respect of A, B, C and D, each individually. All SPC applications relied on the first marketing authorization (MA1) that covered the combination product (A+B+C+D).

As outlined above, previous decisions of the CJEU were interpreted to establish a principle of “one SPC per product per patent”. It was therefore clear that a single patent may serve as the basis for multiple SPCs, as long as the SPCs were each directed to different products. However, in the case underlying *Georgetown II*, the Dutch patent office interpreted the reasoning of the more recent decisions, in particular *Georgetown I* (C-422/10) and *Medeva* (C-322/10), such as to call into question whether a holder of a patent may obtain more than one SPC on the basis of a single basic patent, irrespective of the fact that these SPCs would cover different products. For instance, paragraph 34 of *Georgetown I* (C-422/10), stated that “where a patent protects a product, in accordance with Article 3(c) of Regulation No 469/2009, only one certificate may be granted for that basic patent” (emphasis added); the decision of *Medeva* (C-322/10) contains a similar passage⁹. The Dutch patent office, referring to CJEU Decisions of *Medeva* (C-322/10) and *Georgetown I* (C-422/10), therefore denied *Georgetown* the grant of those pending SPC applications for the single ingredients on the basis of Article 3(c) of the Regulation, as it would be apparent from that provision that only one SPC may be granted for each basic patent. *Georgetown University* had, however, already obtained two SPCs (to A+B+C+D and to C+D) on the basis of its basic patent prior to the *Medeva* decision. Hence, one of the questions referred to the CJEU was whether:

[...] Regulation No 469/2009 ..., more particularly Article 3(c) thereof, preclude, in a situation where there is a basic patent in force which protects several products, the holder of the basic patent from being granted a certificate for each of the protected products.

The CJEU in *Georgetown II* (C-484/12)

⁹ cf. paragraph 34 of the reasoning of C-422/10: “where a patent protects a product, in accordance with Article 3(c) of Regulation No 469/2009, only one certificate may be granted for that basic patent (see *Biogen* [C-181/95], paragraph 28, and *Medeva* [C-322/10], paragraph 41)”

emphasized that the situation in that case is different from the one in *Actavis* (C-443/12), where the patent holder relied upon a *later* MA in order to obtain an SPC for a combination product. In *Georgetown II*, the *first* MA was relied on and was directed to a combination of four active ingredients (A+B+C+D). This first MA was found suitable to apply for an SPC for the combination of these active ingredients as well as for the individual active ingredients. In *Georgetown II* (paragraph 35), the CJEU states that it was important that the SPC applications were made on the basis of the earlier MA, because all SPCs, even if their scope of protection would overlap, would expire on the same day as Article 3(c) of the Regulation would preclude the grant of an SPC on the basis of the later MA.

In *Georgetown II* (C-484/12), the CJEU ruled:

[...] where, on the basis of a basic patent and a [MA] for a medicinal product consisting of a combination of several active ingredients, the patent holder has already obtained [an SPC] for that combination of active ingredients, protected by that patent within the meaning of Article 3(a) of Regulation (EC) No 469/2009 [...], Article 3(c) of that regulation must be interpreted as not precluding the proprietor from also obtaining [an SPC] for one of those active ingredients which, individually, is also protected as such by that patent. (Emphasis added.)

In other words, this decision confirms previous decisions such as *Biogen* (C-181/95) that one may obtain, on the basis of the same basic patent, an SPC for *each* of the products that are protected as such by the basic patent.

III. Some Open Questions

III.1 *Eli Lilly* (C-493/12)

In principle, the CJEU accepts functional definitions as a means to fulfill Article 3(a).

However, when it comes to the details, there are uncertainties with regard to the criteria that are to be applied for determining whether the product is protected by the claims in the sense of Article 3(a) of the Regulation. The concrete answer to the third question of the referral (or to the one question the CJEU formulated based on the questions referred to it), i.e., whether a functional definition is sufficient, remains vague from the ruling in *Eli Lilly* (C-493/12). The requirements set by the ruling for a functional definition to protect a given product are that the claims must relate implicitly but necessarily and specifically to the active ingredient in question. However, what does 'implicitly but necessarily and specifically' mean?

In fact, the CJEU refers to Article 69 EPC and its Protocol of interpretation¹⁰ to determine whether Article 3(a) is met for an EP patent. Both provisions leave much room for interpretation and ultimately refer to the national courts to decide each case on its respective merits. Furthermore, after the ruling of *Eli Lilly* (C-493/12), the national courts will have to interpret what "implicitly, but necessarily and specifically" means in the context of functional definitions.

At the end of the day, it appears that the judgment of *Eli Lilly* (C-493/12) leaves a lot of uncertainties as to when a given product is protected by a basic patent in the sense of Article 3(a).

The CJEU raises another consideration that makes the judgment of *Eli Lilly* (C-493/12) very peculiar. In paragraphs 42 and 43 of the decision, the CJEU's decision can be interpreted to define a further requirement that needs to be fulfilled in order to obtain an SPC, namely the requirement for a patentee, to be in line with the objective of the Regulation, according to Recital (4) of the Regulation¹¹. The objective for implementing

¹⁰ Protocol on the Interpretation of Article 69 EPC of 5 October 1973 as revised by the Act revising the EPC of 29 November 2000

¹¹ Recital (4) reads: *At the moment, the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market makes the period*

SPCs in general was to encourage research by ensuring that parties having invested in such research have a chance of realizing a return on their investment. In *Eli Lilly*, however, the CJEU voiced doubts whether HGS, which had not invested in the development of tabalumab, should be entitled to an SPC. The CJEU reasoned in paragraph 43 of the decision that

[...] the refusal of an SPC application for an active ingredient which is not specifically referred to by a patent issued by the EPO relied on in support of such an application may be justified [...] where the holder of the patent in question has failed to take any steps to carry out more in-depth research and identify his invention specifically, making it possible to ascertain clearly the active ingredient which may be commercially exploited in a medicinal product corresponding to the needs of certain patients. In such a situation, if an SPC were granted to the patent holder, even though – since he was not the holder of the MA granted for the medicinal product developed from the specifications of the source patent – that patent holder had not made any investment in research relating to that aspect of his original invention, that would undermine the objective of [the Regulation], as referred to in recital 4 in the preamble thereto.

This reasoning sharply questions the practice that one may rely on a third-party MA, the validity of which was established by the CJEU years ago in its *Biogen* decision (C-181/95).

The future will have to show whether the national courts will take into account whether the SPC applicant has fulfilled the objectives of the SPC Regulation, i.e., when the applicant is relying on a third-party MA, to determine whether the applicant has fulfilled his “duty” to carry out more in-depth

of effective protection under the patent insufficient to cover the investment put into the research. (Emphasis added)

research. Judged from the recent decision ([2014] EWHC 2404 (pat)) of the High Court (England and Wales) that considered the CJEU's *Eli Lilly* decision (C-493/12), it appears that at least the High Court is not inclined to undertake any such assessment.

III.2 *Actavis* (C-443/12)

One key argument of the CJEU in *Actavis* (C-443/12) in denying an SPC was that the further active ingredient, HCTZ, was not protected as such in the basic patent and that only products belonging to the “core inventive advance” of the basic patent can be subject of an SPC. Now, does that mean that only products belonging to the core inventive advance are eligible for an SPC based on a given basic patent? This would require determining the “core inventive advance” of a patent to find out whether a combination product is a new product in the sense of Article 3(c) of the Regulation. Unfortunately, the CJEU does not further describe the requirements of how to determine whether a combination product belongs to the “core inventive advance” of a basic patent. It appears that further case law will have to clarify this point.

Although the CJEU ruled in *Actavis* (C-443/12) that Article 3(c) precludes the grant of an SPC to a combination product based on a subsequent MA, where a patentee has already obtained an SPC for a particular active ingredient entitling him to oppose the use of that active ingredient, either alone or in combination with other active ingredients, the CJEU indicated that the situation may be different

[...] if a combination consisting of an innovative active ingredient in respect of which an SPC has already been granted, and another active ingredient, which is not protected as such by the patent in question, is the subject of a new basic patent within the meaning of Article 1(c) of [the Regulation]. In such a case the new patent could, in so far as it covered a totally separate innovation, confer

entitlement to an SPC for that new combination that is subsequently placed on the market. (*Paragraph 42 of C-443/12; emphasis added*)

This raises a couple of questions. For instance, does it suffice that the new combination is protected in a divisional application? And what are the criteria for deciding whether the innovation that may lie within such a combination is a totally separate one? Must applicants provide arguments and data that show that the combination product is *patentable* over the product containing only the single active ingredient?

Although it is not expressly stated, it appears that the CJEU, with its ruling, intended to prevent some sort of “evergreening” of protection for active ingredients by simply reformulating them with other known active ingredients. However, in view of the CJEU’s arguments put forward in paragraph 41 of *Actavis* (C-443/12), one question comes into mind, in particular in view of Recital 10 of the Regulation: would an SPC to the combination product (irbesartan-HCTZ) have been allowable if the total extension of term for irbesartan would not have exceeded 5 years? Interestingly, a question just along these lines was recently referred to the CJEU by the High Court of Justice (England and Wales) and is currently pending before the CJEU as case C-577/13 (*Actavis Group vs. Boehringer Ingelheim*)¹².

¹² Question 3: Where the basic patent in force “protects” pursuant to Article 3(a) [a] product comprising active ingredient A (“Product X”); and [a] product comprising a combination of active ingredient A and active ingredient B (“Product Y”), and where [a MA for] Product X [...] has been granted; [and an SPC has been granted in respect of Product X; and [a] separate [MA for] Product Y [...] has subsequently been granted, does the Regulation, in particular Articles 3(c), 3(d) and/or 13(1) [...] preclude the proprietor of the patent being issued with an SPC in respect of Product Y? Alternatively, if an SPC can be granted in respect of Product Y, should its duration be assessed by reference to the grant of the authorisation for Product X or the authorisation for Product Y?

III.3 *Georgetown II* (C-484/12)

In the case of *Georgetown II*, the *earlier* MA covering a combination of four active ingredients was seen as representing a valid MA for any combination of active ingredients and also for the single active ingredients individually. This leads to an interesting problem: if in *Georgetown* the sequence of marketing authorizations were inverted, i.e. the first MA (MA1) were for C+D and the later MA (MA2) were for A+B+C+D, can a patentee obtain a first SPC for C (or C+D) on the basis of MA1 and a further SPC for e.g. A+C (or A+B+C+D) on the basis of MA2?

The decision of *Georgetown II*, paragraph 40, indicates that this would not be admissible; after expiry of the first SPC “it must be possible for third parties to place on the market not only medicinal products consisting of that single active ingredient or that combination of active ingredients, which were formerly protected, but also any medicinal product containing that active ingredient or that combination, in conjunction [...] with other active ingredients”¹³.

Does this imply that it is only possible to obtain an SPC for those active ingredients for which the later MA is the first one?

IV. Messages to take away

In *Georgetown II*, the CJEU clarified that it is possible, in principle, on the basis of a patent which protects several different ‘products’, to obtain several SPCs in relation to each of those different products, provided that each of those products is ‘protected as such’ by that ‘basic patent’ within the meaning of Article 3(a) the Regulation. This decision is thus to the relief of patentees having developed a class of active ingredients encompassing a number of members. They may obtain an SPC for each active ingredient for which they have a MA on the basis of a single basic patent.

In view of *Actavis*, SPC applicants are well

¹³ Paragraph 36 of *Actavis* (C-443/12) also points into this direction, as it reiterates the foregoing.

advised to file claims for combination products (e.g. A+B), where one component is not protected as such by the basic patent in separate basic patents, if possible. It also appears that the CJEU requires that the combination product (A+B) is patentable vis-à-vis the mono-product (A).

In view of *Eli Lilly*, structural definitions of active ingredients should be considered. Although a structural definition of the product in the claims is not mandatory, the claims must relate 'implicitly but necessarily and specifically' to the active ingredient in question. For applicants this means that the claims and the underlying patent may suffer from a too broad (general) definition of a given product. Hence, applicants are well advised to include claims that ensure a sufficiently precise definition of a product so that at least one claim is regarded to protect a specific product in the sense of Art. 3(a). Where both functional and structural definitions are available, structural definitions appear to be less prone to problems of interpretation.

Furthermore, when it comes to the question of whether a (combination) product is protected by a basic patent according to Article 3(a), the latest decisions of the national courts ([2014] EWHC 2404 of the British High Court and 3 Ni 5/13 of the German Federal Patent Court) suggest that one should not rely ultimately on the infringement test. Rather, it appears that what can be *subsumed* under the wording of the claims (with due regard to the description) is decisive. If, for example, the specification does not contain any disclosure of combination products (A+B), a claim directed to only A (or a product comprising A) as an active ingredient would not be a proper basis for an SPC directed to A+B under Article 3(a). It therefore appears advisable to draft patent applications so as to include as much information as possible on conceivable combinations of active ingredients and their respective nature.

SPC applicants are also well advised to review the respective national legislation of the country in which they apply for an SPC in

order to ensure that their product is deemed protected by their basic patent under the national jurisdiction.

The three latest decisions (and *Medeva*) taken together have not conclusively answered the question of "what are the criteria for deciding whether a product is protected by a basic patent in force". Judging from the various references to the objectives of the Regulation, it appears to be the general intention of the CJEU that SPC applicants ought to be entitled to a return (i.e., an SPC) only if they have made a contribution e.g., in the form of providing a new innovation or conducting research in order to identify a specific active ingredient.

For now, it appears we will have to await further decisions before true and reliable recommendations can be given to SPC applicants. As long as future decisions continue the tune of the recent cases, raising more questions than answers, it may remain difficult to extract a consistent and complete picture of the options available to SPC applicants.

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