Supplementary Protection Certificate Provisions for Pharmaceutical and Biotechnological Products in Europe: An Era after Medeva and Georgetown Decisions*

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The Supplementary Protection Certificate (SPC) is a valuable intellectual property which allows its holder to maintain monopoly in the European Economic Area. The recent rulings by Court of Justice for Europe have considerably changed the understanding of the Article 3 of Regulation No 469/2009 which governs SPC provisions. The changes relating to the pharmaceutical and biotechnological products are of considerable importance for the innovator as well as generic companies. This article is an attempt to analyse the rulings involving pharmaceutical products before and after the Medeva and Georgetown cases and rulings. These decisions have an impact on the future strategies to be adopted by the innovator as well as generic pharmaceutical companies to be successful in European market, which is the second largest market in the world.

Keywords: SPC, Medeva, Georgetown, Losartan, Valsartan, CJEU

SPC Provisions in Europe
The Supplementary Protection Certificate (SPC) is a unique form of intellectual property (IP) which can also be deemed as an extended term of protection similar to patents. These certificates are granted to innovators in return of significant investments made in research, particularly in the areas of pharmaceuticals and biotechnology. The grant of SPCs are of prime importance to innovator companies who always aim to maintain monopoly of their products in the market.

On the other hand, SPCs are road blocks to generic companies which try to enter into market immediately after an innovator’s patent expires. The grant of SPCs to block patents can extend the monopoly of innovators thereby delaying access to affordable generic products.

The Court of Justice for European Union (CJEU), the highest authority in Europe and National Intellectual Property Offices across Europe, have always aspired to maintain the balance between providing medicines to the people at affordable price (i.e., early generic product entry) by refusing SPC applications demanding unjustified patent extensions while at the same time promoting innovation and research by granting legitimate SPCs to innovators.

Generally, an innovator company files the basic patent application at a very early stage of discovery to protect its intellectual property. After filing the patent application, the discovery progresses through various stages. For pharmaceutical products, molecules are first tested in animals in preclinical trials and then in mammals like rodents, for assessing their potential to develop these products further. Final stage involves human clinical trials, which are essential for any drug molecule to get approval for human use. This process takes years to complete after patent filing date. It is only after the molecule clears the hurdle of regulatory process that it gets launched into the market (see Fig. 1).

Term of SPC
The maximum term of any SPC is five years which can be added to the normal twenty year term of the patent. The formula “(X–Y) – 5” years is used to calculate the SPC term for any pharmaceutical or biotechnological product.
Here ‘X’ is date of First Marketing Authorisation (FMA) meaning the date of first approval of the product in the European Economic Area, ‘Y’ is the date of application of basic patent protecting that product.

As per Regulation (EC) No 1901/2006, an additional six months of pediatric exclusivity (PED) is available which can be added to the five year term of SPC.\(^1\) Thereby, the maximum period of protection that can be available under SPC regulation is five years and six months as described in Fig. 2.

The Regulation (EC) No 469/2009 of the European Parliament (henceforth the Regulation) and of the Council of 6 May 2009 governs the supplementary protection certificate for medicinal (pharmaceutical and biotechnology) products.\(^1\)

According to Article 3 of the Regulation: ‘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; and
- (d) the authorisation referred to in point (b) is the first authorisation to place the product on the market as a medicinal product.’\(^1\)

Whereas Article 4 of the Regulation pertains to the subject matter of protection,\(^2\) Article 5 provides that the rights conferred by the certificate are the same as that conferred by the basic patent.\(^3\)

Articles 3, 4 and 5 have been widely disputed and variously interpreted by national IP Courts across Europe. The article explores the changing attitude of the courts before and after the Medeva decision. Following cases involving pharmaceutical and biotechnological products are illustrative of the disparity among member countries of European Union before the Medeva decision in November 2011.

**Era before Medeva and Georgetown decisions**

**Valsartan Case in France**

Novartis AG was the owner of the European Patent no EP 0443983 claiming Valsartan (an antihypertensive drug) and compositions containing Valsartan.\(^4\)

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**Fig. 1**—Product approval process from discovery of molecule till launch

**Fig. 2**—Maximum term of any European basic patent with SPC and PED
The normal 20 year term of the patent expired on 12 February 2011. Novartis successfully obtained SPC as well as pediatric extension which extended the patent term to 13 November 2011. Novartis marketed two products in France, Valsartan and the other a combination of Valsartan and Hydrochlorothiazide (HCTZ).\(^5\)

Actavis obtained Marketing Authorisation (MA) for its pharmaceutical product containing combination of Valsartan and HCTZ on 30 November 2009. Novartis immediately filed for an injunction prohibiting Actavis from marketing their combination product in France until 13 November 2011. Novartis’ main argument was the SPC granted for Valsartan patent could be asserted against any product containing Valsartan including combinations containing Valsartan.

On 28 January 2011, the Judge of Tribunal de Grande Instance of Paris granted injunction as requested by Novartis against Actavis. Actavis subsequently appealed the decision. Cour d’Appel of Paris reversed the decision and dismissed the injunction against Actavis.\(^6\)

According to the Cour d’Appel of Paris, Article 4 included two things: (i) the product, namely the sole active ingredient Valsartan in this case, that the holder of the SPC held rights to; and (ii) the product against which the holder of the certificate could assert the rights conferred by the SPC (for instance, against any other person who manufactured or marketed, without his authorisation, the subject matter of the SPC, i.e., the sole Valsartan). Consequently, the holder of the SPC could not assert his rights against any other products, excluding the single ingredient Valsartan; e.g., the combination of Valsartan and HCTZ which was the subject matter of the dispute.\(^6\) Thus the interpretation implied that the SPC holders for ‘A’ could not block others from selling combination products, for instance, ‘A+B’ or ‘A+C’ containing ‘A’.

**Losartan Case in France**

In another case, relating to Losartan (another antihypertensive medicine), the Cour d’Appel of Paris, on 15 March 2011, took a contrasting position. In this case, Du Pont de Nemours and Merck, on the basis of a SPC relating to Losartan alone, obtained preliminary injunctions from the Tribunal de Grande Instance against Mylan and Qualimed, which were trying to market a product containing Losartan and another active ingredient, hydrochlorothiazide. Here the District Court held that in view of Article 4 which protected any subsequent use (medicinal) of the product, the combination product containing Losartan as the main ingredient was also protected. The Cour d’Appel of Paris affirmed the order on the basis of a combined reading of Articles 4 and 5 of the Regulation.\(^7\)

In effect, French Court of Appeal took contrary positions in the Valsartan and Losartan cases. However, in other member countries like Norway, Austria and Germany, Novartis was successful in obtaining injunctions against generic companies, prohibiting them from marketing Valsartan as well as its combination products.

This indicates that Europe was divided over the interpretation of SPC regulation before the ruling in the Medeva case. Clearly, there were two opinions: (i) “infringement test” based on the assumption that if the product ‘A+B’ for which SPC application is filed falls under the scope of patent for ‘A’, then SPC application for ‘A+B’ could be granted even though patent claims fail to identify or specify ‘A+B’ in words and (ii) the “disclosure test” based on the fact that grant of SPC application for ‘A+B’ was only possible if such product was disclosed in the claims of patent.

**The Medeva Case**

In the Medeva case, CJEU clarified meaning of the Article 3 of SPC regulation. The facts of the case were thus: Medeva held European Patent 1666057, covering method for preparation of vaccine against Bordetella pertussis (whooping cough agent), consisting of a combination of two antigens, as active ingredients.\(^8\)

Medeva filed five SPC applications with the UK Patent Office, primarily seeking supplementary protection for different types of vaccines. In support of these applications, Medeva submitted MAs granted by the French, German and United Kingdom authorities for medicinal products, each of which contained, in addition to the combination of pertactin and filamentous haemagglutinin, other active ingredients, the total number of which was between 8 and 11.

The UK Patent Office refused to grant the SPCs, concluding that, in case of four of the applications (SCP/GB09/015, 09/016, 09/017 and 09/019), more active components or ingredients were specified in the applications for SPCs covering those components than were identified in the wording of the claims of the basic patent, and they were not therefore protected.
by the basic patent within the meaning of Article 3(a) of Regulation. In case of the fifth application (SPC/GB09/018), the Patent Office concluded inter alia that, although the active components or ingredients identified in the patent were the same as those specified in the SPC application, namely the combination of pertactin and filamentous haemagglutinin, the MA submitted in support of that application did not fulfil the conditions laid down in Article 3(b) of the Regulation, because they related to medicinal products containing nine active ingredients.

In other words, the vaccines contained other ingredients besides the active components or ingredients specified in the SPC application and in the patent claims.

Medeva then appealed against that judgment to the Court of Appeal (England and Wales) (Civil Division), which decided to stay the proceedings and refer questions to the Court of Justice for a preliminary ruling.\(^8\)

On 24 November 2011 in its ruling the CJEU held that Article 3(a) of Regulation concerning the SPC for medicinal products must be interpreted as meaning, provided the other requirements laid down in Article 3 are also met, that the medicinal product for which the marketing authorisation is submitted in support of the supplementary protection certificate for an active ingredient specified in the wording of the claims of the basic patent relied on in support of the application for such a certificate.

The CJEU also ruled that Article 3(b) of Regulation must be interpreted to mean (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 SPC 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.

The CJEU also confirmed that the meaning of Article 3(a) of Regulation is to be interpreted as meaning, provided the other requirements laid down in Article 3 are also met, that a single active ingredient or combination of active ingredients where:

(a) a basic patent in force protects the single active ingredient or combination of active ingredients within the meaning of Article 3(a) of … Regulation [No 469/2009]; and

(b) a medicinal product containing the single active ingredient or combination of active ingredients together with one or more other active ingredients is the subject of a valid authorisation granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC which is the first [MA] that places the single active ingredient or combination of active ingredients on the market.”\(^9\)

The CJEU held that the Article 3(b) of Regulation concerning SPC for medicinal products must be interpreted as meaning, 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 an active ingredient 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 supplementary protection certificate application contains not only that active ingredient but also other active ingredients.\(^9\)

Medeva and Georgetown decisions clarified the interpretation of Article 3 (a) and (b) of the SPC regulation. The long lasting effects of these decisions are evident from the decisions that were handed down by the CJEU after Medeva and Georgetown.

Era after Medeva and Georgetown Decisions

SPC for Single Active Ingredient in Yeda

Yeda owned a European patent that disclosed a therapeutic composition of two ingredients. The patent also claimed the administration of both components separately. Yeda applied for two SPCs, one for combination of the two ingredients and one for only one active ingredient. The supporting MA covered only one product (for which the SPC was filed) but indicated that it should be administered along with the other ingredient.\(^10\)

Some of the national IP offices granted the SPCs applied by Yeda, but UK IPO refused both the SPCs. Yeda appealed the decision to CJEU.

On 25 November 2011, the CJEU affirmed the decision of UK IPO stating that SPC cannot be granted ‘where the active ingredient specified in the
application, even though identified in the wording of the claims of the basic patent as an active ingredient forming of a combination in conjunction with another active ingredient, is not the subject of any claim relating to that active ingredient alone.\textsuperscript{10}

This confirmed the UK IPO’s understanding that if the patent claims ‘A+B’ in combination, an SPC cannot be granted for just ‘A’. Further, SPC could not be granted for the combination ‘A+B’ because the supporting MA only covered ‘A’.

The \textit{Medeva} and \textit{Yeda} cases also explained the following two facts:

(i) MA can have additional active ingredients (C, D, E…) in addition to those described in SPC application for ‘A+B’ as long as ‘A+B’ combination is defined in the wordings of the claims.

(ii) SPC application cannot have additional active ingredients (C, D, E…) other than those identified in the wordings of the claims (A+B).

\textbf{Product by Process Claims in Queensland}

Queensland was the owner of a parent patent and two divisional patents. The parent patent claimed a number of active ingredients by product through process claims and the divisional patents claimed additional active ingredients. The MA relied on for the SPC applications contained combinations of active ingredients both from the divisional patents and parent patent.\textsuperscript{11}

One of the questions referred to CJEU was in case of product by process claims in basic patent, ‘is it necessary for the product to be obtained directly by means of that process?’

In this case, the CJEU ruled that it is irrelevant whether the product is derived directly from the process, but that Article 3(a) of the SPC regulation ‘precludes an SPC 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’.\textsuperscript{11}

In short, if a product is not specified /identified in the wording of the claims, SPC cannot be obtained for that active ingredient.

\textbf{Daiichi’s SPC for Combination Products}

Daiichi owned a patent claiming the active ingredient Olmesartan. It obtained an SPC for this product based on an MA containing Olmesartan as sole active ingredient. Daiichi invested considerable time and resources in undertaking clinical trials and studies in order to secure MA for a combination of Olmesartan and HCTZ. Daiichi applied for an SPC relying on the MA for the combination product and on same basic patent. The UK IPO refused the SPC stating that the combination product is not covered by basic patent under the meaning of Article 3(a). In November 2011, the CJEU again affirmed the UK IPO understanding, on appeal, that Medeva ruling is not limited to multi-disease vaccines but applies to all combination products.\textsuperscript{12}

The \textit{Daiichi} case has had significant effect on SPCs relating to combination products in the pharmaceutical industry as follow-on products or improvement products are common in this field. After this ruling, protection for combination products will only be possible if the basic patent covers the combination product and is properly disclosed in the wordings of the claim of the basic patent.

\textbf{Valsartan Case in UK}

The UK case on Valsartan involving Novartis and Actavis was identical to the French case as described earlier. In the UK case, the High Court of Justice (England & Wales), Chancery Division (Patents Court) decided to stay the proceedings and to refer the following question to the Court of Justice for a preliminary ruling:

“Where a supplementary protection certificate has been granted for a product as defined by Regulation … No 469/2009 for an active ingredient, are the rights conferred by that certificate pursuant to Article 5 of the Regulation in respect of the subject matter as defined in Article 4 of the Regulation infringed:

(a) by a medicinal product that contains that active ingredient (in this case valsartan) in combination with one or more other active ingredients (in this case hydrochlorothiazide); or

(b) only by a medicinal product that contains that active ingredient (in this case valsartan) as the sole active ingredient?”

Based on the \textit{Medeva} case, the CJEU ruled the following:\textsuperscript{13}

“Articles 4 and 5 of Regulation (EC) No 469/2009 of the European Parliament and of the Council of May 6, 2009 concerning the supplementary protection certificate for medicinal products must be interpreted as meaning that, where a ‘product’ consisting of an active ingredient was protected by a basic patent and the holder of that patent was able to rely on the protection conferred by that patent for that ‘product’ in order to oppose the marketing of a medicinal
product containing that active ingredient in combination with one or more other active ingredients, a supplementary protection certificate granted for that ‘product’ enables its holder, after the basic patent has expired, to oppose the marketing by a third party of a medicinal product containing that product for a use of the ‘product’, as a medicinal product, which was authorised before that certificate expired.”

This decision by CJEU marked the line of distinction between grant of SPC and enforcement of patent right. In effect, in order to obtain SPC for ‘A+B’, it is necessary that the combination ‘A+B’ should be identified/specified in the wordings of the claim of basic patent. But if the SPC is granted for ‘A’ for basic patent then holder of such SPC can block others from selling any product which contains ‘A’ as an active ingredient in combination with other active agents like ‘B’, ‘C’ etc.

Based on these decisions, SPC protection can be interpreted as summarized in Table 1.

Valsartan Case in Supreme Court of France
On 15 January 2013, the French Cour de cassation followed the CJEU’s ruling (C-442/11) in the parallel UK case and decided that the proprietor of an SPC for a product (Novartis for Valsartan in this case) may prevent third parties like Actavis from marketing a drug combining Valsartan and HCTZ. As a result, the ruling made before the outcome of Medeva case by Cour d’Appel of Paris was reversed by Supreme Court to bring the France in line with the UK decision.14

Telmisartan Case in High Court of Justice (England and Wales)
Boehringer Ingelheim, the owner of patent EP (UK) 0502314 marketed Telmisartan as a single composition (claim 5 of the patent) for which the first SPC granted expired on 10 December 2013.15

Claim 12 of the patent covered a combination of Telmisartan and HCTZ marketed by Boehringer Ingelheim as combination product for which a second SPC was granted (to expire on 30 January 2017).

<table>
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<tr>
<th>Basic patent claims</th>
<th>MA granted for</th>
<th>SPC applied for</th>
<th>Based on Medeva, SPC is</th>
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<tr>
<td>A</td>
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<td>A+B</td>
<td>A+B</td>
<td>A</td>
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Actavis wanted to sell a combination of Telmisartan and HCTZ, but there was a risk of infringement of the combination SPC. Actavis contended that the combination SPC was invalid. Justice Birss of High Court of Justice referred following important question to the CJEU:

“Can a patent that has been amended after the grant of the patent and after grant of the SPC be relied upon as the basic patent in force for the purposes of fulfilling the condition set out in Article 3(a) of the regulation?”15 The CJEU is yet to rule on this question.

Meaning of ‘Specified and Identified’ in Sanofi Case
Sanofi owned a patent claiming Irbesartan as well as combination of Irbesartan with a diuretic. Sanofi got approval for its SPC for Irbesartan alone on the basis of a MA granted for medicinal product containing Irbesartan alone as active ingredient.16

Sanofi also got approval for its follow-on product containing a combination of Irbesartan and HCTZ. On that basis, Sanofi applied for second SPC for combination based on the same basic patent.

UK IPO referred the question about grant of second SPC for Irbesartan and HCTZ to CJEU. In its ruling in December 2013, CJEU held that although basic patent claims a combination of Irbesartan and a diuretic (which is therapeutic class of HCTZ), HCTZ was not specified or identified in the claims or the specification.

Further, CJEU ruled that under Article 3(c) of the regulation, it is not possible for a patent holder to obtain SPC on the basis of same patent but a subsequent MA for different medicinal product containing that active ingredient specified in the wording of the claims (Irbesartan) in conjunction with another active ingredient (HCTZ) which is not protected as such by the patent.

The Sanofi ruling made disclosure requirement for combination products more stringent, as since it was found that it is not sufficient to describe the invention generically in the claims. This ruling highlights the fact that CJEU now required the product to be identified and specified in the claims as well as in the description.

Meaning of ‘Specified and Identified’ in Lilly Case
Human Genome Sciences (HGS) was the holder of a patent relating to discovery of new protein ‘neutrokine alpha’. The patent also claimed antibodies that bind specifically to that protein and pharmaceutical
composition comprising that antibody. Lilly obtained MA for composition of Tabalumab for autoimmune diseases. According to Lilly, the antibody Tabalumab infringed the HGS patent claims.

Lilly sought declaration from UK Court that no SPC should be granted for HGS patent based on MA for Tabalumab. The reason cited by Lilly was HGS patent fails to meet the requirement of Article 3(a) of the regulation in that Tabalumab antibody was not covered by HGS patent. In short, there was no structural definition of active ingredient Tabalumab in HSG patent nor claims were specifically directed to Tabalumab antibody.17

According to HGS, the product could be regarded as being identified in the claims of the basic patent and thus, protected by the patent where the product is identified by means of functional formula or definition.

On 12 December 2013, CJEU ruled that, in order to satisfy the Article 3(a) requirement, it is not necessary for the active ingredient to be identified in the claims of the patent by a structural formula in the claims of the patent issued by European patent office. The CJEU further stated that Article 3(a) of the regulation did not preclude the grant of SPC for the active ingredient on the condition that claims cover that active ingredient when interpreted in light of description of the patent.17

As per Article 69 of Convention of the Grant of European Patents and the Protocol on the interpretation of that provision, CJEU further left the question of interpretation of meaning of ‘necessarily and specifically’, concerning the active ingredient to the national courts.

In view of the above CJEU decision, the UK Court found that Lilly’s product Tabalumab was protected by the HSG patent within the meaning of Article 3(a) of SPC regulation.18

The UK Court explained that the CJEU has clearly held that functional definitions can, in principle, be sufficient to bring an active ingredient within the protection of a basic patent. This is on the condition that the “claims relate implicitly but necessarily and specifically” to the active ingredient.

The Court held that the correct reading of the CJEU’s judgment required application of the relevant rules (i.e. Article 69 EPC or Section 125 of the Patents Act 1977) to ascertain the extent of the invention and what the claims relate to. If the active ingredient in question is covered by the claims, it is protected for the purposes of Article 3(a) – subject to a proviso. This proviso is explained at paragraph 66 of the judgment and is necessary to reveal the approach of the CJEU in Medeva in relation to products containing combinations of active ingredients. A product is not protected within the meaning of Article 3(a) solely by virtue of a claim containing general wording that extends the claim beyond its principle scope (such as “comprises”).

However, in the absence of such extending words, the Court held that “the claims have a focused scope and the question is simply whether the product falls within the scope of the claims”. Lilly had conceded during the course of these proceedings that tabalumab falls within the scope of claim 13 of the patent, and the proviso did not apply since there were no extending words. Tabalumab was therefore protected by the patent within the meaning of Article 3(a).18

Finally, the Court considered that paragraph 43 of the CJEU’s decision, which relates to whether a patent owner has made any investment in the research leading to the MA, was more relevant to the discontinued ‘third party issue’ than to the test under Article 3(a). However, the Court made clear that SPCs are intended to be available without discrimination for the type, or stage, of research leading to the grant of the basic patent.

This ruling is available to appeal and the authors feel that Lilly will most likely appeal the decision. This decision by UK court is just the beginning of interpretation of CJEU decisions by national courts in Europe. The other Courts will no doubt produce their own interpretations in the time to come.

The question that still remains is whether Lilly’s acceptance that tabalumab falls within the ambit of HSG patent claim resulted in the National Court’s decision or the Court on its own believed that HSG patent claims and specification are adequate to cover tabalumab. One has to wait till the appeal decision and decision by other national courts for more clarity. More and more appeals to CJEU are to be anticipated in future.

Lingering Questions

The CJEU rulings in Sanofi and Lilly however pose questions in case of patents with Markush claims. Patents with Markush claims have clinical data for a limited number of compounds, but the claims themselves cover thousands of compounds.
Is the ruling in Lilly or the Sanofi case applicable to Markush claims?

The Sanofi case highlights the fact that the compound should be identified and specified in the claim wordings, but Lilly caselaw implies that functional language of claim is sufficient; hence SPC for compounds based on Markush claims are under question. Questions to the CJEU regarding such cases cannot be ruled out in future.

Another question is about the expiry of a Markush claim including compounds for which a number of SPCs are granted. Like in the Lilly case, HSG had its own SPC for Belimumab but based on Lilly’s invention of tabalumab, an additional SPC could be granted to same patent. As a result, patents can be revived multiple times by filing application for compounds covered in Markush claims. What will be life term of such patents?

Another question which is currently under CJEU referral is patent amendment after grant of patent and SPC. Should such amendment be allowed?

The rise of the ‘Unitary Patent System’ (UPC) in Europe wherein one patent can be granted throughout Europe are likely to pose additional questions. For instance, in case of patents granted under UPC where SPCs have been granted, which ruling shall apply (Lilly or Sanofi); since the CJEU left the interpretation of ‘identified and specified’ to discretion of national courts. This is surely going to increase the number of appeals in future.

Conclusion

As can be seen from the Valsartan and Losartan cases, there is a significant impact of Medeva and Georgetown rulings on the regulation of SPCs in Europe. The Losartan and Valsartan rulings are clearly in favour of innovator pharmaceutical companies in that, if SPC is granted for ‘A’ then such SPC would be effective in blocking others from selling any products containing ‘A’ in combination with additional active agents. At the same time, the Daichii case clarified that no SPC is possible for the combination product, ‘A+B’, if claims of the basic patent failed to identify them. The Sanofi ruling is a significant check for innovator companies; since the CJEU went on to invalidate the SPC for a combination product where the combination was claimed generically in the basic patent. These rulings have also clarified certain aspects for biotechnology companies especially involved in research for vaccines in Europe as vaccines are always complex products or mixture of multiple active ingredients.

While the Lilly case highlighted the fact that it is not necessary for the product under Article 3(a) to be identified or specified in the wording of the claims, the functional language of the claim can also provide support for the generic claims of product; it left the decision as to the extent of disclosure required for satisfying Article 3(a), to national IP courts across Europe. One interpretation of the CJEU decision has already been delivered as a UK court judgment. Thus by leaving the interpretation to national courts, the door for further litigation has been left wide open.

At the same time, the CJEU has not dealt with any patent containing Markush claims where the compound is disclosed generically but not specifically in the claims.

The ultimate question that still begs answers is between Sanofi and Lilly, which is the ruling that governs specific disclosure and identification of product in the claims? Even the Medeva case did not clarify the extent of disclosure required for the active ingredients to be ‘specified and identified’ in the claims of the basic patent.

The referrals made to CJEU in Telmisartan case are equally important for innovator companies as they dealt with amendment in the claims of granted patent made after MA granted for the product. The answers to the questions raised in the Telmisartan case are somewhat clear in light of Sanofi ruling by CJEU. However, the Telmisartan case referral to CJEU will be crucial as it will tell us whether amendment is possible after the patent and SPC are granted.

On the other hand these rulings are not averse to generic companies, since they specify that if the scope of basic patent does not match with the combination for which SPC is applied, then grant of SPC is not possible. Medeva and Georgetown rulings are applicable to previously granted SPC too; and thus, provide opportunities for generic companies to find avenues for challenging SPCs in order to obtain early market entries.

Further interpretation of Article 3 of SPC regulation will be helpful for generic companies in order to successfully launch generic products in the European market.

Acknowledgement

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