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COMMENTARY ON THE ROYALTY PHARMA RULING OF THE CJEU OF 30 APRIL 2020

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THE TWO-PART TEST FOR GRANT OF SUPPLEMENTARY PROTECTION CERTIFICATES IS HERE TO STAY, BUT AT WHAT PRICE? COMMENTARY ON THE ROYALTY PHARMA RULING OF THE CJEU OF 30 APRIL 2020

Josep Montefusco
(Partner, Clifford Chance)

ABSTRACT

The interpretation of Regulation (EC) No. 469/2009 concerning the supplementary protection certificate for medicinal products and its predecessor, Council Regulation (EEC) No. 1768/92, has been the issue of numerous matters referred to the Court of Justice of the European Union (CJEU) for preliminary rulings. One of the provisions subject to the greatest scrutiny from the CJEU is Article 3(a), which establishes one of the requirements for the grant of a supplementary protection certificate ("the product is protected by a basic patent in force"). The CJEU offered the latest chapter in this saga on 30 April 2020 with the Royalty Pharma case. While this ruling appears to have clarified certain important aspects of the interpretation of Article 3(a) of Regulation (EC) No. 469/2009, in reality it leaves other matters unresolved which will no doubt continue to cause major headaches for both applicants and national patent offices and courts.

KEY WORDS:
Supplementary protection certificate; product protected by a basic patent in force; subject matter of a patent; two-part test; reference for a preliminary ruling.

SUMMARY

The interpretation of the provisions of Regulation (EC) No. 469/2009, concerning the supplementary protection certificate for medicinal products and those of its predecessor, Regulation (EEC) No. 1768/92, has been the subject of multiple requests for a preliminary ruling referred to the Court of Justice of the European Union. One of the provisions which has more often captured the attention of the Luxembourg Court was article 3(a) of both Regulations, which sets forth one of the requirements for the grant of a supplementary protection certificate ("the product is protected by a basic patent in force"). The Court of Justice of the European Union released the most recent episode of this saga on 30 April 2020 (case "Royalty Pharma"). While this judgment appears to have clarified some important aspects of the interpretation of Article 3(a) of Regulation 469/2009/EC, it raises many questions which will likely become a new source of headaches for applicants, Patent Offices and national Courts.

KEY WORDS
Supplementary protection certificate; product protected by a basic patent in force; subject-matter of a patent; two-steps test; preliminary rulings.

1. INTRODUCTION

The supplementary protection certificate ("SPC") constitutes a sui generis intellectual property right regulated in the European Union by Regulation (EC) No. 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products ("SPC Regulation"). The SPC Regulation replaced Council Regulation (EEC) No. 1768/92 of 18 June 1992, which was the first legislation by the European Economic Community to address SPCs (although the concept was not completely unknown in Europe as it already existed in the national law of some Member States). Following certain partial amendments to the original version, the Regulation was codified with the passing of the current SPC Regulation, which currently governs the requirements, scope and duration of SPCs (both of these Regulations will be referred to as the "SPC Regulation").

Since its promulgation in the early 1990s, the SPC Regulation has given rise to numerous issues regarding its interpretation which have led to referral of a number of questions to the CJEU for a preliminary ruling. These matters referred to the Court address a range of very different issues, although undoubtedly the majority have sought to clarify the meaning and scope of the requirements to obtain an SPC as laid down in Article 3 of the SPC Regulation.

This article will review the judgment of the CJEU issued on 30 April 2020 in Case C-650/17 Royalty Pharma Collection Trust (Royalty Pharma). This ruling constitutes yet another attempt to clarify the interpretation of Article 3(a) of the SPC Regulation.

Despite its apparent simplicity ("the product is protected by a basic patent in force"), this requirement for grant of an SPC is proving to be one of the thorniest issues in the 28-year history of the SPC Regulation, giving rise to irreconcilable interpretations which faithfully reflect the long-standing conflict between the economic and business interests of the innovative pharmaceutical industry, which seeks to ensure protection of its investment, and the generic pharmaceutical industry, which is interested in marketing generic versions of these innovative medicinal products as soon as possible.

As will be seen in the following analysis, the ruling in Royalty Pharma clarifies certain important aspects of the interpretation of Article 3(a) of the SPC Regulation. Nonetheless, as tends to be the case every time the CJEU is faced with this provision, it also leaves other issues unresolved which will undoubtedly cause headaches in the coming years for SPC applicants and the patent offices responsible for granting them.

Before analysing the ruling, the following is a brief overview of the legal framework of SPCs to allow the legal matters at issue in Royalty Pharma to be understood in their context.

2. LEGAL FRAMEWORK OF SPCs

As is well known and as recalled in the recitals to the SPC Regulation, the holders of patents to protect active ingredients of medicinal products do not effectively enjoy a 20-year period to allow them to cover their considerable investment. This is due to the fact that following the application for a patent to protect an active ingredient, the holder must undergo a laborious process of development, testing and trials aimed at demonstrating the quality, effectiveness and safety of the product before it may be marketed as a medicinal product. The current law prevents a medicinal product being marketed if it does not have the corresponding marketing authorisation issued by the competent national or European authority after completing the evaluation procedure established by law. These tests and trials can take years to complete, not to mention the additional time required by health authorities to evaluate applications and where applicable issue the marketing authorisation, meaning that in practice the 20-year protection period generally conferred to patents is considerably reduced. To compensate for this deficit in the period of protection enjoyed by pharmaceutical patents, European legislators introduced the concept of SPCs in EU law.

Although regulated by a Community instrument, SPCs constitute national rights and as such they must be applied for independently from the patent offices of each of the Member States where protection is sought.

Article 1 of the SPC Regulation establishes a series of definitions, of which the following are of interest:

> a) 'medicinal product means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;
>
> b) 'product' means the active ingredient or combination of active ingredients of a medicinal product. It should be noted that for the purposes of the SPC Regulation, 'product' includes both one active ingredient and where applicable a combination of two or more active ingredients;
>
> c) 'basic patent' means a patent which protects a product as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate.

According to Article 2 of the SPC Regulation, any product protected by a basic patent and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in the pharmaceutical legislation in force in the European Union may be the subject of a certificate. This is consistent with the fundamental objective of the SPC Regulation, namely to compensate the holders of patents for delays in the commercial exploitation of their products due to the need to prepare, process and obtain marketing authorisation for their medicinal products from the health authorities. SPCs are therefore based on two pillars: a patent and a marketing authorisation for medicinal products. Accordingly, only the active ingredients protected by a patent and which have received marketing authorisation in the case of medicinal products may be the subject of an SPC.

These two criteria must be met to obtain an SPC, although this alone is insufficient. Under Article 3 of the SPC Regulation, four further criteria must be met in the Member State and at the date of the application for an SPC:

> 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.

In terms of the scope of the protection afforded, the SPC confers the same rights as those conferred by the basic patent and is subject to the same limitations and obligations (Article 5 of the SPC Regulation), but solely for products covered by the authorisation to place the corresponding medicinal product on the market and for any use of the products as a medicinal product that has been authorised (Article 4). In other words, SPCs extend the duration of a patent for a specific period, but only in relation to products or combinations of products that have been authorised as medicinal products (not the rest of the products covered by the basic patent).

The application for an SPC must be lodged within six months from the date on which the basic patent is granted or the date on which the authorisation to place the product on the market as a medicinal product is granted, whichever is the latest. Given that the SPC prolongs the effects of a patent during a certain period of time, thereby potentially restricting the economic activities of third parties, the intention is for such third parties to be aware of these restrictions as soon as possible to provide greater legal certainty (at the most, six months from the time of meeting the two fundamental requirements for grant of an SPC).

To conclude this general introduction, we will briefly mention Article 13 of the SPC Regulation, which specifies the duration of an SPC. To calculate the duration of an SPC, two dates must be taken into account: firstly, the date on which the application for the basic patent was lodged and secondly the date of the first authorisation to place a medicinal product on the market in the Community which contains the product as an active ingredient. The duration of the SPC, which is counted as from the expiry of the basic patent, is the difference between these two dates reduced by a period of five years. For example, if there is a difference of seven years between lodging the application for the basic patent protecting a given product and the date of the first authorisation to place a medicinal product on the market which contains that product, the SPC will have a duration of two years starting from the expiry date of the basic patent. Regardless, the duration of the SPC cannot exceed a maximum of five years, meaning that if the result of applying this general formula exceeds this period (for example, because the first marketing authorisation in the Community is 12 years after the application for the basic patent), the duration of the SPC will be reduced by the corresponding amount so that it is limited to five years. Except in the above cases involving application of the five-year limit, the formula to calculate the duration of the SPC ensures that the holder of the patent enjoys a period of fifteen years to exclusively market the medicinal product patented.

3. BRIEF OVERVIEW OF PREVIOUS CJEU RULINGS ON ARTICLE 3(a) OF THE SPC REGULATION

To better understand the issues raised in Royalty Pharma which were resolved by the Ruling of the CJEU on 30 April 2020, we will previously outline the main conclusions that may be reached from the most important rulings of the CJEU to date regarding Article 3(a) of the SPC Regulation and the meaning of the term "product (...) protected by a basic patent.

The first time the CJEU considered the interpretation of Article 3(a) of the SPC Regulation was in Case C-392/97 (Farmitalia) on 16 September 1999. This was the first time the CJEU had been called upon to address one of the most heated debates relating to the interpretation of Article 3(a): whether in order to determine if a product is "protected" by a basic patent it is necessary to apply the "disclosure theory" (products are only protected if they are disclosed in the claims of the patent) or the "infringement test" (all products that would infringe the basic patent are protected).

The CJEU noted that patents had yet to be harmonised at European Union level, meaning that the extent of patent protection and accordingly whether a product is protected by a basic patent could be determined only in light of the national legislation of each Member State, which was a task for the courts of those Member States.

The lack of a clear answer by the CJEU to this controversial issue led to considerable legal uncertainty and differing practices by patent offices and national courts across Europe in the following years. The problem was particularly evident in cases where patents which claimed certain active ingredients ("A") were invoked as basic patents for SPC applications relating to combinations of active ingredients ("A+B"). While there was no doubt that the combinations were protected by the basic patent applying the infringement test, a different conclusion could be reached applying the disclosure theory.

This situation of legal uncertainty led to one of the most famous and controversial rulings by the CJEU regarding the interpretation of Article 3(a) of the SPC Regulation: Case C-322/10 (Medeva) on 24 November 2011. In this ruling, the CJEU rejected application of the infringement test and opted for the so-called disclosure theory. Applying confusing reasoning which has been strongly criticised, the CJEU concluded that Article 3(a) of the SPC Regulation prevented the grant of an SPC for a product (for example, a combination of active ingredients) that was not included in the claims of the basic patent.

More specifically, the CJEU held that Article 3(a) required that the product for which the SPC application is lodged must be "specified" in the wording of the claims of the basic patent invoked to support the application, and that it was insufficient that the product infringed the basic patent. The reasoned order of the CJEU in Daiichi (C-6/11) on 25 November 2011 (one day later), did not use the term "specified", but rather "identified" [in the wording of the claims] to answer exactly the same question, fuelling certain jurisprudential theories which argued that different interpretations could be reached based on each of these terms. However, in practice there has been no major debate regarding any possible difference between situations where products are "specified" or "identified" in the claims of the basic patent.

While these decisions helped to clarify certain matters, they also left other issues unresolved which further exacerbated the situation of legal uncertainty. For example, how specific must the description be for the product to be considered as "specified" in a claim? Do products that are not expressly disclosed but which are included in a Markush formula meet these criteria? What is the status of products not defined structurally but which are included in a functional definition? And products defined in terms of processes for their preparation (product-by-process claims)?

Some of these issues were addressed in the second wave of rulings by the CJEU on 12 December 2013, a date known as "Super Thursday" among patent law specialists. On this day, the CJEU issued preliminary rulings in the cases Eli Lilly (C-493/12), Actavis I (C-443/12) and Georgetown II (C-484/12).

In Eli Lilly, el CJEU confirmed the rejection of the infringement test and held that a functional definition of a product (for example, "product capable of binding to protein X") could meet the condition imposed by Article 3(a) of the SPC Regulation provided that it may be concluded on the basis of a correct interpretation of those claims that they relate "implicitly but necessarily and specifically, to the active ingredient in question." The CJEU clarified that because the European Union was not a party to the European Patent Convention, it was not competent to provide any indication as to how the claims should be interpreted pursuant to Article 69 of the above Convention. Nonetheless, the Court suggested that in the circumstances of the case, in which the active ingredient was not expressly specified in the claims and the holder of the patent had not made any investment to further develop and specify its invention in order to clearly identify the active ingredient capable being marketed as a medicinal product (it was a third party and not the holder of the patent who had obtained authorisation to market a product that complied with the functional definition claimed), the rejection of the SPC application could be justified.

In any event, the abstract wording of this legal test far from resolved the issue and led to further debate as to what should be understood as a specific, implicit but necessary reference to an active ingredient. In Actavis I, the CJEU had to decide whether a combination of telmisartan and hydrochlorothiazide could be considered to be "protected" under Article 3(a) due to a claim of the basic patent referring to combinations of irbesartan and a diuretic, or whether the claim had to expressly specify the presence of hydrochlorothiazide. The CJEU avoided answering this first question. However, when considering the other question relating to Article 3(c) of the SPC Regulation, the Court stated that the fundamental objective of the SPC Regulation is to compensate for the delay in the commercial exploitation of what constitutes "the core inventive advance embodied by the basic patent" and not for the delay in connection with the marketing of the invention in all its possible forms (such as, for example, all the successive marketing of an active ingredient protected by the patent in combination with an unlimited number of other active ingredients not protected by that patent, but merely stated generally in the wording of the claims).

The next milestone in the interpretation of Article 3(a) of the SPC Regulation by the CJEU was Actavis II (C-577/13) on 12 March 2015. This case addressed once again the criteria necessary to determine whether a combination of active ingredients is protected by a basic patent. The CJEU reasoned that Articles 1(c) and 3(a) of the SPC Regulation require the basic patent to protect the product "as such" for which the SPC application is lodged, adding that the mere fact the two ingredients are specified in one of the claims does not per se meet the condition imposed by Article 3(a) of the SPC Regulation. In the opinion of the CJEU, this condition may only be considered to be met when the product "as such" " (in that case the combination) constitutes the "subject matter of the invention" covered by the basic patent.

Gilead (C-121/17, 25 July 2018) was the next ruling of the CJEU to consider the interpretation of Article 3(a) of the SPC Regulation. Due to the dissatisfaction with the previous judgments of the CJEU, the decision was made to hear the matter before the Grand Chamber in the hope that once and for all it would provide useful and definitive criteria for interpretation and application of Article 3(a) by national patent offices, courts and other interested parties.

In this ruling, the CJEU coined what has come to be known as the "two-part test". The Court concluded that in order to determine whether a product is protected by a basic patent in force under Article 3(a) of the SPC Regulation, whether that product is a sole active ingredient or a combination of two or more active ingredients, it is necessary to consider whether (i) the product is expressly mentioned in the claims or if not, whether (ii) those claims relate to that product necessarily and specifically (two-part test), which must be assessed from the perspective of a person skilled in the art and on the basis of the prior art at the priority date of the patent in the light of all the information disclosed by that patent, in accordance with the following guidelines:

- Necessarily: the expert must be able to understand without any doubt, on the basis of their general knowledge and in the light of the description and drawings of the patent, that the product (or combination of two active ingredients) is a specification required for the solution of the technical problem disclosed by that patent.

- Specifically: the product (or in the case of a combination, the two active ingredients) must be identifiable specifically by a person skilled in the art in the light of all the information disclosed by the patent and the prior art at the priority date.

4. THE RULING OF THE CJEU (FOURTH CHAMBER) IN CASE C-650/17 (ROYALTY PHARMA)

A matter of months before the CJEU issued its ruling in Gilead, two new cases were brought before the CJEU: Royalty Pharma (C-650/17), referred by the Bundespatentgericht (Federal Patent Court, Germany) and Sandoz (C-114/18), referred by the Court of Appeal (England & Wales) (Civil Division). Following the ruling in Gilead in July 2018, the CJEU asked both the above courts whether, in the light of that judgment, they wished to maintain their request for a preliminary ruling and, if so, on what grounds. Both courts expressly indicated that they maintained the request, submitting that further clarification was required on the point.

However, the Court of Appeal (England & Wales) (Civil Division) ended up withdrawing its request in relation to the Sandoz case on 11 December 2019, three months after the Advocate General, Mr Gerard Hogan, presented his opinion (and barely a month and a half before the UK completed the Brexit withdrawal agreement).

The ruling in the Royalty Pharma case was handed down by the CJEU on 30 April 2020. The questions referred by the German Federal Patent Court related to the degree of specification of the active ingredient required to satisfy the requirement imposed by Article 3(a) of the SPC Regulation if the claims of the basic patent only contain functional definitions (and therefore no specific mention of the product in question).

The relevant facts of the case are outlined below. Royalty Pharma Collection Trust ("Royalty Pharma") held a patent that protected a procedure to lower blood sugar levels in mammals through the administration of inhibitors of the enzyme DPP-4. Royalty Pharma's patent contained claims based on functional definitions (products capable of inhibiting DPP-4) and explained that by inhibiting this enzyme the blood sugar levels of patients with diabetes mellitus could be controlled.

Sitagliptin belongs to the group of DPP-4 inhibitors. This product was subsequently developed by Merck Sharp & Dohme ("MSD"), a licensee of Royalty Pharma, with MSD obtaining a new patent from the European Patent Office. MSD also obtained authorisation to market the medicinal product (sitagliptin) under the name Januvia and based on its patent and the above marketing authorisation filed an application for an SPC for sitagliptin.

At the same time, Royalty Pharma also applied for an SPC for sitagliptin from the German Patent and Trademark Office, invoking its own patent and the marketing authorisation for the medicinal product Januvia by MSD. The German Patent and Trademark Office rejected the application on the basis that although sitagliptin satisfied the functional definition in the claims of the basic patent (it was a DPP-4 inhibitor), it could not be considered to be included in the "subject matter of the patent", as it offered no information on sitagliptin (the precise active ingredient was not provided to the expert), and in reality this specific product was the result of subsequent research and development (by MSD).

Royalty Pharma appealed this decision before the Bundespatentgericht (Federal Patent Court), arguing that the German Patent and Trademark Office had not taken into account that the "the core inventive advance" of the basic patent did not consist of the use of one product or another, but rather discovering what the target enzyme was to treat diabetes mellitus. The point was also raised that both Medeva and Eli Lilly establish that it is unnecessary to provide the structural definition of the products patented and the presence of functional characterisations in the claim is sufficient to meet the requirements of Article 3(a). Meanwhile, the Federal Patent Court argued that the 'core inventive advance' test applied by the CJEU in Actavis I was not a relevant criteria for the purposes of paragraph (a) of Article 3, but had rather been used by the CJEU to resolve issues relating to the interpretation of paragraph (c). In the opinion of the German court, the test to be applied in relation to paragraph (a) was whether the product was necessarily and specifically identified in the claims. However, due to the doubts the case raised, the Federal Patent Court referred the following questions to the CJEU for a preliminary ruling:

> "1)Is a product protected by a basic patent in force pursuant to Article 3(a) of Regulation [No 469/2009] only if it forms part of the subject matter of protection defined by the claims and is thus provided to the expert as a specific embodiment?
>
> 2) Is it not therefore sufficient for the requirements of Article 3(a) of Regulation [No 469/2009] if the product in question satisfies the general functional definition of a class of active ingredients in the claims, but is not otherwise indicated in individualised form as a specific embodiment of the method protected by the basic patent?
>
> 3) Is a product not protected by a basic patent in force under Article 3(a) of Regulation [No 469/2009] if it is covered by the functional definition in the claims, but was developed only after the filing date of the basic patent as a result of an independent inventive step?'

As indicated above, following the decision in Gilead which introduced the two-part test, the CJEU asked the Federal Patent Court whether it wished to maintain its request for a preliminary ruling. It replied in the affirmative, submitting that it was unclear if the core inventive advance test was still relevant for the purposes of Article 3(a) of the SPC Regulation, given that the reasoning of the CJEU in Gilead did not expressly adopt the criticisms of Advocate General Wathelet in his opinion issued on 25 April 2018.

The judgment of the CJEU on 30 April 2020 began by confirming the irrelevance of the concept of 'core inventive advance' when interpreting Article 3(a) of the SPC Regulation. The CJEU recalled that Gilead and other previous judgments established the key role played by the claims under Article 69 of the EPC and Article 1 of the Protocol on the Interpretation of Article 69 when determining whether a product is protected by a basic patent under Article 3(a). This judgment confirmed that the subject matter of the protection conferred by an SPC must be restricted to the technical specifications of the invention covered by the basic patent as stated in the claim, and therefore the concept of "core inventive advance" was irrelevant.

With respect to the first two questions referred to the CJEU, the Court confirmed the application of the two-part test ("necessary" and "specific" reference to the product) to the case of patents that define products via their functional characteristics. The Court pointed out that the fact a product that meets the function claimed is not structurally described and identified in the patent (that is, it is not provided in its individualised form as a specific embodiment) is not sufficient grounds per se to reject an SPC application. The CJEU held that the relevant criteria is to determine whether the product is included "necessarily and specifically" in any of the claims from the point of view of a person skilled in the art, in the light of all the information disclosed by the patent and the prior art at the priority date.

The CJEU indicated in its ruling that everything appeared to indicate that sitagliptin should "necessarily" be considered to be included within the scope of the invention, as it undoubtedly meets the functional definition used by one of the claims. In relation to the second condition ("specifically"), the CJEU commented that the competent national court must decide whether a person skilled in the art is able to infer directly and unequivocally from the patent as it was filed that sitagliptin is covered by the patent, based on that person's general knowledge and in the light of the prior art at the priority date.

In relation to the third question, the CJEU held that a product cannot be considered to be "protected by a basic patent" pursuant to Article 3 (a) of the SPC Regulation if although it is covered by the functional definition given in the claims of that patent, it was developed after the filing date of the application for the basic patent following an independent inventive step. The CJEU based its conclusion on the argument that the subject matter of the protection conferred by the basic patent must be determined at the priority date, and the idea that if the results from research which took place after the priority date of that patent were taken into account, an SPC could enable its holder to "unduly" enjoy protection for those results, even though they were not known on that date. The CJEU also recalled that as stated in previous case law, the purpose of the SPC is not to extend the protection conferred by the basic patent beyond the invention that patent covers, and it would be contrary to the objective of the SPC Regulation to grant an SPC for a product that is not covered by the invention which is the subject of the basic patent, given that the SPC would not relate to the results of the research claimed under that patent but rather subsequent research.

Undoubtedly one of the most relevant (and controversial) conclusions of the CJEU's judgment in Royalty Pharma is that a product included in a functional definition that has been developed after the priority date of the basic patent following an independent inventive step cannot be regarded as coming within the scope of the subject matter of the protection conferred by that patent for the purposes of obtaining an SPC.

5. IMPLICATIONS OF THE ROYALTY PHARMA DECISION

The judgment of the CJEU of 30 April 2020 clarifies highly relevant issues regarding the interpretation of Article 3(a) of the SPC Regulation. However, it also raises other doubts which will only be resolved with the passage of time.

The first key conclusion that can be drawn from this ruling is the definitive rejection of the 'core inventive advance' test to determine whether the requirements of Article 3(a) have been met. Where a product for which an SPC application has been lodged (for example, a combination of active ingredients) is expressly specified in the claims of a basic patent, it will no longer be possible to deny the grant of the SPC on the basis that the product does not constitute the core inventive advance of the basic patent. The only relevant criteria for the purposes of compliance with the requirements of Article 3(a) will be the subject matter of the claims of the basic patent.

Secondly, in cases in which the product is not expressly specified in the claim of the basic patent, the CJEU has made a definitive commitment to the two-part test formulated in its judgment of 25 July 2018 (Gilead). While in the former case the CJEU applied the test to assess whether a combination of two active ingredients could be considered to be protected by a basic patent, in Royalty Pharma the same principle was applied to a functional definition of active ingredients, confirming what Advocate General Hogan referred to as the 'technological neutrality' of the two-part test. Given that the Court of Appeal (England & Wales) (Civil Division) withdrew its referral in the Sandoz case, for the moment it is unclear whether this 'technological neutrality' would allow application of the test to products included in a Markush formula and not specifically identified in the patent (it should be noted that Advocate General Hogan recommended that the CJEU apply the two-part test to the case of Markush formulas as well, although it is well-known that the CJEU does not always follow the recommendations of the Advocate General).

As regards the test itself, the CJEU held that in order to meet the second condition ("specifically"), a person skilled in the art must be able to infer "directly and unequivocally" from the patent as it was filed that the product comes within the scope of its protection. Perhaps inadvertently, the CJEU used certain terms ("directly and unequivocally") which have a very specific meaning in patent law, more specifically in relation to the concepts of novelty and additional material. The question therefore arises whether the CJEU actually wished to infer that national patent offices should apply the novelty and/or additional material tests to determine whether a claim refers specifically to a product that is not expressly identified in its wording (which would raise the bar considerably for the grant of an SPC) or whether on the contrary the terms 'direct and unequivocal' have a different (and less strict) meaning for the purposes of Article 3(a) of the SPC Regulation, an option which seems more plausible.

However, apart from the above, one of the aspects of the judgment which has undoubtedly caused the most controversy is the conclusion that a product cannot be considered to be within the scope of the subject matter of a basic patent if although it is covered by the functional definition it was developed after the filing date of the application for the basic patent following an independent inventive step. This is a development with major repercussions and will undoubtedly give rise to significant controversy,

given that in practice it could shut the door on the possibility of obtaining SPCs for the holders of many patents that protect significant and valuable inventions in their most embryonic states (concept tests) and open the door for those who, based on the findings of others, have finished off or completed a task which they would perhaps not have carried out from beginning to end by themselves.

Aside from all the above, once again some of the terms used by the CJEU in its reasoning are open to different interpretations. Examples include 'developed', 'inventive step' and 'independent'. For example, doubts may arise as to the degree of development of a product necessary to prevent the grant of an SPC to the holder of the basic patent protecting a conceptual invention. Should the term 'developed' be interpreted in the context as a synonym of 'invented' or is it sufficient for there to be a certain degree of preclinical or clinical development? In relation to the term 'inventive step', it is well-known that this has a very specific meaning in patent law. This raises the question whether the CJEU was referring in its ruling to an 'inventive step' in the sense of the requirement for patentability, or whether on the contrary it was granting this term a different meaning in the context of Article 3(a) of the SPC Regulation. Finally, the meaning of the word 'independent' may also give rise to controversy in this specific context. Can a product developed by the holder of the basic patent be the result of an 'independent' inventive step? Or does this concept solely apply to developments by third parties? And what is the maximum degree of exploitation of the knowledge of the prior basic patent to consider that the development of a product is truly the result of an 'independent' inventive step?

As can be seen, the ruling in Royalty Pharma raises a host of issues which will undoubtedly be dealt with in future cases before the CJEU.

6. CONCLUSION

Despite the efforts of the CJEU to provide a definitive legal test which is wide enough to allow its application to any case, the fact is that the issues regarding the interpretation of Article 3(a) of the SPC Regulation are far from being resolved by the two-part test proposed in Gilead and Royalty Pharma. The cases that can be brought before national patent and trademark offices are so varied and complex that no test that seeks to cover the majority of cases will be exempt from specific situations which raise doubts regarding its interpretation and application.

In our opinion, this is a complex matter which is not adequately resolved by abstract guidelines and considerations along the lines of those proposed by the CJEU. By rejecting the infringement test, it is now painfully obvious how difficult it is to formulate a test that strikes a satisfactory balance. Regardless of the intentions, a test which is too general will be overly abstract, holes will inevitably appear and it will end up generating legal uncertainty.

The two-part test reaffirmed by Royalty Pharma is not exempt from these issues. As can be seen from the above analysis, this ruling may end up becoming a new source of headaches for national patent offices if it is interpreted as requiring assessment of SPC applications not only in light of the classical requirements for grant under Article 3 of the SPC Regulation, but also other concepts and considerations more closely linked with patentability requirements. This could lead to much more complex and costly administrative procedures and is also very likely to increase the amount of litigation in national courts.

To sum up, everything seems to indicate that the heated debate regarding the meaning of the requirement “protected by a basic patent” in Article 3(a) of the SPC Regulation will continue to smoulder despite the efforts of the CJEU to dampen the doubts regarding its interpretation.

We will no doubt continue to see a steady flow of referrals for preliminary rulings by the CJEU in the coming years regarding this aspect of such vital importance to the pharmaceutical industry to ensure their products are protected by an SPC. On the other hand, the frequency of referrals to the CJEU may also drop considerably following the entry into force of the Brexit agreement on 1 February 2020, given that it has largely been the UK courts which have persevered over the last decade with their tireless efforts to bring proceedings before the CJEU to consider essentially identical issues, a reflection of their manifest dissatisfaction with the answers given by the CJEU to the questions they have posed regarding the interpretation of Article 3(a) of the SPC Regulation.

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