Fostering paediatric research and the right to extend supplementary protection certificates
Montserrat López-Bellosta and Ana Benetó Santa Cruz*

Extension of the supplementary protection certificate as an incentive for paediatric research

Regulation 1901/2006\(^1\) was approved in response to the need to have medicinal products suitably adapted for the paediatric population (ie those between the ages of 0 and 18). As mentioned in its text, many of the medicinal products currently administered to the paediatric population have not been specifically studied or authorized for its use. This leads to problems such as an increase in the risk of adverse (and sometimes lethal) reactions and the inefficacy of treatments derived from underdosing.

In order to handle such situations, Regulation 1901/2006 seeks three specific objectives: facilitating access to medicinal products for paediatric use, ensuring they are the result of quality ethical research, and that they are specifically authorized for the paediatric population, and improving the information available on them. All this is to be achieved while searching for a balance between attention to the paediatric population (ensuring a greater availability of medicinal products for paediatric use, without carrying out unnecessary clinical trials) and a lack of delays in the authorization of medicinal products for other age groups apart from the paediatric population.

Regulation 1901/2006 recognizes that ‘market forces’ are insufficient for moving towards the obtaining of these objectives. Thus, in order to do so, Community legislation provides a system of obligations and of rewards and incentives.

One of the most relevant incentives established in the text is the grant of an extension to the supplementary protection certificate (‘SPC’) for a period of 6 months. The SPC, regulated under the SPC Regulation\(^2\) is a mechanism for extending the patent’s life, created for the purpose of compensating the reduction which the duration of this exclusive right suffers in practice, a reduction caused by the time that is necessary for obtaining a marketing authorization for medicinal products protected by patents. The SPC is granted based on a patent right which is effective within the territory of at least one Member State, and it can last for a maximum term of 5 years counting from the expiry date of the legal validity of the basic patent. Extension of the SPC as an incentive for the development of paediatric studies implies an additional term of 6 months to the original length of the SPC.

As just mentioned, in reward for the effort made in performing clinical trials specifically designed for paediatric use, Regulation 1901/2006 amends the SPC

Key issues

- While the 6-month SPC extension recognized by Regulation 1901/2006 falls within a fully harmonized and directly applicable system, the extension is awarded by the competent industrial property offices in each Member State; this leads to conflicting interpretations of the requirements for obtaining the SPC extension and, ultimately, to legal uncertainty.
- The system of incentives set out by Regulation 1901/2006 should focus on the promotion and development of paediatric research, not on other factors such as obtaining marketing authorizations.
- The interpretation of the requirements set out in Article 36 of Regulation 1901/2006 for obtaining an SPC extension should not make compliance with these requirements depend on factors which are beyond the applicant’s control and diligence.

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Regulation, establishing the possibility of requesting an extension of 6 months beyond the length of the SPC. In order to obtain this, however, the applicant must meet two requirements, the interpretation of which comprises the object of this paper. To such end, the grant of SPCs and their extensions is reserved, by Article 9.1 of the SPC Regulation, to the competent industrial property office in each Member State. This gives rise to various interpretations of the legal requisites for requesting the extension, which means that such requirements should be clarified. The need for a standard interpretation is growing, as the EFPIA (European Federation of Pharmaceutical Industries and Associations) has shown, since the extension of the SPC falls within the framework of a fully harmonized system directly applicable in the Member States.

In order to alleviate these interpretative differences, various contacts have been established for some time between the European Commission, the European Medicines Agency, national Patent Offices, the competent health authorities in the Member States, and other agents such as pharmaceutical companies and associations representing the pharmaceutical sector.

Requisites for obtaining an SPC extension

The right to an SPC extension is enshrined in Article 36 of Regulation 1901/2006 for those applicants who have performed studies in accordance with a previously agreed paediatric investigation plan. As indicated, the purpose of the extension right is to compensate applicants for the costs involved in the development of these types of studies. Four requisites are expressly or tacitly included in Article 36 of Regulation 1901/2006 for obtaining a right to an extension of the SPC.

Existence of the SPC

Evidently, the prerequisite for the application of Article 36 is that an SPC exist for which the extension can be requested. This requisite, which might seem obvious, has also been the object of debate. In this sense, it is interesting to refer to the Decision of 14 April 2008 handed down by the UK Intellectual Property Office, granting a ‘zero term’ SPC, precisely taking Regulation 1901/2006 into account.

The applicant, Merck & Co. Inc. (‘Merck’), wished to obtain an SPC and, at the appropriate time, apply for an extension under Regulation 1901/2006. In accordance with Article 13 of the SPC Regulation, the duration of the certificate is determined by first calculating the difference between the application date of the basic patent and the date of the first marketing authorization granted in the Community. Five years should be subtracted from this figure, the result being the term of the SPC (with a maximum of 5 years).

In this case, the calculations produced a negative term for the SPC requested. In its initial decision, the UK Intellectual Property Office chose not to grant Merck a ‘zero term’ SPC, bearing in mind the stance of the European Commission at meetings of experts held on 3 February 1995 and 9 October 2006, where the Commission defended the non-issuance of these types of SPCs, as well as the impossibility of granting extensions to SPCs in such cases.

Nevertheless, after reviewing the case, the UK Intellectual Property Office ruled that, even though it had analysed the arguments of the European Commission, there was no requirement under the SPC Regulation or Regulation 1901/2006 that the SPC have a positive term, nor was there any express prohibition against granting an SPC with a zero or even a negative term. Thus, the Office granted Merck an SPC for a period of minus 3 months and 14 days, following the reasoning that if Merck were to subsequently request and obtain a 6-month extension under Article 36 of Regulation 1901/2006, the term of the SPC would become positive (thus rendering it effective).

During the meeting of national SPC experts held on 26 September 2008 at the EMEA, most Member States agreed with this interpretation. However, the European Commission in principle continued to maintain it was not possible to grant ‘zero term’ SPCs.

‘Proof’ that the studies have been conducted ‘in compliance with an agreed paediatric investigation plan’

In relation to this second requisite, the basic problem of interpretation is that Regulation 1901/2006 fails to specify the means through which the applicant might demonstrate compliance with the requirement of having performed relevant studies under the previously agreed

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paediatric investigation plan. This problem should be studied in the light of Article 8(1)(d)(i) of the SPC Regulation, which establishes the necessary points to be included in an SPC application or in the application for its extension. As we will show, various arguments lead to the conclusion that there exist several types of evidence, not restricted to the statement indicating compliance with the agreed completed paediatric investigation plan, issued by the competent authorities and set forth in Articles 28.3 and 36.2 of Regulation 1901/2006.

The medicinal product protected by the patent for which the extension of the SPC is requested should be ‘authorised in all Member States’

The literal wording of the Regulation raises the issue whether the requisite of authorization ‘in all Member States’, enshrined in Article 36.3 of Regulation 1901/2006, implies that the applicant should have obtained a marketing authorization in each Member State indicating that the studies performed have been carried out in accordance with the agreed paediatric investigation plan, also containing its results and updating the summary of the product characteristics in accordance with such results (the ‘qualified authorization’) or whether the term ‘authorization’ can be taken to include any type of marketing authorization. Through the logic of the right to the extension of the SPC, it can be shown that the authorization required by Article 36.3 of Regulation 1901/2006 does not necessarily have to be a qualified authorization but rather, to satisfy this requirement, any type of marketing authorization obtained in all Member States would also be valid, even when a qualified authorization has not yet been obtained.

Time

A final question arising from the interpretation of Article 36 of Regulation 1901/2006 addresses the moment at which the applicant should satisfy these requirements. From the content of Article 36 of Regulation 1901/2006, we may deduce that the applicant should be provided with the procedural mechanisms to evidence the substantive requirements of that provision until the expiry of the SPC.

Proof: ‘studies carried out in accordance with an agreed paediatric investigation plan’

In what ways may the applicant for an SPC extension prove it is meeting the requirements of Article 36.1 of Regulation 1901/2006 in order to show entitlement to it by proving that the studies carried out are in accordance with the agreed paediatric investigation plan?

Before analysing Article 36.1 of Regulation 1901/2006, one must look briefly at the definition of ‘agreed paediatric investigation plan’, as well as the procedure for obtaining it.

An agreed paediatric investigation plan is defined in Article 2.2 of Regulation 1901/2006 as a research and development programme aimed at ensuring that the necessary data are generated determining the conditions in which a medicinal product may be authorised to treat the paediatric population.

The development of studies in accordance with such a plan is the main obligation imposed on pharmaceutical companies by Regulation 1901/2006. In effect, from its coming into force, any marketing authorization application for medicinal products for human use in the European Community has only been valid if it includes the results of the studies made and detailed information gathered in accordance with the agreed paediatric investigation plan. The only exception is when the European Medicines Agency grants any type of exemption or deferral.

The procedure for obtaining a marketing authorization was thus substantially amended after the coming into force of Regulation 1901/2006. First, any pharmaceutical company intending to obtain the authorization should submit a paediatric investigation plan to the European Medicines Agency which, after verifying its formal requirements, sends it to the Paediatric Committee—a scientific committee created within the European Medicines Agency—for that body to hand down a decision on whether the studies intended to be carried out under the paediatric investigation plan ensure the provision of the information needed in order to determine the conditions of use of the medicinal product in the paediatric population, as well as on whether the expected therapeutic benefits justify the studies proposed.

Subsequently, on filing the application to obtain a marketing authorization, the competent authority will examine whether it effectively complies with the agreed paediatric investigation plan (in other words, whether the studies carried out comply with the paediatric investigation plan approved by the Paediatric Committee and the European Medicines Agency).

As we have pointed out, compliance of the studies carried out with the agreed paediatric investigation plan constitutes the essential part of the first requisite for obtaining an extension of the SPC under Article
Article 8(1)(d)(i) of the SPC Regulation: ‘1. The statement indicating compliance with an agreed paediatric investigation plan. Obviously, they cannot evaluate the compliance in itself since (i) this is not their responsibility and (ii) they cannot be expected to have the knowledge or availability necessary to perform such an evaluation.6 We base this assessment on the fact that Community legislation has imposed the burden of proof on the applicant, who must provide the documentation set forth in Article 8 of the SPC Regulation to demonstrate compliance with the agreed paediatric investigation plan.

Problems of interpretation arise when determining which documents (and other materials) are appropriate and sufficient for the applicant to be able to prove that the studies performed have been carried out in accordance with the agreed paediatric investigation plan. The root of these interpretative discrepancies lies in an apparent contradiction (which, as we shall see, is not the case) between Article 36.1 of Regulation 1901/2006 and Article 8(1)(d)(i) of the SPC Regulation.

First we must examine the literal wording of both provisions:

- Article 36.1 of Regulation 1901/2006: ‘Where an application under Article 7 or 8 includes the results of all studies conducted in compliance with an agreed paediatric investigation plan, the holder of the patent or supplementary protection certificate shall be entitled to a six-month extension of the period referred to in Articles 13(1) and 13(2) of Regulation (EEC) No 1768/92.’

- Article 8(1)(d)(i) of the SPC Regulation: ‘1. The application for a certificate shall contain: . . . (d) where the application for a certificate includes a request for an extension of the duration: i) a copy of the statement indicating compliance with an agreed completed paediatric investigation plan as referred to in Article 36(1) of Regulation (EC) No 1901/2006.’

An initial reading seems to suggest that the expression contained in Article 8 of the SPC Regulation is more restrictive than that used in Article 36 of Regulation 1901/2006.

In this sense, it could be considered that Article 8 of the SPC Regulation, referring to the ‘statement indicating compliance’, actually refers to the ‘statement indicating compliance of the application with the agreed completed paediatric investigation plan’ contained in Article 28.3 of Regulation 1901/2006, a statement issued by the competent authorities having verified that the authorization application complies with all measures of the agreed paediatric investigation plan and that the summary of product characteristics displays the results of the studies carried out in accordance with the investigation plan.

From this reasoning, one can conclude that the statement of compliance contained in Article 28 of Regulation 1901/2006 is the sole means of complying with the first of the two requisites established under Article 36 of that Regulation for an entitlement to the right to extension of the SPC’s duration. Below we analyse the arguments leading to the conclusion that, on the contrary, the statement of compliance of Article 28 is not the only way to prove the compliance of the studies carried out with the agreed paediatric investigation plan.

Supplementary, non-restrictive nature of procedural norms v substantive norms

First, understanding the provisions of Article 8(1)(d)(i) of the SPC Regulation as being equivalent to Article 36 of Regulation 1901/2006 implies overlooking the distinction between substantive and procedural norms. The former establish rights and specify the conditions under which they may be claimed; in contrast procedural norms, which are supplementary, seek to ensure that the rights in question can be acquired by anyone entitled to do so (in other words, they establish the procedure or formal mechanism to be followed in order to enjoy the substantive right).

In this case, the two articles in dispute are of a different nature: Article 36 of Regulation 1901/2006 is substantive, as it regulates the right to obtain an extension of the SPC provided certain requirements are fulfilled, while Article 8(1)(d)(i) of the SPC Regulation is procedural, establishing the formalities that must be observed in order to obtain a substantive right (the extension of the SPC). Nevertheless, the latter article does not refer to whether an applicant is entitled to an extension; this provision is contained exclusively in the substantive rule, Article 36 of Regulation 1901/2006.

6 The same reasoning led Law 19/2006, of 5 June (enacting in Spain Directive 2004/48 on the enforcement of IP rights), to suppress the obligation established in Article 128 of Spanish Patent Act 11/1986, of 20 March, according to which in the event a patent were challenged, the judge would transfer the proceedings to the Spanish Patent and Trade Mark Office for it to issue a report on the opposition within a period of 30 days. The reason behind such amendment is closely related to the non-viability of issuing such reports, due to the hindrances and delays this would cause to other activities of the Office. The same would presumably occur should the Patent Offices of each Member State be obliged to evaluate the compliance of the studies carried out with the agreed paediatric investigation plan.
Accordingly, Article 8 of the SPC Regulation, as a procedural rule, should be interpreted in the least restrictive manner possible to implement the substantive right (in this case the extension of the SPC). The restriction of the means through which an applicant can demonstrate that it fulfils the requirement of compliance with the paediatric investigation plan is reserved for the substantive norm, Article 36 of Regulation 1901/2006, and under no circumstances the procedural norm.

It could seem that Article 36.2 of Regulation 1901/2006, which refers specifically to Article 28.3 of the same legal text, introduces such a restriction. However, the wording of the second section of Article 36 ("The inclusion in a marketing authorization of the statement referred to in Article 28(3) shall be used for the purposes of applying paragraph 1 of this Article") clearly indicates that the statement of compliance of Article 28.3 is considered an appropriate way—but not the only way—of accrediting fulfilment of the first of the requirements established in order to obtain an extension of the SPC. Article 36.2 merely states that the declaration contained in Article 28.3 'shall be used for the purposes of applying paragraph 1'; in other words, it will be sufficient to fulfil the requirement, but it will not be the only way of doing so.

In any event, we must remember the underlying logic of Regulation 1901/2006; as mentioned earlier, this legal text seeks to achieve specific objectives on the basis of a system of obligations and incentives. One of the most important incentives is precisely the right to an extension of the SPC. The extension would hardly be an incentive if, ab initio and without an explicit, reasonable justification, the measures available to the applicant for opting for it are restricted.

Thus, the reference to Article 36.3 of Regulation 1901/2006 should be understood as the affirmation that the declaration of compliance is one of the ways of presenting accreditation of compliance with the paediatric investigation plan. However, there may be other ways of evidencing compliance. In this regard, if not even the substantive norm itself (Article 36 of Regulation 1901/2006) introduces restrictions on the mechanisms of proof, nor will a supporting procedural norm such as Article 8(1)(d)(i) of the SPC Regulation.

**Explicit reference to section 1 of Article 36**

Article 8(1)(d)(i) clearly makes an explicit reference to section 1 of Article 36 of Regulation 1901/2006, and not to Article 36 in general. This is important because, as we have seen, only section 2 of Article 36 expressly mentions the declaration of compliance introduced by Article 28 of Regulation 1901/2006. Thus, the concept used in Article 36.1 of Regulation 1901/2006 is clearly broader than the mechanism referred to in section 2 of the same rule, which merely specifies that the declaration contained in Article 28.3 'shall be used' to accredit the requirement of Article 36.1.

Accordingly, the fact that Article 8(1)(d)(i) refers only to the first section of Article 36 indicates that, as Article 8 adopts the same concept of 'proof of compliance' as Article 36.1, Community legislation did not want to limit the methods for accrediting compliance with the agreed paediatric investigation plan to the declaration of Article 28 of Regulation 1901/2006.

**Absence of time limits implicit in Regulation 1901/2006**

To consider that Article 8(1)(d)(i) refers to Article 28.3 of Regulation 1901/2006 would be tantamount to considering that Community legislation has introduced an implicit time limit regarding the moment at which the applicant can obtain an SPC extension. The competent authority 'shall include' within a marketing authorization the statement indicating compliance defined in Article 28.3 of Regulation 1901/2006; this statement may only be obtained once a final decision on the marketing authorization has been reached, meaning that an additional period of time will be necessary to process the statement in question.

In this regard, we consider that interpreting Article 8 of the SPC Regulation in light of Article 28.3 of Regulation 1901/2006 introduces an implicit limit, because that interpretation could lead to situations that are difficult to reconcile with the provisions of Articles 7.4 and 7.5 of the SPC Regulation, which already contain certain time restrictions in relation to the application for an extension of the SPC:

4. The application for an extension of the duration of a certificate already granted shall be lodged not later than two years before the expiry of the certificate.

5. Notwithstanding paragraph 4, for five years following the entry into force of Regulation (EC) No 1901/2006, the application for an extension of the duration of a certificate already granted shall be lodged not later than six months before the expiry of the certificate.

Thus, the restrictive interpretation of the means of accrediting compliance could lead to situations such as the following: the holder of a marketing authorization and an SPC wants to obtain a new authorization for
paediatric indications (or for new indications, new pharmaceutical forms, and new means of administration) of the authorized medicinal product protected by patent + SPC, as well as to apply for the right to extend the SPC. According to Article 7 of the SPC Regulation, it would have to apply for the extension 6 months before the date of expiry of its SPC. The first requirement for obtaining the extension is compliance with the agreed paediatric investigation plan. According to the restrictive interpretation of Article 36 of Regulation 1901/2006, the only way the applicant would be able to accredit compliance would be by means of the statement of Article 28.3 of Regulation 1901/2006 which, as we have seen, is only obtained after the marketing authorization has been granted (in this case, it would be after the granting of the authorization for the paediatric indication). It may be the case that the marketing authorization for paediatric indications, as well as the subsequent statement indicating compliance, is issued before the term of applying for the extension of the SPC has expired. Nevertheless, practice shows us that the opposite can be true: the authorization and the statement indicating compliance may be issued after the expiry of the term or even after the SPC itself has expired.

Therefore, if the restrictive interpretation is applied, fulfilment of the requirements for the extension of the SPC would be unjustifiably left to factors that are beyond the applicant’s control—we must not forget that the time necessary to approve a marketing authorization varies significantly from one Member State to the next—despite the applicant acting with all possible diligence in complying with the legal formalities.

Object of the incentive

The reason for which Article 36 of Regulation 1901/2006 aims to compensate pharmaceutical companies is for carrying out studies in accordance with an agreed paediatric investigation plan; that compensation cannot depend on whether the marketing authorization containing the results of those studies has been obtained (and whether, subsequently, the statement indicating compliance is obtained from the competent authorities), which is the conclusion reached by following the restrictive interpretation of Article 8(1)(d)(i) in relation to Article 28.3 of Regulation 1901/2006.

The principle of effet utile developed by the European Court of Justice

Closely connected to the teleological reasons set forth in the previous point—which dealt with the system of incentives established by Regulation 1901/2006—is another argument that Article 8(1)(d)(i) does not introduce restrictions regarding the means for proving compliance with the agreed paediatric investigation plan: the principle of effet utile developed by European Court of Justice case law.

This principle proposes to interpret Community legislation by seeking the greatest efficiency possible for its practical implementation. In our case, it is not hard to conclude that the restriction on the means through which an applicant might prove compliance with the agreed paediatric investigation plan would imply less practical efficacy of Regulation 1901/2006, since it would unjustifiably hinder the envisaged incentive system.

This reasoning is closely connected to the argument already set forth according to which Article 8 of the SPC Regulation does not introduce any additional implicit time limits to those already established under Article 7 of that law, which would end up connecting the existence of the requirements for obtaining the SPC to factors beyond the control of the applicants.

Means of proving compliance

We have already mentioned the role of the Paediatric Committee, the determining body for evaluating the paediatric investigation plan proposed by pharmaceutical companies and subsequently for deciding whether the studies actually carried out by the applicant comply with the agreed paediatric investigation plan. The applicant, the European Medicines Agency and the Committee for Medicinal Products for Human Use may ask the Paediatric Committee to issue an opinion on some of these points. The applicant may even request this opinion before presenting a marketing or variation authorization, under Article 23(2)(a) of Regulation 1901/2006. This should lead to the conclusion that Community legislation considers that the Paediatric Committee’s opinion is a source of reliable information, sufficient for meeting the proof of compliance required by Article 36.1 of Regulation 1901/2006.

Since Community legislation has not drawn up a closed list of means whereby the applicant may prove compliance, the means available for the applicant to evidence the existence of this requisite will depend on the reliability and probative efficacy of the information it contributes.

In this context, a distinction must be made between the information provided by official bodies and that provided by non-official entities. Thus a priori,
information provided by the competent authorities in each Member State for granting marketing authorizations, as well as the opinion of the Paediatric Committee or the European Medicines Agency, constitutes a reliable means for proving compliance. In addition, although there are no reasons for disregarding the statements of the applicants, it is highly likely that such statements will be deemed to be useful additional information, but not suitable information as sole proof of the existence of the requirement of compliance.

**Concept of ‘authorization’ of the drug in ‘all’ Member States**

The third requirement, established in Article 36.3 of Regulation 1901/2006, is that the drug in question be ‘authorized’ in all EU Member States. This requirement also appears in Article 8(1)(d)(ii) of the SPC Regulation. Unlike with the case of the previous requirement, here the literal wording of Article 36.3 of Regulation 1901/2006 and of Article 8(1)(d)(ii) coincide absolutely. Both refer to authorizations in all of the Member States.

In this case, the doubts regarding interpretation that have arisen in relation to this provision have to do with how ‘authorization’ is to be construed in all Member States. The question lies in determining whether the authorizations are authorizations as such, or if they should be qualified in the sense of including the studies carried out according to the agreed paediatric investigation plan. The need for qualified authorizations is the interpretation that the European Commission has supported to date. However, we feel there are solid arguments to defend that authorizations need not necessarily be qualified in order to consider that the requirement of Article 36.3 has been fulfilled.

First, Article 36.3 contains no specification regarding the basis for the ‘authorizations’. Moreover, there are other articles in the same Regulation, such as Article 8.1, in which Community legislation did choose to specify the authorizations, by referring to ‘new indications, including paediatric indications, new pharmaceutical forms and new routes of administration’. This demonstrates that Community legislation did qualify the authorizations in those articles where it felt it was necessary. In contrast, where such specification is not made, there are reasons to justify the position that all granted marketing authorizations can be used to fulfil the requirement under analysis.

The context of Article 8(1)(d)(ii) also supports this position. As we have seen, Article 8.1 sets out what an application for a SPC must contain. The necessary documentation includes a copy of the marketing authorization for the product (given that, according to the provisions of Article 3 of the SPC Regulation, the certificate can only be obtained when the product in question has been authorized for being placed on the market). There are no grounds for justifying the contention that the wording of Article 3 of the SPC Regulation should be understood differently to the wording contained in Article 8 of the same Regulation.

Meanwhile, the application for a marketing authorization for new indications, pharmaceutical forms, or routes of administration (according to Article 8 of Regulation 1901/2006) will not always result in the granting of the authorization. This means that it is not possible to consider the ‘authorization’ in all Member States required by Article 36.3 of Regulation 1901/2006 as a qualified authorization that includes the studies carried out under an agreed paediatric investigation plan. If the term is so understood, certain situations remain unprotected and the applicant—despite having performed studies under a paediatric investigation plan, which is what the Regulation aims to promote—ultimately fails to obtain the marketing authorization for the new indications, pharmaceutical forms, or routes of administration. That is, interpreting the term ‘authorization’ as a qualified authorization (including paediatric studies) again causes confusion in relation to what Community legislation attempts to reward: we must not forget that the compensation is for performing this kind of study, not for obtaining marketing authorizations.

Since the main objective of the Regulation is to provide more (and more reliable) information on the effects of medicinal products on the paediatric population, to achieve this aim, the Regulation establishes a system of incentives for pharmaceutical companies who carry out the necessary studies to obtain this information. Thus, compensation (in the form of the SPC) is for the costs associated with the development of paediatric studies—but under no circumstances for granting or varying marketing authorizations as a result of paediatric studies.

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This shows that the argument that the authorizations that are valid for fulfilling the requirements are the ‘qualified’ authorizations leads to a situation in which the fulfilment of this requirement depends not on the applicant but on circumstances beyond its control (principally, the time it takes each Member State’s competent authority to grant or vary the corresponding marketing authorization), regardless of the diligence shown by the applicant in acting. Thus, if the application for an SPC extension cannot take place until the applicant has obtained the ‘qualified’ authorization in each Member State from its competent authority because this is the only way of fulfilling the requirement set out in Article 36.3 of Regulation 1901/2006 (in relation to Article 8(1)(d)(ii)), the SPC may have expired before all these marketing authorizations have been granted. This risk is obviously greater when we are dealing with a mutual recognition or decentralized procedure.

Although the European Commission maintains that the term ‘product’ in Article 36.3 of Regulation 1901/2006 should be understood as a medicinal product authorized under the agreed paediatric investigation plan (ie that the authorization required in all Member States must be qualified), the Commission recognizes the problems highlighted and is committed to finding a reasonable solution.8

Meanwhile some Patent Offices, such as the French—despite having initially leaned toward the interpretation of the requirement of qualified authorization in all Member States—have recently begun to consider that it is unnecessary to obtain qualified authorization in all States. Indeed, the French Patent Office stated as much to the LEEM—the French pharmaceutical companies’ association— which, on 20 March 2009, issued a Clarification addressed to its members regarding a Circulaire (Communication) published by the LEEM on 24 February 2009.9 This Clarification stated that the French Patent Office does not require qualified authorization in all Member States in order to consider the requirement set out in Article 36.3 of Regulation 1901/2006 fulfilled (unlike the position initially stated in the Circulaire).

Similarly, the Swedish Patent Office has recently evolved towards a more flexible and pragmatic approach in relation to the interpretation of Article 36. In contrast, even those offices responsible for IP that have tended to support the interpretation contrary to the one we are defending—such as the UK Intellectual Property Office—expressly acknowledge, in decisions such as those of 6 February10 and 9 April 200911 (the second having been upheld by the Judgment handed down by the United Kingdom High Court on 22 May 200912), that: (i) the objective of Regulation 1901/2006 is to provide incentives and rewards to companies so they will carry out the paediatric testing of medicinal products, and that (ii) delays on the part of competent authorities in processing an application and granting an updated marketing authorization should not be allowed to prevent applicants obtaining a reward for carrying out an agreed completed paediatric investigation plan and for making the information about this available.

In any event, the existence of this kind of situation—where delays beyond the applicant’s control would prevent it from obtaining the reward granted by Regulation 1901/2006—again apparently contravenes the principle of effet utile, discussed above.

It has been accepted that, regarding the means of evidence available to the applicant to accredit the existence of the marketing authorization in all the Member States, while the most practical solution is for the applicant itself to certify that it has its authorizations, if national Patent Offices prefer not to follow this route they should keep the Biogen case13 in mind, which determined that the applicant can ask the Office to contact the competent authorities in the other Member States to obtain copies of the authorizations, if there are objective reasons to justify that the applicant is not in a position to supply such evidence.

**Time requirement**

Having analysed the three requirements of Article 36 of Regulation 1901/2006, it becomes necessary to consider the moment when the applicant should fulfil these requirements.

Article 7 of the SPC Regulation contains time limits in relation to the lodging of the application for an extension of the SPC, but not regarding the point when the *substantive requirements* must be fulfilled.

Further, Article 3 of the SPC Regulation, in establishing the conditions for issuing SPCs, does state that

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9 LEEM (Les Entreprises du Médicament): Circulaire No. 09-0105 [2009].
the certificate will be issued if certain requirements are fulfilled at the time the application referred to in Article 7 is presented. However, the Regulation contains no equivalent provision for the extension of SPCs. Nor does Article 36 of Regulation 1901/2006 specify a limit as regards the time when the requirements should be fulfilled. This supports the idea that it should be possible to fulfil the substantive requirements for entitlement to an extension of the SPC until the moment the SPC expires. This situation is clearly different to that of the SPC application, when the requirements for obtaining it should be fulfilled at the time the application is filed.

How then can we reconcile the possibility for the applicant to fulfil the requirements up until the moment of expiry of the SPC with the time limit for requesting the extension established in Articles 7.4 and 7.5 of the SPC Regulation? What is required is an appropriate interpretation of Article 10 of the SPC Regulation which strengthens the arguments we have developed throughout this paper.

According to Article 10.3 of the SPC Regulation, when an SPC application fails to fulfil the requirements established in Article 8, the national patent office will call on the applicant to rectify the irregularities. Unless these irregularities are rectified in time, section 4 of the provisions states that the application for the SPC will be rejected.

The interpretation of Article 10(3), however, currently remains controversial among the Community Member States

The interpretation of Article 10(3), however, currently remains controversial among the Community Member States. Thus, while the judgment handed down by the United Kingdom High Court on 22 May 2009 (upholding the UK Intellectual Property Office decision dated 9 April 2009) stated that not all deficiencies in the application for an SPC extension could be described as ‘irregularities’ within Article 10, the decision handed down by the Dutch Patent Office on 2 June 2009 admitted the granting of an SPC extension (protecting the same active ingredient, losartan, as in the case decided by the UK High Court) and accepted that the applicant was entitled to an amendment period as recognized under Article 10(3) of the SPC Regulation.

However, in the Judgment handed down by the United Kingdom Court of Appeal on 17 September 2009 regarding the SPC extension for losartan,14 the Court of Appeal offers a different interpretation of Article 10(3) from that of the United Kingdom High Court in the above-mentioned judgment. Thus, the Court of Appeal essentially agrees with the High Court in its interpretation of the substantive requirements to be met in order to obtain an SPC extension (from which, incidentally, the interpretation defended in this paper differs), but it disagrees as to the applicability of Article 10(3) for the purpose of amending deficiencies in the compliance with these requirements. The Court of Appeal holds that there is no reason for interpreting the term ‘irregularity’ in Article 10(3) restrictively: nothing in its context suggests it, and no Recital or substantive provision in Regulation 1901/2006 sets out this restrictive meaning. Additionally, according to the Court of Appeal, a narrow interpretation of the term does not aid achieving the main objective of Regulation 1901/2006: the development of research for paediatric uses of medicinal products. For these reasons, the Court of Appeal finally concludes that the failure to include all materials set out in Article 8(1) of the SPC Regulation—as interpreted restrictively by the Court—constitutes an irregularity susceptible of being amended pursuant to Article 10.

Meanwhile, Article 10.6 of the SPC Regulation states: ‘paragraphs 1 to 4 shall apply mutatis mutandis to the application for an extension of the duration’. This becomes even more relevant as of the moment any of the national patent offices gives priority to the restrictive interpretation of the two requirements of proof and type of authorization, as opposed to the interpretation we have defended, as it ultimately subjects the granting of the extension to factors that are beyond the applicant’s control. It can be argued that the above-mentioned decision reached by the United Kingdom Court of Appeal responds to this logic.

Therefore, as we have seen, Article 10 of the SPC Regulation should introduce an element of necessary flexibility in the system for granting extensions to SPCs. Its provisions allow the applicant to supply new documentation/information as soon as it is at its disposal (and in those cases in which its initial absence is not attributable to the applicant), meaning that the applicant is allowed to accredit the requirements that lead to the granting of the extension to the SPC, provided that studies have been carried out in accordance

with the agreed paediatric investigation plan. In the procedure for obtaining an SPC extension, factors completely beyond the control of the applicant should have no influence; in other words, at the point of time when the studies have been carried out in accordance with the agreed paediatric investigation plan, the applicant should be entitled to request and obtain an SPC extension, and the procedure for obtaining it before the national patent offices (who should oversee the granting of that right) should be characterized by the necessary flexibility to allow this.

**Underlying logic**

The interpretations defended in this paper sit perfectly with the underlying logic of Regulation 1901/2006, the objective of which is to respond to the need to have medicinal products that are properly adapted to the paediatric population. To obtain the necessary information on the effects of medicinal products on this sector of the population, it is necessary to carry out specific studies in that age group; this will only be possible through the actions of pharmaceutical companies, which Community legislation wants to reward for performing such studies by establishing a system of incentives that includes the right to extend SPCs.

A restrictive interpretation of the requirements set out in Article 36 of Regulation 1901/2006 entails two serious problems for the application of this text: it overlooks that what is behind the recognition of the right to an extension of an SPC is compensation for the performance of studies in the paediatric population; and, by emphasizing the actions of the competent authorities of the Member States, introduces factors that are beyond the control of the applicants when considering whether the requirements set out in Article 36 of Regulation 1901/2006 exist, irrespective of whether applicants may act in the most diligent manner possible.

For these reasons, we consider that (i) the means of accrediting compliance by the studies carried out with the paediatric investigation plan are not limited to the statement indicating compliance set out in Article 28.3 of Regulation 1901/2006; (ii) in order to comply with the requirement of having obtained a marketing authorization in all Member States, it will not be necessary for such authorization to be ‘qualified’, in the sense of having been granted on the basis of studies carried out in accordance with a paediatric investigation plan; and (iii) the two requirements mentioned and contained in Article 36 of Regulation 1901/2006 may be met up to the moment of expiry of the SPC.