



**REGULATION (EC) 469/2009 OF THE
EUROPEAN PARLIAMENT AND OF THE
COUNCIL CONCERNING THE
SUPPLEMENTARY PROTECTION CERTIFICATE
FOR MEDICINAL PRODUCTS**

and

**REGULATION (EC) No 1901/2006 OF THE
EUROPEAN PARLIAMENT AND OF THE
COUNCIL ON MEDICINAL PRODUCTS FOR
PAEDIATRIC USE**

APPLICANT	Chiesi Farmaceutici S.P.A.
ISSUE	Whether the application for a six-month paediatric extension to granted UK supplementary protection certificate SPC/GB11/051 is a valid application
HEARING OFFICER	Dr L Cullen

DECISION

Introduction

- 1 This decision relates to an application, dated 13 July 2019, that was filed by Chiesi Farmaceutici S.P.A (“the applicant”) for a six-month extension to the period of protection provided by the supplementary protection certificate (SPC) granted to the applicant, and accorded the number SPC/GB11/051 (“the SPC”)¹.
- 2 The SPC was granted on 3 March 2016 for the medicinal product ‘Fostair/Formodual’, comprising the active ingredients beclomethasone dipropionate and formoterol fumarate dihydrate (“the product”) which is authorised for the treatment of asthma, where use of a combination product is appropriate. This medicinal product combines

¹ This decision relates to an application for an extension to a granted SPC that was applied for in 2019 and as such it is necessary to apply the relevant law that was in force at that time in the UK. This is set out in the decision below.

a corticosteroid and long-acting *beta*₂-agonist for inhalation. The SPC entered into force on 18 May 2021 and it expired on 13 July 2021. In the UK, this medicinal product is marketed under the FORMODUAL (RTM) name.

- 3 The basic patent on which the granted SPC relies is EP (UK) 1787639 B1 filed on 18 May 2011 and which was granted on 23 March 2011. The basic patent expired on 17 May 2021.
- 4 An authorisation to place the product on the market in the UK was granted on 15 November 2007. The first marketing authorisation for the product in the EU was marketing authorisation 64261.00.00 granted on 14 July 2006 by the national competent authority (NCA) in Germany for granting marketing authorisations, referred to as BfArM (see Annex 2 for Glossary of Terms used in this decision). Regulatory approval for this medicinal product in the EU was gained using the mutual recognition procedure (MRP)². The NCA for Germany acted as the reference member state (RMS) for the MRP.
- 5 On 18 June 2019³ the applicant applied for a six-month extension to the UK SPC which is available under Regulation (EC) No 469/2009 ('the Medicinal Products SPC regulation')⁴. In support of their application, the applicant provided the relevant Patents Form SP4, a copy of the Positive Opinion on compliance with a Paediatric Investigation Plan (PIP)⁵ from the Paediatric Committee of the European Medicines Agency (EMA), a copy of the EMA list of nationally authorised medical products containing the authorised combination of active ingredients⁶, copies of the current marketing authorisation for Ireland, Switzerland and Iceland, and a copy of the grant certificate of the original SPC in UK.
- 6 The examiner in their first examination report on 19 July 2019 stated, "*the application does not meet the conditions for obtaining a certificate or contains irregularities*". The reason given was that the positive opinion of the Paediatric Committee on compliance with a paediatric investigation plan did not constitute an amended marketing authorisation containing a compliance statement as required by Article 8(1)(d)(ii) of Regulation (EC) No 469/2009 ('the Medicinal Products SPC regulation') and Article 36

² See Articles 28 and 29 in Chapter 4, entitled 'Mutual recognition and decentralised procedure', of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

³ The deadline for submitting the application for an extension under Article 7(4) of Regulation (EC) No. 469/2009 in the present case was 13 July 2019.

⁴ Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the creation of a supplementary protection certificate for medicinal products is a codification of Council Regulation (EEC) 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products which had been amended substantially several times. Regulation (EC) 469/2009 supersedes Regulation (EEC) 1768/92. Annex II to Regulation 469/2009 indicates the correlation between the recitals and Articles in Regulation 1768/92 and those in Regulation 469/2009.

⁵ Dated 26 April 2019.

⁶ Dated 9 March 2017.

of Regulation (EC) No 1901/2006 (the 'Paediatric Testing Regulation')⁷. Following the Court of Appeal decision in *E I DuPont de Nemours & Co*⁸ (hereafter '*DuPont*'), the examiner recognised that deficiencies in the application could be rectified by the applicant under Article 10(3) of the Medicinal Products SPC regulation. Consequently, the examiner requested that the applicant provide a copy of an amended UK marketing authorisation that included the compliance statement and also requested confirmation or evidence that the equivalent marketing authorisations in each member state and EEA country had been similarly amended. The applicant was requested to provide this information by 22 November 2019.

- 7 On 5 November 2019, the applicant requested a further extension of two months to the period for responding to the first examination report as which was granted by email on 7 November 2019. A further extension of 2 months was requested on 10 January 2020 as the applicant was still waiting for the national regulatory authorities and the EMA to complete various formal steps following the issuance of the Positive Opinion of the Paediatric Committee of the EMA on compliance with the PIP. The further extension was granted on 14 January with a latest date for reply set for 23 March 2020.
- 8 The BfArM amended the marketing authorisation for Germany to include the statement of compliance on 6 February 2020. On 21 February 2020, the Medicines and Healthcare products Regulatory Authority (MHRA) which is the NCA for the UK, issued the compliance statement and necessary amendments to the UK marketing authorisation. The applicant provided copies of these updated authorisations to the Intellectual Property Office (the Office) on 6 March 2020. However, updated marketing authorisations for all EU member states and EEA countries were not yet available, and a further extension of two months was requested and subsequently granted.
- 9 Between June 2020 and May 2021, there followed a number of rounds of correspondence between the applicant and the examiner where the applicant provided updates regarding the progress and, where they had received them, copies of the amended marketing authorisations that had been issued⁹. On each occasion a further extension of time was requested (and subsequently granted) to allow time to obtain the remaining authorisations.
- 10 On 23 June 2021, the applicant confirmed that marketing authorisations had been amended in all EU member states and EEA countries save for Romania and Portugal. The applicant summarised the position in both countries and also provided emails between their local representatives and the regulatory authorities in Romania¹⁰ and

⁷ Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for Paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004.

⁸ *E I Du Pont De Nemours & Co v UK Intellectual Property Office* [2009] EWCA Civ 966, reported as [2010] R.P.C. 6. (see also <http://www.bailii.org/ew/cases/EWCA/Civ/2009/966.html>)

⁹ Applicant's letters dated 25 June 2020, 13 November 2020, 21 January 2021, 18 March 2021 and 18 May 2021. UK IPO responses dated 25 June 2020, 17 November 2020, 25 January 2021, 24 March 2021 and 19 May 2021.

¹⁰ Emails dated 13 May 2020 and 12 November 2020.

Portugal¹¹ as evidence of the efforts they were making to obtain the outstanding authorisations.

- 11 They further observed that the extension request had been granted by the Romanian Patent Office, despite the updated authorisation not being available. They requested a further short extension of time in this letter as *“it is hoped that the remaining documents will become available very soon.”* In response to this, two further short extensions were granted, until the 5 July 2021 and then 12 July 2021. However, by the end of this last extension of time the outstanding amended marketing authorisations had not been obtained.
- 12 On 12 July 2021, the applicant confirmed that they were still awaiting issuance of updated marketing authorisations in Romania and Portugal. The applicant noted that the SPC would expire on 13 July 2021 and set out detailed reasons why the examiner could, and should, exercise discretion to extend the term for providing evidence of the updated marketing authorisations in Romania and Portugal beyond 13 July 2021. On the same day, the examiner issued their second examination report in which they disagreed with the applicant’s arguments and held that an extension beyond the expiry date of the SPC was not possible. In the examiner’s view that application should be refused under Article 10(4) of the Medicinal Products SPC regulation. The applicant was invited to request a hearing, which they subsequently did.
- 13 In advance of the hearing, on 17 and 31 August 2021, the Office wrote to the agent on behalf of the Hearing Officer and requested that the applicant be prepared to address a number of issues in their submissions before or at the hearing. A skeleton argument and supporting documents were filed by the agent on behalf of the applicant on 3 September 2021. This material was very helpful and I would like to record my thanks to the applicant for it in advance of the hearing.
- 14 The matter came before me at an oral hearing on 10 September 2021. The applicant was represented at the hearing by Mr Daniel Selmi of Three New Square (instructed by J A Kemp LLP). Dr Laura Starrs was in attendance as assistant to the hearing officer.
- 15 As agreed at the hearing, the applicant provided some additional material after the hearing relating to the interaction between the applicant and the national competent authorities for granting marketing authorisations in the two outstanding member states – Romania and Portugal. This consisted primarily of copies of email correspondence between the applicant (or their representative in the respective country) and the respective NCA.
- 16 The applicant wrote to the Office by email dated 3 November 2021 and enclosed a copy of the compliance statement for Romania dated 28 October 2021 confirming that the marketing authorisation in that country had been updated with all the necessary details related to testing in the paediatric population.
- 17 The applicant wrote again to the Office by email dated 17 November 2021 and enclosed a copy of the compliance statement for Portugal confirming that the marketing authorisation in that country had been updated with all the necessary details

¹¹ Emails dated 24 November 2020, 9 December 2020, 16 March 2021 and 15 June 2021.

related to testing in the paediatric population. The applicant also stated in this email correspondence that this was the final PIP compliance statement and that “*PIP compliance statements for all EU/EEA countries had been submitted.*” They then went on to state “*The outstanding formal requirements for grant of the paediatric extensions have therefore now been satisfied*”.

Issue to be decided

- 18 The question before me is whether the irregularity identified under Article 10 of the Medicinal Products SPC Regulation in the present application for a six-month extension to the SPC can be cured after the expiry date of the SPC on which this application is based.
- 19 As identified by the examiner, the irregularity to be addressed is the absence of proof that the applicant possessed an updated marketing authorisation and the necessary compliance statement in all other EU member states as required under Article 8(1)(d)(ii) of this regulation at the expiry date of the SPC. Proof for two member states (Romania and Portugal) was not provided.
- 20 I note that the applicant was able to provide proof of the possession of these final two authorisations within the six-month period immediately following the expiry date of the SPC, which if the paediatric extension (PE) was granted, it would take effect.

The Relevant Law

- 21 In this case, we are concerned with the Medicinal Products SPC Regulation⁴ and the Paediatric Testing Regulation⁷ in the form in which both EU regulations applied in the UK when this application for a PE was made. I have reproduced the relevant parts of this EU legislation below (with my emphasis added in **bold**).
- 22 It is a common tenet of EU law that it is defined having regard to both the purpose of the relevant legislation - as set out in the recitals - and the substance of this legislation - as set out in the articles.

The Medicinal Products SPC Regulation – EC Regulation 469/2009

- 23 Article 8(1)(d) of the Medicinal Products SPC Regulation entitled “*Content of the application for a certificate*” sets out the requirements for the grant of a six-month extension to the duration of an SPC as follows:

Article 8

Content of the application for a certificate

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;

(ii) where necessary, in addition to the copy of the authorisation to place the product on the market as referred to in point (b), proof of possession of authorisations to place the product on the market of all other Member States, as referred to in Article 36(3) of Regulation (EC) No 1901/2006.

- 24 Article 9 of the Medicinal Products SPC Regulation entitled “*Lodging of an application for a certificate*” indicates that applications for a paediatric extension (PE) to an SPC are dealt with by the competent industrial property office of the member state concerned:

Article 9

Lodging of an application for a certificate

1. The application for a certificate shall be lodged with the competent industrial property office of the Member State which granted the basic patent or on whose behalf it was granted and in which the authorisation referred to in Article 3(b) to place the product on the market was obtained, unless the Member State designates another authority for the purpose.

The application for an extension of the duration of a certificate shall be lodged with the competent authority of the Member State concerned.

2...

The relevant competent industrial property office is responsible for deciding whether a PE can be granted in the respective member state. In the UK, the competent industrial property office of the member state which granted the basic patent, is the Intellectual Property Office (IPO) of the United Kingdom of Great Britain and Northern Ireland (the Office)

- 25 Article 10 of the Medicinal Products SPC Regulation entitled “*Grant of the certificate or rejection of the application for a certificate*” sets down the conditions necessary for the grant or rejection of an application for an extension to an SPC and for the correction of irregularities:

Article 10

Grant of the certificate or rejection of the application for a certificate

1. Where the application for a certificate and the product to which it relates meet the conditions laid down in this Regulation, the authority referred to in Article 9(1) shall grant the certificate.

2. The authority referred to in Article 9(1) shall, subject to paragraph 3, reject the application for a certificate if the application or the product to which it relates does not meet the conditions laid down in this Regulation.

3. Where the application for a certificate does not meet the conditions laid down in Article 8, the authority referred to in Article 9(1) shall ask the applicant to rectify the irregularity, or to settle the fee, within a stated time.

4. If the irregularity is not rectified or the fee is not settled under paragraph 3 within the stated time, the authority shall reject the application.

5. Member States may provide that the authority referred to in Article 9(1) is to grant certificates without verifying that the conditions laid down in Article 3(c) and (d) are met.

6. Paragraphs 1 to 4 shall apply mutatis mutandis to the application for an extension of the duration.

26 Article 11 of the Medical Products SPC Regulation, entitled “*Publication*”, sets out requirements for the relevant authority (in this case UK IPO) to publish the fact that an extension for an SPC has been granted or rejected. Specifically, Article 11 states:

Article 11

Publication

1. Notification of the fact that a certificate has been granted shall be published by the authority referred to in Article 9(1). The notification shall contain

...

2. Notification of the fact that the application for a certificate has been rejected shall be published by the authority referred to in Article 9(1). The notification shall contain at least the information listed in Article 9(2).

3. Paragraphs 1 and 2 shall apply to the notification of the fact that an extension of the duration of a certificate has been granted or of the fact that the application for an extension has been rejected

The relevant authority, as set down in Article 9 (see above), is the Office.

27 Article 13 entitled ‘Duration of the certificate’ sets down how to work out the duration of an SPC. It sets down that the maximum period that an SPC can take effect is 5 years and 6 months. The maximum term for the SPC itself 5 years with the additional possibility of one six-month extension for successfully completing the paediatric testing requirements set down in the Paediatric Testing Regulation (see below):

Article 13

Duration of the certificate

1. The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the Community, reduced by a period of five years.

2. Notwithstanding paragraph 1, the duration of the certificate may not exceed five years from the date on which it takes effect.

3. The periods laid down in paragraphs 1 and 2 shall be extended by six months in the case where Article 36 of Regulation (EC) No 1901/2006 applies. In that case, the duration of the period laid down in paragraph 1 of this Article may be extended only once.

4.

28 Article 19, entitled “*Procedure*”, as set down below indicates that in the absence of any specific procedural provisions under national law for dealing with SPCs, the provisions in force for dealing with the basic patent, will apply to SPCs.

Article 19

Procedure

1. *In the absence of procedural provisions in this Regulation, the procedural provisions applicable under national law to the corresponding basic patent shall apply to the certificate, unless the national law lays down special procedural provisions for certificates.*

2.

The Paediatric Testing Regulation – EC Regulation 1901/2006

29 Recital (4) of the Paediatric Testing Regulation sets out the aims of this Regulation as follows:

This Regulation aims to facilitate the development and accessibility of medicinal products for use in the paediatric population, to ensure that medicinal products used to treat the paediatric population are subject to ethical research of high quality and are appropriately authorised for use in the paediatric population, and to improve the information available on the use of medicinal products in the various paediatric populations. These objectives should be achieved without subjecting the paediatric population to unnecessary clinical trials and without delaying the authorisation of medicinal products for other age populations

30 Article 28 of this regulation explains the purpose and circumstances under which a compliance statement is issued indicating that the marketing authorisation has been updated to include all the details and results of the studies conducted on the paediatric population.

Article 28

1. Applications may be submitted in accordance with the procedure laid down in Articles 5 to 15 of Regulation (EC) No 726/2004 for a marketing authorisation as referred to in Article 7(1) of this Regulation **which includes one or more paediatric indications on the basis of studies conducted in compliance with an agreed paediatric investigation plan.**

Where authorisation is granted, the results of all those studies shall be included in the summary of product characteristics and, if appropriate, in the

package leaflet of the medicinal product, provided that the competent authority deems the information to be of use to patients, whether or not all the paediatric indications concerned were approved by the competent authority.

2. Where a marketing authorisation is granted or varied, any waiver or deferral which has been granted pursuant to this Regulation shall be recorded in the summary of product characteristics and, if appropriate, in the package leaflet of the medicinal product concerned.

3. If the application complies with all the measures contained in the agreed completed paediatric investigation plan and if the summary of product characteristics reflects the results of studies conducted in compliance with that agreed paediatric investigation plan, the competent authority shall include within the marketing authorisation a statement indicating compliance of the application with the agreed completed paediatric investigation plan. For the purpose of the application of Article 45(3), this statement shall also indicate whether significant studies contained in the agreed Paediatric Investigation Plan have been completed after the entry into force of this Regulation.

The competent authority referred to in Article 28(3) is the body responsible for granting marketing authorisations. In the circumstances of this case, this is the national competent authority who grants marketing authorisations valid in that member state. For example, the MHRA is the national competent authority that grants marketing authorisation valid in the UK. This body is also responsible for producing the compliance statement, i.e. the statement indicating that the marketing authorisation complies with all the measures contained within the agreed completed PIP. In order to provide the compliance statement, the competent authority has to ensure that the summary of product characteristics (SmPC) has been updated to include the details and results of the studies conducted on the paediatric population in compliance with the agreed PIP.

- 31 In Article 36 of the Paediatric Testing Regulation the rewards and incentives for carrying out the necessary testing in the paediatric population and incorporating details of the outcome of this testing – whether the active substance does or does not have a beneficial impact in this population - are identified as follows:

TITLE V

REWARDS AND INCENTIVES

Article 36

1. 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.

The first subparagraph shall also apply where completion of the agreed paediatric investigation plan fails to lead to the authorisation of a paediatric indication, but the results of the studies conducted are reflected in the summary of product

characteristics and, if appropriate, in the package leaflet of the medicinal product concerned.

2. The inclusion in a marketing authorisation of the statement referred to in Article 28(3) shall be used for the purposes of applying paragraph 1 of this Article.

3. Where the procedures laid down in Directive 2001/83/EC have been used, the six-month extension of the period referred to in paragraph 1 shall be granted only if the product is authorised in all Member States.

4. Paragraphs 1, 2 and 3 shall apply to products that are protected by a supplementary protection certificate under Regulation (EEC) No 1768/92, or under a patent which qualifies for the granting of the supplementary protection certificate. They shall not apply to medicinal products designated as orphan medicinal products pursuant to Regulation (EC) No 141/2000.

5. ...

Council Regulation (EEC) 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products was codified and replaced by Regulation (EC) 469/2009 (see footnote 4).

The Patents Act 1977

32 The procedural provisions that apply to SPCs under UK law are found in the Patents Act 1977, as amended, (hereinafter referred to as “the Act”) and its related Rules, the Patent Rules 2007, as amended (hereinafter referred to as “the Rules”).

33 Section 128B of the Act provides as follows:

Supplementary protection certificates

128B.-(1) Schedule 4A contains provision about the application of this Act in relation to supplementary protection certificates and other provision about such certificates.

(2) In this Act a “supplementary protection certificate” means a certificate issued under –

(a) Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6th May 2009 concerning the supplementary protection certificate for medicinal products, or

(b).....

34 Paragraphs 1(1) and 1(2) of Schedule 4A set down which of provisions of the Act apply to applications for extensions of the duration of an SPC:

SCHEDULE 4A (section 128B)

SUPPLEMENTARY PROTECTION CERTIFICATES

References to patents etc

1.-(1) In the application to supplementary protection certificates of the provisions of this Act listed in sub-paragraph (2) –

(a) references to a patent are to a supplementary protection certificate;

(b) references to an application or the applicant for a patent are to an application or the applicant –

(i) for a supplementary protection certificate, or

(ii) for an extension of the duration of a supplementary protection certificate

.....

(2) The provisions referred to in sub-paragraph (1) are –

.....

sections 117 to 118 (administrative provisions);

section 123 (rules);

...

35 Thus, the provisions that are applied to applications for an extension to the duration of an SPC include Section 117B:

Extension of time limits specified by comptroller

117B.-(1) Subsection (2) below applies in relation to a period if it is specified by the comptroller in connection with an application for a patent, or a patent.

(2) Subject to subsections (4) and (5) below, the comptroller shall extend a period to which this subsection applies if –

(a) the applicant or the proprietor of the patent requests him to do so; and

(b) the request complies with the relevant requirements of rules.

(3) An extension of a period under subsection (2) above expires –

(a) at the end of the period prescribed for the purposes of this subsection, or

(b) if sooner, at the end of the period prescribed for the purposes of section 20 above.

(4) If a period has already been extended under subsection (2) above –

(a) that subsection does not apply in relation to it again;

(b) the comptroller may further extend the period subject to such conditions as he thinks fit.

(5) Subsection (2) above does not apply to a period specified in relation to proceedings before the comptroller.

A period may be extended only once under s.117B(2); further extensions are at the comptroller's discretion and may be subject to conditions. A request for a further extension should include a statement of reasons for the request.

- 36 Section 117B(2) of the Act indicates that a request under this section has to comply with the relevant "*requirements of the rules*". Paragraphs 1(1) and 1(2) to Schedule 4A of the Act also apply Section 123, entitled 'Rules', to applications for paediatric extensions. Section 123(1) and 123(3A) of the Act read as follows:

Rules

123.-(1) The Secretary of State may make such rules as he thinks expedient for regulating the business of the Patent Office in relation to patents and applications for patents (including European patents, applications for European patents and international applications for patents) and for regulating all matters placed by this Act under the direction or control of the comptroller; and in this Act, except so far as the context otherwise requires, "prescribed" means prescribed by rules and "rules" means rules made under this section.

.....

(3A) It is hereby declared that rules –

(a) authorising the rectification of irregularities of procedure, or

(b) providing for the alteration of any period of time, may authorise the comptroller to extend or further extend any period notwithstanding that the period has already expired.

.....

- 37 For the purposes of the present case, Rules 107 and 109 of the Rules are relevant.
- 38 Rule 109 of the Rules refers to Section 117B(2) of the Act (see above) and provides more detail on how requests for extensions of time are to be made. The rule reads as follows:

Extension of time limits specified by comptroller

109.—(1) A request under section 117B(2) must be—

(a) made in writing; and

(b) made before the end of the period prescribed by paragraph (2).

(2) The period prescribed for the purposes of section 117B(3) is two months beginning immediately after the expiry of the period to which section 117B(2) applies.

Thus, the applicant (or proprietor) for the patent is entitled to one request for a single extension of a period that is specified by the comptroller in connection with the application or patent, provided that the requirements of r.109(1) are satisfied, i.e., that the request is made in writing (e.g. by letter or email) and is made before the end of the extended period.

- 39 Rule 107 of the Rules makes provision for the correction of irregularities and reads as follows:

Correction of irregularities

107.—(1) Subject to paragraph (3), the comptroller may, if he thinks fit, authorise the rectification of any irregularity of procedure connected with any proceeding or other matter before the comptroller, an examiner or the Patent Office.

(2) Any rectification made under paragraph (1) shall be made—

(a) after giving the parties such notice; and

(b) subject to such conditions, as the comptroller may direct.

(3) A period of time specified in the Act or listed in Parts 1 to 3 of Schedule 4 (whether it has already expired or not) may be extended under paragraph (1) if, and only if—

(a) the irregularity or prospective irregularity is attributable, wholly or in part, to a default, omission or other error by the comptroller, an examiner or the Patent Office; and

(b) it appears to the comptroller that the irregularity should be rectified.

Relevant Case Law

UK Court Decisions

- 40 The most relevant UK authority on correction of irregularities in an application for a paediatric extension to an SPC is the Court of Appeal judgement in *DuPont*⁸ which I will summarise in more detail below.
- 41 The applicant's representative referred to several other UK Court judgements in both the skeleton arguments and at the oral hearing. I shall refer to these as necessary at the relevant points in the discussion below.

*E I DuPont De Nemours & Co v UK Intellectual Property Office (DuPont)*⁸

- 42 The case in *DuPont* was about an application for a PE to an SPC for a medicine called losartan. *DuPont* applied for a patent for losartan on 9 July 1987 and the patent expired 20 years later, on 9 July 2007. The first marketing authorisation (MA) to place losartan on the market within the EU was granted on 26 September 1994 by the Danish regulatory authority. MAs for each other EU Member State were subsequently granted using the MRP². *DuPont* applied in the UK and 12 other Member States for

an SPC. An SPC was granted in all states. The SPCs were due to expire on 1 September 2009.

43 On 18 February 2009, *DuPont* applied for paediatric extensions in the UK and 12 other Member States. Extensions were granted in 8 out of the 13 states and refused in none, save for the UK.

44 The UK IPO¹² rejected the application for an extension on the grounds that the relevant criteria had not been satisfied at the date of application. Specifically, the application was found to be deficient because:

(i) the application did not contain a Marketing Authorisation containing a statement of compliance with a paediatric investigation plan (PIP) as referred to in Article 28(3) of the Paediatric Testing Regulation;

and

(ii) the product was not authorised in all Member States as required by Article 36(3) of Paediatric Testing Regulation.

45 At the time of application for this extension, *DuPont* could not provide an updated marketing authorisation containing a statement of compliance with a PIP because none existed until it was issued by the Dutch reference authority on 9 April 2009. Connected to this, *DuPont* did not acquire the modified marketing authorisations in all member states until 9 August 2009.

46 The applicant appealed to the Patents Court¹³ which dismissed the appeal. When the subsequent appeal came before the Court of Appeal, the information necessary to overcome the identified defects was available and could be provided by the applicant.

47 The Court of Appeal in considered whether the defects could be corrected after the date of application for the extension of the SPC. In doing so the Court, at paragraphs [37] and [38] of its judgment, stated the aims and objectives of the Medicinal Products SPC Regulation as follows:

“37 First that the aims and objectives of the Regulation are three-fold as set out in the key recital (4). They are:

(i) To facilitate the development and accessibility of medicinal products for use in the paediatric population.

(ii) To ensure that medicinal products that are used to treat the paediatric population are subject to ethical research of high quality and are appropriately authorised for use in the paediatric population.

(iii) To improve the information available on the use of medicinal products in the various paediatric populations.

¹² For full text of IPO decision BL O/096/09 (E I du Pont de Nemours & Co.), see IPO decision database on IPO website [here](#)

¹³ See decision [2009] EWHC 1112(Ch) from Patents Court dated 22 May 2009 reported as [2010] R.P.C. 5.

And these objectives are to be achieved by the following substantive requirements:

- (1) All the measures in the agreed PIP must have been complied with [Recitals 9-11, 17, 26; Arts. 7-8, 28(3), 36(1); Explanatory Memorandum].
- (2) The authorised product information must include relevant information on the results of the studies [Recitals 17, 26, 28; Arts.28(3), 36; Explanatory Memorandum].
- (3) The product must be authorised in all Member States [Recitals 17, 21, 26; Art. 36(3); all travaux].

38 *I accept those submissions. I think they are inescapable. Mr Purvis tried to answer the need for dissemination of information point by showing us other provisions for dissemination of information. **But in the end it is what is on and in the packet which counts. And that is not determined finally until the MA is settled.***

48 The Court of Appeal held that the defects in the application were irregularities which could be corrected according to Article 10(3) of the Medicinal Products SPC Regulation. The Courts reasoning at paragraphs [51] – [58] is important in the present case and I have reproduced it below (my emphasis added):

51 *I see no reason for giving "irregularity" such a restrictive meaning and every reason to give it a wide enough meaning to encompass cases such as the present where the defect is cured after the date of application.*

52 *Firstly and most tellingly, all the Recitals and the Explanatory Memorandum which Miss May deployed so effectively in persuading me on the first two points turn against her argument on this point. For they are all about the reward of an extension being made available if the applicant complies with its PIP and gets the necessary MAs. The reward is for that, not for doing all that before the application is made.*

53 *Most tellingly there is no Recital or other material indicating everything must be in the application or capable of being in the application by the date it must be made.*

54 *Moreover if she were right, then the problem of the laggard Member State would be significant and it would be unrealistic to think that the Community legislator was so innocent as to think that all Member States would be certain to get it right within the 90 days provided for. There is no indication of any intention that the reward should be contingent upon all Member States doing the right thing in time. And no indication that the legislator intended to draw a distinction between what might be called a "mere irregularity" and something more fundamental.*

55 *Nor do I think her point about the last dates for an application particularly telling. She sought to allay it with a point about certainty for third parties, submitting that competitors should be in a position to know where they stand at an early date. But there is nothing about that in either Regulation. The nearest Miss May could point to was the first sentence of ninth Recital of the SPC Regulation codified version):*

"All the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should nevertheless be taken into account."

That is far from saying that everything must be complete by the date of the application.

- 56 *The "third party certainty" point is further undermined by the fact **that there is no requirement that third parties shall be entitled to see sufficient of the details of the application to form a view as to whether it will succeed.** Or any of the details of an application for an MA or a variation of an MA. Nor is there any requirement that a national authority must come up with a decision by a particular time after the application. So third parties must wait for an indeterminate time — which on any view may include an Art. 10(3) time extension — before knowing the result of the application for an extension.*
- 57 *Besides, on any rational view, the importance of research into paediatric uses of medicines stands ahead of the purely commercial interests of third parties. The importance of that research being conducted and the results disseminated is the whole point of the Paediatric Regulation. A narrow construction of "irregularity" is inimical to that fundamental purpose.*
- 58 *Miss May indicated that, for future guidance, it would be helpful for the Comptroller to know **just how late an applicant can be in supplementing its application with missing material. As at present advised (and of course this is strictly a question not before us) I would only say this: that in setting the Art. 10(3) period the Comptroller can and should take into account all relevant factors.** These will include the reasons for the failure to include all the Art.8(l) materials in the application, the extent to which the applicant is guilty of unreasonable conduct or delay, and how close to the date of expiry of the SPC full compliance with Art.8(l) is expected. **The guiding principle is the purpose of the Regulation. The upshot is that unless the applicant has behaved unreasonably, time should be extended so that it gets its reward.***

Analysis

- 49 At the expiry date of the SPC, the applicant was able to provide an updated marketing authorisation to place the medicinal product 'Fostair/Formodual' on the market in the UK which included a statement of compliance with an agreed paediatric investigation plan and was also able to provide proof of the possession of an updated authorisation with the necessary compliance statement provided by the relevant national competent authority in all but 2 EU states – Romania and Portugal.
- 50 The period of the applied for paediatric extension in question in this case would run from 14 July 2021 to 13 January 2022 if granted. As noted above, although the applicant was not able to provide the necessary proof for the remaining member states before the expiry date of the SPC, they were able to do so within the period that any such paediatric extension would be in effect.

The View of the Applicant

- 51 It is the view of the applicant that the comptroller has discretion to extend the deadline for correcting irregularities in the application for a paediatric extension beyond the expiry date of the SPC and that such discretion should be applied in the present case.
- 52 The essential points of their argument as follows:
- (i) An unexpired SPC is not one of the basic conditions for obtaining an extension under the Regulations
 - (ii) Domestic legislation allows the comptroller to extend time limits (even those that have expired)
 - (iii) If discretion was exercised as proposed, the extended SPC would expire on the same day as it would have done if granted under a subsisting SPC (i.e., the applicant would not get any more time than they are entitled under Article 13(3) of the Medicinal Products SPC Regulation)
 - (iv) The reference to the “*improbably extreme case*” in para 43 of *DuPont* refers to the scenario where discretionary factors point against grant (e.g., the applicant had behaved unreasonably) and not the scenario as in this case where factors are beyond the applicant’s control. The Court of Appeal in *DuPont* considered (in paras 53-54) that there was nothing in the Paediatric Testing Regulation to suggest that the reward available “*should be contingent upon all Member States doing the right thing in time*”.
 - (v) When asked for guidance on how late an application for a paediatric extension can be supplemented to provide missing material, the Court of Appeal in *DuPont* did not say that expiry of the SPC was fatal. Furthermore, the comments from the Court of Appeal in response to this request for guidance are *obiter* (see para 58). Therefore, *DuPont* does not fetter the comptroller’s discretion in relation to this situation at issue in the present case.

The View of the Examiner

- 53 The examiner’s view¹⁴ is that the present application for an extension should be refused under Article 10(4) of the Medicinal Products SPC Regulation because the irregularities identified in the application have not been rectified. The irregularities that were not resolved are the provision of updated marketing authorisations for Portugal and Romania as required by Article 8(1)(d)(ii) of the Medical Products SPC Regulation.
- 54 Taking account of the decision in *DuPont* the examiner considered that the missing marketing authorisations was an irregularity that could be rectified under Article 10(3) and during prosecution of the application several extensions of time were granted. However, the examiner did not consider that any further extensions of time, beyond the expiry date of the SPC, could be allowed.

¹⁴ See pre-hearing report of 26 July 2021

- 55 The examiner highlighted comments in paragraph [11] of the *DuPont* judgement where the Court recognised that it was not clear that an SPC can be extended after it's expiry. The examiner concluded that reference to how close to the date of expiry of the SPC full compliance is expected to mean that the expiry date must be taken into account and that compliance before expiry is required.

Interpretation of DuPont

- 56 The fact that it is possible to rectify the application for an extension of an SPC after the deadline under Article 7 of the Medicinal Products SPC Regulation for submitting the application is not in dispute. This has been clearly established by the Court of Appeal's decision in *DuPont*¹². What is in question however is whether or not irregularities in the application can be rectified after the expiry of the SPC. In addition, I would have to add that any such rectification would have to take place within the six-month period that a paediatric extension would be in effect. The maximum period that an SPC can be in force is 5 years and 6 months as set down in Article 13 of the Medicinal Products SPC Regulation.
- 57 To come to a conclusion on this question I must consider what in law is actually established by *DuPont*. The applicant would have me interpret the fact that *DuPont* does not explicitly mention a cut-off date by which irregularities must be rectified as an indication that the deadline may be extended beyond the expiry date of the SPC.
- 58 It seems to me that *DuPont* only establishes that correction of deficiencies under Article 10(3) is permitted. I cannot agree with the applicant's broader interpretation. The fact that *DuPont* is silent on the possibility of rectifying the application for an extension after the expiry of the SPC is not in my view permission to allow rectification post-expiry. Equally, I accept that *DuPont* does not say that post-expiry rectification is not allowed. The question of whether rectification post SPC expiry was allowed did not need to be answered in *DuPont* because the appeal had been expedited and an oral decision was delivered on the day of the hearing to allow matters to be resolved before the expiry of the SPC in question occurred. Jacob LJ noted at paragraph [11] of the judgment that "*it is not clear whether an SPC can be extended after it has expired*". I accept, as the applicant pointed out, that this comment was not part of the *ratio* of the decision.
- 59 When invited to make a clear statement on how late an application for an extension could be corrected in order to provide assistance to the Comptroller, the Court indicated, in paragraph 58 of the judgement, that "*the Comptroller can and should take into account all relevant factors.*" It went on to say that these factors will include "*the reasons for the failure to include all the Art.8(l) materials in the application, the extent to which the applicant is guilty of unreasonable conduct or delay, and how close to the date of expiry of the SPC full compliance with Art.8(l) is expected.*" The applicant would have me interpret this latter instruction to consider how close to the date of expiry of the SPC as meaning how close after expiry as well as how close before expiry full compliance of the SPC application with Article 8(1) is expected. They emphasise the comment from the Court of Appeal in paragraph [58] of *DuPont* that the "*guiding principle is the purpose of the Regulation. The upshot is that unless the applicant has behaved unreasonably, time should be extended so that it gets its reward.*" This they argue means that the applicant who has behaved reasonably should receive their reward irrespective of whether the SPC has expired or not.

60 I do not consider that matters are as clear cut as the applicant argues. Based on this argument, I do not think that I can clearly conclude that the Court of Appeal in *DuPont* intended for the time-period for correction of deficiencies to be extended after the expiry of the SPC. This was not a question that was before the Court of Appeal in *DuPont* to answer. The comments in paragraphs 11 and 58 are suggestive that the Court was not clear that granting a paediatric extension post-expiry was possible. Thus, the most I can draw from *DuPont* is that such post-expiry extensions are neither allowed nor disallowed. Their possibility is acknowledged – but it was not necessary to decide the issue in *DuPont*.

The Present Case

61 The facts of the present case are different to those in *DuPont*. In *DuPont*, the SPC had not yet expired and it is in the context of this scenario that the factors listed in paragraph 58 should be taken into account by the Comptroller. It is, in my view, a stretch to assume the present scenario of being close to but after the expiry date should be treated in the same manner as being close to but before the expiry date of the SPC

62 In the present case, the SPC has already expired and the proofs that authorisations are available in all member states was not available at the expiry date of the SPC. They only became available approximately 4 months after this expiry date - in November 2021 (see above). I have considered both sets of documents. I am satisfied that, if accepted, they would fulfil the requirement under Art 8(1)(d)(ii) to demonstrate the necessary proof of updated authorisations in these member states, i.e. they would rectify the irregularity identified by the examiner. Thus, this case turns on the whether or not all the requirements for grant of the paediatric extension have to be fulfilled before the expiry date of the SPC or whether they can be deemed fulfilled if provided in the 6 month period immediately after expiry of the SPC when a paediatric extension, if granted, would be in force.

63 The situation at issue in this case appears to have arisen because the NCAs responsible for granting marketing authorisations and providing the necessary compliance statement under Article 28(3) of the Paediatric Testing Regulation appear to have taken much longer than is expected to complete the steps they are responsible for under the MRP. Thus, the situation appears to have arisen because of the behaviour of the NCAs from the member states concerned and not from the behaviour of the applicant. As a result, it would appear that the applicant has an arguable case that circumstances beyond their control outside the UK would appear to be preventing them from gaining the reward under the Paediatric Testing Regulation in the UK.

Requirement for an Updated Marketing Authorisation in all EU Member States

64 As already mentioned, the court in *DuPont* concluded that the applicant for a paediatric extension must be able to show that their application meets both requirements of Article 8(1)(d) of the Medicinal Products SPC regulation. The applicant for a PE in the UK must be able to provide a statement confirming compliance with all the requirements of the paediatric investigation plan (PIP) in the UK as required under Article 8(1)(d)(i) of the Medicinal SPC regulation which, in turn, refers specifically to Article 36(1) of the Paediatric Testing Regulation. In addition, the applicant for a PE in the UK must be able to provide “*proof of possession of authorisations to place the*

product at issue on the market of all other member states” of the European Union that includes the details of the testing in the paediatric population as required under Article 8(1)(d)(ii) of the Medicinal Products SPC regulation which, in turn, refers specifically to Article 36(3) of the Paediatric Testing Regulation.

- 65 The applicant confirmed that this requirement was clear and that they were not attempting to argue to the contrary. They noted however that the competent industrial property office in some of the Member States had granted a PE even though an updated marketing authorisation in that member state had not yet been delivered by the relevant NCA for granting marketing authorisations in that member state. They referred specifically to the action of the competent industrial property office (IPO) of Romania in this regard. In the letter to the Office dated 23 June 2021, the applicant reports that the competent IPO in Romania had recently granted a paediatric extension (PE) to the SPC in Romania. The applicant further commented that “*The actions of the Romanian Patent Office may reflect a recognition that ANMDM RO does not act quickly and that the applicant should not be penalised for delays beyond its control*”. Thus, the competent IPO in Romania was apparently satisfied that the applicant should be granted a PE even through the counterpart agency in Romania responsible for granting the updated marketing authorisation with the necessary compliance statement (ANMDM-RO) had not yet completed this task.

Grant of Paediatric Extension in Romania before Updated Marketing Authorisation available

- 66 While I recognise that under Article 10, the competent industrial property office in Romania is responsible for deciding whether or not, and under what circumstances, to grant a paediatric extension application in that jurisdiction, in the UK, I am bound by the decision of the Court of Appeal in *DuPont* which requires that evidence of an updated marketing authorisation in all member states is necessary in order to qualify for the reward. Therefore, the flexibility shown by the Romanian IPO (as it was termed by the applicant at the hearing and in the above-mentioned letter), is not available to me when determining the issue in the UK. As stated in *DuPont*, at paragraphs [37] and [38] (especially “...*in the end it is what is on and in the packet which counts. And that is not determined finally until the MA is settled*”), it is necessary for the applicant to have proof that the marketing authorisation has been updated in all other member states in addition to the UK, before the reward can be granted in the UK. The consequences of this is that the applicant is in danger of being denied the paediatric extension in the UK because of delays by the NCAs responsible for providing updated marketing authorisations in other EU member states.

Requirements and Purpose of the Regulations

- 67 The applicant has argued that an unexpired SPC is not one of the requirements for obtaining an extension under the relevant legislation. The requirements for obtaining a paediatric extension are set out across a number of different provisions in the Medical Products SPC Regulation and the Paediatric Testing Regulation: specifically Articles 7(4), 8(d)(i) and 8(d)(ii) of the Medicinal Products SPC Regulation and Articles 7, 8, 28 and 36 of the Paediatric Testing Regulation. The Court of Appeal has also confirmed these requirements in the judgement in *DuPont* and Mr Selmi very helpfully summarised them in the skeleton argument and at the oral hearing as follows:

(1) *All the measures in the agreed PIP must have been complied with [Recitals 9-11, 17, 26; Arts. 7-8, 28(3), 36(1); Explanatory Memorandum].*

(2) *The authorised product information must include relevant information on the results of the studies [Recitals 17, 26, 28; Arts.28(3), 36; Explanatory Memorandum].*

(3) *The product must be authorised in all Member States [Recitals 17, 21, 26; Art. 36(3); all travaux].*

- 68 Mr Selmi argued that, crucially, an unexpired SPC does not feature among these basic conditions for obtaining a paediatric extension. Furthermore, Mr Selmi pointed out that Article 10(3) states that where “*the application for a certificate does not meet the conditions laid down in Article 8,*” the UK IPO is required to give the applicant the chance to address this, i.e. the Office “*shall ask the applicant to rectify the irregularity, or to settle the fee, within a stated time*”. The applicant pointed out that Article 10(3) makes no further qualification that the stated time must be before the expiry of the SPC.
- 69 The line of reasoning that Mr Selmi presented to me at the hearing assumes that the legislators deliberately and consciously decided to leave open the possibility for a paediatric extension to be granted on an expired SPC. The argument would appear to be that if it were intended for extensions only to be available on un-expired SPCs then the legislators would have explicitly said this in the articles, recitals, explanatory memoranda or preparatory works of these regulations. There is nothing in the regulations or their supporting documents which suggests that this is a reasonable assumption to make. It may be argued that the reason there is no reference to an un-expired SPC is because it was considered so obvious that the SPC must still be in force that it was considered unnecessary to explicitly stipulate this. On the other hand, if the possibility was to be specifically excluded, then it is fair to assume that this would have been made clear in the legislative text.
- 70 I agree that there is nothing in the recitals, articles, explanatory memoranda, or preparatory work of the two regulations at issue in this case that explicitly states that an unexpired SPC is a requirement for obtaining a paediatric extension. However, I am not sure that I agree that the consequence of this is that one may grant a paediatric extension on the basis of an expired SPC.
- 71 Mr Selmi provided further support for his view, arguing that Article 16 of the Medicinal Products SPC Regulation which provides discretion to revoke a paediatric extension also permits the grant of an extension after the expiry date of the SPC. This article sets out provisions whereby a paediatric extension may be revoked if it was granted contrary to the provisions of Article 36 of the Paediatric Testing Regulation. The important point which Mr Selmi stressed was that the power to revoke was discretionary. This has been established in the case of *Dr Reddy’s Laboratories (UK) Ltd v Warner Lambert Co LLC*¹⁵ (hereafter *Dr Reddy*). *Dr Reddy* had applied under Article 16 to set aside the six-month paediatric testing extension to an SPC for atorvastatin, which had been granted to SPC holder, on the basis that the grant had been contrary to Article 36 because while the PIP required three studies only two of

¹⁵ *Dr Reddy’s Laboratories (UK) Ltd v Warner Lambert Co LLC* [2012] EWHC 3715(Pat); reported as [2013] R.P.C. 31. (see also <http://www.bailii.org/ew/cases/EWHC/Patents/2012/3715.html>)

these had been approved by the Paediatric Committee of the EMA. The SPC holder argued that Article 16 conferred upon the court a discretion to revoke the paediatric extension but not an obligation to do so.

72 The Court agreed with the SPC holder and stated that “*if by error a paediatric extension was granted notwithstanding the absence of one of the necessary marketing authorisations, it would be anomalous if a third party’s application to revoke the extension had to be granted although in the meantime the missing marketing authorisation had been obtained*”¹⁶. Thus, it is necessary to look at the context in which this error to grant took place and consider if it is appropriate to revoke or not. By analogy, Mr Selmi has argued in relation to the present case that having a situation that does not comply with Article 36 (because of two missing marketing authorisations) does not mean that the UK IPO is barred from granting the extension once all the requirements are complied with. Discretion exists because if one considers that an extension is granted contrary to Article 36, it is still not a certainty that it will be revoked under Article 16.

73 This is an interesting line of argument. I find that I do not fully agree with Mr Selmi’s reasoning. First of all, the facts of the case currently before me are different to those in *Dr Reddy*. In *Dr Reddy* an extension had already been granted but, in the present case, an extension has not yet been granted and the SPC has already passed its expiry date.

74 Secondly, in paragraph [37] of his decision Roth J. considered the situation where not all the marketing authorisations were in place (my emphasis added in bold):

*“If at the time the SPC was granted the product was not authorised in one of the 27 Member States but such authorisation was granted a few weeks later but **before the period of paediatric extension would commence**, the Court might well conclude that it would be inappropriate to revoke the extension. Accordingly, if by error a paediatric extension were granted notwithstanding the absence of one of the necessary marketing authorisations, it would be anomalous if a third party’s application to revoke the extension had to be granted although in the meantime the missing marketing authorisation had been obtained”*

Thus, it appears to me that the situation envisaged is one where the extension has already been granted, albeit in error, before the SPC has expired. That is not the situation in the present case. In my view it is not reasonable to stretch the argument from *Dr Reddy* (that discretion to revoke an extension exists) to mean that there also exists a discretion to grant an extension after expiry of the SPC.

Does the Comptroller have discretion to extend the deadline for correcting deficiencies in the application after expiry of the SPC?

75 Article 19 of the Medicinal Products SPC Regulation states that in the absence of procedural provision in the Regulation, procedural provisions applicable under national law to the basic patent shall apply. In their skeleton argument, the applicant has set down how, based on Article 19 of the Medicinal Products SPC Regulation, the provisions of the Patent Act 1977 and the Patents Rules 2007 (as amended), the

¹⁶ Paragraph [37] from *Dr Reddy* judgment (see footnote 15)

Comptroller has the discretion to extend the deadline for correcting irregularities in the application for a paediatric extension. This was further discussed at the hearing.

- 76 Provision for supplementary protection certificates (SPCs) in UK law is made in Section 128B of the Patents Act 1977 which refers to Schedule 4A of the Act. Paragraphs 1(1) and 1(2) to Schedule 4A, entitled '*References to patents etc*' apply a number of provisions of the Act to applications for extension of the duration of an SPC (Schedule 4A, paragraph 1(1)(b)(ii)). The provisions of the Act which are applied to applications for an extension to the duration of an SPC include Sections 117 to 118 (administrative provisions), specifically Section 117B, as well as Section 123 (rules) [see Schedule 4A, paragraph 1(2)].
- 77 Section 117B makes provision for the Comptroller to extend certain time periods set by the Comptroller subject to receiving a request from the applicant or proprietor (117B(2)(a)) that complies with the relevant requirements of the rules (117B(2)(b)). Section 117B(2) entitles the applicant to a single extension of time to comply with a deadline set by the Comptroller. Rule 109 sets down the requirements for an extension of a time limit made under Section 117B of the Act. The first "as-of-right" extension must be made in writing (Rule 109(1)(a)) and must be made before the end of the 2-month period beginning immediately after the expiry of the deadline (Rule 109(1)(b) and Rule 109(2)). Any further extensions of time to comply with the deadline are discretionary under Section 117(4)(b) and are subject to such conditions as the Comptroller sees fit to apply. Some further guidance is provided in the Office's Manual of Patent Practice (MoPP)¹⁷ which states:
- "A period may be extended only once under s.117B(2); further extensions are at the comptroller's discretion and may be subject to conditions. Any request for a further extension should include a statement of reasons for the request."*
- 78 Applying these provisions to the present application Mr Selmi argued that a first "as-of-right" extension to the deadline for correcting irregularities in the paediatric extension application was requested, and granted, on 5 November 2019. This was in response to the official report of the Office dated 19 July 2019 which identified deficiencies in the application for a paediatric extension and which set a response date of 22 November 2019 to correct these deficiencies. All subsequent extensions of time have been discretionary and granted in response to the applicant providing reasoned statements (see paragraphs 6 to 12 above for a summary of these further requests) which had set out the latest situation with the applicants efforts to gain the necessary updated MA and compliance statement for the two remaining member states.
- 79 It is the applicant's view that the Patents Act provisions regarding discretionary extensions of time not only apply to the application for a paediatric extension but that there is no provision in UK law which says the discretion to give more time stops upon the expiry of the SPC.
- 80 At the oral hearing Mr Selmi argued that the Comptroller can continue to exercise their discretion, exactly as they have been done so far, provided the applicant continues to provide reasoned statements. That is to say that further extensions of the deadline to

¹⁷ Paragraph 117B.04 ([Section 117B: Extension of time limits specified by comptroller - Manual of Patent Practice - Guidance - GOV.UK \(www.gov.uk\)](https://www.gov.uk/guidance/section-117b-extension-of-time-limits-specified-by-comptroller))

correct the identified deficiencies in the application can be granted after the expiry date of the SPC. The reason for this being the interaction of the Medicinal Products SPC Regulation and UK national law.

- 81 According to Mr Selmi's argument, the Medicinal Products SPC Regulation only sets two "hard" deadlines. The first is the deadline for lodging the application for a paediatric extension under Article 7 which is two years before the expiry of the SPC (Art. 7(4) Regulation EU No. 1901/2006)). The applicant has complied with this first hard deadline (13 July 2019) by submitting their application on 18 June 2019.
- 82 The second and final "hard" deadline is the date where a paediatric extension would expire according to Article 13 of the Medicinal Products SPC Regulation and Article 26 of the Paediatric Testing Regulation, i.e. 6 months after the expiry date of the SPC that it is based on. Up to that point in time, Mr Selmi argued that the Comptroller can continue to exercise discretion. At the time of the oral hearing, almost two months of the possible paediatric extension period (if granted) had already passed. Mr Selmi argued that if the missing marketing authorisations were not provided before the end of this 6-month period "*that would be the absolute hard stop that is mandated by the regulations*". That is to say that it would no longer be possible to provide any further extension of the deadline beyond this 6-month paediatric extension period. I agree that only one six-month extension is possible and it can only take place immediately after the expiry date of the SPC it is based on.
- 83 Thus, Mr Selmi argues that, in the absence of any specific provisions in the SPC regulations which would allow me to accept corrections to the application after the SPC expires, the Comptroller does have the power to exercise discretion to accept such corrections under domestic patent law as it applies to paediatric extensions.

Extension of Time to Correct Irregularity

- 84 I consider that the argument made by the applicant in relation to Section 117B and Rule 109 has merit. I am not in full agreement with the approach proposed by the applicant in so far as their argument suggests that the Comptroller should exercise discretion to extend the time period for allowing the rectification of an irregularity with a paediatric extension application by successive periods of two months and that this can extend past the expiry date of the SPC if, as the applicant argues, there is a reasoned statement provided by the applicant explaining why this is necessary.
- 85 However, I consider that the essential and operative matter here has to be that the applicant actually has the additional material that will properly and fully correct the irregularity identified. In such a situation, one is not being asked to provide an extension of time without a clear idea of whether or not some or all of it will be needed and whether there will be a further request for an additional extension of time. If, as proposed by Mr Selmi, a discretionary extension of time was granted by the Office for two months, a total of three such extensions might be sought in the period up to the 'hard' deadline when the six-month paediatric extension (if granted) would expire. Instead, it seems to me that this situation should be better considered as one where the applicant has actually obtained the documents to address the identified irregularity within the window of the possible six-month paediatric extension and is seeking to file them late, i.e. after the expiry date of the SPC. Thus, the decision to be made is whether to accept the late filled materials as correcting the irregularity rather than

continuing to provide a time period within which such material could be provided but is not clear when they will be provided. The applicant should provide the documents before this potential six-month paediatric extension passes, as there is no reward left to be gained after this so-called second and 'hard' final deadline (as identified by the applicant) takes effect. I believe that such an approach will take proper account of the rights of third parties while also giving the applicant in circumstances such as in the present case the possibility to demonstrate that they are entitled to the reward of a paediatric extension in the UK.

- 86 I consider, that it would be possible for the Comptroller to continue to extend the period for providing the necessary proof of updated MAs and compliance statements for the two remaining member states past the expiry date of the SPC, if the circumstances merit it, based on the discretion allowed under Section 117B(4).
- 87 In order to do so, it is first necessary in my view to consider what are the circumstances that would merit such action by the Comptroller. I will now turn to consider the situation in each of the member states concerned where the applicant has not yet been able to fully provide the relevant proofs of possession of an updated marketing authorisation and compliance statement under Art 28(3) of the Paediatric Testing Regulation before the date of expiry of the SPC in the UK.

Situation in Relation to Proof of Updated Marketing Authorisation for Portugal

- 88 I have considered the materials provided by the applicant to explain the nature of the engagement with the NCA, InfraMed, in Portugal. The applicant does not have an affiliate in Portugal so they have appointed an agent, Pharmaffairs, to follow up matters on the applicant's behalf with InfraMed. This local agent was not appointed by Chiesi until September 2020 – this was 5 months after the original request was filed with InfraMed to update the MA and provide the related compliance statement following the recommendation of the RMS.
- 89 Nothing in the material shows a response from InfraMed explaining what was happening with the case or timing for completion of the steps it was responsible for under the MRP. However, there is one email response from InfraMed, dated 9 July 2021, which was provided with the letter from the applicant dated 6 October 2021 after the hearing (see D29A, pages 6&7 thereof). This is from a named person at InfraMed confirming that the FOSTAIR marketing authorisation is being looked at. I note that this email from InfraMed was sent and received in the week before the expiry date of the SPC in the UK. The updated MA and compliance statement and confirmation that the changes were being entered into the appropriate and relevant register in Portugal were sent to the applicant by InfraMed in October 2021. A copy of the compliance statement for Portugal was then sent to the IPO on 17 November 2021.
- 90 Thus, although the update to the MA and the request for the necessary statement of compliance were sent to the NCA in Portugal in April 2020, nothing appears to have happened with this request until July 2021 (15 months later). It was completed and the updated MA and compliance statement were forwarded to the applicant in October 2021 (18 months after application) and to the IPO in November 2021 (19 months).
- 91 I have no information in relation to why matters took so long to complete in Portugal. I do not know whether or not the operation at InfraMed was adversely affected by the

COVID pandemic which we are all aware was occurring throughout Europe from Feb/Mar 2020 and is still with us. I have no information whether or not there were any problems with the application made to InfraMed which lead to a lost or delayed application. I have no idea whether this is a usual timescale for InfraMed to complete such a procedure. Whatever, the reason, there does appear to have been a significant delay by the relevant national competent body in Portugal in providing the updated MA and associated compliance statement and it is not clear why. I think that in the same way that operations at the Office and at the MHRA were in effect slowed down while working arrangements were adjusted to deal with the pandemic, I cannot discount that this was not also the case in Portugal. However, it has come about, I cannot ignore the fact that the relevant national competent authority in Portugal has taken a significant period of time to provide the updated MA and associated compliance statement. I also cannot ignore the potential impact that this is having on the ability of the applicant to gain the reward they are seeking in the UK.

- 92 It is appropriate to note in relation to this point that 19 months is very much longer than the period advised for doing so in the Guidance note from the Co-ordination group for Mutual recognition and Decentralised procedures – human (CMDh)¹⁸ [see document D20C filed with the skeleton argument and the papers for the hearing] and in the relevant guidance on EUDRALINK¹⁹. I have included the timescale proposed for MRP from the latter in Annex 1 to this decision. The expectation is that this step will take 1 month.

Situation in Relation to Proof of Updated Marketing Authorisation for Romania

- 93 Having considered the materials provided by the applicant to explain the nature of the engagement with the national competent authorities in Romania, I note that although that the updated marketing authorisation had been agreed by the RMS (Germany) and updated on 6 February 2020, there does appear to have been a delay on the part of the applicant in submitting the materials requesting the updates in Romania. Although the applicant had a local affiliate in Romania, the papers requesting the updated compliance statement and marketing authorisation were not filed until 13 May 2020 – almost 5 weeks after the equivalent papers were filed in Portugal where the applicant did not have an agent (see above). There is no explanation given for this delay. After the documents were filed in May 2021 a series of emails were then sent to the NCA by the applicant’s Romanian affiliate, hereafter Chiesi Romania, asking for the updated marketing authorisation and compliance statement (see Exhibit 5 attached to agents letter dated 23 June 2021 and also documents D29D, D29E filed on 6 October 2021 after the hearing).
- 94 The NCA in Romania appears to have had this application from May 2020, 14 months before expiry date of the SPC in the UK. The NCA in Romania still had not completed

¹⁸ CMDh is the Co-ordination group for Mutual recognition and Decentralised procedures – human (CMDh). See [Heads of Medicines Agencies: CMDh \(hma.eu\)](https://hma.eu). The CMDh was set up in Directive 2004/27/EC (which amended Directive 2001/83/EC (see footnote 2 above) for the examination of any question relating to marketing authorisations of a medicinal product in two or more Member States in accordance with the mutual recognition procedure or the decentralised procedure.

¹⁹ See [Microsoft Word - Chap 2 rev 2007 Feb 14 clean fin.doc \(europa.eu\)](#)

all the necessary steps to update the MA and issue the compliance statement before 13 July 2021 the expiry date of the SPC in the UK.

- 95 The applicant reports that contact with the NCA in Romania can only be by email to a single named contact person (see D29C, second statement from C Malvoti). In addition, the applicant has commented that the NCA in Romania does appear to be impacted adversely by staffing issues:

“Since a few years, the industry representatives are not allowed anymore to contact the assessors, to call on landline but the communication between company and the drug agency is by email only through on nominated person for the department (for Chiesi is Cristina Dinu). In addition, the agency is suffering from a big lack of personnel nowadays.”

- 96 A first response to Chiesi Romania from the relevant NCA in Romania was on 18 Dec 2020 – at least 7 months after the papers were submitted for consideration. Unfortunately, according to the applicant (see first statement from Chiara Malvoti, D28A) this related to changes needed to a previous draft of the SmPC that did not include all the necessary revisions sent in February 2020 to account for the results of testing in the paediatric population. Examples of this material was not set before me but I am content to accept the applicant’s statement on this point

- 97 Then in June 2021, the NCA emailed Chiesi Romania and requested the applicant to send translations of the SmPC into the Romanian language in a different format to that submitted previously. The applicant responded by email within 1 week providing the documents requested (email sent on 14 June 2021). This led to one further round of correspondence where the NCA sent some comments on the updated SmPC, dated 17 June 2021 (see email dated 17 June 2021 in D20D) and, Chiesi replied to these in turn on 22 June 2021. The final approval of the changes to the SmPC was granted and made available by NCA on 21 September 2021. This related only to the MA and the SmPC. It did not also include the compliance statement confirming that the MA had been updated to include all the necessary changes in line with the PIP and the changes agreed by the RMA. This is explained in the second statement from Ms Malvoti (see D29C) and associated exhibits D29D and D29E. This appears to be the latest communication between the NCA responsible for granting MAs in Romania and the applicant prior to the expiry of the SPC in the UK.

- 98 However, in their letter dated 23 June 2021 and again at the hearing the applicant indicated that a Paediatric Extension (PE) had already been granted in Romania for this medicinal product, i.e., before the date of this letter and, as a consequence, before the date of expiry of the SPC in the UK. However, it is clear that the updated marketing authorisation and the associated compliance statement had not been issued by the relevant national competent body in Romania when the NPO in Romania made the decision to grant the PE for doing so. Thus, these latter documents could not be supplied with the application for a PE filed in the UK or at any time up to the expiry date of the SPC in the UK

- 99 Thus, although the necessary changes to update the text of the SmPC in Romania were agreed, the compliance statement under Article 28(3) of the Paediatric Testing Regulation had not yet been issued. Thus 13 months (from May 2020 to June 2021) had already passed and still the compliance statement had not been issued.

- 100 Similar to the situation in Portugal discussed above, I have no information in relation to why matters took so long to complete in Romania. I do not know whether or not the operation at ANMDM-RO was adversely affected by the COVID pandemic which we are all aware was occurring throughout Europe from Feb/Mar 2020 and is still with us. I have no information whether or not there were any problems with the application made to ANMDM-RO which lead to a lost or delayed application. I have no idea whether this is a usual timescale for ANMDM-RO to complete such a procedure. However, I think that in the same way that operations at the Office and at the MHRA were in effect slowed down while working arrangements were adjusted to deal with the pandemic, I cannot discount that this was not also the case in Romania. Whatever, the reason, there does appear to have been a significant delay by the relevant national competent authority in Romania in providing the updated MA and associated compliance statement and I cannot ignore the impact that this may have for the reward the applicant is seeking in the UK.
- 101 As the hearing officer dealing with the situation in relation to the PE application in the UK, I cannot ignore the fact that the UK Court of Appeal in *DuPont* confirmed that, in order to qualify for the reward, it was necessary to have proof of authorisation and compliance in all member states of the EU. As discussed by the applicant in their skeleton and at the hearing, the NPO in Romania may not be bound by case law in the same way as the Office is. As a result, the NPO in Romania can take steps to grant a PE without the same requirement for proof of compliance in all other MS if it considers the circumstances merit it. In this instance, it would appear that they have done so. I note also that they had already done so in advance of the expiry of the SPC in UK. Such an option is not available to the Office because of the Court of Appeal decision in *DuPont* (discussed above)¹².

Impact of Delayed Procedures in Other Members States on Procedure in the UK

- 102 As noted above without proof of the possession of an updated marketing authorisation and compliance statement for all Member States, the applicant cannot qualify for the reward of a PE in the UK.
- 103 It does seem unfortunate that the applicant is in danger of being denied the reward in the UK as a result of what appear to be long delays arising in circumstances which (as outlined above) do appear to be beyond the applicant's control. The applicant has to wait for the necessary authority in the relevant state to approve the updated MA and compliance statement.
- 104 However, use of either of the non-centralised routes (MRP or DCP) for gaining marketing approval for a medicinal product under Directive 2001/83/EC, will by their very nature involve having to gain a bundle of national approvals involving a number of relevant national competent authorities². I do not think that it is a surprise that it might well take more time and effort to gain such a bundle than it would to gain a single centralised approval through the EMA. However, the latter option was not available in this case. The process to secure approval in all member states cannot be started until the RMS has approved the changes to the MA and recommended these to all the CMS (see footnote 2 above and Annex 1 attached). The applicant will be aware of this and will also be aware that this is a complication that can arise, i.e. not all national

competent authorities will deal with the process for approving a change to a market authorisation in exactly the same way or on the same timescale.

- 105 The reward of an additional six months SPC protection that applies to all uses of the product, not just the paediatric use, is a significant one and so it is not surprising that the effort required to gain it is also significant – it is commensurate with this reward.

Can Discretion be Exercised?

- 106 The *DuPont* decision requires proof of possession of updated MAs in all member states to be furnished before the reward can be granted in the UK, and as a result the court considered it reasonable to allow the applicant to be able to provide the necessary documents to show this until the expiry date of the SPC (i.e. which was up two years after the application deadline for the paediatric extension).
- 107 As the applicant has pointed out on a number of occasions and emphasised again at the hearing, the Court of Appeal in *DuPont* did not have to decide on whether the identified matters could be rectified after the expiry date of the SPC. Having looked again at this judgement and taken account of the skeleton argument in relation to the relevance of the *Dr Reddy* judgement, I believe that the court was of the view that a PE should not be refused for failure to provide the necessary documents by the deadline required to make the application. The court in *DuPont* considered that the remaining two years before expiry of the SPC could also be used to provide this information.
- 108 In the present case, I am being asked to extend that approach and say that the applicant should not be refused the PE for failure to provide the necessary documents in the 6 month period immediately after the expiry date of the SPC when any such PE will be in place. The main reason for doing so is because this circumstance has arisen through no fault of the applicant.
- 109 I have considered the material provided by the applicant in relation to the efforts made to obtain the necessary proof that the marketing authorisations (MAs) for Portugal and Romania have been updated (see above). While I consider that the applicant might have been more proactive in starting the process in Romania, they did make their application for the updated compliance statement in this member state reasonably quickly after gaining the confirmation for the RMS that the MA should be updated to show the approved outcomes of the testing in the paediatric population. In relation to both these two states, I cannot ignore the fact that, based on the guidance from the Co-ordination group for Mutual recognition and Decentralised procedures – human (CMDh)²⁰, the NCAs in both countries have been very, very slow to complete their part of the MRP process, i.e., in Portugal the process took approximately 19 months, in Romania, approximately 18 months. The CMDh Guidance suggests 1 month is

²⁰ The CMDh is a working group set up under Directive 2001/83/EC (see Article 27 and Chapter 4) to coordinate and facilitate the operation of the Mutual Recognition Procedure (MRP). It is made up of one representative from each of the NCAs responsible for approving medicines in each Member State as well as the EEA states. It has as one of its principle aims to solve disagreements between the Member States involved in mutual recognition or decentralised procedures for authorisation of human medicinal products. For further details on work and role of CMDh which come under the Heads of Medicines Agencies network - see website at [Heads of Medicines Agencies: About HMA](#)

sufficient to achieve this. As the CMDh is a working body set up under Directive 2001/83/EC to coordinate and facilitate the operation of MRP, I consider that their guidance on this issue is relevant²¹.

- 110 Further, before the expiry date of the SPC in the UK, there was evidence that the respective NCAs in Portugal and in Romania were aware of the outstanding issues and were taking steps to deal with the update to the MA and/or providing a PE, even if this was not yet complete. In Portugal, prior to the expiry date of the SPC in UK, the NCA had issued a final version of the updated SmPC and sent it to the applicant for approval. In Romania, the competent IPO had already decided to grant the PE for Romania in anticipation of this update to the MA and the issue of the compliance statement.
- 111 The actual final documents needed to confirm that the applicant possessed proof of possession of an updated MA in all MS were provided to the Office by the applicant in respect of Romania on 3 November 2021 and in respect of Portugal on 17 November 2021. Thus in effect what I am being asked to consider is whether these documents submitted approximately 4 months after the expiry date of the SPC in the UK (but within the potential six-month period that the PE would take effect) can be considered as late filled documents and accepted as providing the necessary confirmation and proof that the present application is complete.
- 112 I consider that it is appropriate to take account of these facts to decide whether or not the Comptroller can accept these additional documents filed after the expiry date of the SPC in the UK to supplement the application, These documents were filed before the expiry date of the six-month paediatric extension and, in this instance, I am satisfied that there is no ambiguity or uncertainty that these documents provide the proof to confirm that the UK applicant has all the necessary MAs and related compliance statements in all MS to qualify for the reward under Art 36(3) of the Medicinal Products SPC Regulation in UK.
- 113 As I have discussed above, the comptroller does in my view have the power to exercise discretion in this circumstance – to allow for the late filing of documents that correctly address the irregularity identified. I consider that given the specific facts of the present case, that the Comptroller can exercise discretion under 117B(4)(b) to allow the documents filed by the applicant on 3 November 2021 in relation to Romania and 17 November 2021 in relation to Portugal to be accepted. These documents address the irregularity identified with this application by the examiner at the expiry date of the SPC (see examiner’s pre-hearing report, dated 26 July 2021, setting out the issues to be addressed at the hearing). These documents, filed after the expiry date of the SPC, but, and this is important in my view for clarity of third parties, before the notional expiry date of the six-month PE, are accepted as providing the necessary proof that the PE in UK should be granted.
- 114 In the specific circumstances of this case, I consider that it is appropriate for me to exercise the discretion available to the comptroller to accept late filed documents which overcome the irregularity identified by the examiner. The documents provided

²¹ See Doc D20C discussed above or Guidance document CMDh/161/2009, Rev.2 dated December 2015 from the CMDh hosted on the Heads of Medicines Agencies (HMA) website at [CMDh_161_2009_Rev1_2014_06 - clean \(hma.eu\)](https://www.hma.eu/CMDh_161_2009_Rev1_2014_06_clean).

in relation to Portugal on 3 November 2021 and to Romania on 17 November 2021 provide the necessary answer to correct this irregularity. It is important to note that although the updated marketing authorisation for Romania was available in September 2021, the related compliance statement was not. In line with the Court of Appeal decision in *DuPont*, the compliance statement is the means identified by the relevant EU legislation – the Paediatric Testing Regulation – to provide the necessary proof of authorisation in the respective member state.

115 It was possible to establish, based on the materials provided by the applicant, that certain actions had taken place in each respective NCA, before expiry of the SPC in the UK, that indicated that progress was being made:

- (i) the applicant had made numerous attempts to contact and get confirmation from each of the NCAs (as evidenced by email exchanges between applicant and NCAs asking when the updated MA and compliance statement would be available). While much of this consisted of emails sent by the applicant or its affiliate or an agent acting on their behalf, there was also a small number of responses from the NCAs involved included;
- (ii) the applicant had received some direct acknowledgement from the relevant NCAs (e.g., email, letter) that the task to update the MA in question was progressing before expiry date of the SPC in UK, thus there was evidence to show engagement with the NCAs involved;

and

- (iii) the task in (ii) was then completed within the six-month period immediately following the SPC expiry date when the PE would take effect.

In light of these actions, it is possible and appropriate for the Comptroller to exercise discretion to allow the late filing of the documents in relation to Portugal and Romania in November 2021 which confirm that the task to provide proof in all member states was complete and fulfilled the necessary requirement under Article 8(1)(d)(ii). This will prevent the applicant from losing the reward of a paediatric extension in the UK because of circumstances beyond their control, i.e., the very noticeable delay by the respective NCAs in providing the proof necessary to show authorisation in all member states. This delay extended until after the expiry of the SPC in the UK.

116 I find support for my view in paragraph 61 of *DuPont* where, Stanley-Burnton LJ, supporting the conclusion of Jacob LJ in the main judgment, added that the “.. the requirements of Article 8 are documentary.” In his view, “If an applicant produces the right documents, he is entitled to his extension.” He indicated that the irregularity being addressed in *DuPont* was “a failure of the application to contain the requisite documents.” As this was documentary, he considered that providing the documents was the key and not whether they came into existence “before the latest date for the submission of the application.” Thus, it was important to have the right documents and less important when they were available.

117 In addition, the procedure for grant or rejection of SPC applications and applications for an extension to the duration of an SPC described in Article 10 of the Medicinal Products SPC Regulation describes the ‘what’ but not the ‘how’. The Office has to

consider whether the application at issue meets the requirements of the Medicinal Products SPC Regulation. However, it does not give any details of how this procedure should be carried out, for example, when applications should be examined, what deadlines for responses apply. As mentioned already, Article 19 indicates that in the absence of such procedural provisions, those that are applicable to the corresponding basic patent shall apply unless the national law sets down special procedural provisions for SPCs. As discussed above Section 128B and Schedule 4A of the Act indicates how certain provisions of the Act are modified to apply to SPCs and applications for extensions to SPCs. The timing of the examination process for SPCs is not provided for under the Regulation or Section 128B and Schedule 4A. As a result, the approach used for examination of patent applications is adopted, for example, as advised in the Office's Manual of Patent practice, the response period for the examination report on an SPC is set as 4 months, extendable by a further two months as-of-right, in the same manner as the response period for an examination report on a patent application²². As explained in the Office Manual of Patent Practice²³, the Comptroller has power to refuse an application for a patent under s.18(3) where the applicant fails to file a satisfactory response to an official report within the period specified therein. This period is set at the examiner's discretion, but there are certain standard periods which should normally be set unless the circumstances dictate otherwise. The standard period for response is four months from issue of the examination report, which is extendable as-of-right by 2 months. If a response is received outside the time period for response for such a report on a patent application, discretion can be exercised to accept a late response should the circumstances merit it. This is in the context of the relevance of Section 117B and Rule 109 – already discussed above.

- 118 As I have explained above, I consider that in this instance the circumstances are such that I should accept the documents filed after the expiry date of the SPC. I should extend the period for providing the necessary proofs of coverage in all member states past the expiry date of the SPC to the date when the final set of documents were provided by the applicant in November 2021.
- 119 The expiry date of the SPC is not equivalent to the compliance date of a patent and Section 20 is not a section of the Act that is referred to in Schedule 4A as being one that applies to SPCs. However, the expiry date of the SPC is also not the same as the normal response date for an SPC exam report which can be extended under once as-of-right and then, as was the case in with this application, a number of times on a discretionary basis. The expiry date of the SPC, has in my view a status, in between these two. It is a date that has greater significance than the response date for an examination report as it indicates the earliest date when third parties may come to market with their own version of the medicinal product covered by the SPC, but it is not as significant as the compliance date because it does not carry the same consequences if it is exceeded. I consider that it is necessary to consider carefully whether it is appropriate to exceed this date but, that if the circumstances merit, one

²² See for example Paragraph SPM10.12 in [Supplementary Protection Certificates for Medicinal and Plant Protection Products - Manual of Patent Practice - Guidance - GOV.UK \(www.gov.uk\)](http://www.gov.uk/government/uploads/system/uploads/attachment_data/file/442222/Supplementary-Protection-Certificates-for-Medicinal-and-Plant-Protection-Products-Manual-of-Patent-Practice-Guidance-2019.pdf).

²³ See Paragraph 18.49 in [Section 18: Substantive examination and grant or refusal of patent - Manual of Patent Practice - Guidance - GOV.UK \(www.gov.uk\)](http://www.gov.uk/government/uploads/system/uploads/attachment_data/file/442222/Supplementary-Protection-Certificates-for-Medicinal-and-Plant-Protection-Products-Manual-of-Patent-Practice-Guidance-2019.pdf).

is not prevented from doing so. However, I do consider that part of this decision is confirming that, if accepted, the documents filed do rectify the irregularity with the application for the paediatric extension under Article 10 of the Medicinal Products SPC Regulation. Also, under Section 117B(4), the comptroller has the flexibility to set such conditions as they think fit – in this case – to extend the deadline for filing the necessary documents to provide the necessary proofs from the expiry date of the SPC (13 July 2021) until 17 November 2021 when the final documents were provided to the Office by the applicant.

- 120 The applicant provided further support to their argument that the Comptroller has discretion to extend the deadline for correcting any deficiencies in the application for a paediatric extension by reference to Section 123 of the Act and Rule 107 of the Rules which concerns correction of irregularities. In addition to Section 117B, Schedule 4A of the Act also indicates that Section 123 of the Act, entitled “Rules”, applies to applications for extension of the duration of an SPC. As explained in MoPP²⁴, Section 123 gives a general power for the appropriate authority to make rules as necessary for “*regulating all matters placed by this Act under the discretion or control of the comptroller*”. Section 123(3A) makes provision for the Comptroller to extend or further extend any time period when applying rules that authorise the rectification of irregularities [see Section 123(3A)(a)] or alter any period of time [see Section 123(3A)(b)]. Such time periods may be extended even though the time periods have expired. Rule 107 of the Patent Rules relates to the correction of irregularities and states that the Comptroller may “*authorise the rectification of any irregularity of procedure connected with any proceeding or other matter before the comptroller, an examiner or the Patent Office*”. The applicant considered that, as none of the periods of time identified in Parts 1 to 3 of Schedule 4 to the Rules, refer to applications for paediatric extensions (unlike the situation that arose in the in the recent *Master Data* case, concerning the time period for payment of fees for an SPC (set down in rule 116(2) and referred to in Part 1 of this Schedule), the present case falls under rule 107(1) but not rule 107(3). As such, in their view, the Comptroller has discretion to correct an irregularity of procedure in relation to paediatric extensions.
- 121 However, I do not need to consider the argument in relation to Section 123 and Rule 107 advanced by the applicant given my finding above in relation to Section 117B and Rule 109. I consider that the comptroller can exercise discretion under Section 117B(4) and Rule 109 to accept the documents filed after the expiry date of the SPC.

Possible Impact on Third Parties

- 122 As well as considering the rights of the applicant to obtain their just reward, we must also be aware of the impact on third parties. In particular, third parties have a need for certainty around when they are able to enter the market. In the absence of a paediatric extension having been granted, third parties could reasonably assume that they are free to enter the market once an SPC had expired. As recital (10) to the SPC regulation reminds us “*All the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should nevertheless be taken into account.*”

²⁴ See paragraphs [123.01-123.03], [Section 123: Rules - Manual of Patent Practice - Guidance - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/publications/section-123-rules-manual-of-patent-practice-guidance)

- 123 In this specific case, the applicant has argued that a third party would know that there is still the possibility of a paediatric extension being granted. An application for a paediatric extension was made within the time period set down under Article 7(4) of the Medicinal Products SPC Regulation. The duration of such an extension (if granted) is clear, it can only be for the six-month period immediately following the expiry of the SPC. It is not subject to an algorithm such as that in Article 13 of the Medicinal Products SPC Regulation which determines the duration of the SPC itself. Notification that an application for a PE has been made is also recorded on the Official Register in relation to the basic patent and the SPC.
- 124 No expiry date had been published for this SPC (see discussion re publication below) so third parties would be aware that this SPC was potentially still valid and in-force and that care would need to be taken if they were interested in coming to market..
- 125 Thus, I consider that third parties will be aware that the SPC may be extended until 13 January 2022. This is further reinforced by the fact that the applicant has sought a hearing on this application.
- 126 It is clear that the SPC either expires on 13 July 2021 if the extension is not granted or will expire on 13 January 2022 if the extension is granted. Given the significant amount of work that the applicant has to do to (a) complete the testing in the paediatric population; (b) disseminate the outcomes of this testing; (c) achieve a positive opinion on the PIP; and (d) obtain proof of possession of an updated MA in all member states and that all of this has to be in place in advance of the time when it will be possible to claim any reward for doing all this work, it does not seem unreasonable to conclude that any third parties with an interest in such products will be aware that the SPC can expire on one of these two dates six months apart. While it is uncertain which date it will be in this case, it is clear that after the 13 January 2022, there will be no possibility that the SPC will be in force. Thus, a third party will be clear, for example, that they can definitely come onto the market after this date with their own version of this product but that they may be able to do so sooner depending on whether the PE is granted or not.
- 127 I consider that (a) third parties with any interest in the present case will likely be monitoring the progress of this case and so will know that the matter of the grant of a paediatric extension is being contested; (b) third parties with any interest in the present case will also know that if a paediatric extension is granted it will expire 6 months after the expiry date of the SPC that it is related to, and (c) that the final cut-off date when all monopoly rights relate to the active ingredients protection by the SPC with a paediatric extension (13 January 2022) does not change. Therefore, any uncertainty that may exist for third parties is limited in time.
- 128 I find support for this view from the *DuPont* decision. The court of Appeal considered that it was acceptable for third parties to have to wait for the irregularity on the application to be dealt with because “... *on any rational view, the importance of research into paediatric uses of medicines stands ahead of the purely commercial interests of third parties. The importance of that research being conducted and the results disseminated is the whole point of the Paediatric Regulation.*” The goal of the Paediatric Testing Regulation cannot be achieved if the results of the testing carried out in the paediatric population have not been disseminated in all the member states.

Conclusion regarding Impact on Application for Paediatric Extension in the UK

- 129 In the present case, the difficulty in gaining the necessary proof that the results of the paediatric testing had been included in the respective MAs for the final two member states, should not have the consequence that the applicant is prevented from having the reward of a six-month paediatric extension in the UK.
- 130 I will take this opportunity to note that I consider the applicant was very diligent in attempting to obtain the necessary proofs and in engaging with the relevant NCAs to seek and update on progress. They were also very good in keeping the Office informed of progress and providing regular updates. The materials provided by the applicant explaining these efforts were very important in being able to establish that discretion should be exercised (as explained above and summarised below).
- 131 Taking all of the above into account, I consider that the applicant is in the position where they would not be able to qualify for the reward of a paediatric extension in the UK because of delays in gaining the documents necessary to provide proof in the UK that an updated marketing authorisation describing the outcome of the paediatric testing is available in all other member states. This delay has occurred because the relevant competent authorities of the states concerned have not been able to carry out the relevant tasks and so is not under the applicant's control. Mindful of the factors identified by the Court in paragraph 58 of *DuPont*, I do not think that the applicant can be said to have behaved unreasonably in terms of conduct or delay. The applicant made the applications in the two member states concerned in a reasonable time after they received notification from the RMS. The time that the relevant NCAs have had to deal with this request has significantly surpassed the timescale suggested in the Guidance from the Heads of Medicines Agencies discussed above. The applicant was able to show that there was some progress in the relevant member states before expiry of the SPC in the UK but that these efforts had not reached completion. They have been able to provide the necessary documents as prove coverage in the two remaining member states, albeit, after the expiry date of the SPC. These documents were provided as soon as they became available to the applicant and, before the end of the six-month period, immediately following the expiry date of the SPC, i.e. the period in which the paediatric extension will actually apply if granted. Thus, third parties will not be placed in a different position to before, they are aware that this is one of the two possible dates that the SPC will expire. On balance, I do not consider that it would be an equitable outcome, given the specific facts and circumstances in this case, to conclude that as the applicant did not have the necessary proofs at the expiry date of the SPC, that they be denied the sought-after reward in the UK. As detailed above, I consider that based on the discretion available to the comptroller under Section 117B(4)(b) of the Act I can extend the period from the expiry date of the SPC to the date of receipt of the final set of documents (concerning Romania) and so these documents should be accepted

Other matters

Deferral of Publication of Details of Expiry

- 132 The applicant argued that because the Office agreed to defer publication of the fact that the SPC had expired, it was, in effect, approving the possibility that the SPC expiry date could be 6 months after the current expiry date advertised in the journal and on the Register of SPCs. However, I disagree with the applicant on this point. This situation has arisen because of a request from the applicant that the Office not publish details of the expiry of the SPC. Article 11(3) of the Medicinal Products SPC Regulation requires that details of the grant or rejection of an application for a paediatric extension to be published by the competent IPO. Although the examiner was minded to reject this application, he cannot do so without the applicant being given the opportunity to be heard on the matter (as is clear from Section 101 of the Act). Thus, the decision on rejection of the application for a paediatric extension was not finalised. The applicant asked to be heard on this matter and the present decision will result in either acceptance of the view of the examiner and rejection of the application for an extension or acceptance of the view of the applicant and grant of the application for a paediatric extension (see conclusion below). The applicant made the request to defer publication of the view of the examiner as they had requested a hearing on the matter. As such the matter has not yet been decided and, until it is (which is the purpose of the present decision), there is nothing to publish.

Conclusion

- 133 I consider that discretion should be exercised under Section 117B(4) of the Act, given the specific circumstances in this case, to accept the documents filed by the applicant on 3 November 2021 in relation to Portugal and the documents filed by the applicant on 17 November 2021 in relation to Romania as late filed documents after the expiry date of the SPC. These documents confirm that the applicant has proof of possession of an updated marketing authorisation and compliance statement as required under Art 36(3) of the Paediatric Testing Regulation in all other member states, as required to confirm qualification for the reward of a paediatric extension in the UK.
- 134 For clarity, the provision of proof that the applicant has an updated authorisation in relation to all other member states in the European Union is necessary for a successful application for a paediatric extension in the UK²⁵. The reward of a paediatric extension cannot be granted in the UK until this proof is available. This follows from the Court of Appeal decision in *DuPont*.
- 135 I consider that the irregularity identified under Article 10(3) of the Medicinal Products SPC Regulation with the application for a paediatric extension to granted UK certificate SPC/GB11/051 has, as a consequence, been rectified. The paediatric extension will take effect from 14 July 2021 and will expire on 13 January 2022.

²⁵ Given the legislative framework that was in place in the UK at the time when the application for a paediatric extension was made in 2019. This was prior to exit of the UK from the European Union.

136 I remit this application back to the examiner to complete the necessary steps for grant of the PE and to complete the related arrangements for publication.

Appeal

137 Any appeal must be lodged within 28 days after the date of this decision.

Dr L Cullen

Deputy Director, acting for the Comptroller

Annex 1

FLOW CHART FOR THE MUTUAL RECOGNITION PROCEDURE¹

Timing	Event
Approx. 90 days before submission to CMS	Applicant requests RMS to update Assessment Report (AR) and allocate procedure number.
Day -14	Applicant submits the dossier to CMS. RMS circulates the AR including SPC, PL and labelling to CMSs. Validation of the application in the CMSs.
Day 0	RMS starts the procedure
Day 50	CMSs send their comments to the RMS and applicant
Day 60	Applicant sends the response document to CMSs and RMS
Until Day 68	RMS circulates their assessment of the response document to CMSs.
Day 75	CMSs send their remaining comments to RMS and applicant. A break-out session can be organised between day 73 – 80)
Day 85	CMSs send any remaining comments to RMS and applicant.
Day 90	<p>CMSs notify RMS and applicant of final position (and in case of negative position also the CMD secretariat of the EMEA).</p> <p>If consensus is reached, the RMS closes the procedure.</p> <p>If consensus is not reached, the points for disagreement submitted by CMS(s) are referred to CMD(h) by the RMS within 7 days after Day 90.</p>
Day 150	<p><u>For procedures referred to CMD(h):</u> If consensus is reached at the level of CMD(h), the RMS closes the procedure.</p> <p>If consensus is not reached at the level of CMD(h), the RMS refers the matter to CHMP for arbitration.</p>
5 days after close of procedure	Applicant sends high quality national translations of SPC, PL and labelling to CMSs and RMS.
30 days after close of procedure.	Granting of national marketing authorisations in the CMSs subject to submission of acceptable translations.

¹ Taken from February 2007 edition of Chapter 2: *Mutual Recognition*, of Volume 2A: *Procedures for Marketing Authorisation*, in Volume 2: *the Notice to Applicants* (see Annex I, page 37) of "*The Rules governing Medicinal Products in the European Union*" - see [EudraLex - Volume 2 - Pharmaceutical legislation on notice to applicants and regulatory guidelines for medicinal products for human use | Public Health \(europa.eu\)](#)

Annex 2

GLOSSARY OF ABBREVIATIONS USED IN THIS DECISION

<i>ANM-RO or ANMDN-RO</i>	the NCA in Romania for granting marketing authorisation and compliance statement under Art 28(3) of the Paediatric Testing Regulation
<i>BfArM</i>	<i>Bundesinstitut für Arzneimittel und Medizinprodukte</i> [the Federal Institute for Drugs and Medical Devices] – the NCA in Germany for granting marketing authorisations and compliance statements under Article 28(3) of the Paediatric Testing Regulation
<i>CJEU</i>	Court of Justice of the European Union
<i>CMDh</i>	Co-ordination group for Mutual recognition and Decentralised procedures – human
<i>CMS</i>	Concerned Member State
<i>DCP</i>	DeCentralised Procedure (for authorisation of medicinal products)
<i>EU</i>	European Union
<i>EMA</i>	European Medicines Agency
<i>EEA</i>	European Economic Area
<i>HMA</i>	Heads of Medicines Agencies
<i>InfraMed</i>	the NCA in Portugal for granting marketing authorisation and compliance statement under Art 28(3) of the Paediatric Testing Regulation
<i>IPO</i>	Industrial Property Office – responsible for granting PE in relevant member state
<i>MA</i>	Marketing Authorisation
<i>MHRA</i>	Medicines and Healthcare products Regulatory Authority – the NCA in the UK for granting marketing authorisation and compliance statement under Art 28(3) of the Paediatric Testing Regulation
<i>MRP</i>	Mutual Recognition Procedure (for authorisation of medicinal products)
<i>MS</i>	Member State (of the European Union)
<i>NCA</i>	National Competent Authority
<i>PE</i>	Paediatric Extension
<i>PIL</i>	Product Information Leaflet
<i>PIP</i>	Paediatric Investigation Plan
<i>PL</i>	Package Label
<i>RMS</i>	Reference Member State
<i>RTM</i>	Registered Trademark
<i>SPC</i>	Supplementary Protection Certificate
<i>SmPC</i>	Summary of Product Characteristics