



PATENTS ACT 1977

APPLICANTS Genentech, Inc. and Master Data Center, Inc.

ISSUE Whether to allow requests to extend the duration of supplementary protection certificate SPC/GB07/012 and whether to allow an application for a paediatric extension to the certificate

HEARING OFFICER B Micklewright

DECISION

Introduction

- 1 This case concerns whether to allow a request to extend the duration of a supplementary protection certificate (“SPC”) in the name of Genentech, Inc. and whether to allow an application for a paediatric extension to the SPC. In brief the facts are that, despite the maximum term of the SPC in question being nearly four years from the date the SPC entered into force, annual fees were only paid to cover two of those years.
- 2 Two separate parties have requested decisions on the papers in relation to this case, both making different arguments on different grounds. The SPC holder, Genentech, has made submissions in relation to enabling the SPC to be extended to its maximum duration and allowing the application for a paediatric extension to the SPC. The company responsible for the administration of the SPC in question, Master Data Center, Inc. (“MDC”), has made submissions on a different legal basis in relation to extending the SPC to its maximum term. I have considered the submissions from the two parties separately but, given that the issues are related, I have decided to deal with them in a single decision. I should emphasise that the two parties have not put forward a joint case but have put forward separate cases.
- 3 In relation to Genentech’s case, the following questions arise:
 - a. Does rule 116(5) of the Patents Rules 2007 allow further annual fees to be paid if an application for a paediatric extension is made, thereby extending the SPC to its maximum term?
 - b. Can a paediatric extension be allowed for an SPC in circumstances where the SPC is not in force for the full maximum term?

- c. Should I allow a request to correct the forms used to pay the prescribed fee for the SPC to take effect, so as to extend the duration of the certificate, under sections 117 and/or 32(2)(d) of the Patents Act 1977?
- 4 In relation to MDC's case, the following question arises:
- d. Has there been an irregularity in procedure, a mistake or an error attributable at least in part to the Office and, if there has, should the irregularity be rectified under rule 107?
- 5 The SPC in question is SPC/GB07/012 in respect of the product ranibizumab which was protected by basic patent EP 0973804. This SPC took effect on 03 April 2018. The maximum possible duration of the SPC was for a period of 3 years and 9 months to 23 January 2022. The original Form SP2 filed to accompany the prescribed fee, which must be paid before the SPC takes effect, however indicated a duration of two years and a fee that reflected this shorter duration. This was the fee which was actually paid. The SPC is therefore currently set to expire on 02 April 2020. On 12 July 2019 Master Data Center requested that the Office correct an irregularity of procedure connected with the payment of this fee so that the SPC remains in force for its maximum duration until 23 January 2022. On 24 September 2019 Genentech, in a separate action, made an application for a paediatric extension to the SPC and at the same time enclosed a further Form SP2 in respect of the annual fees payable for the third and fourth years so as to extend the SPC to its maximum duration.
- 6 The requests from both parties were progressed separately with the examiner. In a letter dated 20 December 2019 Genentech also requested the original Form SP2 and the associated fee sheet FS2 be corrected under section 117.
- 7 There was initially a debate between Genentech and the examiner concerning whether the Office could accept the late filing of Genentech's application for a paediatric extension but this has now been resolved in Genentech's favour. The examiner did not however accept that the paediatric extension request could be allowed in the circumstances of this case and did not accept that further annual fees could be paid with the application for the paediatric extension to extend the SPC to its maximum duration. Genentech disagreed and the matter was therefore referred to me for a decision on the papers. Genentech has been represented by Mewburn Ellis in prosecuting their case. I confirm that I have read all the correspondence on file and have taken this into account in making my decision.
- 8 The examiner and MDC could not agree on the question as to whether rule 107 could be used to correct an irregularity of procedure in relation to the filing of original Form SP2. This matter was also therefore referred to me for a decision on the papers. MDC have been represented by Fieldfisher in prosecuting their case. Once again, I confirm that I have read all the correspondence on file and have taken this into account in making my decision.

The law

Supplementary protection certificates

- 9 Regulation (EC) 469/2009 of the European parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (“the SPC Regulation”) sets out the law concerning supplementary protection certificates. This Regulation is a codification of Council Regulation (EEC) No 1768/92 of 18 June 1993 concerning the creation of a supplementary protection certificate for medicinal products which had been amended several times. The 2009 Regulation has since been amended but these amendments do not impact on the present case.
- 10 The SPC Regulation provides for two kinds of fees: application fees and annual fees. Article 8(4) provides for application fees:

Article 8

Content of the application for a certificate

4. Member States may provide that a fee is to be payable upon application for a certificate and upon application for the extension of the duration of a certificate.

- 11 Provision for annual fees is made in Article 12:

Article 12

Annual Fees

Member States may require that the certificate be subject to the payment of annual fees.

- 12 The duration of the certificate is specified in Article 13:

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.

...

- 13 The consequences of a failure to pay the annual fee in time is set out in Article 14:

Article 14

Expiry of the certificate

The certificate shall lapse:

...

- (c) if the annual fee laid down in accordance with Article 12 is not paid in time.

- 14 Article 19 deals with procedural provisions:

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. Notwithstanding paragraph 1, the procedure for opposition to the granting of a certificate shall be excluded.

- 15 The Regulation providing for the extension of a supplementary protection certificate for medicinal products for paediatric use (a “paediatric extension”) is Regulation (EC) No 1901/2006 of the European parliament and of the Council of 12 December 2006 (“the Paediatric Regulation”). Recitals (26) and (27) state:

(26) For products falling within the scope of the requirement to submit paediatric data, if all the measures included in the agreed paediatric investigation plan are complied with, if the product is authorised in all Member States and if relevant information on the results of studies is included in product information, a reward should be granted in the form of a 6-month extension of the supplementary protection certificate created by Council Regulation (EEC) No 1768/92 (1). Any decisions by Member States' authorities as regards the setting of prices for medicinal products or their inclusion in the scope of national health insurance schemes have no bearing on the granting of this reward.

(27) An application for an extension of the duration of the certificate pursuant to this Regulation should only be admissible where a certificate is granted pursuant to Regulation (EEC) No 1768/92.

- 16 This principle is implemented in Article 36 with the six-month extension provided for in Article 36(1):

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.

- 17 The UK introduced special provisions for SPCs into the Patents Act 1977 (“the Act”) on 17 December 2007. These provisions specified how the Act applied to SPCs and a new section 128B was introduced. It reads:

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) Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products.

- 18 Schedule 4A to the Act sets out the various provisions of the Act which apply to SPCs and the manner in which they are to be given effect. Paragraph 5 of Schedule 4A makes provision for annual fees and states:

Fees

5. A supplementary protection certificate does not take effect unless -

- (a) the prescribed fee is paid before the end of the prescribed period, or
- (b) the prescribed fee and any prescribed additional fee are paid before the end of the period of six months beginning immediately after the prescribed period.

- 19 Rule 116 of the Patents Rules 2007 (“the Rules”) sets out further details in relation to the operation of the SPC system in the UK:

...

(3) The comptroller must send a notice to the applicant for the certificate—

- (a) before the beginning of the period of two months immediately preceding the start date; or
- (b) where the certificate is granted as mentioned in paragraph (2)(b), on the date the certificate is granted.

(4) The notice must notify the applicant for the certificate of—

- (a) the fact that payment is required for the certificate to take effect;
- (b) the prescribed fee due;
- (c) the date before which payment must be made; and
- (d) the start date.

(5) The prescribed fee must be accompanied by Patents Form SP2; and once the certificate has taken effect no further fee may be paid to extend the term of the certificate unless an application for an extension of the duration of the certificate is made under the Medicinal Products Regulation.

(6) Where the prescribed fee is not paid before the end of the period prescribed for the purposes of paragraph 5(a) of Schedule 4A to the Act, the comptroller shall, before the end of the period of six weeks beginning immediately after the end of that prescribed period, and if the fee remains unpaid, send a notice to the applicant for the certificate.

(7) The notice shall remind the applicant for the certificate—

- (a) that payment is overdue; and
- (b) of the consequences of non-payment.

(8) The comptroller must send the notices under this rule to—

(a) the applicant's address for service; and

(b) the address to which a renewal notice would be sent to the proprietor of the basic patent under rule 39(2).

20 The prescribed fee itself is set out in rule 6 of the Patents (Fees) Rules 2007 (as amended):

6.—(1) The prescribed fee payable for a supplementary protection certificate to take effect is set in accordance with paragraph (2).

(2) Where the certificate expires during the period of one year beginning with—

(a) the start date, the fee is £600;

(b) the first anniversary of the start date, the fee is £1,300;

(c) the second anniversary of the start date, the fee is £2,100;

(d) the third anniversary of the start date, the fee is £3,000; or

(e) the fourth anniversary of the start date, the fee is £4,000.

(3) The period in paragraph (2) shall be calculated without reference to any extension of the duration of a supplementary protection certificate under Article 13(3) of the Medicinal Products Regulation(a).

(4) The additional fee prescribed for the purposes of paragraph 5(b) of Schedule 4A to the Act (supplementary protection certificates) shall be half the prescribed fee.

(5) In this rule "start date" is the first day following the day on which the basic patent expires.

Corrections

21 Section 117 of the Act gives the comptroller discretion to correct errors in patents and applications, or in documents filed in connection with such patents or applications. Schedule 4A to the Act applies section 117 to SPCs. Section 117(1) states:

117.—(1) The comptroller may, subject to any provision of rules, correct any error of translation or transcription, clerical error or mistake in any specification of a patent or application for a patent or any document filed in connection with a patent or such an application.

22 Rule 105(3) provides:

105.—(3) Where the request is to correct a specification of a patent or application, the request shall not be granted unless the correction is obvious (meaning that it is immediately evident that nothing else could have been intended in the original specification).

Correction of irregularities

23 Rule 107 provides for the rectification of irregularities of procedure in certain circumstances. It states:

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.

- 24 The period for paying the prescribed fee required for the SPC to take effect is prescribed in rule 116(2) and is listed in Part 1 of Schedule 4 to the Rules. Rule 107(3) therefore applies to this period of time.

Assessment

Genentech's case

- 25 I will begin with the case made by Genentech who have made submissions on the three questions listed above. I will consider each of these questions in turn.

Does rule 116(5) of the Rules allow further annual fees to be paid if an application for a paediatric extension is made, thereby extending the SPC to its maximum term?

- 26 As I have already said, the SPC Regulation provides for two types of fees: application fees and annual fees. The UK has made provision for both types of fees. The provision for annual fees is made in paragraph 5 of Schedule 4A and further requirements are set out in rule 116(5).
- 27 Rule 116(5) states that this prescribed fee must be accompanied by Form SP2. It specifies that “once the certificate has taken effect no further fee may be paid to extend the term of the certificate”. It is evident therefore that a general principle is that the term of the certificate cannot be extended by the payment of a further fee once the certificate has taken effect. One consequence is that it gives third parties certainty as to the duration of the certificate, subject to the possibility of a paediatric extension.
- 28 Rule 116(5) provides one exception to this general principle, namely that no further fee may be paid to extend the term of the certificate “unless an application for an extension of the duration of the certificate is made under the Medicinal Products Regulation”, that is that an application for a paediatric extension has been made. This rule does not explicitly list which further fees could be paid in these circumstances, but rather states that no further fees may be paid except in these circumstances.

- 29 There are two possible candidates for fees which could extend the duration of the certificate in these circumstances: the £200 fee specified in the Patents (Fees) Rules which must accompany the application for a paediatric extension, and the annual fee specified in paragraph 5 of Schedule 4A to further extend the term of the certificate to, for example, its maximum term.
- 30 In relation to the first of these fees, Genentech expresses doubt that this could be properly characterised as a “fee paid to extend the term of the certificate” as this is a fee charged for processing Form SP4, authorised and prescribed by rule 2(2)(b) of, and Schedule 1 to, the Patents (Fees) Rules, rather than one charged to extend the term of the certificate *per se*. I am not convinced by this argument as the Patents (Fees) Rules merely state that Form SP4 should be accompanied by the specified fee and this form is entitled “Application for grant of an extension to a Supplementary Protection Certificate”. The fee may well be charged to cover the cost of processing the form and is, of course, paid to apply for an extension, but this does not mean that it is not a “fee paid to extend the term of the certificate”. The fee in question must accompany the application, and an application for a paediatric extension is an application to extend the duration of the SPC by six months. It seems to me that, following a plain and common-sense reading of the rule, it is a fee which is “paid to extend the term of the certificate”.
- 31 The second candidate fee is a further annual fee as is prescribed by paragraph 5 of Schedule 4A. Genentech submits that rule 116(5), according to its natural and ordinary interpretation, allows payment of such a fee to extend the duration of a certificate to its maximum term in circumstances when an application for a paediatric extension has been made. There are five factors I will consider in deciding whether Genentech’s submission is correct. These are:
- the natural and ordinary interpretation of rule 116(5);
 - the nature of the fee specified in paragraph 5 of Schedule 4A to the Act;
 - the requirements of the SPC Regulation and the Paediatric Regulation;
 - the extent to which the IPO’s consultation document and concordance on the Patents Rules 2007 can be relied on to interpret rule 116(5);
 - the teaching of *Tulane Education Fund* [2013] EWCA Civ 890

The natural and ordinary interpretation of rule 116(5)

- 32 Genentech submits that the natural and ordinary meaning of rule 116(5) is clear, namely that once the certificate has taken effect no further fee may be paid to extend the term unless an application (for a paediatric extension) is made. They argue that this is not limited to the “application fee” for a paediatric extension as, if the legislature had intended to permit only particular fees, such as the £200 application fee, to be paid upon a paediatric extension being made, rule 116(5) could and would expressly provided as such. The natural, ordinary meaning of the rule does not lead to a perverse result that could reasonably lead one to suppose that some other meaning was intended by the legislature. In support of these arguments on the

interpretation of the provision Genentech refers to the House of Lords' confirmation in *Pinner v Everett* [1969] 1 W.L.R 1266 (as per Lord Reid) that:

"In determining the meaning of any word or phrase in a statute the first question to ask always is what is the natural or ordinary meaning of the word or phrase in its context in the statute? It is only when that meaning leads to some result which cannot reasonably be supposed to have been the intention of the legislature, that it is proper to look for some other possible meaning of the word or phrase. We have been warned again and again that it is wrong and dangerous to proceed by substituting some other words for the words of the statute."

- 33 I am not convinced that Genentech has correctly portrayed the natural and ordinary meaning of rule 116(5). The rule expresses a general rule that no further fee may be paid to extend the term of the certificate once the certificate has taken effect and specifies a single scenario where this rule does not apply, namely when an application for a paediatric extension is made. It is however silent on the fees which may be paid to extend the duration in that scenario. The natural and ordinary meaning of the rule therefore does not go as far as specifying which fees may be paid to extend the term of the certificate in this scenario. Other factors must be considered when answering this question, such as the other legislative provisions to which this rule relates and the other factors I have referred to above and will go on to consider. Lord Reid says in the above quote that the natural and ordinary meaning of the word or phrase must be considered in the *context of the statute* (my emphasis). I will now consider this context.

The nature of the fee specified in paragraph 5 of Schedule 4A to the Act

- 34 Paragraph 5 of Schedule 4A states that "a supplementary protection certificate does not take effect unless – (a) the prescribed fee is paid before the end of the prescribed period". It therefore seems to me that the "prescribed fee", which is the "annual fee" referred to in Article 12 of the SPC Regulation, is a fee intrinsically linked with the certificate taking effect. The value of the fee will depend on the intended duration of the certificate but paragraph 5 of Schedule 4A envisages a single fee paid before the certificate comes into effect. It does not envisage further payment of "prescribed fees" after the certificate has come into effect. It is this fee which, in accordance with rule 116(5), must be accompanied by Patents Form SP2 and whose value is set in rule 6 of the Patents (Fees) Rules.
- 35 There is therefore a specific statutory regime which makes clear that a single fee is paid, once, and then the term of the SPC is set. It would be wrong to construe another specific rule as undermining that clear position and there is no basis in rule 116(5) for doing so. Rule 116(5), when read in the context of the primary legislation, cannot therefore be interpreted as allowing a further fee prescribed by paragraph 5 of Schedule 4A to be paid to extend the duration of the certificate once the certificate has taken effect, whether an application for a paediatric extension has been made or not, as this would contravene the clear requirements of paragraph 5 of Schedule 4A.

The requirements of the SPC Regulation and the Paediatric Regulation

- 36 I have considered the UK primary legislation above, but I must also consider the requirements of the EU legislation, namely the SPC Regulation and the Paediatric Regulation.

- 37 Genentech refers to the Paediatric Regulation and, with reference to recitals (26) and (27) of this Regulation, notes that Article 36 includes a requirement that the relevant product is protected by an SPC but does not impose any additional requirement that the annual fees for the certificate have previously been prepaid for its entire maximum term. Article 36(1) grants the SPC holder an entitlement to a six-month extension of the period defined in Article 13(1) and (2) of the SPC Regulation. Genentech's primary position is to agree with the examiner's view that the "reward" provided for the Paediatric Regulation only takes effect at the end of the maximum duration of the SPC. They argue that, in that context, it is not at all unreasonable or unsurprising that rule 116(5) provides a general permission for paediatric extension applicants to pay further fees to extend the term of the certificate and does not only provide only for payment of the paediatric extension fee. This ensures that the applicants that have satisfied the requirements of the Paediatric Regulation are not precluded from obtaining the reward to which they are entitled by virtue of non-payment of fees. Genentech argues that the UK's implementation of the Paediatric Regulation would be defective if procedural rules would limit the availability of the extension only to applicants that had previously pre-paid for the maximum amount of annual fees, contrary to the purposes and provisions of the Paediatric Regulation.
- 38 Recital (26) of the Paediatric Regulation states that "a reward should be granted in the form of a 6-month extension of the supplementary certificate". This is implemented in Article 36 which states that the reward is entitlement to a six-month extension of the period defined in Article 13(1) and (2) of the 1992 Regulation¹. This Article clearly defines the maximum duration of the certificate. It seems therefore that the reward envisaged by Article 36 of the Paediatric Regulation is an extension to the maximum duration of the certificate as defined in Article 13(1) and (2) of the SPC Regulation. This is also made clear in Article 13(3) of the SPC Regulation which implements Article 36 of the Paediatric Regulation. There is no implication in Article 36 of the Paediatric Regulation or in Article 13(3) of the SPC Regulation that the reward should have any other effect and nothing to suggest that an extension should be available to applicants who have not taken their SPC for the maximum duration. There is therefore nothing in either the Paediatric Regulation or the SPC Regulation to suggest that that rule 116(5) should be interpreted so as to allow a further fee to be paid to extend the duration of the certificate to its maximum duration.

The extent to which the IPO's consultation document and concordance on the Patents Rules 2007 can be relied on to interpret rule 116(5)

- 39 The examiner referred to the consultation document and associated concordance produced for the Patents Rules 2007 in his interpretation of rule 116(5). Genentech argues that the examiner was wrong to do this as recourse may only be made to sources other than the statutory provision itself if the wording of the provision is unclear or ambiguous and sources extrinsic to the relevant legislation should be treated with great caution. Their view is that the IPO consultation document and concordance is not a document that may properly be used to assist in the interpretation of rule 116(5), particularly given that the document itself includes a comment that "this commentary is not intended to be used to interpret the Patent Rules 2007 if, and when, they come into force". The document does not represent

¹ Article 13(1) and (2) of the 1992 Regulation has identical wording to that of the codified 2009 Regulation.

the settled policy intentions of the government at the time of enactment of the 2007 rules, let alone the legislature. Genentech points out that the comment that “no change in practice is intended” in the commentary cannot be correct because the 2007 Rules implemented for the first time provisions relating to the Paediatric Regulation – there was no provision equivalent to the relevant part of rule 116(5) in the 1997 SPC Rules.

- 40 I agree with Genentech that the consultation document and concordance should be treated with caution, not least because provisions relating to the paediatric extension were implemented for the first time in the 2007 Rules and therefore the concordance is of less relevance for these provisions. I do note however that prior to the 2007 Rules rule 5(8) of the Patents (Supplementary Protection Certificates) Rules 1997 (the Rules in force immediately prior to the 2007 Rules), states “Where the effective period is less than the maximum period of the certificate it shall not subsequently be extended.” It was therefore clearly the case that, prior to the 2007 Rules, a certificate could not be subsequently extended when the effective period was less than the maximum period. I do not however place a great deal of weight on either the concordance and consultation document, or on the earlier version of the Rules.

The teaching of Tulane

- 41 The Court of Appeal’s judgment in *Tulane* is the precedent case most relevant to the present case. The circumstances in that case were different as they related to a failure to pay any annual fees rather than a question as to whether additional annual fees could be paid. In his judgment Kitchin LJ (as he then was) did however confirm that the UK’s rules did not conflict with the SPC Regulation:

47. *I believe the starting point for a consideration of these submissions must be Article 12 itself and I would make two general points at the outset. First, the provision is permissive; there has never been a requirement that Member States must implement an annual fee regime. Second, save that any fees must be “annual”, no restriction or limitation has ever been imposed upon Member States as to the level of the fees or when or how they must be paid. All of these matters have been left to Member States to decide for themselves and Article 18 of the 1992 Regulation (now Article 19 of the 2009 Regulation) permitted them to lay down special procedural provisions to give effect to those decisions.*

48. *That brings me to paragraph 5 of Schedule 4A, rule 116 of the Patents Rules and rule 6 of the Patents (Fees) Rules. These all relate to matters arising under the provisions of the 1992 Regulation and, as such, plainly fall within the scope of s.2(2) of the European Communities Act 1972, subject to the overriding requirement that they must of course impose a regime for the payment of annual fees.*

49. *In considering the crucial issue whether they impose a regime for the payment of annual fees, I think it important to have in mind that, for the reasons I have explained, an SPC may be granted some time before it is due to take effect. Further, the maximum term of each SPC will vary from certificate to certificate and depend upon the date on which the application for the basic patent was filed and the date of the first authorisation to place the product on the market in the EU, subject to the requirement that the duration of the certificate may not exceed five years from the date on which it takes effect.*

50. *Turning now to the fee structure set out in rule 6 of the Patents (Fees) Rules, it can be seen that as the number of years for which the certificate is to have effect increases, so also does the fee. Further and importantly, an applicant is not required to take a certificate for the whole period permitted by the Regulation. He may elect to take the certificate for a shorter period and, if he does so, he will only pay a fee in respect of those years for which he*

has elected. Thus far, as it seems to me, the prescribed fee may properly be described as an annual fee. It is calculated by reference to the number of years for which a certificate is to have effect.

51. I come then to consider the impact on this analysis of the requirement imposed by rule 116 of the Patents Rules that the fee must be paid before the SPC takes effect. Here I believe that Mr Johnson's submissions confuse the nature of the fee and the date upon which the liability to pay it arises. I do not believe that the fee ceases to be an annual fee because the rules impose an obligation to pay it in advance. Nor does the fee cease to be an annual fee because the rules impose an obligation to pay it all at once. Further, I do not consider that these rules are in conflict with Article 13. Provided the fee is paid within the prescribed period, the certificate will automatically take effect on the day after expiry of the basic patent.

- 42 Genentech submits that, in *Tulane*, Kitchin LJ did not consider the effect of rule 116(5) in circumstances where a paediatric extension application had been made as the point did not arise for consideration. They therefore argue that *Tulane* does not provide support for the construction of rule 116(5) suggested by the examiner.
- 43 Although these paragraphs do not directly address the present question, they nevertheless provide some useful further guidance. Firstly, in paragraph 47 Kitchin LJ states that, save that any fees must be "annual", no restriction or limitation has ever been imposed upon Member States as to the level of the fees or when or how they must be paid. All these matters have been left to Member States to decide for themselves. This confirms my conclusion that the SPC Regulation itself does not imply a particular interpretation of rule 116(5). Secondly, as is clear from the judgment as a whole, in paragraph 51 Kitchin LJ, is referring to the fact that the fee should be paid in advance and all at once. He does not address the situation as to what happens when an application for a paediatric extension is made, and therefore this judgment does not definitively decide the question, but nevertheless it adds weight to the evidence that the general principle is that the fee should be paid all at once and in advance of the certificate coming into effect.

Conclusions on this question

- 44 Taking into consideration all the factors I have discussed in the above paragraphs, and Genentech's written submissions on the question, I reach the conclusion that rule 116(5) cannot be interpreted in a way which allows further annual fees to be paid when an application for a paediatric extension is made.

Can a paediatric extension be allowed for an SPC in circumstances where the SPC is not in force for the full maximum term?

- 45 Genentech's primary position is that the paediatric extension only takes effect at the end of the maximum duration of the SPC. This view is however based on their understanding that rule 116(5) ensures compliance of the UK Rules with the Paediatric and SPC Regulations by allowing the payment of any fees necessary to enable the applicant to access the benefit of the paediatric extension when the extensions application is made, including any unpaid annual fees.
- 46 If, however, I conclude that rule 116(5) does not permit the payment of the additional annual fees required to extend the SPC to its maximum duration, as I have done, Genentech takes a different view. They submit that Article 36 of the Paediatric Regulation and Article 13 of the SPC Regulation must be interpreted in a manner

which is consistent with the legislative intention stated in Recital 26 of the Paediatric Regulation to provide a six-month extension to the SPC in the relevant circumstances. Genentech therefore concludes that the extension application should be allowed in any event and the existing term of the certificate extended by six months from 2 April 2020 to 2 October 2020.

- 47 I have already considered this question to an extent above in my consideration of the relevance of the SPC Regulation and the Paediatric Regulation to the construction of the rule 116(5). It is apparent that the Paediatric Regulation provides a six-month extension to the maximum duration of the certificate as defined in Article 13(1) and (2) of the SPC Regulation. This has been implemented in Article 13(3) of the SPC Regulation and this is the nature of the “reward” referred to in Recital (26) of the Paediatric Regulation. I find it difficult to interpret the Regulation in any other way, and it makes sense from a policy perspective too. There is no need to provide incentives to reward an SPC holder who, for whatever reason, has not taken the certificate for its maximum duration as, for what is a comparatively small annual fee, they could have chosen to take the SPC for its maximum duration. It therefore seems to me that the SPC Regulation and the Paediatric Regulation both clearly relate to extending the duration of the certificate as defined in Article 13(1) and (2) of the SPC Regulation and do not provide for an extension to an SPC which takes effect for a duration shorter than this period. I therefore conclude that Genentech’s application for a paediatric extension cannot be allowed on this basis.

Should I allow a request to correct the forms used to pay the prescribed fee for the SPC to take effect, so as to extend the duration of the certificate, under sections 117 and/or 32(2)(d) of the Act?

- 48 Genentech has made a request under section 117 and/or section 32(2)(d) of the Act in conjunction with rules 50 and 105 of the Rules that the comptroller exercises his discretion to correct errors in forms SP2 and FS2 filed by Genentech’s agent MDC on 26 March 2018 in connection with SPC/GB07/012. The requested corrections are:

1. Field 5 of the original Form SP2 incorrectly stated “2 years”. Field 5 of the corrected Form SP2 states “4 years”;
2. Field 6 of the original Form SP2 incorrectly stated that the total amount paid (in Pounds sterling) as “1300.00”. Field 6 of the corrected Form SP2 states “3000.00”;
3. Form FS2 originally recited a fee of “1300.00” in respect of SPC/GB07/012. The corrected form FS2 recites a fee of “3000.00” in respect of SPC/GB07/012, and the total paid has been updated accordingly to “4900.00”.

- 49 Genentech provided evidence to demonstrate that the failure to file their application for a paediatric extension in time was unintentional. The Office accepted this evidence and therefore allowed the late filing of the application. Genentech made the following statement in their letter of 6 December 2019:

“Genentech unintentionally missed the 2 April 2018 date for applying for a paediatric extension because at the time it was not aware that on 26th March 2018 MDC had,

contrary to Genentech's intentions and instructions, paid only two years of annual fees for the SPC, and not four years as had always been intended by Genentech.

It has at all times been Genentech's intention that the maximum available term of the SPC (i.e. to 23 January 2022) should be obtained and that the appropriate fees necessary to obtain the maximum term should be paid. It has never been Genentech's intention that only two years of the SPC term (or any other period apart from the maximum available) should be obtained.

Genentech's intention that the maximum term of the SPC should be obtained is confirmed by the witness statement of Nihan Corakci dated 2 December 2019 enclosed herewith. As that witness statement makes clear, Genentech's consistent instructions to MDC were that the expiry date of the SPC should be 23 January 2022 and that MDC should pay the annual fees necessary to put that intention into effect. MDC's Confirmation of Payment report confirmed to Genentech an expiry date for the SPC of 23 January 2022."

- 50 I have read the witness statement in question and the exhibits attached thereto and am satisfied that it supports Genentech's statement that it was always their intention to obtain the maximum term available for the SPC.
- 51 In the light of this Genentech submits that the entries they seek to correct are therefore unintentional mistakes made by Genentech's agent. Genentech highlights that section 117 allows correction of "any document filed in connection with a patent or such application" and note that section 128B of, and paragraphs 1 and 2 of Schedule 4A to, the Act apply this provision to SPCs. They also comment that, because Forms SP2 and FS2 are not a patent or application for a patent (or equivalent thereof) then rule 105(3) does not apply.
- 52 The examiner argued that this request for a correction should be refused on the grounds that, as there are no discrepancies between Forms SP2 and FS2, and the fees paid are specifically directed to a term of two years, it is not apparent that there is an obvious error. The examiner also dismissed the request to correct under section 32(2)(d) as this provision is directed to correction of the register, not to any forms supplied in support of an application.
- 53 Genentech filed further submissions on this question in a letter dated 20 January 2019. These submissions have not been considered by the examiner but I have considered them fully. In this letter Genentech submits that the requirement in rule 105(3) for an error to be readily identifiable before correction under section 117 can be considered is only applicable to correction of a specification. Corrections to other documents in connection with a patent or such an application, Genentech argues, are not subject to such a requirement. Forms SP2 and FS2 are not the "text" of the SPC but instead "any document filed in connection with an SPC" and hence rule 105(3) does not apply. They submit that this is consistent with section 117 of the IPO's Manual of Patent Practice (particularly paragraphs 117.07-117.11) and is further supported by the commentary in the CIPA Guide to the Patents Acts 9th Ed, making specific reference to section 117.07 of this Guide which reads:

"Rule 105(3) relates only to corrections in specifications. Accordingly, corrections to documents other than specifications are not required to be obvious in the sense "that it is immediately evident that nothing else would have been intended in the original specification". Rule 139 of the EPC is to like effect and, on this basis, the EPO Boards of Appeal have

allowed correction of non-evident mistakes in documents other than specifications, see §117.11.”

- 54 Genentech therefore concludes that the examiner incorrectly applied the requirements that the requested corrections of Forms SP2 and FS2 be “readily identifiable” and that the request for correction of Forms SP2 and FS2 should be allowed.
- 55 Genentech’s request to correct Forms SP2 and FS2, and so extend the duration of the SPC, is not a request to correct the register and therefore I agree with the examiner that section 32(2)(d) does not apply in this case. I will go on to consider section 117 in more detail. I agree with Genentech that the request does not relate to a correction of the SPC text itself but rather to “any document filed in connection with a patent or such application” and therefore rule 105(3) does not apply.
- 56 Section 117 provides that any person may give the comptroller notice of opposition to the correction. Rules 75 and 105(5) requires the comptroller to advertise in the Journal any such events unless the comptroller decides that no person could reasonably object. In the present case I do not consider that to be the case given that the request will extend the duration of the SPC and therefore, if I were minded to allow the correction, it would need to be advertised in the Journal.
- 57 Section 117 gives the comptroller general powers to correct errors of translation or transcription, clerical errors or mistakes in documents relating to patents or applications for patents. It is however a well-established principle that the general powers of section 117 cannot be used to circumvent the clear mandatory specific provisions of the Act. See for example *Antiphon AB.’s Application* [1984] RPC 1 and *Payne’s Application* [1985] RPC 193, both specifically relating to section 117, and *E’s Applications* [1983] RPC 231, relating to an earlier version of rule 107 (which was at that time rule 100) which relates to procedural irregularities. In *E’s Applications* Lord Diplock said:

“An irregularity in procedure is simply a failure to observe procedural rules, whatever the cause of the failure may be. Where there is a discretion to rectify the failure, the reason for it may be of the utmost relevance to the way in which that discretion should be exercised; but if rule 100 confers upon the comptroller jurisdiction to excuse failure to observe a time limit which is made inextensible by rule 110(1) and (2), on the ground that it is an irregularity in procedure, that jurisdiction must extend to all such failures whatever the reason for them may be, with the result of rendering the express prohibition of extensions of specified time limits by rule 110(1) and (2) wholly nugatory. So to construe rule 100 in relation to rule 110 would be to turn on its head the well-established canon of construction generalia specialibus non derogant.”

- 58 In *Payne’s Application*, Falconer J said, quoting his own judgment in *Antiphon*:

What I said in the Antiphon case, and perhaps I may be forgiven if I read it again and then make some comments about it, was this:

“Section 117(1), which I have already read, is, of course, expressed in general terms, but to allow, under its provisions and those of rule 91 (which is the rule made pursuant thereto), correction of an error or mistake such as that sought to be corrected in this case”—that is the Antiphon case—“so as to allow the application to proceed as if the drawings filed later were part of the documents initially filed, would be to allow the provisions of section 117(1) and rule 91 to be used to circumvent the clear mandatory provisions of section 15(2). Section 15(2) is a particular enactment in

the statute and, although section 117(1) is an enactment in general terms in the statute, it seems to me that it can have no application to a case which falls within the terms of section 15(2) and must be taken to affect only the other parts of the statute to which it may properly apply: see Halsbury's Laws of England, 3rd Edition, Volume 36, paragraph 597 at page 397."

I concluded:

"In my judgment, under the provisions of section 117(1) and rule 91, a correction may not be allowed if the effect of it would be to allow an applicant to circumvent the clear mandatory requirements of section 15(2)."

- 59 These cases therefore demonstrate the applicability of the principle that a general provision cannot be used to circumvent a specific mandatory legislative provision.
- 60 As these cases were not referred to by the examiner I offered Genentech an opportunity to make submissions on them. Such submissions were received in a letter dated 11 February 2020 and I have fully considered them. Genentech submits that none of these cases were applicable to the present matter as Genentech does not seek to circumvent any such mandatory provisions through its correction of Forms SP2 and FS2. Genentech is not seeking to pay a further fee to extend the term of the SPC but rather is seeking only to correct the erroneous references made by MDC on Forms SP2 and FS2 to the term of the SPC and to correct the amount of the fee paid in March 2018. This, Genentech argues, is to be distinguished from a situation where a certificate holder intentionally opts for an effective period less than the maximum period of the certificate and requests subsequently that this initially-requested period be extended (without applying for a paediatric extension) – such a certificate holder could not rely on section 117 as there would be no mistake capable of correction. MDC's deposit account at all material times contained sufficient funds to cover the entire correct fee of £3000. Allowance of Genentech's application would not therefore entail any further payment – the fees have already been paid – but would ensure that the previously paid fees are correctly allocated by the Office to the proper term of the SPC. The effect of correcting forms SP2 and FS2 as requested by the applicant is not therefore a request to pay a "further" fee.
- 61 I do not agree with Genentech's point that they are not seeking to pay a further fee but rather that the fees have already been paid due to the funds being available in MDC's deposit account at the material times. A fee is not paid until such funds are allocated to a fee-bearing action, in this case the filing of original Form SP2. Correcting Forms SP2 and FS2 does therefore have the effect of further money being allocated to Form SP2 and therefore a further fee, or at least an additional part of a fee, being paid. I will therefore go on to consider the specific legislative framework governing the payment of such fees.
- 62 In the present case the specific legislative framework is governed by paragraph 5 of Schedule 4A and rule 116. Paragraph 5 specifies that an SPC does not take effect unless, according to sub-paragraph (a), "the prescribed fee is paid before the end of the prescribed period". Sub-paragraph (b) provides a six-month period for late payment of the fee. Rule 116(5) specifies that no further fee may be paid to extend the term of the certificate unless an application for a paediatric extension is made. I have discussed these provisions in detail above. For present purposes it suffices to say that paragraph 5 of Schedule 4A and rule 116(5) make specific provision for the

payment of the annual fee, namely that it must be paid in order for the certificate to take effect and, in accordance with my interpretation of rule 116(5) above, no further fee can be paid to extend the term of the SPC apart from an application fee for a paediatric extension. Although this rule is in secondary legislation rather than primary legislation, it does stem from the provisions of paragraph 5 of Schedule 4A to the Act. The annual fee must therefore be paid in full and in advance of the certificate taking effect, and no further fee can be paid to extend the term of the SPC apart from an application fee for a paediatric extension. This is the specific legislative framework which governs the payment of the annual fees.

- 63 I note that there is one situation where the Act makes specific provision for section 117 to overcome what otherwise would be a specific provision in the legislation. Section 14(9) of the Act states that a withdrawal of a patent application may not be revoked. Section 14(10) has however been introduced which states that section 14(9) does not affect the power of the comptroller to correct a mistake or error in a withdrawal of an application. Special provisions have also been introduced into section 117 for this situation, namely that the comptroller must publish a notice if the application in question had been published and details of its withdrawal published and that the comptroller may only correct such an error or mistake under section 117 by order. No specific legislative provision has however been provided to enable the payment of annual fees for an SPC once the SPC has taken effect, or for extending the duration of an SPC, by way of correcting Form SP2. Whether the additional fee can be considered a "further" fee or part of the original fee is immaterial, the legislation makes specific provision that the prescribed fee must be paid before the certificate takes effect.
- 64 Moreover, in the present case the comptroller is being asked to correct Form SP2 in a manner which would extend the duration of the SPC, and therefore the SPC holder's monopoly on the product covered by the SPC, by nearly two years, nearly doubling its duration. Thus the correction would have a very significant impact on the SPC in question and could potentially have a very significant impact on third parties.
- 65 I therefore take the view that the principle in the cases I have referred to above, namely that the general powers of section 117 cannot circumvent specific provisions in the Act, applies in the present case. The general powers given to the comptroller by section 117 cannot circumvent the specific provisions for the payment of the annual fees set out in Schedule 4A to the Act and in rule 116 of the Rules. I therefore conclude that the request to correct Forms SP2 and FS2 cannot be allowed.

Master Data Center's case

Has there been an irregularity in procedure, a mistake or an error attributable at least in part to the Office and, if there has, should the irregularity be rectified under rule 107?

- 66 I turn now to the submissions made by MDC, the company responsible for the administration of SPC/GB07/012. MDC's submissions are based on rule 107 of the Rules. In brief MDC's argument is essentially that UK practice, whereby an SPC holder can choose a duration for the SPC which is shorter than the duration defined in Article 13(1) and (2) of the SPC Regulation, is not permissible under the SPC

Regulation. This resulted in an irregularity in procedure attributable to Office which can and should be rectified in accordance with rule 107.

67 MDC highlights the provisions of rule 116(3) and (4) which require the comptroller to send a notice to the applicant for the certificate within the specified period. This notice must, amongst other things, notify the applicant of the prescribed fee due. In the present case the relevant part of the notice read:

“The maximum period of duration for the certificate in accordance with Article 13 will expire on 23 January 2022, therefore the period is made up of 4 effective years as defined by Fees Rule 6(2), for which the prescribed fees are:

- for first year or part thereof £600
- for second year or part thereof £700
- for third year or part thereof £800
- for fourth year or part thereof £900
- for fifth year or part thereof £1000.

As set out in Rule 116(5) the desired effective period of the certificate, which may be less than the maximum period allowable, should be specified on Form SP2 ... which ... should accompany the fees due for that period.”

68 MDC considers this approach to be fundamentally flawed. They submit that Article 13(1) of the SPC Regulation only sets out one duration of an SPC which is calculated in accordance with the formula set out in the Article and is clear from the language of the Article. There is no provision for a shorter period and there is no room for discretion on this issue. If a proprietor wants a shorter duration for their SPC then, MDC submits, the proper course is to surrender the SPC in accordance with Article 14(b).

69 MDC therefore concludes that the IPO’s notice issued under rule 116(3) and (4) was wrong to suggest the proprietor can choose a different duration from that dictated by Article 13 and is not consistent with the SPC Regulation. MDC also argues that this is not consistent with rule 116(5) which does not give the proprietor the right or power to choose a different duration. Instead, this part of rule 116(5) simply makes clear that there is one prescribed fee and one duration, and the only opportunity for extending the duration is by way of a paediatric extension.

70 MDC also submits that the notice failed to set out the prescribed fee due as is required by rule 116(4)(b). That requirement makes clear that there is only one fee, which reflects the fact that there is only one duration. In this case, according to MDC, the notice should have clearly stated that the fee due was £3,000 in accordance with rule 6 of the Patents (Fees) Rule 2007, rather than the generic breakdown provided which left it to the proprietor to work out the relevant fee themselves. As a result of this irregularity Form SP2 was incorrectly completed to state that the fees amounted to £1300 and the resulting duration of the SPC was two years.

71 In a similar vein MDC argues that the comptroller failed to send any notice of unpaid fees, as he is required to do by rule 116(6). They submit that, if the comptroller’s

practice is only to send a reminder notice under rule 116(6) if a proprietor has failed to pay any fee at all by the due date, this will lead to inequitable results. In both cases the proprietor has failed to pay the fee specified in rule 6 of the Patents (Fees) Rules 2007 and should be given the same chance to do so.

- 72 MDC is seeking a rectification of procedure such that the duration of the SPC is extended to expire on 23 January 2022.
- 73 There was some debate between MDC and the examiner as to the relevance of the Court of Appeal's judgment in *Tulane* to the present case. This centres on a comment Kitchin LJ (as he then was) made in paragraph 50 (set in out in full above) that an SPC applicant "may elect to take the certificate for a shorter period and, if he does so, he will only pay a fee in respect of those years for which he has elected." MDC takes the view that Kitchin LJ's conclusion in paragraph 50 was based on pre-existing IPO practice without any assessment of the compliance of that practice with the SPC Regulation or the Rules. In merely recording what this practice is, Kitchin LJ was not purporting to analyse (let alone decide) the issue which arises in this case. There was no discussion of whether this practice was permissible in the *Tulane* Court of Appeal judgment precisely because it was not an issue in that case. Nor does it appear to have been argued in *Tulane* that, insofar as the term of the SPC was limited to a period that was shorter than that set out in Article 13 of the SPC Regulation, that could only be done through surrender of the SPC.
- 74 Before I go into the detail of this question I will comment briefly on the extent to which rule 107(3) applies in the current circumstances. For further annual fees to be paid I would need to agree to extending the period for filing such fees prescribed in rule 116(2). This period is listed in Part 1 of Schedule 4 to the Rules and therefore is one to which rule 107(3) applies. MDC's case is, of course, that there has been an irregularity attributable to an error by the Office and so rule 107(3) is relevant.
- 75 UK practice has always been to allow SPC holders to choose a duration for an SPC which is shorter than the maximum duration. This practice was explicitly set out in rule 5(3) of the Patents (Supplementary Protection Certificates) Rules 1997 and, prior to the 1997 Rules, in rule 5(3) of the Patents (Supplementary Protection Certificate for Medicinal Products) Rules 1992. The 1997 Rules were replaced by the current 2007 Rules. In the UK's current legislation, the situation is set out in paragraph 5 of Schedule 4A to the Act which states that an SPC does not take effect unless the prescribed fee is paid before the end of the prescribed period, and in rule 116(5) of the Rules. Rule 116(5) sets out the requirement that the prescribed fee be accompanied by Form SP2. It also specifies that no further fee may be paid to extend the term of the certificate once the certificate has taken effect except in the case of an application for a paediatric extension. I have discussed this provision in detail above. For the purposes of this discussion it will suffice to say that I can see nothing in this rule that prohibits allowing SPC holders to pay a fee to bring the SPC into effect for a duration which is less than its maximum duration. In fact it could be argued that the rule, in addressing (and forbidding) the possibility of filing a further fee to extend the term of the certificate once the certificate has taken effect, implies that it is possible to select a duration, and pay the appropriate fee, which is shorter than the maximum duration. Nor do I consider that it follows from the fact that rule 116(4)(b) states that the notice must notify the applicant of "the prescribed fee due" that the fee must correspond to the maximum possible term of the SPC. I do not

therefore accept MDC's submissions that current IPO practice is inconsistent with the Rules.

- 76 I am also not convinced of MDC's interpretation of the SPC Regulation. Article 13(1) does indeed define "a period" for which the certificate shall take effect which is equal to what, under UK practice, would be considered its maximum term. Article 13(2) sets an upper limit for the duration of the certificate, namely five years. Article 13(3) provides for an extension to this maximum duration in the case of a paediatric extension. But Article 12 states that "Member states may require the certificate to be subject to annual fees" and Article 14(c) provides that the certificate shall lapse if the annual fee is not paid in time.
- 77 MDC seems to suggest that the only means the SPC Regulation provides for reducing the term of the SPC is by way of surrender under Article 14(b) but clearly the SPC Regulation provides for another means, namely if annual fees are not paid in time. This suggests a system whereby applicants for SPCs can choose a duration of their certificate for less than the period defined in Article 13 by choosing not to pay the relevant annual fees. If a Member State implements a system whereby annual fees are paid each year then a failure to pay a fee in time for a specific year would, in accordance with Article 14(c), cause the SPC to lapse.
- 78 The UK has taken up the option to implement annual fees but, rather than requiring that they be paid on a year-by-year basis, requires them to be paid in advance as a single up-front prescribed fee. I have already found that, in *Tulane*, the Court of Appeal held that the UK system of requiring a prescribed fee in advance of the SPC coming into effect was consistent with Article 12 of the SPC Regulation and could be considered a system for requiring annual fees in accordance with that Article. As MDC has pointed out, Kitchin LJ went further in his judgment and stated that an SPC applicant "may elect to take the certificate for a shorter period and, if he does so, he will only pay a fee in respect of those years for which he has elected." I agree with MDC that this point wasn't at issue in *Tulane* and there does not seem to have been any arguments presented by either party on this point. Nor is there any analysis set out in the judgment. Nevertheless, it is a clear, explicit statement made by the Court of Appeal.
- 79 If the fee paid does not cover the full possible duration of the SPC then in effect it lapses at the end of the final year which is covered by the fee paid. I do not therefore agree with MDC that, in enabling SPC applicants to choose a term for their SPC shorter than the maximum term, UK practice is not permitted by the SPC Regulation. I also consider that, given this flexibility available to SPC holders, the notice provided by the Office satisfies the requirements of rule 116(4).
- 80 I therefore conclude that the IPO's practice of allowing an applicant for an SPC to select a duration shorter than that of the maximum possible duration is consistent with all the SPC Regulation and with the relevant UK legislation, as was confirmed by the Court of Appeal in *Tulane*. I can therefore find no irregularity in procedure attributable, wholly or in part, to a default, omission or other error by the comptroller, an examiner or the patent office. Rule 107 may not therefore be used to correct any irregularity of procedure in the present case.

- 81 I will comment briefly on two pieces of evidence provided by MDC. Firstly, MDC provided evidence in the form of a witness statement of Stacey Marie Nalepka with various exhibits to the effect that, had they received a reminder from the IPO to pay the remaining part of the annual fee before the end of the period prescribed for doing so, they would have acted on this. I have no reason to doubt this evidence but, as I have found that there was not irregularity in procedure in the Office, this point falls away.
- 82 Secondly MDC has provided evidence in the form of a witness statement of David Knight and various exhibits to the effect that, if the duration of the SPC was extended to its maximum term, it would have minimal effect on third parties, as third parties are already proceeding on the basis that SPC/GB07/012 expires on 23 January 2022. This point could be relevant to the question as to whether and how the comptroller should exercise discretion but, as I have found that there is no irregularity in procedure in the Office, there is no basis upon which the comptroller may exercise his discretion under rule 107 in the present case and this point therefore falls away. I will not therefore consider it any further.

Conclusion

- 83 In conclusion I have found the following:
- a. Rule 116(5) does not allow further annual fees to be paid in the situation where an application for a paediatric extension is made.
 - b. A paediatric extension extends the maximum possible duration of an SPC and would not therefore extend the actual duration of SPC/GB07/012.
 - c. The request to correct Form SP2 and Form FS2 so as to extend the duration of the SPC to its maximum term, made under section 117, cannot be allowed.
 - d. There has been no irregularity of procedure, clerical error or mistake attributable, wholly or in part, to a default, omission or other error by the comptroller, an examiner or the Patent Office and therefore there is no basis upon which the comptroller may exercise his discretion under rule 107 to extend the period for paying further annual fees.
- 84 I therefore refuse the request to pay further annual fees for SPC/GB07/012 and refuse the application for a paediatric extension. The duration of SPC/GB07/012 therefore remains as it currently is and the SPC will lapse on 02 April 2020.

Appeal

- 85 Any appeal must be lodged within 28 days after the date of this decision. Although the parties have argued their cases separately this decision covers the arguments made by both parties. It is therefore open to either party to appeal.

B MICKLEWRIGHT

Deputy Director, acting for the Comptroller