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Case No: A3 2020 0524  
A3 2020 0527

**IN THE COURT OF APPEAL (CIVIL DIVISION)**  
**ON APPEAL FROM THE HIGH COURT OF JUSTICE**  
**BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES**  
**INTELLECTUAL PROPERTY LIST**  
**MR RECORDER DOUGLAS CAMPBELL QC (sitting as a Judge of the Patents Court)**  
**[2020] EWHC 572 (Pat)**

Royal Courts of Justice  
Strand, London, WC2A 2LL  
Date: 31/03/2020

**Before :**  
**LORD JUSTICE FLOYD**  
**LADY JUSTICE NICOLA DAVIES**  
**and**  
**LORD JUSTICE ARNOLD**

**Between :**  
**GENENTECH INC.**

**Appellant**

**- and -**  
**THE COMPTROLLER GENERAL OF PATENTS**

**Respondent**

**And between:**  
**MASTER DATA CENTER, INC**

**Appellant**

**- and -**  
**THE COMPTROLLER GENERAL OF PATENTS**

**Respondent**

**Andrew Lykiardopoulos QC (instructed by Marks & Clerk Law LLP) for Genentech Inc.**  
**Charlotte May QC (instructed by Fieldfisher LLP) for Master Data Center, Inc**  
**Michael Silverleaf QC (instructed by Government Legal Department) for The Comptroller  
General of Patents**

Remote hearing date: 26 March 2020

## **Approved Judgment**

**Covid-19 Protocol: This judgment was handed down remotely by circulation to the parties' representatives by email, release to BAILII and publication on the Courts and Tribunals Judiciary website. The date and time for hand-down is deemed to be 2 pm on Tuesday 31 March 2020.**

**Lord Justice Floyd:**

1. There are two appeals before the court, both from a decision of Mr Recorder Douglas Campbell QC (sitting as a Judge of the Patents Court) given on 11 March 2020. The appeals are concerned with a Supplementary Protection Certificate (SPC) designated SPC/GB07/012 (“the SPC”) in the name of Genentech Inc. (“Genentech”), the appellant in the first appeal. The appellant in the second appeal is Master Data Center, Inc (“MDC”). MDC’s interest in its appeal is that it acted as Genentech’s agent in connection with the payment of fees for the SPC. Both appeals are concerned with the fact that, contrary to instructions given by Genentech to MDC to apply for an SPC for the maximum duration (which would have expired on 23 January 2022), MDC only applied for a two-year SPC, with the consequence that the SPC will lapse in a few days’ time, on 2 April 2020.
2. Recorder Campbell’s order was made on appeals by Genentech and MDC from a combined decision of Mr B. Micklewright, a Hearing Officer acting for the respondent, The Comptroller General of Patents (“the Comptroller”). By various procedural applications to which I shall come, the Comptroller had been asked to grant a remedy which would have the effect of allowing the SPC to continue in force until its maximum duration. In a decision arrived at on the papers alone dated 21 February 2020 Mr Micklewright refused the several applications before him. The Recorder dismissed both appeals from that decision after an expedited hearing on 4 March 2020 at which all parties were represented by leading counsel. On 20 March 2020 I granted permission to appeal to this court. A remote hearing of the appeals was held by video conferencing on 26 March 2020 pursuant to Practice Direction 51Y- Video or Audio Hearings during Coronavirus Pandemic, signed by the Lord Chancellor and the Master of the Rolls on 24 March 2020. This avoided the need for any member of the court, party or legal representative to attend court. A media representative was able to access the proceedings remotely, by joining the video conference, and accordingly the proceedings were held in public, pursuant to paragraph 3 of that Practice Direction.
3. At the hearing of the appeal, as they were below, MDC was represented by Miss Charlotte May QC, Genentech by Mr Andrew Lykiardopoulos QC and the Comptroller by Mr Michael Silverleaf QC. The court was provided with efficient access to electronic bundles via a Dropbox link. The parties and their representatives deserve the court’s praise for their ability to adapt at extremely short notice to these new arrangements.
4. The SPC is a form of protection regulated by European Parliament and Council Regulation 469/2009/EC of 6 May 2009 concerning the supplementary protection certificate for medicinal products (“the SPC Regulation”). SPCs have the effect of extending the life of a patent for a medicinal product which has been granted a marketing authorisation for a period of up to five years beyond its normal expiry date, under the conditions laid down in the SPC Regulation. Their purpose is to compensate a patentee for the delay in bringing a medicinal product to market consequent on the need to obtain regulatory clearance in the form of a marketing authorisation.

5. EU legislation also provides the opportunity for the duration of an SPC to be extended where the holder has undertaken specified research into paediatric indications for the medicine concerned. Regulation (EC) No. 1901/2006 of the European Parliament and the Council of 12 December 2006 on medicinal products for paediatric use (“the Paediatric Regulation”) allows for a single six month extension to the duration of the SPC where the holder of the SPC has undertaken research of a specified kind into paediatric indications for the medicine in question. The purpose of offering this reward is to encourage such research, which is considered to be in the public interest.

*The relevant EU legal regime*

6. The SPC Regulation, whilst laying down the basic architecture of the scheme for the grant of SPCs, leaves many matters of finer detail to the laws of Member States. The principal provisions of the SPC Regulation which are of relevance are the following:

**Article 7**

Application for a certificate

1. The application for a certificate shall be lodged within six months of the date on which the authorisation referred to in Article 3(b) to place the product on the market as a medicinal product was granted.
2. Notwithstanding paragraph 1, where the authorisation to place the product on the market is granted before the basic patent is granted, the application for a certificate shall be lodged within six months of the date on which the patent is granted.
3. The application for an extension of the duration may be made when lodging the application for a certificate or when the application for the certificate is pending and the appropriate requirements of Article 8(1)(d) or Article 8(2), respectively, are fulfilled.
4. The application for an extension of the duration of a certificate already granted shall be lodged not later than two years before the expiry of the certificate.
5. ...

**Article 8**

Content of the application for a certificate

...

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

## **Article 12**

### Annual fees

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

## **Article 13**

### Duration of 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 [the Paediatric Regulation] applies. In that case, the duration of the period laid down in paragraph 1 of this Article may be extended only once.

## **Article 14**

### Expiry of the certificate

The certificate shall lapse:

- (a) at the end of the period provided for in Article 13;
- (b) if the certificate holder surrenders it;
- (c) if the annual fee laid down in accordance with Article 12 is not paid in time;
- (d) ...

## **Article 15**

### Invalidity of the certificate

1. The certificate shall be invalid if:
  - (a) it was granted contrary to the provisions of Article 3;
  - (b) the basic patent has lapsed before its lawful term expires;

(c) the basic patent is revoked or limited to the extent that the product for which the certificate was granted would no longer be protected by the claims of the basic patent or, after the basic patent has expired, grounds for revocation exist which would have justified such revocation or limitation ...

## **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...

7. Article 13 paragraphs (1) and (2) contain a formula from which the unique duration of an SPC can be calculated from (a) the date on which the application for a basic patent was lodged and (b) the date of the first authorisation to place the product on the market in the Community. The period between these two dates is then reduced by a period of five years to get the length of the certificate, capped at a maximum of 5 years.
8. The EU regime, by Article 8(4), allows (but does not compel) Member States to impose an *application* fee for an SPC or for a paediatric extension. Additionally, Article 12 allows (but equally does not compel) Member States to impose *annual* fees, to which the SPC is “subject”. If a Member State does impose a system of annual fees, however, then Article 14(c) provides that the SPC “shall lapse” in the event of non-payment of the annual fees. As can be seen from its title, Article 14 treats “lapse” as a species of “expiry”.

### *The relevant national procedural regime for SPCs*

9. The UK procedural provisions for SPCs are to be found in the Patents Act 1977 (“the Act”), the Patents Rules 2007 (as amended) (“the Rules”) and the Patents (Fees) Rules 2007 (as amended) (“the Fees Rules”).
10. Section 128B of the Act (as amended by the Patents (Supplementary Protection Certificates) Regulations 2014 with effect from 1 October 2014) provides:

### **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) ... .

11. Paragraph 5 of Schedule 4A to the Act, provides as follows:

**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.

12. The “prescribed additional fee” is thus an extra fee which allows the applicant to pay in the six months after the end of the prescribed period. “The prescribed fee”, “the prescribed period” and “the prescribed additional fee” are all defined in the Rules and the Fees Rules, which also contain obligations on the Comptroller to serve various notices. Rule 116 deals with the prescribed period and the notices. It provides as follows, so far as relevant:

**Supplementary protection certificates**

116. ...

(2) The period prescribed for the purposes of paragraph 5(a) of Schedule 4A to the Act is—

(a) three months ending with the start date; or

(b) where the certificate is granted after the beginning of that period, three months beginning immediately after the date the supplementary protection certificate is granted.

(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.

...

13. “The prescribed fee” and “prescribed additional fee” are defined in the Fees Rules at rule 6:

#### **Supplementary protection certificates**

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.

14. Other provisions of the Act and the Rules are relevant to the applications which were made to remedy the effect of the failure to apply for an SPC for the maximum duration. I will set those out in the appropriate context.

*The facts*

15. The factual chronology is not in dispute. The SPC was applied for in February 2007 and was granted to Genentech on 17 July 2007. The certificate states as follows:

“In accordance with Article 10(1) of the [SPC] Regulation, Supplementary Protection Certificate No SPC/GB07/12 is hereby granted to Genentech Inc. in respect of the product ‘ranibizumab’ protected by basic patent No EP0973804 entitled ‘Anti-VEGF Antibodies’.

This certificate will take effect (subject to the payment of the prescribed fees) at the end of the lawful term of the basic patent and its maximum period of duration in accordance with Article 13 will expire on 23 January 2022 subject to the provisions of Articles 14 and 15.”

16. Ranibizumab is the active ingredient of the medicine Lucentis, which has found application in the treatment of wet age-related macular degeneration. The expiry date is the date calculated in accordance with Articles 13(1) and (2), but is expressly stated to be subject to Articles 14 and 15 of the SPC Regulation. In other words, it is recognised that the SPC may expire on an earlier date if, for example, the applicant fails to pay an annual fee, surrenders the SPC, or the SPC is invalid for any of the reasons specified in Article 15.
17. On 5 January 2018, the UK Intellectual Property Office sent a letter to Genentech’s patent attorneys. This was the Comptroller’s notice under rule 116(3) of the Rules, sent within the period of 2 months of the start date of the SPC, as required by that rule. The full text of the notice is included as Annex 1 to the Recorder’s judgment. It is common ground that the notice correctly notified Genentech of the fact that payment was required for the certificate to take effect; the date before which payment must be made; and the start date of the SPC, all as required by rule 116(4)(a), (c) and (d). MDC contends, however, that it did not notify Genentech of the “prescribed fee due” in breach of rule 116(4)(c). The letter did contain the following paragraph:

“The maximum period of duration of 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<sup>1</sup>”.

18. The fee structure specified in the notice is not in the same format as in rule 6(2) of the Fees Rules. Those in the notice are based on the incremental fee for each year, whereas rule 6 gives accumulated fees depending on the date of expiry. The notice went on as follows:

“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 (blank copy enclosed) which, together with the fee sheet FS.1, should accompany the fees due for that period.

**Pursuant to Rule 116(5), where the effective period chosen by the applicant is less than the maximum allowable period of the certificate it cannot subsequently be extended unless an application for an extension of the duration of the certificate is made under the Regulation on medicinal products for paediatric use, Regulation (EC) No 1901/2006 .**

If the fees have not been paid by the due date, or (together with the additional late payment fee) within the further period of six months prescribed by paragraph 5(b) of Schedule 4A to the Patents Act 1977, the certificate will lapse in accordance with Article 14(c) of the Regulation.

**WARNING: IT IS NOT POSSIBLE FOR THE APPLICANT TO OPT TO PAY RENEWAL FEES ANNUALLY ON SUPPLEMENTARY PROTECTION CERTIFICATES IN THE UNITED KINGDOM. THIS IS A REQUEST FOR A ONE-OFF PAYMENT OF FEES TO COVER THE EFFECTIVE PERIOD CHOSEN BY THE APPLICANT FOR WHICH HE REQUIRES PROTECTION AND CANNOT BE EXTENDED. SPC PRACTICE IS THEREFORE DIFFERENT FROM THAT ON PATENT RENEWALS DURING THE FIRST 20 YEARS OF LIFE OF THE PATENT AND SPC ANNUAL RENEWAL PRACTICE IN OTHER EC STATES SUCH AS FRANCE.”**

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<sup>1</sup> The fee for expiry in the fifth year was obviously redundant in this case, but nothing turns on that.

19. There are three things to bring out at this point. First, it is MDC's case that, contrary to what is offered by this notice, it was not open to the Comptroller to operate a system which allows the applicant to select a shorter period of duration than the one laid down by Article 13 of the SPC Regulation. MDC's contention is that the notice was in error in suggesting that fees could be paid for part only of that period. Secondly, Genentech relies on the notice for what is said in the first of the emboldened paragraphs cited at [18] above. It contends that that paragraph is consistent with its own construction of the Rules, under which it is possible for an applicant to select a duration shorter than the maximum for its SPC, but then to extend it to the maximum term of the SPC by paying the fees for extra years for the SPC as well as the fee for the paediatric extension. Thirdly, the emboldened and capitalised paragraph at the end draws attention to the fact that the UK system for the payment of fees differs from that of other member states in that the UK fees are not permitted to be paid annually, that is to say on a year-by-year basis as they fall due. That is not to say that they are not "annual fees" as permitted by Article 12 of the SPC Regulation, as we shall see.
20. Genentech adduced evidence from Ms Nihan Coracki, Global Head of IP Data & Annuities in Global Patent Operations and employed at F.Hoffman-La Roche AG ("Roche"). She explained that MDC was contracted to make annuity payments on behalf of the Roche group of companies, which includes Genentech. She said that MDC had standing instructions to pay the full annuity fees for all relevant rights which had payments due. Although there were some exceptions to these instructions, none of these exceptions applied to this SPC. Genentech's instructions to MDC were thus that the annual fee should be paid for the maximum available term of the SPC. MDC was also specifically instructed that the expiry date of the SPC was 23 January 2022.
21. Acting on behalf of Genentech, MDC filed Patents Form SP2 on 26 March 2018. Form SP2 has the following two questions of importance:
  - “5. What period do you want the certificate to be effective for?”
  6. Amount of annual fees”
22. Despite Genentech's instructions, this form stated in answer to question 5 that the applicant wanted the period to be effective for "2 years" and in answer to question 6 that the amount of annual fee was "£1300". Given that Genentech wanted the SPC for the maximum term, the correct answers to these two questions would have been "Until 23 January 2022" (or an expression of this period in years) and "£3000" respectively.
23. Ms Stacey Nalepka, a Data Integrity Specialist at MDC stated that the insertion of a two-year term on the form was an "error". The reason she gave for her belief that this was an error was that "it had been the intention", presumably meaning Genentech's intention, to seek the maximum term of protection. Ms Nalepka added that if the UKIPO had sent a reminder under rule 116, MDC would have paid any additional fees due. Ms Nalepka stated that there had been "several instances in the past" where the UKIPO had notified MDC of underpayments. She gave "two such examples", one from March 2015 and another in July 2015. In both instances MDC had originally

paid for a shorter term than the maximum; the UKIPO had noticed this and expressly drawn it to MDC's attention; and MDC had then gone on to pay the shortfall.

24. The fee of £1300 was duly paid. On 12 July 2019 MDC made an application to the Comptroller to rectify an irregularity in procedure connected with the payment of this fee to enable the SPC to remain in force for its full duration until 23 January 2022. In a separate request, Genentech made an application for a paediatric extension. At the same time, it enclosed a further Form SP2 in respect of the annual fees payable for the remainder of the duration of the SPC so as to extend the SPC to the maximum duration. Finally, in the array of applications made, on 20 December 2019 Genentech sought the correction of the original Form SP2 and the associated fee sheet FS2 to be corrected under section 117 of the Act.
25. An initial dispute as to whether the Comptroller could proceed at all with the application for a paediatric extension given its late filing was resolved in Genentech's favour, but that has no direct bearing on the issues which arise on this appeal.

### **MDC's appeal**

26. MDC's case relies on rule 107 of the Rules which affords the Comptroller a discretion to rectify an "irregularity of procedure". It provides:

#### **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.

27. MDC seeks an extension of time to the prescribed period under rule 116(2) of the Rules to enable it to pay the fees for the third and fourth years of the duration of the SPC. Rule 116(2) is listed in Part 1 of Schedule 4 and is therefore one of the time periods that can be extended under rule 107(3) (but not rule 107(1)). Accordingly,

MDC needs to identify an irregularity attributable at least in part to the Comptroller. MDC relies on three such irregularities. First, it is said that the Rule 116(3) notice failed to notify the applicant of the prescribed fee due, contrary to rule 116(4)(b). There was only one prescribed fee, namely the fee for the maximum duration of the SPC, which in the present case would have been £3000. Secondly, that notice and the Form SP2 wrongly indicated that the applicant could select a period of protection which was shorter than the duration prescribed by Article 13 of the SPC Regulation. Thirdly, the Comptroller failed to notify the applicant of the failure to pay the prescribed fee due, contrary to rule 116(6).

28. MDC contends that the Act, the Rules and the Fees Rules all proceed on the underlying basis that there is only one prescribed fee for an SPC, namely the fee which is appropriate to the duration of the SPC laid down in Article 13 of the SPC Regulation. Thus, paragraph 5 of Schedule 4A to the Act refers to “the prescribed fee” being paid, and rule 6(2) of the Fees Rules explains how that single prescribed fee is set or calculated from its duration. Rule 6(3) is also drafted in terms of the fee being calculated from the duration rather than the other way around. The different fee levels set out in rule 6(2) of the Fees Rules, are no more than prescribing the fee that is appropriate to the SPC’s actual maximum duration. They do not allow an applicant to select a fee, and thereby choose an SPC with a term less than the Article 13 term. As Miss May pithily expressed it, the duration determines the fee: the fee does not determine the duration.
29. Viewed in isolation, this submission as to the construction of rule 6 of the Fees Rules has attraction. In my judgment, however, the submission is not in accordance with authority or with the wider legislative context.
30. In *Tulane Education Fund’s Supplementary Protection Certificate* [2013] EWCA Civ 890; [2014] RPC 10 (“*Tulane*”), the applicant for an SPC had failed to pay the prescribed fee. The applicant’s case was that the UK national fee regime was *ultra vires*. An aspect of this argument was that the prescribed fee which the applicant had failed to pay was not properly regarded either as an application fee (within Article 8(4) of the SPC Regulation) or as annual fees (within Article 12).
31. At paragraph 47 of the judgment of Kitchin LJ (with which Sir Terence Etherton C and Underhill LJ agreed) he refers to Article 12 of the SPC Regulation in these terms:

“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.”

32. As Kitchin LJ went on to explain, paragraph 5 of Schedule 4A, rule 116 of the Rules and rule 6 of the Fees Rules all related to matters arising under the SPC Regulation, and accordingly all fell within the law-making powers in section 2(2) of the European Communities Act 1972, provided that they imposed a regime for annual fees. Kitchin LJ continued as follows:

“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.”

33. From this I conclude:

1. The prescribed fees in rule 6 are annual fees for the purposes of the SPC Regulation.

2. This is for two reasons. First, the sums payable increase as the term of the SPC gets longer. Secondly (and this is said to be important) the applicant can elect to take a certificate for a shorter period.
  3. The fees do not cease to be annual fees because they are required to be paid before the certificate comes into effect, or because they are required to be paid all at once.
  4. Such a scheme does not conflict with Article 13 of the SPC Regulation which defines the maximum duration of the SPC.
34. Miss May did not quarrel with proposition 1, 3 or 4 above. She recognised, however, that the second reason in proposition 2 conflicted with her submission as to the proper understanding of the UK national scheme. She submitted, firstly, that the second reason, that an applicant can elect for a shorter period, was not part of Kitchin LJ's reasoning in *Tulane*. Alternatively, she submitted, that the second reason was a mere statement of law or practice which was assumed to be correct for the purposes of *Tulane* but which did not create binding precedent for this court.
35. I cannot accept the first of these submissions. It seems to me that both the reasons given by Kitchin LJ formed an essential part of his reasoning for holding that the prescribed fees were annual fees. He explained that the fees had two qualities which made them annual fees: they varied with the duration of the SPC, and, importantly, the applicant could elect to take a shorter SPC. I can see no reason for supposing that he would have reached the same conclusion if the fees did not have the second quality.
36. In support of her second submission, Miss May relied on *R (Kadhim) v Brent London Borough Council Housing Benefit Review Board* [2001] QB 955. The issue in that case was whether the applicant was residing with a close relative and thus not entitled to housing benefit under the applicable housing legislation. The judge had held himself bound by a previous decision of the Court of Appeal to the effect that sharing accommodation in addition to a bathroom, lavatory and communal area provided a complete test of residence. Buxton LJ (with whom Schiemann LJ and Jacob J agreed) concluded that this proposition formed part of the *ratio decidendi* of the previous case. Nevertheless, relying on "a slender line of authority" the court went on to hold that a *ratio* or part of a *ratio* is not binding if, in the previous case, it had been assumed (as opposed to decided) to be correct without the benefit of argument to that effect. At [38] Buxton LJ went on to point to the limitations of the rule. It was only to "be applied in the most obvious of cases and limited with great care". He continued:

"The basis of it is that the proposition in question must have been assumed, and not been the subject of decision. ... And there may of course be cases, perhaps many cases, where a point has not been the subject of argument, but scrutiny of the judgment indicates that the court's acceptance of the point went beyond mere assumption. Very little is likely to be required to draw that latter conclusion: because a later court will start from the position, encouraged by judicial comity, that its predecessor did indeed address all the matters essential for its decision."

37. Miss May, who appeared as counsel in *Tulane*, informed us that there was in fact no argument in *Tulane* about whether the UK national regime properly permitted applicants to elect for a shorter period of duration by electing to pay the corresponding fee under rule 6 of the Fees Rules. She submitted that it was simply assumed to be correct. I accept, of course, what she tells us. As Buxton LJ pointed out, however, the absence of argument does not necessarily lead to the conclusion that the point has not been considered and decided by the court. In my judgment it is clear beyond doubt that, in the passage of his reasoning in *Tulane* which is in question in this case, Kitchin LJ was deciding what, as a matter of interpretation, rule 6 permitted. If it were the case that an applicant was not entitled to elect for a shorter period of SPC than the maximum, so as to cause the SPC to lapse at some intermediate date, that would have been highly relevant to the applicant's argument that the prescribed fees were not annual fees. Kitchin LJ decided to the contrary. The *Kadhim* principle does not permit us to depart from *Tulane*.
38. Miss May's submission also runs into conflict with the language of rule 116(5). That rule provides that, once the certificate has taken effect, no further fee may be paid to extend the term of the certificate (except in certain circumstances related to paediatric extensions to which I will have to come). This rule cannot be read as if it contemplated (in order to prohibit) a fee to extend the certificate beyond the maximum term of the SPC (i.e. the term calculated under Article 13). Such an extension would be prohibited by the SPC Regulation and no domestic legislation would be necessary to point out that no such extension was possible. The rule is only consistent with a scheme in which an applicant might contemplate paying a fee for part only of the maximum duration and then seek to "top-up" the duration by payment of a further fee. The rule makes it clear, therefore, that "topping-up" is not possible. Such a rule is only consistent with a scheme in which it is open to an applicant to elect for a shorter duration than the maximum, contrary to MDC's position.
39. Reading rule 6 of the Fees Rules and rule 116(5) of the Rules together makes it clear that the scheme is intended to require a decision in advance as to how many years the applicant wishes to pay annual fees in respect of. The applicant is prohibited by rule 116(5) from later paying top-up fees to extend the term beyond that specifically chosen pursuant to rule 6. It follows that, at the end of the period chosen by the applicant, the SPC will lapse under Article 14(c) of the SPC Regulation, because the applicant will not be able to pay the further annual fees.
40. Although Miss May said that she did not challenge the conclusion in *Tulane* that the UK has implemented annual fees, I do not see how the scheme, as she submits it should be understood, in fact does so. Under the SPC Regulation, although annual fees are optional, a Member State which implements annual fees must provide for the SPC to lapse if annual fees are not paid: Article 14(c). The UK scheme as it is interpreted by MDC, however, does not provide for the SPC to lapse for non-payment of annual fees in any meaningful sense, because the fees must always be paid in advance for the whole term and before the SPC comes into effect. That is not something which is permitted by the SPC Regulation, and would render the UK national scheme non-compliant therewith.
41. Miss May submitted that the UK national scheme did allow the SPC owner to elect for a period shorter than the maximum term, but by a different route, namely by paying the prescribed fee for the whole term, but then surrendering the SPC under

Article 14(b). National practice allows for a refund of part of the fee in those circumstances. The judge gave this argument short shrift and so would I. It goes no way to meet the problems of collision with *Tulane* or with Article 14(c).

42. It follows, in my judgment, that the salient features of the UK scheme are as follows:
  1. The prescribed fee is the total of specified annual fees, albeit payable in one go and in advance.
  2. By paying a prescribed fee appropriate to something less than the full term, the applicant “may elect to take the certificate for a shorter period”.
  3. The applicant is not permitted to pay top-up annual fees, or annual fees as if they fell due year by year.
  4. If the applicant chooses a shorter period than the maximum, the SPC lapses at the end of the chosen period.
43. For all those reasons, I would reject the submission that the UK scheme does not permit the applicant to elect and pay for a shorter period of protection than the full Article 13 term.
44. Against that background I turn to the irregularities in procedure on which MDC relies. First, did the notice under rule 116(3) fail to notify the applicant of the prescribed fee due, contrary to rule 116(4)(b)? This submission can only succeed if the applicant is not permitted to elect for a shorter period of SPC than that prescribed by Article 13, and pay a reduced prescribed fee. I have held to the contrary.
45. Secondly, did that notice and the Form SP2 wrongly indicate that the applicant could select a period of protection which was shorter than the duration prescribed by Article 13 of the SPC Regulation? Again, this submission can only succeed if the applicant is not permitted under the scheme to elect for a shorter period of SPC and pay a reduced fee. I have held to the contrary.
46. Thirdly, did the Comptroller fail to notify the applicant of the failure to pay the prescribed fee due, contrary to rule 116(6)? It is true that, as a result of the structure of the fees set out in the rule 116(3) notice, the Comptroller did not specifically notify the applicant of the fee due for a maximum duration SPC. For the reasons I have given, the notice did not have to. The notice adequately identified the prescribed annual fees which the applicant would have to pay, depending on the term of SPC it elected for. As the Comptroller, therefore, correctly notified the applicant of the prescribed fee due, this submission fails as well.
47. It is not therefore necessary to decide whether, if there had been an irregularity in procedure, this would be a proper case in which to exercise the discretion to rectify it. Any consideration of discretion under rule 107(3) would have to start from the factual premise that there had been some irregularity in procedure for which the Comptroller was at least partly responsible, and there was none. It would be an artificial exercise to decide discretion in these circumstances. I would dismiss MDC’s appeal.

## **Genentech’s appeal**



48. There are three limbs to Genentech's case which form the subject of Genentech's three grounds of appeal. These are:
1. On the true construction of rule 116(5) of the Rules, is an applicant for an SPC who has paid less than the full amount of the annual fees at the outset, entitled to pay a further fee to make up the shortfall if he applies for a paediatric extension?
  2. In the alternative, does section 117 of the Act permit a correction to Form SP2 so as to substitute the correct period for the SPC to take effect and the correct fee?
  3. In the further alternative, is a paediatric extension of 6 months from the current expiry date of 2 April 2020 permissible?

*Rule 116(5)*

49. I have already considered rule 116(5) to some extent at [38] to [39] above. That rule provides that "... once the certificate has taken effect no further fee may be paid to extend the term of the certificate *unless* an application for [a paediatric extension] is made..." (my emphasis). I shall refer to the clause beginning "unless" as "the proviso". Mr Lykiardopoulos accepts that, absent an application for a paediatric extension, the part of the rule before the proviso prevents top-up fees being paid so as to extend the term of the certificate beyond that corresponding to the fee originally paid. He submits, however, that once a paediatric extension is applied for, the effect of the proviso is that the applicant may pay any necessary top-up fees as well as the fee for the paediatric extension. Why, he asks forensically, would the fees dealt with by the proviso not be referring to, or at least include, the annual fees which are the subject of the earlier part of the rule? He prays in aid the purpose of the Paediatric Regulation, namely to provide a reward for those who undertake the necessary research into paediatric indications, which is in the public interest. He also submits that the fact that paediatric extensions can be granted after the SPC has taken effect explains why the rules would allow the payment of top-up fees where a paediatric extension application is made. He further points to the first emboldened paragraph in the Rule 116(3) notification (see [18] above), which he submits is only consistent with his interpretation. That paragraph is only dealing with the case where an applicant has chosen less than the maximum duration, yet it expressly contemplates an extension of the certificate under the Paediatric Regulation.
50. I am not able to accept these arguments. If an applicant establishes that it is entitled to a paediatric extension, then the consequence in EU law is that the duration of the certificate for the SPC, as laid down by Article 13(1) and (2) of the SPC Regulation, "shall be extended by 6 months": see Article 13(3). The period laid down by Articles 13(1) and (2) is that which is calculated using the formula laid down by those paragraphs. The paediatric extension of six months is then added to that period. The paediatric extension is not a separate SPC: the original SPC remains, but with a longer duration. That is the only reward required or allowed by EU law to be given to an applicant who meets the conditions for a paediatric extension. Article 14(c) still provides that the certificate, whether extended or not, shall lapse if the annual fees are not paid.

51. One would expect the national provisions to be consistent with that background of EU law. In particular, one would not expect the national scheme to provide that the filing of a paediatric extension application would have any other benefit apart from a potential extension to the maximum term. One would also not expect the filing of a paediatric extension application to affect the lapsing of the certificate for non-payment of annual fees. I have already explained that, under the UK scheme, an applicant who elects to pay less than the fee for the maximum duration of an SPC also elects to allow the SPC to lapse for non-payment, as provided for by Article 14(c). Genentech's construction of Rule 116(5) allows a paediatric extension application to countermand the effect of that election. I do not accept that this is justified by the fact that a paediatric extension can be granted after the SPC has come into effect.
52. Whilst, as both Mr Micklewright and the judge accepted, Genentech's construction of rule 116(5) is a possible one, in my judgment it is not correct. First, paragraph 5 of Schedule 4A to the Act envisages a single fee paid to bring the certificate into effect. It does not envisage the payment of further prescribed fees after the certificate has come into effect. It is true that it does not prohibit them either, but that does not prevent the point from providing important context as to what rule 116(5) was seeking to achieve.
53. Secondly, as I have foreshadowed, Genentech's construction would mean that an applicant for a paediatric extension was placed in a uniquely privileged position as to the payment of top-up fees as compared with other SPC applicants. I can see no justification for granting this class of SPC holders this additional benefit, when it goes well beyond the actual reward provided for in EU law.
54. Thirdly, as I have again foreshadowed, on my analysis of the UK national scheme, by paying a reduced fee for a reduced term, an applicant commits to allowing the SPC to lapse in accordance with Article 14(c). I can see no reason why the filing of a paediatric extension application should be allowed to interfere with this. The paediatric extension affects the maximum duration, but should have no impact on the arrangements for lapsing under Article 14(c).
55. Fourthly, I am unable to derive much assistance from the first emboldened paragraph of the rule 116(3) notice. Mr Silverleaf submitted, and I accept, that it was based on a misinterpretation of the rule. It is not a legitimate aid to construction of the Rules.
56. In my judgment, read against the background of EU law, and of Schedule 4A paragraph 5, rule 116(5) should be understood to mean that no further fee may be paid to extend the certificate *except* the fee for a paediatric extension application. I would therefore reject this ground of appeal.

### *Section 117*

57. Section 117 provides as follows:

#### **Correction of errors in patents and applications.**

- (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.

(2) Where the comptroller is requested to correct such an error or mistake, any person may in accordance with rules give the comptroller notice of opposition to the request and the comptroller shall determine the matter.

58. Section 128B of the Act and paragraphs 1 and 2 of Schedule 4A to the Act apply section 117 as if references to a patent are to an SPC and references to an application for a patent are references to an application of an SPC or an extension thereto. Rule 105(3) of the Rules makes a distinction between mistakes in a specification of a patent, where it is necessary to show that correction is obvious, and mistakes in other documents, where, by implication, it is not required to show that the correction is obvious.
59. Genentech rely on this provision to seek to correct the mistakes in Form SP2 as to the length of time for which the SPC was to take effect and the corresponding fee.
60. The difficulty with this argument is that it is not sufficient for Genentech to rectify the mistake in Form SP2. It must also pay the further annual fees. Further annual fees are, however, specifically prohibited by rule 116(5). To read section 117 as permitting the Comptroller to rectify not only the document, but also the failure to pay the fees would be to allow section 117, an entirely general provision about rectifying errors in documents, to nullify the effect of rule 116(5). The argument offends against the principle that general provisions should not be construed so as to derogate from more specific ones<sup>2</sup>. The Hearing Officer and the Recorder both referred to *Antiphon AB. 's Application* [1984] RPC 1 and *Payne's Application* [1985] RPC 193, both decisions of Falconer J, for the application of that principle in the area of procedure before the Comptroller, but the principle is a general one. It was not in issue either before the Recorder or in Genentech's appeal.
61. Mr Lykiardopoulos sought to circumnavigate this difficulty by submitting that the missing annual fees were not a further fee, but the fee which should originally have been paid had the mistake not been made. He allied this with a submission that at all material times the balance of MDC's deposit account with UKIPO had within it sufficient funds to pay the full fee of £3,000.
62. I cannot accept this argument. The shortfall in the annual fees which Genentech now wish to pay is two further annual fees. The money in MDC's deposit account with the UKIPO was held to MDC's order. It was never paid to the order of the UK Intellectual Property Office, and history cannot be rewritten to make it so.
63. The Recorder indicated that he would in any event have exercised his discretion against Genentech under section 117 on the grounds that MDC had itself confessed to a series of mistakes of this character. Had I considered that section 117 gave rise to a discretion to rectify the non-payment of the annual fees, it would have been necessary to go further and consider whether there was any basis for this court to interfere with the exercise of the discretion by the Recorder, and if there was, how the discretion

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<sup>2</sup> Formerly referred to by the Latin maxim "*generalia specialibus non derogant*".

should be re-exercised. In the circumstances it is not necessary for me to examine either of those questions.

64. I would therefore reject this ground of appeal.

*Paediatric extension from 2 April 2020*

65. This ground is based on the contention that, if Genentech cannot pay the missing annual fees to extend the life of the SPC to its maximum duration, Genentech is nevertheless entitled to a paediatric extension of six months from the date on which the SPC lapses.

66. Mr Micklewright dealt with this argument at paragraphs 46 to 47 of his decision and the Recorder at paragraphs 72-73. Both regarded the suggestion as incompatible with the EU regime, which treated the only possible extension as one which extended the maximum term of the SPC.

67. Mr Lykiardopoulos took the point equally shortly. He submitted that the purpose of the Paediatric Regulation would be served by rewarding the research by the grant of an SPC. I do not regard that as an adequate basis for contemplating the grant of an SPC with a duration not contemplated in the Regulations. I would therefore reject this ground of appeal also.

**Conclusion**

68. It follows, for the reasons I have given, that I would dismiss both appeals.

**Lady Justice Nicola Davies:**

69. I agree.

**Lord Justice Arnold:**

70. I also agree.