Neutral Citation Number: [2020] EWHC 572 (Pat)

IN THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS
OF ENGLAND AND WALES
INTELLECTUAL PROPERTY LIST (ChD)
PATENTS COURT

The Rolls Building
7 Rolls Buildings
Fetter Lane
London EC4A 1NL

Date: 11 March 2020

Before:

RECORDER DOUGLAS CAMPBELL QC
(Sitting as a Judge of the Patents Court)

- -

Between:

Claim Number: CH-2020-000062

MASTER DATA CENTER, INC. **Appellant**
- and -
THE COMPTROLLER GENERAL OF PATENTS **Respondent**

and Between:

Claim Number: CH-2020-000065

GENENTECH INC. **Appellant**
- and -
THE COMPTROLLER GENERAL OF PATENTS **Respondent**

- -
- -

MISS CHARLOTTE MAY QC (instructed by Fieldfisher LLP) appeared for MASTER DATA CENTER, INC.

MR. ANDREW LYKIARDOPOULOS QC (instructed by Marks & Clerk Law LLP) appeared for GENENTECH, INC.

MR. MICHAEL SILVERLEAF QC (instructed by Government Legal Department) appeared for The Comptroller General of Patents.

Hearing date: 4 March 2020

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APPROVED JUDGMENT

I direct that pursuant to CPR PD 39A paragraph 6.1 no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

Mr Recorder Douglas Campbell QC:

Introduction

1. This is another case about Supplementary Protection Certificates, or SPCs, granted pursuant to Regulation (EC) No. 469/2009 ("the SPC Regulation").

2. More specifically these appeals concern SPC/GB07/012 in the name of Genentech, Inc. ("Genentech"). This SPC protects a product known as ranibizumab, sold under the brand name "Lucentis®" for the treatment of various eye diseases. By a decision dated 21 February 2020 Mr Ben Micklewright, on behalf of the Comptroller, held that this SPC will lapse on 2 April 2020 on the grounds that Genentech's patent administration company, Master Data Center Inc. ("Master Data") only requested and paid for a 2-year term on the relevant form, rather than a 4-year term.

3. Both Master Data and Genentech appeal from that decision. Whilst they adopt each other's arguments generally, Master Data's principal argument is that the SPC should extend to 23 January 2022 (the actual duration of the SPC being just over 3 years and 9 months, rather than a precise 4 years). Genentech's principal argument is that the SPC should extend to 23 July 2022. This is on the basis that such date includes a 6-month paediatric extension pursuant to Regulation (EC) No. 1901/2006 ("the Paediatric Regulation"), for which its licensee Novartis has undertaken the necessary work to qualify.

4. Master Data also relies on rule 107 of the Patents Rules 2007 (as amended) which relates to the correction of irregularities generally. Similarly Genentech relies on s. 117 of the Patents Act 1977, which provides for correction of errors and mistakes in certain documents, and upon one further ground of appeal.

5. The above is merely a brief summary intended to orient the reader. I will begin by setting out the relevant law before considering each appeal in more detail.

Legal context

6. The most relevant provisions of the SPC Regulation for present purposes are as follows:

> **Article 8(4)**
> **Content of the application for a certificate**
>
> … 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 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.

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 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. In relation to Article 19, the UK has enacted special procedural provisions for SPCs. These are to be found in the Patents Act 1977, the Patents Rules 2007 (as amended) and the Patents (Fees) Rules 2007 (as amended).

8. The most important part of the Act is paragraph 5 of Schedule 4A, as referred to in s. 128B. Paragraph 5 states 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.

9. Rule 116 of the Patents Rules 2007 (as amended) provides as follows, so far as presently 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.

…

10. The prescribed fee is defined in the Patents (Fees) Rules 2007 (as amended) 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.

11. Rule 107 of the Patents Rules 2007 (as amended) provides as follows:

> **Correction of Irregularities**
>
> 107.—(1) Subject to paragraph (3), the comptroller may, if he thinks fit, authorise the rectification of any irregularity of procedure connected with any proceeding or other matter before the comptroller, an examiner or the Patent Office.
>
> (2) …
>
> (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.

12. Rule 116(2), ie the prescribed period for payment of the prescribed fee, is listed in Part 1 of Schedule 4, hence it is one of the periods of time which may be extended under rule 107.

13. These provisions need to be read carefully but the upshot is as follows.

a) From the European perspective, Member States can decide whether or not they want to require application fees and/or annual fees for SPCs, and if so in what amount: see the SPC Regulation at Articles 8(4), 12, 19. The duration of the certificate is determined by Article 13. The certificate shall lapse in any of the situations set out in Article 14.
b) From the UK perspective, the SPC does not take effect unless the relevant fees are paid in time. "In time" means either in the 3 months ending with the start date (if the certificate is granted before that 3-month period, which it usually will be) or in the 3 months beginning when the certificate is granted (if the certificate is granted later): see paragraph 5(a) of Schedule 4A and rule 116(2). Paragraph 5(b) can be disregarded for present purposes.
c) For payments made in time, the relevant payment is the "prescribed fee".
d) The prescribed fee is determined by rule 6(2). It will be seen that the amount of the fee depends on when the certificate expires relative to the start date. I will return to this below. For the moment it should be noted that the prescribed fee is paid once, not every year.
e) The comptroller has to send a notice to the applicant containing the information required by rule 116(4). This must be sent at least 2 months before the start date for normal certificates or on the date of grant for later certificates: see rule 116(3).
f) If the fee is not paid when it should be, the comptroller has to send a reminder within 6 weeks of the end of the relevant period: see rule 116(6).

The facts

14. The essential facts were not in dispute and are as follows.

The SPC certificate

15. The SPC was applied for in February 2007 and was granted to Genentech on 17 July 2007. The actual 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. As the Comptroller submitted, without objection by Master Data or Genentech, this certificate complies precisely with the requirements of Article 13(1) of the SPC

Regulation. It states that the maximum period of duration of the SPC will be until 23 January 2022. This is subject to the payment of the appropriate fees, which are permitted by Article 12 to be levied.

The UKIPO letter

17. The UKIPO sent a letter to Genentech's patent agents on 5 January 2018, which is Annex 1 to this judgment. Master Data accept that this letter complies with rule 116(4)(a), (c), and (d) but do not accept that it complies with 116(4(b), ie as regards the prescribed fee. In particular Master Data complain of 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"

18. Master Data submit that this letter does not actually identify the prescribed fee. Specifically Master Data submit that the letter should have said, for example, *"the prescribed fee is £3000"*, that being the correct figure for 4 effective years. Master Data also said it was wrong to mention any figures other than £3000, on the grounds that it was not permissible for the UKIPO to offer, or for the applicant to pay, any fee other than that corresponding to 4 effective years.

Genentech's instructions to Master Data

19. 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 Master Data were contracted to make annuity payments on behalf of Roche's group of companies, including Genentech. Her evidence showed that Master Data had standing instructions to pay the full annuity fees for all relevant rights which had payments due, and that although there were some exceptions to these instructions none of these exceptions applied to this SPC. Thus Genentech's instructions to Master Data were that the annual fee should be paid for the maximum available term of the SPC. Master Data were also specifically instructed that the expiry date of the SPC was 23 January 2022.

Master Data's acts

20. Master Data filed patents form SP2 in relation to the SPC on 26 March 2018. Despite Genentech's instructions, this form stated in handwriting that the applicant wanted the period to be effective for "2 years" and that the amount of annual fee was "£1300".

21. Master Data adduced evidence from Ms Stacey Nalepka, a Data Integrity Specialist at Master Data. She exhibited 2 flow charts, one showing the procedure for Patent Data Specialists (who are responsible for resolution of patent payment data

errors) and one showing the procedure for Payment Coordinators (who instruct the payments for patent annuities to patent offices and agents). Ms Nalepka stated that the listing of a two-year term on the form was an "error". However she did not claim to have done this listing herself nor did she set out details of any investigations among Payment Coordinators. The only 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.

22. Ms Nalepka added that if the UKIPO had sent a reminder under rule 116, Master Data would have paid any additional fees due. Indeed Ms Nalepka gave evidence that there had been *"several instances in the past"* whereby the UKIPO had notified Master Data of underpayments. She gave *"two such examples"*, one from March 2015 and another in July 2015. In both instances Master Data had originally paid for a shorter term than the maximum; the UKIPO had noticed this and expressly drawn it to Master Data's attention; and Master Data had then gone on to pay the shortfall.

SPC payments in other jurisdictions

23. Ms Nalepka explained that only 3 other states in Europe require SPC fees to be paid in a single lump sum prior to the coming into force of the SPC: Spain, Switzerland and Bulgaria. Furthermore, none of these countries allows an SPC applicant to select a duration shorter than the maximum. This was not disputed.

The Hearing Officer's decision

24. I now turn to the Hearing Officer's decision in detail. He summarised the issues before him at paragraphs [3]-[4] as follows:

> *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?*

25. The Hearing Officer set out the law at paragraphs [8]-[24]. He dealt with Genentech's case first, at [25]-[65], and then with Master Data's case at [66]-[82]. He

held that the answer to all 4 questions was no. Between them, Genentech and Master Data appeal his decision on all 4 points.

26. I will deal with Master Data's appeal first.

Master Data's appeal

27. Master Data have essentially 3 grounds of appeal, which I summarise as follows.

1. First, that the Hearing Officer fell into error by interpreting the SPC Regulation as allowing an applicant for an SPC to choose a duration of their certificate for a period that is shorter than that defined in Article 13.

2. Second, the Hearing Officer fell into error by holding that the Court of Appeal in **Tulane** had confirmed that the UK rules and practice did not conflict with the SPC Regulation.

3. Third, the Hearing Officer fell into error by holding that paragraph 5 of Schedule 4A of the Patents Act 1977 envisages that a single fee must be paid before the certificate comes into effect.

Master Data submitted that these errors gave rise to 3 procedural irregularities which could properly be corrected under rule 107: see its skeleton argument at [30]-[32].

28. The UKIPO submitted that Master Data's arguments all raised the same point. I agree, save as regard the third ground of appeal, but would put Master Data's key argument as follows: it is whether there can be only one "prescribed fee", which is for the duration set by Article 13. The third ground of appeal is not the same argument, but nothing turned on it since it was accepted by the UKIPO that a payment can be made after the date when the certificate takes effect, contrary to what was held by the Hearing Officer at [34] and [62]. See rule 116(2), discussed above.

29. In considering Master Data's key argument I accept the UKIPO's submission that it is important to distinguish between the *duration* of the certificate (which is governed by Article 13 of the Regulation) and its *expiry* (which is governed by Article 14).

30. There can only be one *duration* for any given certificate, which is calculated according to the formula set out in Article 13. Article 13 also provides that the certificate "shall take effect" at the time specified in Article 13 "for a period equal to" the calculated duration. There is no discretion. However Article 14 provides that the certificate "shall lapse" in any of the circumstances set out therein, including surrender and "if the annual fee laid down in accordance with Article 12 is not paid in time". Hence there is no discretion about this either. Furthermore these provisions have the same effect in all Member States. None of this was disputed.

31. Master Data submitted that the Hearing Officer did not properly consider their arguments under Article 13. I reject that. The Hearing Officer set out all of the above points, including that on Article 13, at [66]-[71] and considered those on Article 13 at [75]-[80].

32. Master Data submitted that the Hearing Officer was not always precise about his use of the word *"duration"*, citing for example paragraph [75] where he referred to applicants for SPCs choosing a duration for an SPC *"which is shorter than the maximum duration"*; see also paragraph [77]. I accept this, although in each case it is clear that the Hearing Officer meant applicants choosing to let their SPCs expire through non-payment of fees pursuant to Article 14(c).

33. Master Data's real point was that it was not open to the UKIPO to give applicants this option. Master Data argued that if an applicant wanted to let its SPC expire early, it could always surrender the SPC under Article 14(b) instead. They also drew my attention to the UKIPO practice whereby, if an applicant wanted to surrender its SPC, the UKIPO refunded the portion of the fee originally paid which corresponded to the unused term.

34. The Hearing Officer disagreed with Master Data for the reasons given at [75]-[80] of his decision. In short he saw nothing wrong with the UKIPO practice whereby applicants were given this option, even if surrender provided another means to the same end result: see [75]-[78]. An important part of his reasoning is based on the decision of the Court of Appeal in **Tulane Education Fund v Comptroller** [2013] EWCA Civ 890, which is mentioned in Master Data's second ground of appeal and to which I now come.

35. It was not disputed that the specific issue before the Court of Appeal in **Tulane** was different to the issue before me. In **Tulane** the argument was whether the single upfront fee charged by the UKIPO was an annual fee at all. That argument did not require the Court of Appeal to consider whether it was lawful to charge anything other than a single fee, namely that for the duration specified in Article 13. Nevertheless Kitchin LJ (with whom Underhill LJ and the Chancellor agreed) held as follows, my emphasis:

> "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."

36. There was considerable debate before me as to whether the underlined sentence in paragraph [50] was *obiter dicta* or part of the *ratio decidendi*; and if it was part of the *ratio*, what consequences followed for the present case which raises a different point. Master Data submitted that this sentence of paragraph [50] was not part of the *ratio* whereas all the other sentences in the same paragraph were. Conversely the UKIPO said it was part of the *ratio*, and was binding upon me as a matter of law even though the point in the present case is different.

37. I consider that the underlined sentence is part of the *ratio* of **Tulane** and it is not open to me to treat it as mere *obiter dicta*. I also accept that as part of the *ratio*, it is binding upon me as a statement of the law. As the UKIPO submitted, Kitchin LJ (as he then was) makes it clear that the fees set out in rule 6 are annual fees payable upfront. This is reinforced by the wording underlined in paragraph [51] where Kitchin LJ explained that these rules were not in conflict with Article 13. If I might respectfully say so, I agree with this reasoning. Hence even if it were open to me to depart from it then I would not.

38. Various consequences follow from this. If the fees prescribed by UK legislation are annual fees, then it must be open to a patentee to elect to pay only for the period he desires. Provided the relevant fee is paid, the certificate shall take effect on the date determined by Article 13. At the end of the period for which the relevant fee has been paid, the certificate shall expire in accordance with Article 14(c). Thus when

Article 13 says that the certificate "shall take effect", this is merely a reference to when the certificate starts. It does not override Article 14(c).

39. It follows that I reject Master Data's key argument. It is and was properly open to the UKIPO to give applicants the option of taking a certificate for a shorter period than that set by Article 13, such that applicants can thereby only pay a fee in respect of those years for which they have elected.

40. I would add that the fact that surrender under Article 14(b) provides an alternative is neither here nor there. Nor does it matter that the UK's approach to annual fees is apparently unique, given Articles 12 and 19. The national provisions for payment of annual fees have nothing to do with Article 13, since they are left to member states under Articles 12 and 19.

41. I have therefore reached the same conclusion as the Hearing Officer for essentially the same reasons. It follows that there was no irregularity which was attributable, wholly or in part, to any default, omission or other error by the UKIPO for purposes of rule 107. I dismiss Master Data's appeal.

Genentech's appeal

42. Genentech pursued largely the same arguments on appeal as it did before the Hearing Officer. I will deal with them in turn.

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?

43. This appeal requires me to consider the specific statutory provisions relating to paediatric extensions more closely.

44. Genentech drew my attention to recitals 1-6 and 26-28, and Article 36 of the Paediatric Regulation. The policy objective is to facilitate the development and accessibility of medicinal products in the paediatric population, and to reward work done in this respect by way of a 6-month extension to an SPC: see eg recital 26 and Article 36. Part of the thinking was that whilst medicinal products will generally have undergone extensive testing prior to launch, these studies may have focussed on adults more than children: see eg recitals 1-4. Genentech submitted that the paediatric work which is being rewarded might therefore have been done relatively late in the life of the patent.

45. There is no dispute that if Article 36 of the Paediatric Regulation applies then the period laid down for the duration of the SPC in paragraphs 1 and 2 of Article 13 of the SPC Regulation "shall be extended by six months", once: see Article 13(3). Nor is it disputed that Genentech satisfied the requirements of Article 36 of the Paediatric Regulation in this case.

46. I have already set out rule 116(5) above. There is no dispute that when an application for a paediatric extension is made, the applicant must be allowed to pay a fee for *the paediatric extension itself*, which is specified by the Patents (Fees) Rules to be £200. Indeed the entitlement to a paediatric extension may only became clear after the SPC has come into effect. The dispute is as to whether the applicant is also

allowed to pay for more *annual* fees than he or she originally paid for when filing form SP2.

47. The Hearing Officer dealt with this argument at paragraphs [31]-[43] of his decision. He considered 5 factors, namely (1) the natural and ordinary interpretation of rule 116(5); (2) the nature of the fee specified in paragraph 5 of Schedule 4A to the Act; (3) the requirements of the SPC Regulation and the Paediatric Regulation; (4) 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); and (5) the teaching of **Tulane.** He did not place a great deal of weight on the fourth factor, but I agree with Genentech that he should have not considered this at all. It is not a statutory source, merely the UKIPO's non-binding view of the 2007 Rules.

48. The Hearing Officer held that on the natural and ordinary meaning of the words, they were silent on the fees which might be paid: see paragraph [33]. This is clearly correct and was not criticised. Instead the main thrust of Genentech's argument was that the Hearing Officer had gone from a finding that paragraph 5 of Schedule 4A did not "envisage" further payment of prescribed fees (specifically, annual fees) after the certificate had come into effect (see [34]) to a conclusion that they were prohibited (see [38]). Furthermore Genentech submitted that by doing so the Hearing Officer had failed properly to take into account the reward granted by Article 36 of the Paediatric Regulation.

49. I reject these criticisms. First, it seems to me (as it did to the Hearing Officer) that the natural and ordinary interpretation of rule 116(5) in this context is that when an application for extension is made, the applicant is permitted, and only permitted, to pay for the paediatric extension itself. As noted above the applicant may not know at the time of the original payment whether he is entitled to an extension, so there is no reason to require him or her to pay for the extension at that stage and every reason to allow later payment. However the same logic does not apply to the annual fees, which have nothing to do with the paediatric extension. This conclusion is supported by his reasoning on factors (2) and (3).

50. I also accept the UKIPO's submission that there is no reason why SPC holders who are entitled to a paediatric extension should be uniquely privileged in relation to unpaid annual fees as compared to those who are not so entitled. Everyone else has to put their money where their mouth is. Genentech had no answer to this anomaly, other than that they believed it was part of the reward granted under Article 36. The Hearing Officer provided the answer to that at paragraph [38], where he pointed out 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"*. There is no logical reason why the reward should go further than that.

51. Genentech suggested that this result was "startling". I do not agree. As the UKIPO pointed out, patentees who allow their patents to lapse for non-payment of annual fees are not entitled to an SPC. This is merely the same logic being applied to paediatric extensions.

52. It does not seem to me that **Tulane** bears directly on the correct approach to interpreting rule 116(5) since neither that rule nor the proviso contained therein was in issue in **Tulane**. The furthest it can go for this purpose is to confirm the limited role of the SPC Regulation in relation to matters of fees, a point made by the Hearing Officer at [43]. However this much is apparent from the legislative provisions themselves.

53. Finally I accept that in many cases (but not all), the work done to justify the paediatric extension will be done late in the life of the relevant patent but I cannot see that this makes any difference to the legal principles. The policy is to incentivise paediatric work, not late work.

54. For these reasons I dismiss Genentech's first ground of appeal.

Can the form be corrected under s. 117 of the Patents Act?

55. Genentech's second ground of appeal was to say that the form could be corrected under s. 117 of the Act. Genentech did not rely on s. 32(2)(d).

Legal context

56. Section 117 of the Act is headed "Correction of errors in patents and applications". In fact its scope is wider than that since it provides as follows, my emphasis:

> "(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."

57. Rule 105(3) draws an important distinction between requests to correct a specification of a patent or application, and other requests. It provides as follows

> "(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)."

This is a far stricter requirement. It does not apply in this case, as the Hearing Officer accepted at paragraph [55] of his decision.

58. There was a debate about the extent to which this provision could be used to overcome, or "circumvent", the provisions of rule 116(5). *Prima facie* one might have thought that s 117 will generally come into play where the applicant has failed to comply with some mandatory provision or other, since otherwise it would not be necessary to rely upon it. The Hearing Officer dealt with this argument as follows:

> [57] … 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."

59. Genentech argued that the above approach was wrong in law. However this argument was not developed in any detail and I reject it. On the contrary, I consider that the Hearing Officer's analysis of the existing case law is correct. There is no equivalent of, eg, s. 15(8) of the Act in the present context.

60. Genentech's alternative argument was that it was not seeking to circumvent rule 116(5) at all, but merely to reallocate the funds in Master Data's deposit account which at all material times contained sufficient fees to cover the entire correct fee of £3000. The Hearing Officer dealt with this alternative argument at paragraphs [60]-[61]. He rejected it on the grounds that the fee was not actually paid until it was allocated to a fee-bearing action. I agree. That money was held to Master Data's order and could have been withdrawn by Master Data at any time. It was not available to the UKIPO save on Master Data's instruction.

61. It follows that I dismiss Genentech's second ground of appeal. I should however say a little more about two further points which were argued. One was about the potential effect on third parties of allowing a correction, and the other is whether it would be a proper exercise of discretion to allow the correction.

Potential effect on third parties

62. The Hearing Officer addressed the effect on third parties at paragraph [64]. He held that that allowing the correction would nearly double the life of the SPC (which is correct) and that it could potentially have a very significant impact on third parties. It is true that it could have such an impact, but I accept Genentech's submission that this would be sufficiently addressed by advertising it and providing an opportunity for third parties to object under rule 117(2): see also paragraph [56] of the decision.

63. Furthermore Mr David Knight, a partner in Master Data's law firm, served a witness statement indicating that companies currently developing potentially competing products did not plan to launch in the EEA until 2022 at the earliest. The Hearing Officer mentions this briefly at [82]. It was not suggested that Mr Knight's evidence was misleading or incomplete, and in my view it reinforces the suggestion that advertising the correction would have provided sufficient protection for third parties.

Discretion to allow the correction

64. The Hearing Officer did not deal with this under s. 117, nor for that matter under rule 107 although he did make some brief comments in the latter context (see [81]-[82]). The UKIPO submitted there were 3 reasons to refuse to exercise the discretion to allow correction.

65. First, the UKIPO submitted that there was either no mistake at all or that it had been inadequately explained. For instance it was submitted that there may have been some systematic failure by Master Data to process UK payments for SPCs, and/or a malicious employee might have been at work. I agree that the evidence is not clear and that Ms Nalepka's paragraph [18] appears to be merely a statement of her opinion rather than an explanation as to how the relevant handwritten form came to be filled in. As against that, the Hearing Officer does appear to have accepted there was a mistake (see [50]-[55] of the decision) and there is no respondent's notice challenging

this. In these circumstances I do not consider it is fair on Genentech to place any weight on this.

66. The second was said to be the effect on third parties of allowing the correction. I have already addressed that above. I do not consider this is a reason to refuse to exercise the discretion either.

67. The third reason was that this was the third time Master Data had made the same mistake. In particular Master Data kept on making the same mistake despite the UKIPO "going the extra mile" to point out the mistake the first two times. I agree there is real force in this. I also note that Master Data itself relied on this evidence as showing a UKIPO "practice" to write to parties who had paid for less than the duration provided by Article 13. I am not sure that two examples prove a practice, although I agree with Master Data that it may do if the situation is a rare one. More importantly it seems to me that if this evidence does establish any practice then it shows a practice of repeated mistake by Master Data. I accept that this was the mistake of Genentech's agent rather than Genentech itself but nothing turns on that since Genentech had appointed Master Data as its agent for this purpose.

68. Against that Genentech relied on the *"very significant detriment"* to it if a valuable right was lost: see [68]. Master Data went into more detail about this and 2 other points: see its skeleton at [89]-[92].

69. I agree that Genentech could potentially suffer prejudice if the SPC expired ahead of its prescribed duration. Master Data then added that Genentech might seek an indemnity from Master Data. I am sure that is also true. However both aspects of this point are merely stating the consequences of the mistake. It was not suggested that Master Data would be unable to indemnify Genentech. Furthermore I bear in mind Mr Knight's evidence referred to in paragraph [63].

70. Master Data's second point was that neither Genentech nor MDC intended for the SPC to have a shorter duration than under Article 13. This does not seem to add anything to the Hearing Officer's finding of mistake. The third was to say there would be no prejudice to third parties if correction were allowed, citing Mr Knight's evidence again. As stated above I agree that in the circumstances advertising the correction would have provided sufficient protection for third parties.

71. When I consider all of these factors, it seems to me that much the most important factor is that identified in paragraph [67] above and that it outweighs those identified in paragraph [68]-[70]. For this reason I would have refused to exercise the discretion to allow the correction. This therefore is an additional reason to dismiss Genentech's second ground of appeal.

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

72. Genentech's third ground of appeal was its argument that the paediatric extension could still extend the existing term of the SPC by 6 months. It accepted that this was not the period set out in Article 13 but submitted that such an extension would accord with the purpose of the Paediatric Regulation. The Hearing Officer dealt with this at [45]-[47] of his decision.

73. I appreciate the justice of the submission, since Genentech has done the relevant research and ought to be entitled to a reward for it. The problem is that pointed out by the Hearing Officer, namely that it is impossible to reconcile with the wording of Article 13(3). That wording makes it clear that the only possible paediatric extension is one which extends the period set out in Articles 13(1) and 13(2), not some other period. Indeed Genentech itself accepted this elsewhere in its argument: see its skeleton argument at [15], [32]. I therefore dismiss Genentech's third ground of appeal.

Conclusion

74. For the reasons set out above, I dismiss both appeals.

Annex 1 – the UKIPO letter

5 January 2018

Dear Sirs

Council Regulations (EC) No 469/2009 (Medicinal Products)
Patents Act 1977: Patents Rules 2007: Patents Fees Rules 2007.

SUPPLEMENTARY PROTECTION CERTIFICATE NO SPC/GB07/012
NOTIFICATION CONCERNING PAYMENT OF REQUISITE FEES (PLEASE NOTE WARNING AT THE END OF THIS LETTER)

The start date on which the certificate, subject to the requirement to pay the prescribed fees as set out in paragraph 5 of Schedule 4A to the Patents Act 1977, will take effect at the end of the lawful term of basic patent No EP0973804 is 03 April 2018.

Pursuant to Rule 116(5) and Fees Rule 6(5) this start date is also the due date for the payment of fees. These fees should therefore be paid not later than this date.

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

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.

Yours faithfully

Formalities Examiner