

subject of a granted certificate.

- 3 On 27 June 2003 a fax was received from the firm of patent agents, Lloyd Wise, containing observations on the application. This fax stated:

“Under Article 3(c) of the Council Regulation No. 1768/92, it is a requirement for the grant of an SPC in respect of a product that “the product has not already been the subject of a certificate”.

This SPC application relates to the product “Moroctocog alfa as present in the EMEA approved product ReFacto, in all forms subject to the basic patent”. However, this is a product which has already been the subject of SPC certificates, namely SPC/GB99/038, and SPC/GB99/037, copies of which are attached. It is to be noted that the product to which SPC/GB99/038 relates is “Moroctocog alfa (ReFacto)” and the product to which SPC/GB99/037 relates is “Moroctocog alfa”. This product is clearly the same as the product for which the present SPC application relates.

Accordingly, SPC application no. SPC/GB03/013 should be rejected.”

These observations, which were in line with the examiner’s own view, were copied to the applicant on 30 July 2003.

- 4 The applicants’ patent agent responded in a letter dated 24 November 2003 with a detailed rebuttal of the examiner’s view and requested a hearing if the examiner still considered that the application should be rejected. In the event the examiner was not persuaded by the agent’s arguments and he addressed them in a letter, dated 11 February 2004. Eventually, the matter came before me at a hearing on 8 June 2004. Dr Hugh Goodfellow, a patent attorney with the firm Carpmaels & Ransford, appeared for the applicants.
- 5 During the course of the hearing I questioned Dr Goodfellow about a judgment of the European Court of Justice (“ECJ”), which he had referred to, but at that time he was unable to provide an answer. I therefore gave him an opportunity to make a written submission on this matter after the hearing. This he did in a letter dated 18 June 2004. With this letter he also enclosed a copy of the notes he used during the hearing and I am grateful for this.
- 6 Following the hearing the examiner had cause to review the application and as a result wrote to the applicants to question whether it complied with a further requirement of the Medicinal Products Regulation but this is not a matter I can or should address in this decision.

Background

- 7 The basic patent was filed at the European Patent Office (“EPO”) on 11 January 1985, with a claim to priority from two US patent applications, and it was eventually granted on 18 September 2002. This patent was subsequently opposed in June 2003 but this has no bearing on the matter I must decide. By the time the basic patent had been granted to the applicants, the EMEA authorization had already been granted to Genetics Institute of Europe B.V. Armed with their basic patent and the EMEA authorization, the applicants lodged the application for supplementary protection for Moroctocog alfa on 17 March 2003.

- 8 On 11 April 1986 Genetics Institute, Inc. (“Genetics Institute”) filed under the Patent Cooperation Treaty international patent application no. PCT/US 86/00774 which was published as WO 86/06101 and which claimed an earlier priority date of 12 April 1985. This international application entered the European regional phase and eventually was granted by the EPO on 26 February 1992 as EP 0218712 B1 with the title “Novel Procoagulant Proteins”. This European patent and the EMEA authorization provided a basis for an application for a supplementary protection certificate (SPC/GB/ 99/038) for Moroctocog alfa. This supplementary protection certificate application was filed on 13 October 1999 and was granted on 12 February 2001 to Genetics Institute.
- 9 Moreover, on 6 December 1990 Kabivitrum AB filed international patent application no. PCT/SE 90/00809 under the Patent Cooperation Treaty. This international application claimed an earlier priority date of 15 December 1989 and was published as WO 91/09122. After entering the European regional phase it was eventually granted on 26 August 1998 as European patent no. 0506757 B1 with the title “A Recombinant Human Factor VIII Derivative” to Pharmacia & Upjohn Aktiebolag. This European patent and the EMEA authorization led to a further application (SPC/GB/99/037) for supplementary protection of Moroctocog alfa on 13 October 1999. On 20 May 2002 a supplementary protection certificate was granted to Biovitrum AB (“Biovitrum”).
- 10 Thus, supplementary protection certificates for Moroctocog alfa were granted to both Genetics Institute and Biovitrum before the basic patent had been granted to the applicants by the EPO and before the applicants had lodged their application for supplementary protection of Moroctocog alfa. It was the existence of these earlier certificates, which led the examiner to believe that the application should be rejected.

The Regulation

- 11 Before I turn to consider the matter I must decide, it is helpful to set out the relevant provisions of the Medicinal Products Regulation. These are to be found in Articles 1 to 3, 6, 7 and 13 as follows:

“ARTICLE 1

Definitions

For the purpose of this Regulation:

- (a) "medicinal product" means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;
- (b) "product" means the active ingredient or combination of active ingredients of a medicinal product;

- (c) "basic patent" means a patent which protects a product as defined in (b) as such, a process to obtain a product or an application of a product, and which is designated by its holder for the purpose of the procedure for grant of a certificate;
- (d) "certificate" means the supplementary protection certificate."

“ARTICLE 2

Scope

Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorization procedure as laid down in Council Directive 65/65/EEC¹ or Directive 81/851/EEC² may, under the terms and conditions provided for in this Regulation, be the subject of a certificate."

“ARTICLE 3

Conditions for obtaining a certificate

A certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application -

- (a) the product is protected by a basic patent in force;
- (b) a valid authorization to place the product on the market as a medicinal product has been granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC, as appropriate. For the purpose of Article 19(1), an authorization to place the product on the market granted in accordance with the national legislation of Austria, Finland or Sweden is treated as an authorization granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC, as appropriate;
- (c) the product has not already been the subject of a certificate;
- (d) the authorization referred to in (b) is the first authorization to place the product on the market as a medicinal product."

¹ Repealed and consolidated into Directive 2001/83 on the Community Code for medicinal products for human use, Article 128 of which provides that references to the repealed Directive shall be construed as references to Directive 2001/83.

² Repealed and consolidated into Directive 2001/82 on the Community Code for veterinary medicinal products, Article 96 of which provides that references to the repealed Directive shall be construed as references to Directive 2001/82.

“ARTICLE 6

Entitlement to the certificate

The certificate shall be granted to the holder of the basic patent or his successor in title.”

“ARTICLE 7

Application for a certificate

1. The application for a certificate shall be lodged within six months of the date on which the authorization 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 authorization 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.”

“ARTICLE 13

Duration of the certificate

1. The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorization 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.”

- 12 At the hearing Dr Goodfellow reminded me that I should construe the Medicinal Products Regulation teleologically, that is I must look to its underlying, general principles when seeking to find the meaning of its provisions. Indeed, he stated that when taking this approach, the ECJ often departs from a literal interpretation of the legislation in question, even to the extent of flying in the face of the expressed language used. On this matter Dr Goodfellow referred me to *Wagamama Ltd v. City Centre Restaurants Plc and Another* [1995] FSR 713 in which Laddie J construed a provision of the Trade Marks Act 1994, which implemented a provision of Council Directive 89/104 of 21 December 1988, by considering the intent behind the words used by the legislature. Dr Goodfellow also directed my attention to a statement made by Advocate General Fennelly in paragraph 40 of his opinion in *Biogen Inc. v. Smithkline Beecham Biologicals S.A.* (C-181/95) (“*Biogen*”) that:

“The Regulation is a legislative enactment of general application, adopted to achieve certain objectives. The text of the Regulation should be interpreted, as far as possible, to facilitate the achievement of those objectives. Where a provision gives rise to more than one possible interpretation, the alternatives should be examined when the most obvious, literal interpretation fails fully to serve the objective of the Regulation because it is based on partially inaccurate assumptions about the pattern of economic relations in the field addressed by the Regulation and gives rise to contradictions in the legislative text.”

- 13 The patent agent’s letter of 18 June 2004 contains arguments supplementing those put to me at the hearing by Dr Goodfellow as to why a teleological approach should be adopted for the interpretation of European legislation. This letter refers to a recent judgment of the ECJ in the case of *Hässle AB v Ratiopharm GmbH* (C-127/00) and in particular to a statement at paragraph 55 of the judgment that:

“It is, therefore, necessary to place that expression in its context and to interpret it in relation to the spirit and purpose of the provision in question.”

and to another statement at paragraph 60 that:

“Thirdly, that interpretation is the only one which can satisfy the requirements of legal certainty.”

The letter continues by pointing out that this judgment highlights that the intention of the legislation is paramount when interpreting EU Regulations.

- 14 I am mindful that I should interpret the relevant legislation teleologically and in this I am aided not only by its recitals but also by its travaux préparatoires and the jurisprudence of the ECJ. The recitals of the Medicinal Products Regulation state (numbering supplied):

- “1. Whereas pharmaceutical research plays a decisive role in the continuing improvement in public health;
2. Whereas medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research;
3. Whereas at the moment the period that elapses between the filing of an application for a patent for a new medicinal product and authorization to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research;
4. Whereas this situation leads to a lack of protection which penalizes pharmaceutical research;
5. Whereas the current situation is creating the risk of research centres situated in the Member States relocating to countries that already offer greater protection;

6. Whereas a uniform solution at Community level should be provided for, thereby preventing the heterogeneous development of national laws leading to further disparities which would be likely to create obstacles to the free movement of medicinal products within the Community and thus directly affect the establishment and the functioning of the internal market;
7. Whereas, therefore, the creation of a supplementary protection certificate granted, under the same conditions, by each of the Member States at the request of the holder of a national or European patent relating to a medicinal product for which marketing authorization has been granted is necessary; whereas a Regulation is therefore the most appropriate legal instrument;
8. Whereas the duration of the protection granted by the certificate should be such as to provide adequate effective protection; whereas, for this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of fifteen years of exclusivity from the time the medicinal product in question first obtains authorization to be placed on the market in the Community;
9. Whereas all the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector must nevertheless be taken into account; whereas, for this purpose, the certificate cannot be granted for a period exceeding five years; whereas the protection granted should furthermore be strictly confined to the product which obtained authorization to be placed on the market as a medicinal product;”

There are further recitals but they do not have a bearing on the matter before me. Therefore, I see no need to reproduce them here.

The Plant Protection Products Regulation

15 Another matter I need to consider arises from Regulation (EC) No. 1610/96 of the European Parliament and of the Council of 23 July 1996 (“the Plant Protection Products Regulation”). In many ways the Plant Protection Products Regulation is similar to the Medicinal Products Regulation which preceded it. However, it is also intended to serve as an aid to interpreting various aspects of the earlier Regulation. Recital 17 of the Plant Protection Products Regulation states:

“17. Whereas the detailed rules in recitals 12, 13 and 14 and in Articles 3(2), 4, 8(1)(c) and 17(2) of this Regulation are also valid, *mutatis mutandis*, for the interpretation in particular of recital 9 and Articles 3, 4, 8(1)(c) and 17 of Council Regulation (EEC) 1768/92,”

16 Article 3(2) of the Plant Protection Products Regulation, which is one of the detailed rules stated to be available for the interpretation of Council Regulation 1768/92, that is the Medicinal Products Regulation, states:

“2. The holder of more than one patent for the same product shall not be granted more than one certificate for that product. However, where two or more

applications concerning the same product and emanating from two or more holders of different patents are pending, one certificate for this product may be issued to each of these holders.”

The Applicants’ case

- 17 Dr Goodfellow acknowledged that on a natural reading of Article 3(c) the grant of supplementary protection certificates to Genetics Institute and Biovitrum for Moroctocog alfa would close the door on the grant of a further supplementary protection certificate to the applicants on the basis of the application. However, in his submissions to me Dr Goodfellow sought to persuade me that this interpretation of Article 3(c) could not be sustained when account is taken of the underlying purpose of the Medicinal Products Regulation to reward all innovators who had been granted a patent covering a product which had been authorized for marketing. In Dr Goodfellow’s opinion a teleological interpretation of Article 3(c) requires consideration of how the Medicinal Products Regulation has developed since 11 April 1990 when the Commission of the European Communities published its proposal for a Regulation along with an Explanatory Memorandum (COM(90) 101 final).

Can only one certificate be granted for any one product?

- 18 Referring to the Explanatory Memorandum, Dr Goodfellow suggested that the original purpose of Article 3(c) was to permit the grant of only one certificate for each product. In his view this is apparent from statements in paragraphs 11 and 36 of the Memorandum that:

“11. Only one certificate may be granted for any one product,””;

“36. Lastly, the product must not have been the subject of a certificate in the Member State concerned. it would not be acceptable, in view of the balance required between the interests concerned, for this total duration of protection for one and the same medicinal product to be exceeded. This might nevertheless be the case if one and the same product were able to be the subject of several successive certificates.

..... If a certificate has already been granted for the active ingredient itself, a new certificate may not be granted for one and the same active ingredient whatever minor changes may have been made regarding other features of the medicinal product
..... .

In conclusion, it should be noted that, although one and the same product may be the subject of several patents and several authorizations to be placed on the market in one and the same Member State, the supplementary protection certificate will only be granted for that product on the basis of a single patent and a single authorization to be placed on the market, namely the first chronologically given in the State concerned
..... .”

Dr Goodfellow also highlighted a statement in paragraph 56 of the Memorandum indicating the intention that only a certificate granted in respect of a first authorization to place a product on the market in the Member State concerned would be valid when one and the same

product was the subject of several certificates in that State.

- 19 He continued by referring me to Advocate General Fennelly's opinion in *Biogen*. The background to this case was that Smithkline Beecham Biologicals SA ("SKB") produced and marketed a vaccine against Hepatitis-B under licence from Biogen Inc. and the Institute Pasteur who held relevant patents. SKB had obtained Belgian marketing authorizations for the vaccine but had refused to provide copies of these authorizations to Biogen Inc. to enable it to obtain supplementary protection certificates on its patents. Nevertheless, SKB did provide a copy of the first marketing authorization for the vaccine to Institute Pasteur which was thus able to obtain a certificate. SKB contended that under the Medicinal Products Regulation only one certificate may be granted for each product - that is to say, each identical active ingredient - even where the product in question is based on several patents. This led Biogen Inc to bring an action against SKB before the Tribunal de Commerce in Belgium. The Tribunal in turn referred four questions to the ECJ, the second of which was:

"Where one and the same product is covered by several basic patents belonging to different holders, does Regulation No. 1768/92 preclude the grant of a supplementary protection certificate to each holder of a basic patent?"

- 20 Dr Goodfellow began by highlighting the opening statement of Advocate General Fennelly's opinion in *Biogen* that:

"1. The Court is asked here to provide for a situation which was not foreseen by the Community legislator and could not have been foreseen by private parties and was not expressly provided for."

- 21 Later in his opinion the Advocate General took the view that the second question referred to the ECJ should be answered in the negative and Dr Goodfellow was particularly keen that I should note the Advocate General's reasons for taking this view. Thus, at paragraph 29 of his opinion Advocate General Fennelly states:

"29. The text of the Regulation applies simply to a simple situation, in which basic research, product development, production and marketing are vertically integrated: where the holder of the patent or patents relating to a medicinal product, the marketing of which has been authorized in a Member State, is also the holder of the relevant marketing authorization. The Regulation was evidently drafted on the basis of this 'classic' model."

Then in paragraph 30 the Advocate General states:

"30. Article 1(c) may be thought to assume that, in a case where there are numerous patents, possibly of different kinds (product, process or product-application patents), these will be held by a single holder, who is in a position to choose between them and to designate one as the "basic patent" for the purpose of the procedure for grant of a certificate. The statement in Article 6, that the certificate shall be granted to 'the holder of the basic patent' (emphasis added), also seems to be framed in the light of an assumption of integration."

and he continues at paragraphs 31 and 32:

“31. This assumption becomes more important in Article 3(c) of the Regulation, which requires, as one of the conditions for obtaining a certificate, that ‘the product has not already been the subject of a certificate’. . . . In my view, the purpose of the provision is to ensure that the right exclusively to market a medicinal product is not multiply extended over time by obtaining a number of certificates in succession. Otherwise, there could be attempts to bypass the calculation of the period of supplementary protection, including the maximum of five years, which represents a key compromise between a number of competing political, social and economic interests. This could occur, in the absence of the condition set out in Article 3(c), if the product – the active ingredient or combination of active ingredients – were, in different dosages or forms, the subject (as in the present case) of a number of different marketing authorizations over time, the first of each of which in the Community could act as the basis for calculating a further period of supplementary protection for associated patents. This explains the centrality of the concept of ‘the product’ in certain parts of the legislative scheme. One product, the composition of which is fixed, can result from many patents and can result in many marketing authorizations in a single Member State. This is because what is essentially the same product may be administered in different ways, or presented in different dosages, each of which must be separately authorized. As the product represents the essential active ingredient or combination of active ingredients of any given therapeutic, diagnostic, preventative or other medicinal invention, it is the fixed point employed to ensure that the patent protection accorded to that invention and its underlying research is supplemented only once.

32. The assumption that for every product, there will be – and there *need* be – only one corresponding basic patent, designated by its holder, thus entailing the award of a single certificate, underlies the approach adopted in Article 3(c) of the Regulation, but is in no way necessary to the achievement of that provision’s objective. On the contrary, the award of a number of certificates in respect of a number of patents associated with a single product, all on the basis of the same marketing authorization, and for which the period of supplementary protection is calculated from the date of award of the first such marketing authorization in the Community, would result in the protection derived from every such patent expiring on the same day.”

Advocate General Fennelly develops his view on the different kinds of patent that can be designated as the ‘basic patent’ in paragraph 35:

“35. . . . Article 1(c) refers indiscriminately to product, process and product-application patents, indicating that patents arising at any stage in the research which ultimately results in a marketable medicinal product can be designated by their holders for supplementary protection. Moreover, the factual perception which motivated the enactment of the Regulation, that pharmaceutical research suffered from reduced returns due to delays in procuring marketing authorization for medicinal products, is valid for all such research, and would imply that all undertakings engaged in such research should be able to benefit from the

Regulation.”

22 On the basis of these statements made by Advocate General Fennelly in *Biogen*, Dr Goodfellow concluded that the aim of Article 3(c) is to avoid a particular patent holder obtaining more than one supplementary protection certificate on the basis of a particular basic patent and so ensure that the maximum 15 years exclusivity under a patent and a supplementary protection certificate is never exceeded. Dr Goodfellow found support for his conclusion in paragraph 28 of the ECJ’s judgment in *Biogen*:

“28. Under Article 3(c) of the Regulation, however, only one certificate may be granted for each basic patent.”

23 Dr Goodfellow went on to make the point that after considering the effect of Article 1(c) of the Regulation, which mentions three categories of patents, which may be designated for the purpose of supplementary protection, the ECJ concluded in paragraph 27 of its judgment in *Biogen* that:

“27. The Regulation thus seeks to confer supplementary protection on the holders of such patents, without instituting any preferential ranking amongst them.”

before stating in paragraph 28:

“28. Consequently, where a product is protected by a number of basic patents in force, which may belong to a number of patent holders, each of those patents may be designated for the purpose of the procedure for the grant of a certificate.”

24 From this Dr Goodfellow opined that the original premise on which the Regulation was based, that is one supplementary protection certificate per product, no longer applies. In his view this concept has been broadened such that each holder of a basic patent may be granted a supplementary protection certificate, subject to the proviso that only one certificate may be granted on that product to each holder of a basic patent. Moreover, Dr Goodfellow stressed that the ECJ had stipulated only one proviso in its statement at paragraph 28 in *Biogen* and in particular the Court had not added a further proviso that no certificate must have been granted previously for the product in question. He took the view that the ECJ would have added this further proviso if it had considered a certificate should not be granted when a certificate had already been granted for the same product. Indeed he made the further point that to do so would have been inconsistent with the ECJ’s earlier statement about not instituting any preferential ranking amongst patent holders.

25 Furthermore, in Dr Goodfellow’s opinion the ECJ’s statement in paragraph 28 of *Biogen* that:

“28. Under Article 3(c) of the Regulation, however, only one certificate may be granted for each basic patent.”

reflected observations made by the Italian Government and the Commission concerning the questions before the Court. As stated in paragraph 23 of the Court’s judgment:

“23. The Italian Government and the Commission stress that Article 3 of the Regulation, which prohibits renewal of protection for the same product, that is to say in relation to a single patent, nevertheless does not preclude the grant of two certificates (one for each basic patent), even if they relate to the same medicinal product.”

Thus, according to Dr Goodfellow, the ECJ construed Article 3(c) in a way which broadens its original purpose so that when a product is protected by more than one patent, the Regulation does not preclude the grant of an SPC to each holder of a basic patent. However, once any patent holder has obtained a supplementary protection certificate for a product, that patent holder cannot obtain a further certificate for the same product based on another patent.

Preferential ranking

26 Following on from the ECJ’s conclusion in *Biogen* that the Regulation seeks to confer protection without instituting any preferential ranking amongst patent holders, Dr Goodfellow submitted that it made no sense to impose an arbitrary rule that applications for supplementary protection must be co-pending in order to allow the grant of certificates to more than one applicant. Moreover, although Dr Goodfellow recognised that the applications for supplementary protection in *Biogen* were co-pending, he saw no reason to limit the ECJ’s judgment to such a situation since it was not central to the Court’s ruling. Indeed, Dr Goodfellow felt that certain passages in the ECJ’s judgment led one to believe that the Court did consider whether Article 3 as a whole leads to the result that only the first person to apply for a certificate should receive one. I have already quoted one of the passages which Dr Goodfellow relied on. This was the passage setting out the positions of the Italian Government and the Commission in paragraph 23 of the ECJ’s judgment. The other passage, relied on by Dr Goodfellow, is at paragraph 24 of the judgment:

“24. In the French Government’s submission, to interpret Article 3(c) of the Regulation as reserving the right to a supplementary protection certificate to the first patent holder who applies for one would result in an arbitrary choice of the beneficiary of the extension of the period of protection among companies which, in accordance with the aims and subject-matter of the Regulation, are all equally entitled to such protection.”

27 Dr Goodfellow dealt with the ECJ’s rejection of the concept of preferential ranking in *Biogen* by referring once again to the opinion of Advocate General Fennelly. In particular, Dr Goodfellow relied on a statement in paragraph 26 of the Advocate General’s opinion:

“26. There is no provision in the Regulation for any qualitative preference of some patents over others, according, for example, to their relative importance to the marketed medicinal product; any such process of selection would be difficult, if not impossible. The alternative approach, that of ‘first come, first served’, is equally unconvincing, not the least because it would sit ill with the general principle of legal equity.”

Dr Goodfellow remarked that this statement was very important and he contrasted it with

Article 3(c), which on his literal construction, would result in a ‘first come, first served’ approach where the first person to apply gets the reward. In his view it was inconceivable that if there were two patent holders, both possessing patents that protect a particular medicinal product, one should be excluded from the regime and the other included. This would result in an arbitrary selection of the beneficiary of supplementary protection from amongst a set of parties, all of which have an equal right to a certificate given the objective of the Medicinal Products Regulation. Moreover, such an outcome would be inconsistent with the first three recitals of the Regulation, which in Dr Goodfellow’s view established that the purpose of this Regulation was to reward investment in the research and thus the innovation which led to a patent protecting a medicinal product.

Commentary by Brigitte Dauwe on Article 3

28 In further support of his argument Dr Goodfellow referred me to an English translation of an extract from “Octrooirecht en geneesmiddelen”, (CIR-Reeks 16), Van Overwalle, G., (ed.), Brussel, Bruylant, 2000. The extract comprises pages 128 – 132 of a commentary by Brigitte Dauwe on “The Supplementary Protection Certificate for Medicines” and deals with the basic requirements of Article 3 of the Medicinal Products Regulation. Dr Goodfellow took me first to paragraph 2.1.1.1 in which Ms Dauwe states:

“..... Art. 3(c) of Ordinance No. 1768/92 has in practice also prompted application options if a product is protected by several patents, which are held by several patent holders. The question then arises if in these circumstances supplementary protection certificates might not be granted for the same product. The solution given to this problem has been partly evaluated. In the first period, legal doctrine ¹¹ tried to answer the question positively on the grounds of a literal interpretation of art. 3(c), viz. paying attention to the words “if (..) *on the date of this application* (..) a certificate *has not been obtained* earlier for the product”.

This viewpoint was endorsed by the European Commission at the meeting between representatives of the member states on 3 February 1995. In the second phase this option was promoted into a rule in Ordinance (EC) No. 1610/96 of 23 July 1996 with regard to the certificates for Plant Protection Products.

Art. 3(2) second sentence expressly determines that “If for the same product two or more applications from two or more holders of different patents are pending, a certificate can however be issued to each of these patent holders”. As already noted, consideration 17 proposed in the preamble of Ordinance (EC) No. 1610/96 that art. 3(2) *mutatis mutandis* applies to the interpretation of art. 3 of Ordinance (EEC) No. 1768/92¹³.

In a subsequent phase, four months after the issue of the Ordinance (EC) No. 1610/96, the Court of Justice (CoJ) had the opportunity to make a pronouncement in the case *Biogen / SKL* about the same question.”

At this point Dr Goodfellow highlighted the chronological relationship between Regulation 1610/96 and the ECJ’s judgment in *Biogen* before picking up the commentary at a point

where Ms Dauwe states:

“A study of the Ordinance and the Explanation also clearly shows that in fact the European legislator “had not thought” of the possibility that a product could be protected by several basic patents, which are in the hands of *different* patent holders. As already stated, this problem is expressly dealt with in Ordinance No. 1610/96 of 23 July 1996 with regard to an SPC for plant protection products (see art. 3(2) second sentence).”

Ms Dauwe then states what the ECJ decided in *Biogen* and adds as a footnote to the judgment:

“See for an application of this verdict: Decision Office of Industrial Property 9 January 1998, BIE, 1998, 133: ‘In spite of the fact that in a given case an SPV (*sic*) has already been granted for the same product, a certificate will be issued to the holder of *another* basic patent.’”

- 29 Dr Goodfellow saw Ms Dauwe’s commentary as setting out three successive, legal doctrines based on Article 3(c). The first occurred in 1992 and followed a literal interpretation. The second came about as the result of clarification, provided by Article 3(2) of Regulation 1610/96, but it still required applications to be pending. The third doctrine followed the ECJ’s consideration of Article 3(c) in *Biogen*.

Market fragmentation

- 30 Dr Goodfellow next turned to explain how in his view reliance on a literal interpretation of Article 3(2) of the Plant Protection Products Regulation would lead to market fragmentation. He started by referring once again to Advocate Fennelly’s opinion in *Biogen*. At paragraph 38 the Advocate General states:

“38., even in a situation in which a number of undertakings hold patents associated with a product, and each such patent is held by the same undertaking throughout the Community, the restriction of supplementary protection to just one patent in each Member State would almost certainly result in the fragmentation of the market. As certificates are awarded on a country-by-country basis, the different patent holders could succeed in winning supplementary protection in different Member States, depending, presumably, on the terms they were willing to offer the holder of the marketing authorization or, in the alternative, on the policy of the competent public authorities.”

- 31 Dr Goodfellow observed that neither of the two Regulations concerning supplementary protection certificates stipulate the appropriate time of pendency for an SPC application. As a consequence, the time taken for the prosecution of a supplementary protection certificate varies from one Member State to another. In his experience the relevant authorities in some Member States generally grant certificates quickly, whilst the authorities in other Member States take significantly longer. Thus, on a literal interpretation of Article 3(c) of the Medicinal Products Regulation and of Article 3(2) of the Plant Protection Product Regulation, in those Member States where certificates are granted quickly there is a strong

possibility that a first applicant for supplementary protection for a particular product could be granted a certificate and so shut out other applicants wanting to protect the same product before they have an opportunity to apply. Whereas, in other Member States where it takes longer to grant an supplementary protection certificate, the longer pendency of applications for certificates might allow the other applicants to obtain their certificates. Thus, whilst there may be just one supplementary protection certificate for a particular product in one Member State, there could be more than one supplementary protection certificate for the same product in other Member States. Dr Goodfellow stated that this was a situation the European Commission is always keen to avoid, as reflected in recitals 5 and 6 of the Medicinal Products Regulation.

The Sigma-Tau Decision in the Netherlands

- 32 Enclosed with the agent's letter, dated 24 November 2003, was a translation of a decision nullifying an earlier rejection under Article 3(c) of the Medicinal Products Regulation by the Netherlands Industrial Property Office. Dr Goodfellow referred to this decision, which was dated 9 January 1998, at the hearing and explained that in this case the Wellcome Foundation had been granted an SPC in the Netherlands within four months of lodging its application. A second applicant had then applied for supplementary protection certificate but this application was rejected by the examiner because a certificate had already been granted to the Wellcome Foundation for the relevant product. Thus, the circumstances of that case were very similar to those of the present case. However, as already indicated, this decision was ultimately overturned on appeal within the Netherlands Office.

The interpretation of "pending"

- 33 Dr Goodfellow submitted that there was no reason to construe the second sentence of Article 3(2) of the Plant Protection Products Regulation in such a way that only two applications, which are pending at the same time, should be granted. To do so would introduce arbitrariness and overlook the purpose underlying the Regulation to reward all patent holders for their innovation. Dr Goodfellow used the circumstances of the application to illustrate that a holder of a basic patent would be unfairly excluded from the system of supplementary protection if Article 3(2) were limited to the particular situation in which two SPC applications happen to be pending simultaneously between the period of application and grant of one of them. Thus, in his opinion the second sentence of Article 3(2) should be interpreted as meaning where two or more applications, concerning the same product and emanating from two or more holders of different patents, have been filed, one certificate for this product may be issued to each of these holders. In his view there is no rational requirement for Article 3(2) to be limited to the particular situation in which two applications for supplementary protection happen to be pending simultaneously.
- 34 In Dr Goodfellow's opinion the drafters of the legislation had foreseen the problem faced by the applicants and so allowed, in accordance with Article 7, an application for a supplementary protection certificate to be filed within six months from the date of grant of the marketing authorization or six months from the date of grant of the basic patent, whichever was the later. Dr Goodfellow also repeated his point that the ECJ in *Biogen* had commented that the Regulation sought to confer supplementary protection without instituting any

preferential ranking amongst patent holders. From this he concluded that it must be manifestly wrong to apply Article 3(c) in a way which gives preferential treatment to the holder of a first patent protecting the product.

Article 3(2) of the Plant Protection Products Regulation

- 35 At the hearing Dr Goodfellow addressed me at some length on the relevance of Article 3(2) of the Plant Protection Products Regulation to the matter I must decide. In particular, he directed me to comments in the agent's letter, dated 24 November 2003, concerning the legitimacy of using Article 3(2) of the Plant Protection Products Regulation to interpret Article 3(c) of the Medicinal Products Regulation. The letter notes that this method of supposedly amending Article 3(c) of the Medicinal Products Regulation is very unusual in European law. The point is made that normally any amendments of a provision in a Council Regulation take place via amendments to the Regulation itself.
- 36 In the same letter the applicants' agent makes the point that amendment of Article 3(c) of the Medicinal Products Regulation by the Plant Protection Products Regulation cannot have the same credibility as a bespoke amendment to Article 3(c) of the Medicinal Products Regulation itself. Indeed the applicants' agent suggests that the European Parliament and Council did not have the authority to amend the Medicinal Products Regulation using this mechanism and therefore recital 17 of the Plant Protection Products Regulation is of no relevance in relation to the interpretation of Article 3 of the earlier Regulation. The agent's letter, dated 18 June 2004 and filed after the hearing, also argues that amendment of legislation on topic A by legislation on topic B creates confusion and uncertainty, particularly when the amendment is included in the preamble to a different Regulation.
- 37 Both letters suggest it is of interest that there have been occasions in which the ECJ has issued a judgment concerning the interpretation of provisions of the EC Treaty, after which the Member States have amended the provisions of the Treaty in order to ensure consistency with the judgment. Both letters also refer to situations in which the Member States have inserted provisions into the Treaty to prescribe how a judgment of the ECJ should be interpreted.
- 38 The letters refer specifically to the case of *Douglas Harvey Barber v Guardian Royal Exchange Assurance Group* (C-262/88) ("*Barber*"). They explain that in this case the ECJ held that Article 141 (at that time, Article 119) of the EC Treaty forbids discrimination between men and women with regard to occupational pension schemes. However, the ECJ restricted the scope of its judgment to claims with effect from the date of its judgment but made an exception with regard to claimants who had already started legal proceedings or had raised an equivalent claim before the date of the judgment. Since it was possible to interpret this restriction on the scope of the judgment in different ways, a Protocol to the EC Treaty was adopted laying down one of the possible interpretations. The letters develop this line of argument by referring to a later judgment of the ECJ in the case of *David Neath v Hugh Steeper Ltd* (C-152/91) ("*Neath*") which is said to lay down an interpretation of the EC Treaty in line with the Protocol, even though the ECJ did not explicitly refer to the

Protocol.

- 39 The later letter of 18 June 2004 continues by recognising that in the Plant Protection Products Regulation the legislator similarly provided an interpretation of earlier legislation. Moreover, this letter states that in both *Biogen* and *Neath*, the interpretation preferred by the legislator was known at the date of the relevant judgment of the ECJ. However, in *Neath* the ECJ decided to lay down an interpretation in line with the interpretation preferred by the legislator (as established by the Protocol), whilst in *Biogen* the ECJ laid down an interpretation which is not inline with the interpretation preferred by the legislator and as expressed in the Plant Protection Products Regulation. The letter comments that although it might be argued that the *Biogen* case could be interpreted consistently with Article 3(2) of the Plant Protection Products Regulation, the language used by the ECJ in *Biogen* is clearly not in line with Article 3(2) of the Plant Protection Products Regulation. The conclusion drawn from this is that because the ECJ decided not to take Article 3(2) of the Plant Protection Products Regulation into account in *Biogen*, it indicates that this Regulation does not entail amendment of Article 3 of the Medicinal Products Regulation nor is it of any or any significant relevance for the interpretation of Article 3 of the earlier Regulation.
- 40 The applicants' patent agent goes on to consider in the letter dated 18 June 2004 whether the relationship between a Protocol and the EC Treaty is similar or not to the relationship between the Plant Protection Products Regulation and the Medicinal Products Regulation. In the agent's view, the circumstances are different. Firstly, because Article 311 of the EC Treaty provides that Protocols annexed to the EC Treaty form an integral part of the Treaty, whereas the Plant Protection Products Regulation cannot be regarded as an integral part of the Medicinal Products Regulation. Secondly, the Protocol concerning Article 141 EC Treaty was specifically adopted to lay down an interpretation of the EC Treaty. The Plant Protection Products Regulation on the other hand was not adopted to lay down an interpretation of the Medicinal Products Regulation. It was adopted to introduce supplementary protection certificates in relation to plant protection products. Therefore, the opinion of the applicants' patent agent is that the interpretation of the ECJ in *Biogen* should take precedence over an interpretation which is based on a recital in the Plant Protection Products Regulation.

The balance of fairness

- 41 At the hearing Dr Goodfellow referred me to a submission made in the agent's letter dated 24 November 2003 concerning the balance of fairness. In essence this submission was that where there is a degree of doubt as to whether a supplementary protection certificate should be granted, the Patent Office should give the benefit of the doubt to the applicant. The letter argues that granting a supplementary protection certificate does not violate the rights of any other party – such a certificate is only of use to its holder if it is enforced and it can only be enforced if it is valid. The letter goes on to make the point that if the applicants' application were refused, they would have no recourse other than that of appeal, whereas if the certificate were granted, the Court would have the final sanction of finding it invalid if the requirements of Article 3(c) were judged not to be met.

Assessment

Articles 3(c) and 3(2)

- 42 I will begin by considering the relevance of the relationship between Article 3 of the Medicinal Products Regulation and Article 3(2) of the Plant Protection Products Regulation to the matter I must decide. On a natural reading of Article 3 of the Medicinal Products Regulation, a certificate shall be granted if, in the Member State concerned and **at the date of lodging an application** for a certificate, various conditions are met. One of these conditions is set out in Article 3(c) and requires that **the product has not already been the subject of a certificate**. If an application does not meet all of the conditions for the grant of a certificate, Article 10(2) of the Medicinal Products Regulation requires that it shall be rejected. This natural reading of Article 3 corresponds to what Ms Dauwe's described in her commentary on the Regulation as an interpretation based on "legal doctrine". Although Article 3(c) specifically addresses a situation in which a certificate has been granted for a product before a further application is lodged for the same product, it does not explicitly deal with a situation in which there is **a pending** application to protect a product when the further application is lodged.
- 43 According to recital 17 of the Plant Protection Products Regulation, the detailed rules in Article 3(2) of that Regulation are valid, *mutatis mutandis*, for the **interpretation** of Article 3 of the Medicinal Products Regulation. In his submissions to me Dr Goodfellow suggested that Article 3(2) of the Plant Protection Products Regulation amends Article 3 of the Medicinal Products Regulation and that for various reasons this is illegitimate. However, Dr Goodfellow's arguments appear to pay insufficient attention to recital 17 which specifically refers to interpretation and not amendment of Article 3.
- 44 It is helpful to look at the detailed rules in Article 3(2) of Plant Protection Products Regulation when considering whether these rules interpret or amend Article 3 of the Medicinal Products Regulation. Article 3(2) addresses two distinct situations. The first concerns a situation in which one and the same holder of more than one patent for the same product, seeks more than one certificate for that product. I have considered this situation in an earlier decision, which was reported as *Takeda Chemical Industries Ltd's SPC Applications (No. 2)* [2004] RPC 2 ("*Takeda*"), and at the hearing Dr Goodfellow stated that he accepted my interpretation of Article 3 in that case. However, this situation is not the one we have in the present case. The second situation addressed by Article 3(2) is one where there are two or more pending applications for the same product emanating from two or more holders of different patents. According to Article 3(2) one certificate for the product may be issued to each of the holders in such a situation. Whilst this interpretation of Article 3 allows the grant of certificates for the same product to different applicants, it does not conflict with the basic condition of Article 3(c) (on a natural reading) that the product in question must not have already been the subject of a certificate. Therefore, I do not accept that Article 3(2) of the Plant Protection Products Regulation amends Article 3 of the Medicinal Products Regulation. In my view Article 3(2) merely interprets Article 3 and I reject Dr Goodfellow's submissions to the contrary.
- 45 Even so the second situation addressed by Article 3(2) of the Plant Protection Products Regulation, like the first, is different from the one faced by the applicants. Thus, in my opinion, Article 3(2) does not directly assist me in the decision I have to make and I see no

benefit in considering further Dr Goodfellow's submissions concerning the interpretation of Article 3(2) of the Plant Protection Regulation, which itself interprets Article 3(c) of the Medicinal Products Regulation. I must fall back on the basic condition of Article 3(c) of the Medicinal Products Regulation and consider whether there is some further teleological interpretation which would allow the application to proceed.

The "product" and the "medicinal product"

46 Before I move on to consider the other submissions made by Dr Goodfellow, I should establish what the "product" and what the "medicinal product" are in this case. After all the definitions set out in Article 1 of the Medicinal Products Regulation lay at the heart of the Regulation. At no time during the course of the hearing did Dr Goodfellow suggest that the "product" and "medicinal product" of the application were other than Moroctocog alfa and ReFacto, respectively. In other words it was not argued by the applicants that the product of the application is different from the product of the two granted supplementary protection certificates. I accept this and will proceed on the basis that the "product" is indeed Moroctocog alfa and the "medicinal product" is ReFacto.

The Biogen case

47 It is clear from the answer that the ECJ gave to the second question in *Biogen* that where a medicinal product is covered by several basic patents, the Medicinal Products Regulation does not preclude the grant of a supplementary protection certificate to each holder of a basic patent. In reaching its answer to this question the ECJ also stated that:

"28. Under Article 3(c) of the Regulation only one certificate may be granted for each basic patent."

In my earlier decision in *Takeda* at paragraphs 22 and 23 I considered this statement in context and concluded that the ECJ had intended that if a patent holder has more than one patent for the same product, he should not be able to obtain more than one certificate for that product. In his submissions to me Dr Goodfellow interpreted the ECJ's intention slightly differently. In his view the ECJ had intended that **each** holder of a basic patent may be granted a supplementary protection certificate for a product subject to the proviso that only one certificate may be granted on that product to **each** holder of a basic patent.

48 Dr Goodfellow went on to argue before me that the ECJ would have added a further proviso if it had intended that certificates should be granted to different patent holders only when a certificate had not already been granted for the product in question. I have read the Court's judgment with great care, paying particular attention to the passages relating to the views of the Italian and French Governments and the view of the Commission in paragraphs 23 and 24, and I can find nothing to indicate clearly that the Court in its judgment or Advocate General Fennelly in his opinion had this particular issue in mind. Moreover, I do not believe I should attach any weight to the commentary by Ms Dauwe on this matter, particularly her view of the three successive, doctrines surrounding Article 3(c) of the Medicinal Products Regulation. Therefore, I consider it would be unsafe to base my decision on Dr Goodfellow's assumption that the Court would have added a further proviso if it had

accepted that the grant of a certificate to one patent holder should preclude the grant of a second certificate for the same product to different patent holder. Nevertheless, the ECJ's judgment and the Advocate General's opinion in *Biogen* establish principles which are helpful in reaching a decision in the present case.

49 Part of Dr Goodfellow's submissions to me was based on the view that the Medicinal Products Regulation had been built on an understanding that basic research, product development, production and marketing were vertically integrated. This view was based on the observation by Advocate General Fennelly in *Biogen* that the Medicinal Products Regulation was drafted on the basis of a 'classic' model where the holder of a patent relating to a medicinal product is also the holder of the relevant marketing authorization. In this context the Advocate General noted that Article 1(c) may be thought to assume that in a case where there are numerous patents, these will be in the hands of a single holder, who is in a position to choose between them and designate one as the "basic patent" for the purpose of obtaining a supplementary protection certificate. Moreover, the Advocate General observed that the purpose of Article 3(c) was to ensure that the right exclusively to market a medicinal product is not multiply extended over time by obtaining a number of certificates in succession.

50 I have reviewed the Explanatory Memorandum, taking particular note of the passages identified by Dr Goodfellow at the hearing, and I can find nothing in it to suggest that when making its proposal for a Regulation, the Commission had in mind the possibility that different patents, protecting same product, could be in different hands and that each patent holder would want supplementary protection for the product. Nevertheless, in line with the later Advocate General's opinion and ECJ judgment in *Biogen*, paragraph 36 of the Explanatory Memorandum indicates that the purpose of Article 3(c) is to preclude the grant of several **successive** certificates for one and the same product.

51 In reaching its judgment in *Biogen* the ECJ observed at paragraph 29:

"29. Furthermore, as is clear from Article 13 of the Regulation, the duration of such certificates is to be calculated uniformly on the basis of the date of the first authorization to place the product on the market in the Community."

Using the date of award of the first marketing authorization for a product in the Community does not always result in the supplementary protection, derived from a number of patents protecting that product, expiring on the same day. Nevertheless it does provide uniformity and preclude the grant of successive certificates for same product. This is illustrated in the present case where the two earlier certificates (SPC/GB99/037 and SPC/GB99/038) and the present application are based on the same marketing authorization granted on 13 April 1999. However, the two earlier certificates will expire on 12 April 2014 and 10 April 2011, respectively, and if a certificate were granted on the application it would expire on 10 January 2010. These different expiry dates arise from the provision of Article 13(2) which limits the maximum duration of a certificate to five years from the end of the lawful term of the corresponding basic patent when the marketing authorization is granted more than ten years after the filing date of the basic patent. In the present case the duration of SPC/GB/038 is limited in this way, as would be any certificate granted on the application, whereas

SPC/GB/037 provides the maximum fifteen years of combined protection with its corresponding basic patent from the date of the first marketing authorization of the product. Therefore, the expiry of SPC/GB/037 marks the latest expiry date for any certificate based on the marketing authorization granted on 13 April 1999. Thus, a certificate granted on the basis of the application would not successively extend the protection for Moroctocog alfa and so would not undermine the purpose of Article 3(c).

52 Dr Goodfellow highlighted various comment made by Advocate General Fennelly in *Biogen* but one in particular has a particular bearing on the matter I must decide. When referring to the factual perception of reduced returns from pharmaceutical research due to delays in procuring marketing authorizations for medicinal products, the Advocate General commented that this perception was valid for all such research and that this would imply that all undertakings engaged in such research should be able to benefit from the Regulation. I believe it is now well established on the basis of recitals 2 and 3 of the Medicinal Products Regulation that the purpose of the Regulation is to encourage research by compensating for lost time in the exploitation of patented inventions due to the need to obtain authorizations to market medicinal products. Thus, if I were to reject this application because supplementary protection certificates had already been granted to other patent holders by the time the applicants had lodged the application, I would be denying the applicants the benefit of any compensation for the time lost in the exploitation of their invention before Moroctocog alfa was authorized. On the other hand the other patent holders, who have already been granted supplementary protection certificates for Moroctocog alfa, will be compensated even though the terms of their patents were eroded less than that of the applicants.

53 As Dr Goodfellow pointed out to me at the hearing the Advocate General's point is reflected in the ECJ's judgment in *Biogen* when the Court states at paragraph 27 (my emphasis):

“27. Article 1(c) mentions the basic patents which may be designated for the purpose of the procedure for the grant of a certificate, namely those which protect a product as such, a process to obtain a product or an application of a product. The Regulation thus seeks to confer supplementary protection on the holders of such patents, **without instituting any preferential ranking amongst them**”

As I have already mentioned, it was Dr Goodfellow's view that in the light of this statement by the ECJ, it made no sense to impose an arbitrary rule that certificates could only be granted to more than one applicant if the corresponding applications were co-pending. I find this line of argument persuasive, particularly since such an arbitrary rule sits ill with the general principle of legal equity, mentioned by Advocate General Fennelly in paragraph 26 of his opinion.

Market fragmentation

54 Another of Dr Goodfellow's arguments was based on Advocate General Fennelly's opinion in *Biogen* that even in a situation in which a number of undertakings hold patents associated with a product, and each such patent is held by the same undertaking throughout the Community, a restriction of supplementary protection to just one patent in each Member State would almost certainly result in the fragmentation of the market. This situation, in which

there is just one certificate protecting a product in each Member State and the certificates in different Member States are in different hands, differs from the scenario envisaged by Dr Goodfellow. In Dr Goodfellow's scenario there may be just one supplementary protection certificate for a particular product in one Member State and more than one certificate for the same product in another Member State. Whilst this is not the same outcome as that envisaged by Advocate General Fennelly, it would still result in market fragmentation and would in my view run contrary to one of the fundamental objectives of the Medicinal Products Regulation, as set out in recital 6 and as described by Advocate General Fennelly in paragraph 34 of his opinion as:

“34. the goal of greater uniformity of patent protection for the purposes of the internal market.”

Article 7 of the Medicinal Products Regulation

55 I have already concluded that interpreting Article 3(2) of the Plant Protection Products Regulation, which itself provides an interpretation of Article 3 of the Medicinal Products Regulation, does not assist me in this case. However, when addressing me on Article 3(2) Dr Goodfellow made the point that Article 7 of the Medicinal Products Regulation indicates that those, who drafted this provision, had in mind a situation in which an applicant might not be in a position to file an application for supplementary protection of a product before a certificate for the same product was granted to another applicant. I should therefore consider Dr Goodfellow's submission on this point. In my view Dr Goodfellow was clutching at straws here. Article 7 merely recognises that there can be no certainty whether a patent protecting a product or a corresponding marketing authorization will be granted first. It was therefore necessary to cater for both possibilities so that an applicant could comply with the conditions of Article 3(a) and Article 3(b) at the date of lodging an application. Indeed I doubt if the legislator had the problem Dr Goodfellow refers to in mind since, as he argued elsewhere, the legislator did not seem to appreciate the possibility of more than one applicant seeking supplementary protection for the same product. Therefore, I find that Article 7 of the Medicinal Products Regulation does not lend support to the applicants' case.

What is the condition imposed by Article 3(c)?

56 So far I have found no justification for rejecting the application on the ground that a supplementary protection certificate has already been granted for the same product but to a different patent holder when the application was lodged. On the contrary, it seems to me that to reject the application in these circumstances would run contrary to the purpose of the Medicinal Products Regulation when viewed in the light of the ECJ's judgment in *Biogen*. However, if I were to decide that Article 3(c) does not provide grounds for rejection in these circumstances, I could not just ignore it. I believe it is necessary to consider how this condition impinges on an application, such as the present one, filed after an earlier application for the same product has been granted.

57 In considering the purpose underlying the condition of Article 3(c) I am drawn back to the ECJ's statement in *Biogen*:

“28. where a product is protected by a number of basic patents in force, which may belong to a number of patent holders, each of those patents may be designated for the purpose of the procedure for the grant of a certificate. Under Article 3(c) of the Regulation, however, only one certificate may be granted for each basic patent.”

Consistent with my earlier decision in *Takeda* I take the view that the ECJ intended that it is not permissible for one and the same patent holder to multiply extend the protection for a medicinal product over time by obtaining successive certificates. Thus, where there are a number of patents in different hands but protecting the same product, all holders of basic patents may be granted a supplementary protection certificate but only one certificate may be granted for that product to each. Essentially, this is the interpretation of Article 3(c) suggested to me very clearly and succinctly by Dr Goodfellow at the hearing.

58 In my view this interpretation of Article 3(c) is supported by recitals 8 and 9 of the Medicinal Products Regulation and by various statements in the Memorandum. These make it clear that the duration of a supplementary protection certificate should be such as to provide adequate effective protection but that it would be unacceptable, in view of the balance required between the interests concerned, for this duration for one and the same medicinal product to be exceeded. Therefore, it should be possible for all patent holders to benefit from supplementary protection of the same product but the balance between the interests concerned should not be tipped too far towards patent holders by allowing them to multiply extend their protection for the product over time by obtaining successive certificates.

Acte claire

59 I do not accept Dr Goodfellow’s submission to me at the hearing that I should give the benefit of doubt to the applicants if there is a degree of doubt whether a supplementary protection certificate should be granted. In my view I have a duty to resolve any doubt and reach a firm decision to the best of my ability. It would be wrong to take an easy way out and shift the onus onto a third party to invalidate the certificate. However, I am conscious that according to recital 6 one purpose of the Medicinal Products Regulation was to establish a uniform solution at Community level. This was achieved in part by the Regulation itself but it still relies on the competent industrial property offices in all Member States applying the Regulation uniformly. Therefore, if I thought that other industrial property offices might interpret the Regulation differently in identical circumstances, I should consider rejecting this application. I do not believe I have the jurisdiction in proceedings such as these to make a reference to the ECJ but the Patents Court could do so on appeal.

60 So far I have not commented on the *Sigma-Tau* decision of the Netherlands Industrial Property Office. In that case a certificate was granted despite the fact that a certificate had already been granted for the same product, on the basis of a common marketing authorization, to the holder of another basic patent. Having considered the purpose of Article 3(c) in the present case, I am not surprised by this decision. Moreover, whilst I am not bound to follow it, it does seem that if I were to reject the present application I would be out of step with at least the Netherlands Industrial Property Office. Dr Goodfellow did not draw my attention to any other relevant decisions in other Member States and I am not aware of any. However, I am sufficiently confident that my interpretation of Article 3(c) and

that of the Netherlands Industrial Property Office are correct and are so obvious as to leave no scope for any reasonable doubt as to the way in which this condition should be interpreted. Therefore I see no need to reject this application solely because there might be a question that the ECJ should resolve.

Conclusion

- 61 After carefully considering the purpose and operative policy of the Medicinal Products Regulation I conclude that the grant of a supplementary protection certificate for a product to a holder of a basic patent **before** an application is lodged in relation the same product by a different holder of a different basic patent on the basis of a common marketing authorization does not provide a ground for rejecting the later application under Article 3(c) of the Regulation. Therefore, I find that the present application satisfies the condition of Article 3(c).

Next steps

- 62 I remit the application to the examiner to complete his examination.

R J WALKER

Deputy Director acting for the Comptroller