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COUNCIL REGULATION (EEC) No. 1768/92

APPLICANT Knoll AG

ISSUE Whether application number SPC/GB/01/051 complies with Article 3

HEARING OFFICER R J Walker

DECISION

The issue

1 Knoll AG ("the applicant") filed application number SPC/GB/01/051 ("the present application") for the grant of a supplementary protection certificate on 9 November 2001. The present application specified the product to be protected by the certificate as sibutramine hydrochloride monohydrate. It also stated that the first authorizations to place this product on the market in the United Kingdom were PL 00169/0129 and PL 00169/0130 and it identified the basic patent as European Patent (UK) No. 0230742B1. Claim 1 of this basic patent protects sibutramine hydrochloride monohydrate in the following terms:

> "1. Solid *N*, *N* – dimethyl – 1 – [- 1 – (4 – chlorophenyl)cyclobutyl] – 3 – methylbutylamine hydrochloride monohydrate in which one molecule of water is present for each molecule of *N*, *N* – dimethyl – 1 – [- 1 – (4 – chlorophenyl)cyclobutyl] – 3 – methylbutylamine hydrochloride."

There are further claims directed to a process for the preparation of sibutramine hydrochloride monohydrate

2 The applicant filed another application ("the other application") for the grant of a supplementary protection certificate on 9 November 2001 and this other application was given the number SPC/GB/01/053. The product to be protected was once again specified as sibutramine hydrochloride monohydrate and the relevant marketing authorizations were given as PL 00169/0129 and PL 00169/0130. However, the other application was based on a different European Patent (UK) No. 0397831 B1 which has just two claims to:

> "1. The use of *N*, *N* – dimethyl – 1 – [1 – (4 – chlorophenyl)cyclobutyl] – 3 – methylbutylamine hydrochloride in the manufacture of a medicament for the treatment

of obesity.

2. The use of *N, N* – dimethyl –1– [1 – (4 – chlorophenyl)cyclobutyl] – 3 – methylbutylamine hydrochloride monohydrate in the manufacture of a medicament for the treatment of obesity."

3 The examiner, who was dealing with these applications, wrote to the applicant on 8 January 2002 and 9 January 2002 to comment that both applications related to the same product and as a consequence both applications could not be granted. The examiner invited the applicant to withdraw one of the applications. In taking this view the examiner relied on Article 3(c) of Council Regulation (EEC) No. 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products ("the Medicinal Products Regulation") and Article 3(2) of Regulation (EC) No. 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products ("the Plant Protection Products Regulation").

4 The applicant's patent attorney (Elkington and Fife) wrote on 9 September 2002 in response to the examiner's observation with a request for the other application to be given priority over and granted before the present application. The examiner agreed to this request.

5 On 10 October 2002 the applicant was informed that a supplementary protection certificate had been granted in respect of the other application. The examiner then wrote to the applicant on 16 December 2002 stating that in his view the present application should be rejected under Article 10(2) of the Medicinal Products Regulation because a supplementary protection certificate had been granted to the applicant for sibutramine hydrochloride monohydrate. In a letter dated 17 February 2003 the applicant's patent attorney responded to the examiner's objection in some depth but after considering this response the examiner maintained his objection. Another round of correspondence followed before the applicant's patent attorney wrote on 26 May 2004 to request a hearing. The matter eventually came before me at a hearing at which Dr Gordon Wright, a patent attorney with the firm Elkington and Fife, appeared for the applicant. He was accompanied by his technical assistant, Dr Amanda Greenwood.

The Regulations

The interpretation of Community legislation

6 In a letter, dated 3 December 2003, the applicant's patent attorney stressed the need to approach the interpretation of Community legislation teleologically. To illustrate this point the letter referred to Lord Diplock's speech in *R v. Henn, R v. Darby* [1980] 2 CMLR 229, particularly his statement at paragraph 14:

> "The European Court in contrast to English courts, applies teleological rather than historical methods to the interpretation of the Treaties and other Community legislation. It seeks to give effect to what it conceives to be the spirit rather than the letter of the Treaties; sometimes, indeed, to an English judge, it may seem to the exclusion of the letter."

The patent attorney's letter also quoted Lord Denning in *James Buchanan & Co. Ltd. v. Babco Forwarding & Shipping (UK) Ltd.* [1977] 2 CMLR 455 where at paragraph 12 he stated:

> "We had a valuable paper on it by the President of the court (Judge H. Kutscher) which is well worth studying: 'Methods of interpretation as seen by a judge at the Court of Justice, Luxembourg 1976'. They adopt a method, which they call in English by strange words – at any rate they were strange to me – the 'schematic and teleological' method of interpretation. It is not really so alarming as it sounds. All it means is that the judges do not go by the literal meaning of the words or by the grammatical structure of the sentence. They go by the design or purpose which lies behind it. When they come upon a situation which is to their minds within the spirit – but not the letter – of the legislation, they solve the problem by looking at the design and purpose of the legislature – at the effect which it was sought to achieve. They then interpret the legislation so as to produce the desired effect. This means that they fill in gaps, quite unashamedly, without hesitation. They ask simply: what is the sensible way of dealing with this situation so as to give effect to the presumed purpose of the legislation?"

7 These days there is nothing strange about interpreting EU legislation teleologically and I recognise that this is the approach I must take when interpreting the provisions of the Medicinal Products Regulation and the Plant Protection Products Regulation. In determining the purpose behind these Regulations I am aided by their recitals, the jurisprudence of the European Court of Justice ("ECJ") and the relevant *travaux préparatoires*.

8 At the hearing before me Dr Wright suggested that *travaux préparatoires* in the form of an Explanatory Memorandum, produced by the Commission to accompany a proposal for European legislation, cannot be used as an aid to interpretation since it does not represent the final word on any point. In his opinion what the Commission intended at the outset was one thing but what, for example, a Regulation means and how it should be interpreted was another.

9 The Commission's proposal for a Medicinal Products Regulation (COM (90) 101 Final) and its later proposal for a Plant Protection Products Regulation (COM (94) 579 Final) were each supplemented by an Explanatory Memorandum. As is commonly the case, the texts of these Regulations were modified before they were finally adopted but, in my opinion, this does not mean that the Explanatory Memoranda ceased to be relevant. However, it does mean that care has to be taken when relying on an Explanatory Memorandum to interpret a provision which was amended after it was first proposed by the Commission.

10 Dr Wright also referred at the hearing to an observation made by Jacob J (as he was then) in *Draco A.B.'s SPC Application* [1996] R.P.C. 417 ("*Draco*") at page 440 lines 16 to 24:

> "I should also mention the *travaux preparatiores*. Mr. Young did not himself seek to get any assistance from material leading to the enactment of the Regulation. It was Mr. Silverleaf, for the Comptroller, who did. Mr Young found himself warding off arguments based on this material. I do not think it is necessary to go into detail. I

think there is indeed some support for the Comptroller's position to be found in this material, but in any event the point is plain from the Regulation itself. By and large, if a point turns (as this case does not) on the *travaux* then it is unlikely to be *acte claire*."

I do not take from this any criticism of Mr Silverleaf for seeking support for the Comptroller's position from the relevant *travaux préparatiores*. Indeed it seems to me that Jacob J was prepared to consider this material although the outcome was unlikely to be *acte claire* if a point turned on it. Therefore, I do not accept Dr Wright's submission that I should not seek any assistance from the Explanatory Memoranda which accompanied the Commission's proposals for a Medicinal Products Regulation and for a Plant Protection Products Regulation. However, I recognise that I would need to consider the implications if I were inclined to decide in favour of an applicant when my decision turned on the relevant *travaux préparatiores*.

11 It is helpful at this stage to set out the relevant provisions of the Medicinal Products Regulation and of the Plant Protection Products Regulation which I must interpret teologically.

The Medicinal Products Regulation

12 Article 1 of the Medicinal Products Regulation provides a series of definitions which is essential for a proper understanding of the Regulation.

"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."

13 Based on these definitions Article 2 sets out the scope of the Regulation and Article 3 sets out the conditions for obtaining a supplementary protection certificate.

> **"ARTICLE 2**
>
> **Scope**
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> 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/EEC[1] or Directive 81/851/EEC[2] 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."

14 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;

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[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.

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 and so I see no need to reproduce them here.

The Plant Protection Products Regulation

15 The Plant Protection Products Regulation is similar in many ways to the Medicinal Products Regulation which preceded it. Of particular relevance to the matter I must decide is recital

17 which indicates that certain of the detailed rules of this later Regulation should serve as an aid to interpreting various aspects of the earlier Regulation. Recital 17 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 valid for the interpretation of Council Regulation (EEC) 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 Applicant's case

A literal interpretation

17 Dr Wright began by arguing that there can be no objection under Article 3(c) of the Medicinal Products Regulation when the provision is construed literally. This is because the present application and the other application were filed on the same date and the other application was granted later on 10 October 2002. Thus, at the date on which the present application was filed, the product sibutramine hydrochloride monohydrate was not the subject of a certificate.

The purpose of Article 3(c)

18 Dr Wright then went on to explain what he considered to be the purpose of Article 3(c) based on an opinion of Advocate General Fennelly in Case C-181/95 (*Biogen Inc. v Smithkline Beecham Biologicals S.A.*), which arose from a reference to the ECJ by the Tribunal de Commerce, Nivelles. Dr Wright relied in particular on the Advocate General's statement at paragraph 31 of his opinion:

> "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'. As there is only one 'product' corresponding to any one medicinal product, this implies that there can be only one certificate for any one marketing authorization for a medicinal product. It could therefore be argued that Article 3(c) is designed to permit a certificate in respect of only one patent, viz. *the* basic patent chosen by its holder. This, however, does not appear to be its purpose. 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. [15] 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.
>
> [15] – See, to this effect, Case C-350/92 *Spain v Council* [1995] ECR I-1985, paragraphs 38 and 39 of the judgment. See also the ninth recital in the preamble to the Regulation and paragraphs 34 to 36 of the Explanatory Memorandum."

From this statement, Dr Wright concluded that the purpose of Article 3(c) is to stop what is commonly described as "Evergreening", which would involve using successive marketing authorizations to obtain multiple extensions, expiring at different times and perhaps stretching on to infinity. Dr Wright contrasted such a situation with the present situation where a supplementary protection certificate, granted on the present application, would expire earlier than the supplementary protection certificate already granted on the other application.

The Plant Protection Products Regulation

19 In his submissions to me Dr Wright questioned the extent to which a later piece of European legislation can be relied on to interpret an earlier one. With particular reference to Article 3(2) of the Plant Protection Products Regulation, Dr Wright opined that this provision went beyond a mere interpretation of Article 3 of the Medicinal Products Regulation and in effect amended it. He also took the view that it was illegitimate to amend the Medicinal Products Regulation in line with Article 3(2) of the later Regulation. In particular, he argued that the Medicinal Products Regulation would not achieve its original purpose, if a literal interpretation of Article 3(2) were applied, since Article 3(2) lacks legal equity as the result of patents and the holders of those patents being treated differently depending on whether there is one or more of them. The dual aims of a uniform solution at Community level and the grant of certificates under the same conditions by each Member State, as set out in recitals 6 and 7 of the Medicinal Products Regulation, would be frustrated if the holder of more than one patent for a product were denied the right to be granted more than one certificate and yet this right were held to be available to different applicants who are holders of different patents for the same product.

20 The patent attorney's letter, dated 3 December 2003, made the further point that the

particular provisions of the Medicinal Products Regulation, picked out in recital 17 of the Plant Protection Products Regulation, are all given a broad interpretation by the relevant rules of the later Regulation with the exception of Article 3. Thus, to the extent that these rules encourage the grant of supplementary protection certificates and the amendment of incorrectly granted certificates, as well as give a relatively broad interpretation to the scope of protection, it was argued that they fit the policy objective of providing adequate effective protection in line with recital 8 of the Medicinal Products Regulation. The letter went on to contrast the effect of the interpretation placed on Article 3 by Article 3(2) of the Plant Protection Products Regulation, which is to reduce the availability of supplementary protection where two or more applications, concerning the same product, emanate from the same holder of different patents. The point was made that an interpretation, which takes away the ability of a patent holder to apply for a certificate, runs contrary to the purpose of the Medicinal Products Regulation.

The Biogen Case

21 Dr Wright went on to contrast the approach, taken by the legislature of using Article 3(2) of the Plant Protection Products Regulation to interpret Article 3 of the Medicinal Products Regulation, with that taken by the ECJ when interpreting Article 3(c) of the Medicinal Products Regulation in *Biogen Inc. v. Smithkline Beecham Biologicals SA* [1997] R.P.C. 833 ("*Biogen*"). In his view the legislature was trying to find a solution to a problem, highlighted by the circumstances underlying the *Biogen* dispute, whereas the ECJ took the objectives of the Medicinal Products Regulation and came up with an interpretation having greater consistency with those objectives. According to Dr Wright, the Court followed the general principle of legal equity and treated all patents the same and all holders the same.

22 The background to *Biogen* was that Smithkline Beecham Biologicals SA ("SKB") produced and marketed a vaccine against Hepatitis-B under patent licence from Biogen Inc. ("Biogen") and the Institute Pasteur. SKB had obtained Belgian marketing authorizations for the vaccine but refused to provide copies of these authorizations to Biogen to enable it to obtain a supplementary protection certificate. However, SKB had supplied a copy of the first marketing authorization for the vaccine to Institute Pasteur which was then able to obtain a certificate on its patent. Having allowed Institute Pasteur to get its 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.

23 The matter came before the Tribunal de Commerce, Nivelles which sought a preliminary ruling from the ECJ on four questions, 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?"

Answering this second question first, the ECJ observed in paragraphs 26 to 28 of its judgment (Dr Wright's emphasis):

> "26. It must be borne in mind …….. that the third and fourth recitals in the preamble give as a reason for the adoption of the Regulation the insufficient duration of the effective protection under the patent to cover the investment put into pharmaceutical research. The Regulation thus seeks to make up for that insufficiency by creating a supplementary protection certificate for medicinal products, which may be obtained by the holder of a national or European patent under the same conditions in each Member State.
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> 27. Article 6 of the Regulation confirms that the certificate is to be granted to the holder of the basic patent or his successor in title. 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.
>
> 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. Under Article 3(c) of the Regulation, however, only one certificate may be granted for each basic patent."

and concluded in paragraph 30 that:

> "30. The answer to the second question must therefore be that, where a medicinal product is covered by several basic patents, the Regulation does not preclude the grant of a supplementary protection certificate to each holder of a basic patent."

24 Dr Wright observed that this conclusion was consistent with the second sentence of Article 3(2) of the Plant Protection Products Regulation that:

> "……., 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."

However, he went on to opine that the ECJ's conclusion in respect of the second question was inconsistent with the first sentence of Article 3(2) which states that:

> "The holder of more than one patent for the same product shall not be granted more than one certificate for that product."

Dr Wright based this opinion on paragraphs 26 to 28 (reproduced above) of the ECJ's judgment in *Biogen* and in particular the statement he emphasised in paragraph 28. On the basis of this particular statement he argued that the ECJ went beyond the situation it was specifically dealing with and interpreted Article 3 in the round. In other words the ECJ interpreted Article 3 not just for the situation where there were multiple patents from multiple patent holders, but also for the situation where there were just multiple patents. Dr Wright

further suggested that the ECJ may well have had this situation in mind because Biogen had not one but two patents.

25 He went on to submit that I did not need to consider for the purposes of this decision the final sentence of paragraph 28 of the ECJ's judgment, which states that under Article 3(c) of the Medicinal Products Regulation only one certificate may be granted for each basic patent. In his view this statement had to be considered in the context of a particular medicinal product where without Article 3(c) it might be possible to argue that a later authorization, which related to a slightly different form of the medicinal product with the same active ingredient, gave a right to apply for a further supplementary protection certificate.

Examples

26 Dr Wright then sought to strengthen his arguments by giving some examples which in his opinion illustrate the absurdity of literally following Article 3(2) of the Plant Protection Products Regulation. It is easiest if I reproduce these examples as they were set out in the skeleton argument provided by Dr Wright prior to the hearing.

Example 1

"Imagine a situation where an application for a patent discloses both an active ingredient X and its application in the treatment of obesity. During patent prosecution, the applicant for patent protection cancels the product claims in the application and files a divisional application to these. This might happen where the rapid grant of a patent was important to the applicant and there were some dispute with the Office over novelty of the product. Let us further imagine that both patents (A and B) are granted. Product X is claimed per se in B and its use as an anti-obesity agent claimed in A. When a medicinal product having X as its active ingredient is approved in the UK, it seems that the applicant for an SPC must choose between patent A and patent B. Yet, if the claims had been kept in the same patent, the patentee would have had one SPC with the scope of the both A and B."

Example 2

"According to Article 3(2), where the patents are held by different holders, both A and B may be the subject the subject of SPCs – does this mean that the both A and B can be granted SPC by the holder of A and B assigning patent B to a third party, in return for a licence?"

Example 3

"What happens when patents A and B begin in separate hands? Article 3(2) says that both can be the subject of SPCs – this happens often where the respective owners are licensee and licensor. But what happens if the owner of patent B assigns his patent to the owner of patent A? Apparently, now a choice must be made between which of the two patents to extend by means of the SPC. The owner of patent B may have carried out independent research to arrive at invention B – the kind of research which is meant to result in SPCs – but sale of patent B to the holder of patent A takes away the possibility of getting SPC protection."

Example 4

"Further, when patents A and B are in the same hands, it seems that the holder is being forced into taking a gamble on the relative strengths of the two patents – what if he selects A for SPC protection, and the patent is subsequently invalidated, whereas B is found to be both valid and infringed? Where the patents are in different hands, but B is licensed to the holder of A, the holder of A still has the benefit on an SPC on patent B. This absurdity does not seem to have any basi (sic) in the policy behind the SPC Regulations."

27 Dr Wright concluded with the observation that when the Medical Products Regulation was proposed there may have been some fear that if more than one patent relating to the same product was held by the same holder, these patents would be used to extend or evergreen the market exclusivity for the product. However, he urged me to consider how Advocate General Fennelly had dealt with this in his opinion in *Biogen* and to accept that where a product is protected by a number of basic patents, each of those patents may be designated for the purpose of the procedure for the grant of a supplementary protection certificate.

Assessment

28 In essence the question I must answer is whether the holder of more than one patent which protects a product, a process to obtain the product or an application of the product may be granted more than one supplementary protection certificate for that product?

Takeda Chemical Industries Ltd's SPC Applications

29 The letter of 17 February 2003 from the applicant's patent attorney acknowledged an earlier decision of mine concerning *Takeda Chemical Industries Ltd's SPC Applications (No.2)* [2004] RPC 2 ("*Takeda*"). The background to this earlier decision was similar to that of the present case. Takeda Chemical Industries Ltd ("Takeda") had six applications which sought supplementary protection for two identical sets of three different combinations of active ingredients. One set designated a first European patent and the other, identical, set designated a second and later European patent. None of the six applications had been granted but the examiner had objected that supplementary protection certificates could not be granted for identical combinations even if the relevant applications were based on different patents. By coincidence Dr Wright was also the patent attorney who acted for Takeda on that occasion.

30 Some of the issues I had to consider in relation to Takeda's applications were the same or similar to those I need to consider here. For example, in this earlier decision I considered in some depth the statement made by the ECJ in paragraph 28 of its judgment in *Biogen* that (my emphasis):

> "……., 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**."

In paragraphs 21 and 22 of *Takeda* I reasoned:

> "21 In the absence of anything from the applicant, which explains to my satisfaction the Court's view that "only one certificate may be granted for each basic patent", I am left to find my own explanation. I believe that it is useful to begin by considering what the consequences would be of taking the Court's statement at face value and of granting one but only one certificate for each basic patent. Where a patent holder has more than one patent for one and the same product, the grant of successive certificates for that product, each based on a respective one of these patents, would allow him to bypass the restriction on the maximum permitted period of supplementary protection. Such a possibility would undermine what was a key compromise between the various interests at stake in the provision of supplementary protection. Consider now a different situation where a single patent protects several different products, some possibly still undergoing the necessary clinical testing for the marketing approval of the corresponding medicinal products. If the patent holder were allowed only one certificate on this single patent, he would have to choose which of the protected products should receive supplementary protection. In other words he would have to decide which product would provide the "golden egg". I note in passing that the Medicinal Products Regulation would not give him very much time in which to make this decision because a request for a certificate must be made within six months of the grant of the marketing authorisation. The wrong choice could mean that the patent holder would not receive adequate and effective supplementary protection to compensate for the time taken to get marketing authorisation for all the products protected by the patent. On the other hand, he would be in a much better position if he could obtain supplementary protection for more than one of the different products based on the same patent. In my view the first of these two possibilities does not sit well with the conclusions …… that the purpose of the Medicinal Products Regulation is to encourage research by providing supplementary protection which is both adequate and effective. On the other hand, the second possibility sits better with these conclusions. I do not believe therefore that the Court was suggesting in *Biogen* that a patent holder should make this choice when one patent protects more than one different product. Thus, these two different situations, where the patent holder either has more than one patent for the same product or a single patent for different products, illustrate that taking the Court's statement at face value would conflict with the objectives underlying the Medicinal Products Regulation. It is necessary then to look deeper.
>
> 22 In doing so I will start by considering the first sentence of paragraph 28 of the Court's judgment ……. What did the Court mean by "**each** of those patents **may** be designated" in this sentence? The applicant has not addressed me on this matter. However, in line with my conclusion above that the Medicinal Products Regulation aims to prevent the grant of successive certificates for one and the same product on the basis of a series of patents in the same hands, I believe the Court was acknowledging the freedom patent holders have to choose which patent to designate when they hold more than one which protects the same product. I do not believe the Court was suggesting here that the patent holder may designate all such relevant

> patents to obtain more than one certificate for the same product. It follows that when a patent holder has several patents protecting one and the same product, he can designate only one of those patents for the purpose of supplementary protection for that product. Expressing this in slightly different terms, even if a patent holder has more than one patent for the same product, he cannot obtain more than one certificate for that product. It is therefore my view that it is the restriction to one patent of choice that the Court had in mind in the second sentence of paragraph 28 when it stated "Under Article 3(c) of the Regulations, however, only one certificate may be granted for each basic patent".

Then in paragraph 23 I concluded:

> "23 …… the Court's statement cannot be taken at face value. It must be considered not only in the context of the other parts of the Court's ruling on the second *Biogen* question but also in the context of the objectives and provisions of the Medicinal Products Regulation as a whole. Taking this broader view, I think the most plausible conclusion is that when making its observations in the context of the second question, the Court meant 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."

31 In the same *Takeda* decision I considered Article 3(2) of the Plant Protection Products Regulation and was not persuaded that I was prevented from relying on this provision to interpret Article 3 of the Medicinal Products Regulation. Furthermore, I noted that the first sentence of Article 3(2) of the Plant Protection Products Regulation made explicit my conclusion based on the principles underlying the Medicinal Products Regulation.

32 The applicant's patent attorney expressed the view in the letter dated 17 February 2003 that my reasoning in *Takeda* was wrong. Furthermore, at the hearing on the present application Dr Wright commented that the issue I considered in *Takeda* was different from the one I must decide now. Dr Wright suggested that the point under consideration in *Takeda* was whether one patent can be the subject of more than one supplementary protection certificate. Whilst I accept that this was one issue I had to decide in this earlier case, it is equally clear in my view that another issue was whether supplementary protection certificates could be granted for the same product on the basis of two different patents, both of which were held by Takeda. In the event I decided in *Takeda* that none of the applications should be rejected on the ground that they designated the same patent. I also decided that only one certificate could be granted to Takeda for the same product and that Takeda should choose which of the two relevant patents to designate in order to obtain supplementary protection for that product.

33 Thus, in my view *Takeda* is relevant to the matter I must decide in the present proceedings. Furthermore, whilst I am not bound by earlier decisions of hearing officers acting for the Comptroller, including my own decisions, I am not inclined to depart from the reasoning of any earlier decision without good reason. I therefore need to consider the submissions put to me in relation to the present application to determine if there is good reason to conclude, as Dr Wright has done, that my reasoning and conclusion in *Takeda* were flawed.

The literal interpretation of Article 3(c)

34 Dr Wright's submission that I should adopt the literal interpretation of Article 3(c) does not sit easily with his view that I should approach the interpretation of European legislation teleologically. I have already accepted the need to interpret the provisions of the Medicinal Products Regulation and the Plant Protection Products Regulation in this manner and in my view I am not absolved from taking this approach even if the wording of the provision under consideration seems to be clear. Therefore, I do not accept Dr Wright's view that I should decide the matter before me on the basis of a purely literal interpretation of Article 3(c).

A teleological interpretation of Article 3(c)

The purpose of Article 3(c)

35 Recitals 2 to 4 of the Medicinal Products Regulation indicate that the purpose of the Regulation is to encourage pharmaceutical research in Europe by compensating for the period of patent protection eroded as the result of the time taken to obtain authorization to place a medicinal product on the market. This was expressed succinctly by Jacob J. in *Draco* at page 439 lines 50 – 52 where he observed:

> "The scheme is not for the general protection of the fruits of research. It is to compensate for lost time in the exploitation of inventions which are patented."

36 Recitals 8 and 9 of the Medicinal Products Regulation were also considered by Jacob J. in *Draco* at page 438 lines 24 - 28 (Jacob J.'s emphasis):

> "These are important. They reveal the operative policy. There is to be *adequate effective protection*. The period of exclusivity under the patent and SPC combined is a maximum of 15 years. This runs from the time the *medicinal product in question* first obtains authorization. And the scope of protection is *strictly confined* to the *product which obtained authorization* etc."

From recital 9 it is also apparent that the restrictions placed on the duration and scope of protection of a supplementary protection certificate are designed to take account of all the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector. The Commission's objective to achieve a balance between all the interests at stake was addressed in its Explanatory Memorandum, accompanying the proposal for the Medicinal Products Regulation, at paragraph 10:

> "10. The proposal for a Regulation as a whole constitutes a balanced system since each of its essential features has been determined in the light of the aims of the proposal and the interests involved. The Commission takes the view that the proposed system should be effective and appropriate for the industry's requirements without neglecting other substantial aspects of national and Community health policy."

The Memorandum continues at paragraph 11 (my emphasis):

> "11. The proposal for a Regulation therefore concerns only new medicinal products.

It does not involve granting a certificate for all medicinal products that are authorized to be placed on the market. **Only one certificate may be granted for any one product, a product being understood to mean an active substance in the strict sense**. ……."

37 Nevertheless, it is clear from paragraph 29 of the Memorandum that (again my emphasis):

"29. ……. The proposal does not provide for any exclusions. In other words, all pharmaceutical research, provided that it leads to a new invention that can be patented, whether it concerns a new product, a new process for obtaining a new or known product, a new application of a new or known product or a new combination of substances containing a new or known product, must be encouraged, without any discrimination, and must be able to be given a supplementary certificate of protection **provided that all of the conditions governing the application of the proposal for a Regulation are fulfilled**."

Thus, in accordance with Article 1 of the Medicinal Products Regulation, an applicant for a supplementary protection certificate may designate a patent which protects the active ingredient or combination of active ingredients of a medicinal product as such, a process to obtain the active ingredient or ingredients or an application of the active ingredient or ingredients.

38 One of the essential features of the balanced system proposed by the Commission concerns the conditions for obtaining a certificate. These conditions correspond to Article 3 of the Regulation as eventually adopted by the European Parliament and the Council. Commenting on these conditions in its Explanatory Memorandum, the Commission explained at paragraph 33 (my emphasis):

"33. First, it has to be verified whether the product is protected by a patent in force. It is this patent that serves as the basis for the certificate for the purposes of the proposal for a Regulation. It may be that the product is protected by several patents, e.g. by a patent for a product and a patent for the procedure used to obtain the product. **In this case, it is for the holder of the patent concerned to choose one of them as the basic patent. This choice is particularly important if the subject and the content of the protection granted by the certificate are respectively limited by the subject and content of the basic patent**."

In paragraph 36 of the Explanatory Memorandum the Commission explained the purpose underlying Article 3(c) (again my emphasis):

"36. Lastly, the product must not have been the subject of a certificate in the Member State concerned. The certificate is designed to encourage research into new medicinal products so the duration of protection it affords, together with the effective duration of protection by the patent, is sufficient to enable the investments made in the research to be recovered. However, 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.

This calls for a strict definition of the product ……. . **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 (use of a different salt, different excipients, different pharmaceutical presentation, etc.).

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 (the first authorization in the Community being taken only to calculate a uniform duration of different certificates for one and the same product)."

39 It is clear to me from these passages in the Explanatory Memorandum that when a product is protected by more than one patent, the intention was that a supplementary protection certificate for the product should only be granted on the basis a single patent, chosen by the applicant, and the first authorization to place the product on the market in the Member State concerned.

40 The reference to the ECJ in *Biogen* identified a difficulty when patents protecting the same product were in different hands. Advocate General Fennelly observed in paragraphs 29 and 30 of his opinion (my emphasis):

"29. The text of the Regulation applies simply to a simple situation, in which basic research, product development, product 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. However the facts of the instant case do not correspond to this model.

30. The concept of 'the product' is central to the legislative scheme. A 'product' is defined in Article 1(b) as '*the* active ingredient or *combination* of active ingredients of a medicinal product' (emphasis added), indicating that there will be only one 'product' corresponding to any one preventative, therapeutic, diagnostic or other medicinal product. **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 the grant of a certificate.** [14] 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.

[14] – This is evident from paragraph 33 of the Explanatory Memorandum."

41 The Advocate General continues in paragraph 31, which I have already quoted at paragraph 18 above, where he seems to reject the idea that the purpose of Article 3(c) of the Medicinal Products Regulation is to permit a certificate in respect of only one patent, *viz*. the basic patent chosen by its holder. Instead, he takes the view that the purpose of Article 3(c) 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. This was the basis of Dr Wright's submission that the purpose of Article 3(c) is to stop what is commonly described as "Evergreening".

42 It is helpful to pick up the Advocate General's Opinion at paragraph 33 where he states (my emphasis):

> "33. A number of problems would arise if Article 3(c) of the Regulation were interpreted as permitting only one patent to be given the benefit of supplementary protection on the basis of any one product authorized to be marketed as a medicinal product. First of all, contradictions would arise in the text of the Regulation. As was stated above, **Article 1(c) appears to provide that the holder of a number of patents shall designate one as his basic patent for the purposes of the award of a certificate**. Where there is a number of patent holders, this choice cannot take place unless each is free to designate a patent for supplementary protection. If the other legislative conditions were satisfied, each patent holder could then be granted a certificate in respect of his basic patent, in accordance with Article 6 of the Regulation. …….. ."

43 I agree with the view of Advocate General Fennelly that the Medicinal Products Regulation seems to have been drafted on the basis of the "classic" model and that it did not cater for a situation where patents relating to the same medicinal product are in different hands. I also recognise that the Advocate General's view on the purpose of Article 3(c) chimes with the Commission's explanation in paragraph 36 of its Memorandum that it would be unacceptable for the duration of protection for one and the same medicinal product to be exceeded unduly. The Commission thought that this might be the case if one and the same product were able to be the subject of several successive certificates.

44 However, the circumstances surrounding the present application conform to the "classic" model where both patents and the marketing authorization are in the same hands. Rather than choose at the outset just one of these patents as a basis for a supplementary protection certificate, the applicant decided to file two applications for supplementary protection based on respective ones of the patents. The applicant then elected to give the other application priority over the present applicant to obtain a supplementary protection certificate which will expire on 12 January 2014. This expiry date is determined by the cap of five years placed on the duration of a supplementary protection certificate by Article 13(2) of the Medicinal Products Regulation. If a supplementary protection certificate were to be granted on the present application it would expire earlier on 9 December 2011. This expiry date would represent the overall maximum of fifteen years of exclusivity permitted under Article 13 of the Medicinal Products Regulation. Thus, what the applicant has done is elect initially to protect

sibutramine hydrochloride monohydrate when used in the manufacture of a medicament for the treatment of obesity until 12 January 2014 in preference to obtaining broader protection for sibutramine hydrochloride monohydrate in its own right until 9 December 2011. In my view this is the sort of choice the Commission intended by it statement in the Explanatory Memorandum that when the product is protected by several patents:

> "……, it is for the holder of the patent concerned to choose one of them as the basic patent. This choice is particularly important if the subject and the content of the protection granted by the certificate are respectively limited by the subject and content of the basic patent."

It also seems to me that this requirement to choose fits the aim set out in recital 9 of the Medicinal Products Regulation to take account of all the interests at stake and to provide a balanced system. As described by the Commission in paragraphs 10 and 11 of its Explanatory Memorandum, this balance is achieved in part by granting only one certificate for any one product.

45 Moreover, I can find nothing in Advocate General Fennelly's opinion to indicate that according to the "classic" model, this is not a choice that an applicant should make. Indeed, it seems to me that the Advocate General appreciated, albeit from a consideration of Article 1(c), that the holder of a number of patents, possibly of different kinds (product, process or product-application patents), should choose between them and to designate one as the 'basic patent' for the purpose of the procedure for the grant of a certificate. In particular, I can find no support in Advocate General Fennelly's opinion for Dr Wright's submission to me that I should interpret the Medicinal Products Regulation in such a way that would allow the applicant to designate both of its patents as basic patents for the purpose of obtaining two supplementary protection certificates for the same product.

The ECJ's judgment in Biogen

46 I can now turn to the ECJ's judgment in *Biogen*, which unlike Advocate General Fennelly's opinion on this same case, is binding on me. After the hearing Dr Wright supplied the French version of this judgment because at the hearing he suggested that the judgment has a different nuance in French when compared with the English version. However, Dr Wright did not state what this nuance was and I have been unable to detect it. Therefore, I have relied solely on the English version for this decision. The essence of Dr Wright's submissions to me, based on this judgment, was that the ECJ went beyond the situation it was dealing with and interpreted Article 3 of the Medicinal Products Regulation not only for the situation where patents for the same product were in different hands but also for the situation where patents for the same product were in the same hands. As in my earlier decision on *Takeda* Dr Wright's case focuses on a statement made by the ECJ in paragraph 28 of its judgment, which followed its conclusion that the Regulation seeks to confer supplementary protection on the holders of basic patents, without instituting any preferential ranking amongst them. I have already quoted this paragraph but it is helpful to repeat it here:

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

47 I have given further careful thought to what the ECJ intended in the first sentence of paragraph 28 of its judgment but I can only conclude, as I did in my earlier *Takeda* decision, that the Court was acknowledging the freedom a patent holder has to choose which patent to designate as a basic patent for the purpose of obtaining a supplementary protection certificate. In my opinion there is nothing in paragraph 28 or any other part of the Court's judgment to suggest that the balanced system, as proposed by the Commission, should be upset by allowing a patent holder, who has different patents protecting a product, a process to obtain the product or an application of the product, to designate more than one of those patents to obtain a plurality of certificates for the product. Indeed, I believe the second sentence of paragraph 28 addresses this point and, contrary to Dr Wright's view, it is relevant to the circumstances of the present application. It is apparent to me that the necessary balance within the system depends on a patent holder designating just one patent as a basic patent for the purposes of obtaining supplementary protection, even if the patent holder has more than one patent relevant to the product in question.

48 Therefore, I do not accept Dr Wright's submission based on the first sentence of paragraph 28 of the ECJ's judgment in Biogen that a patent holder with multiple patents, relating to the same product, should be allowed to designate each of those patents to obtain more than one supplementary protection certificate based on a common marketing authorization. Equally I must reject Dr Wright's view that the second sentence of paragraph 28 is only relevant to a situation where someone might seek supplementary protection for a product, which is already the subject of a supplementary protection certificate, on the basis of a later marketing authorization for a slightly different form of medicinal product using the same active ingredient.

Article 3(2) of the Plant Protection Products Regulation

49 It appears from recital 17 of the Plant Protection Products Regulation that the intention of the Council and of the European Parliament was that certain specified rules of this Regulation were intended to be valid, *mutatis mutandis*, for the interpretation of the earlier Medicinal Products Regulation. Article 3(2) of the Plant Protection Regulation is one of the detailed rules specified. There is no suggestion in recital 17 that the intention was to amend the Medicinal Products Regulation in any way. Nevertheless, Dr Wright argued before me that Article 3(2) of the Plant Protection Products Regulation goes beyond a mere interpretation of Article 3 of the Medicinal Products Regulation and in effect amends it.

50 Dr Wright pointed out at the hearing that the Commission's original proposal for the Plant Protection Products Regulation did not include a provision corresponding to Article 3(2) of the Regulation as it was eventually adopted by the European Parliament and the Council. However, he noted that the Common Position (EC) No 30/95 adopted by the Council on 27 November 1995 included the provision of Article 3(2). In its analysis of the Common Position, the Council states at Article 11 of its Statement of Reasons:

> "11. Article 3(2)
>
> In its amended proposal, the Commission proposed a new Article 3(2) to make it clear that, while the same holder of a number of patents may not be granted more than one certificate for the same product, two or more certificates may be issued for the same product to holders of different patents under certain circumstances.
>
> The Council has included this new paragraph in its common position.
>
> The statement referred to in the second paragraph in Article 9 also relates to this new paragraph."

The second paragraph of Article 9, which was referred to, states:

> "Lest the inclusion of those recitals in this Regulation and the omission of corresponding recitals in Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products …. give rise to differing interpretations of the two Regulations …, the Council and the Commission plan to enter the following statement in the Council minutes when the Regulation is finally adopted and to make it available to the public:
>
> 'The Council and the Commission consider that 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 and 8(1)(c) and 17 of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products.'"

In the event the above statement was incorporated as recital 17 in the Plant Protection Products Regulation and not as a statement in the Council minutes.

51 A Communication from the Commission to the European Parliament (SEC (95) 1841 final)), concerning the common position adopted by the Council on 27 November 1995, also comments on the new Article 3(2):

> "Article 3(2)
>
> The Council felt that this new paragraph should be inserted into Article 3 to make it clear that, as a rule, the holder of several patents for the same plant protection product may not be granted several certificates for that product and to indicate the specific circumstances in which two or more certificates may be issued for the same product."

52 At the hearing Dr Wright described this attempt to ensure equivalence between the two Regulations as a "noble aim" but in his view Article 3(2) of the Plant Protection Products Regulation did not serve to make the Medicinal Products Regulation any clearer, only different. However, I can see nothing in this history of the Plant Protection Products Regulation to suggest that the purpose behind the inclusion of recital 17 and Article 3(2) was

other than to aid the interpretation of Article 3 of the Plant Protection Products and Medicinal Products Regulations.

53 Dr Wright also contrasted the less favourable consequences of interpreting Article 3 of the Medicinal Products Regulation by reference to Article 3(2) of the Plant Protection Products Regulation with the more favourable consequences of using the later Regulation to interpret other provisions of the Medicinal Products Regulation. I am not persuaded by Dr Wright's point that an interpretation of the Medicinal Products Regulation, which reduces the availability of supplementary protection, runs contrary to the purpose of the Regulation. Whilst I accept that one of the aims of the Regulation is to encourage pharmaceutical research in Europe, it is clear to me that this aim is tempered by other interests, such as those of public health. Thus, by requiring a patent holder to choose one of a plurality of patents for the purpose of obtaining a supplementary protection certificate, a balance is achieved between the needs of the patent holder and other interests at stake.

54 In a letter dated 30 July 2003 the examiner drew the applicant's attention to the reliance the ECJ placed on the Plant Protection Products Regulation when interpreting the Medicinal Products in its judgment in *(Case C-392/97) Farmitalia Carlo Erba Srl's Supplementary Protection Certificate Application* [2000] RPC 580 when it stated at paragraph 20 of its judgment:

> "20. Moreover, it should be bourne in mind that the 13th recital in the preamble to Regulation 1610/96 which, by virtue of the 17th recital, is also valid, *mutatis mutandis*, for the interpretation *inter alia* of Article 3 of Regulation 1768/92, states that the certificate confers the same rights as those conferred by the basic patent, with the result that, where the basic patent covers an active substance and its various derivatives (salts and esters), the certificate confers the same protection."

When I questioned Dr Wright about the ECJ's reliance on the 13th recital of the Plant Protection Products Regulation for the interpretation of the Medicinal Products Regulation, he drew a distinction between what he saw as interpretation by the Court in the *Farmitalia* case and what he saw as a re-writing of a situation when it came to Article 3(2) of the Plant Protection Products Regulation. Whilst the ECJ did not appear to question the validity of using the Plant Protection Products Regulation to interpret a provision of the Medicinal Products Regulation, the provisions in question were different from those I have to consider here. Therefore, I am not inclined to draw any general conclusion from *Farmitalia* and apply it to the circumstances of the matter I must decide.

55 Nevertheless, all in all I do not accept Dr Wright's argument that I should not rely on Article 3(2) of the Plant Protection Products Regulation to interpret Article 3 of the Medicinal Products Regulation. Moreover, in my view, this provision is entirely consistent with the ECJ's judgment in *Biogen*. Thus, I consider that I am bound to take account of Article 3(2) of the later Regulation when interpreting Article 3 of the earlier Regulation.

Equitable treatment

56 Dr Wright further argued that an uniform solution at Community level, whereby certificates

were granted under the same conditions, would not be achieved if the holder of more than one patent were denied the right to be granted more than one certificate, whilst a plurality of certificates for the same product could be granted on the basis of different patents in the hands of two or more holders. I do not see any inconsistency here. It is clear from paragraph 27 of the ECJ's judgment in *Biogen* that the Medicinal Products Regulation seeks to confer supplementary protection on the holders of patents, which protect the same product, without instituting any preferential ranking amongst them. However, the need to take account of all the interests at stake also requires that whilst each holder of a basic patent may be granted a supplementary protection certificate for a product, only one certificate may be granted for that product to each patent holder. In other words if any patent holder has more that one patent, which protects the product, a process to obtain the product or an application of the product, the patent holder must choose just one of these patents as the basic patent for the purpose of obtaining supplementary protection. Thus, a uniform and equitable solution is provided whereby one certificate may be granted under the same conditions to any holder of one or more patents which protect the product in question. It is also wholly consistent with Article 3(2) of the Plant Protection Products Regulation (my emphasis):

> "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."

57 I am therefore not persuaded that it is inequitable to deny a patent holder more that one supplementary protection certificate for the same product whilst allowing other patent holders to obtain one certificate each for that product.

Examples

58 Even if the examples, which were presented by Dr Wright to illustrate the absurdity of literally following Article 3(2) of the Plant Protection Products Regulation, are not hypothetical, as he suggested, I am reluctant to address them in this decision. It seems that at least some of the examples introduce factors which are not directly relevant to the present application and which would require wider consideration, for example lifting the "corporate veil". Therefore, I do not believe they help me in the decision I must make and I have not considered them further.

Summary and conclusion

59 After carefully considering all of Dr Wright's submissions to me I conclude that on a teleological interpretation of the Medicinal Products Regulation the holder of more than one patent, which protects a product, a process to obtain the product or an application of the product, should not be granted more than one supplementary protection certificate for that product. This conclusion is in line with my earlier decision in *Takeda*. Thus, in accordance with Articles 3 and 10(2) of the Medicinal Products Regulation, I reject application number SPC/GB/01/051, which seeks supplementary protection for the product "sibutramine

hydrochloride monohydrate", because a supplementary protection certificate has already been granted to the applicant for this product on the basis of application number SPC/GB/01/053.

Appeal

60 Under the Practice Direction to Part 52 of the Civil Procedure Rules, any appeal must be lodged within 28 days.

R J WALKER
Divisional Director acting for the Comptroller