COUNCIL REGULATION (EEC) NO. 1768/92

IN THE MATTER OF
Application No. SPC/GB/97/080
in the name of Abbott Laboratories

DECISION

The issue and background

1 Abbott Laboratories ("the applicant") filed an application on 25 September 1997 for the grant of a Supplementary Protection Certificate ("certificate") for a product which it identified in its application as difloxacin. The application designated European Patent No. 0131839 B and listed four authorizations (13162/4000, 13162/4001, 13162/4002 and 13162/4003) to place this product on the market in the United Kingdom as a medicinal product. These authorizations which relate to different dosages of difloxacin, were all granted on 19 March 1997. On receipt the Patent Office gave the application the number SPC/GB/97/080.

2 The examiner dealing with the application wrote to the applicant's patent agent, Mr Philip Walters of the Patents and Trade Marks Department of Wyeth Laboratories, on 9 March 1998 to report that the application did not comply with the requirements of Council Regulation (EEC) No.1768/92 concerning the creation of a Supplementary Protection Certificate for Medicinal Products ("the Regulation"). In particular, the examiner noted that the application had been filed after 19 September 1997 which was the latest date for lodging the application in accordance with Article 7(1) of the Regulation. The examiner also informed Mr Walters that further examination of the application would be deferred until this matter was resolved. Nevertheless, details of the application were advertised in the Patents and Designs Journal in the normal manner on 22 October 1997.

3 In a letter dated 5 November 1998 Mr Walters responded to the examiner's objection and argued that it was not well founded and should be withdrawn. This letter also contained an explanation why the applicant did not file the application until 25 September 1997. Mr Walters stated in his letter that difloxacin was originally licensed by the applicant to the animal health business of Solvay-Duphar SA (“Solvay”). During the course of 1997, at around the time of issue of the UK marketing authorizations for difloxacin, the entire animal health business of Solvay, including the interest in difloxacin, was acquired by American Home Products Corporation (“AHP”) and its animal health business, Fort Dodge Animal Health. As a result of the disruption created by this acquisition, an application for supplementary protection for difloxacin in the United Kingdom was not filed by 19 September 1997. However, the application was filed shortly afterwards when AHP became aware that the date for the timely filing of the application had been missed. These events were subsequently confirmed in witness statements made on 15 and 16 February 2000 by Michael J Ward on behalf of the applicant and by Adley F Mandel on behalf of AHP, respectively. The witness statements of Mr Ward and Mr Mandel also revealed that following the conclusion of the purchase of Solvay’s animal health business by AHP in February 1997, there was confusion over whether responsibility for filing the application for supplementary protection for

difloxacin in the United Kingdom rested with the applicant or AHP.

4 At various times after the examiner's initial objection in his letter of 9 March 1998, the applicant presented and pursued various arguments in support of the view that the present application should be allowed to proceed. In particular, it was argued that:

(a) the delay in filing the application was *de minimis*;

(b) to deny a certificate as the result of such a small delay would be contrary to the spirit and intent of the Regulation when account is taken of its recitals, its travaux preparatoires and the jurisprudence of the European Court of Justice;

(c) the failure to meet the deadline specified in Article 7(1) was entirely unintentional and the applicant and its licensee not only exercised reasonable care to see that the application was filed in time but also acted promptly as soon as they became aware of the irregularity;

(d) some European countries have granted certificates where applications were filed later than the six month deadline provided for in Article 7(1);

(e) the comptroller should exercise her discretion under rule 100 of the Patents Rules 1995 ("the 1995 Rules") to allow the late filing of the application; and

(f) the period specified in Article 7(1) runs from the date of publication of the grant of a marketing authorization in a relevant Official Gazette, which in the case of difloxacin was from 23 April 1997 following publication in the London Gazette.

The examiner did not accept any of these arguments and so the matter came before me at a hearing. Mr Ian Karet of Linklaters appeared as the solicitor for the applicant. Mr Karet was accompanied by Dr Sally Mannion, a patent attorney of the Patents and Trade Marks Department of Wyeth Laboratories, and Mr Adley Mandel, a patent attorney from AHP. The examiner, Mr Jason Bellia, also attended the hearing. Before the hearing I had the benefit of seeing a skeleton argument provided by Dr Mannion and I thank her for that.

The applicant's main submissions at the hearing

5 The thrust of Mr Karet's submission to me at the hearing was that on a purposive interpretation of Article 7(1) the period of six months, in which an application for a certificate must be lodged, runs from the date when the public is notified of the grant of the relevant marketing authorization. In the event that I did not accept Mr Karet's submission, Dr Mannion sought to persuade me that I should exercise the comptroller's discretion under rule 110(1) of the 1995 Rules and extend the period of six months specified in Article 7(1). I will consider these two submissions separately and in the order that they were put to me at the hearing.

Article 7 of the Regulation

6 Before considering Mr Karet's and Dr Mannion's submissions, I should turn to the provisions of the Regulation, which establish the procedure for applying for a certificate. These are Articles 7, 8 and 9 but Article 7 is central to the matter I must decide because it establishes the period for lodging an application:

"**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."

7 The authorization "referred to in Article 3(b)" is the first valid authorization granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC, as appropriate, to place the product on the market as a medicinal product in the Member State where the application for a certificate is lodged. The "product" is defined in Article 1(b) of the Regulation as the active ingredient or combination of active ingredients of a medicinal product. In the present case the product has been identified by the applicant as difloxacin which was the subject of several authorizations granted in the United Kingdom under Directive 81/851/EEC on 19 March 1997. These authorizations were granted after the date of grant of European Patent No. 0131839 B and so the provision of paragraph (1) of Article 7, and not that of paragraph (2), applies here.

8 Article 8 (Content of the application for a certificate) and Article 9 (Lodging of an application for a certificate) are not at issue here and so I see no need to spell them out.

9 Although so far I have done no more than recite Article 7, I am mindful that the Regulation is a Community instrument and as such I must take into account the general principles underlying it when interpreting its provisions. However, I propose to defer interpreting Article 7 until I can do so in the context of Mr Karet's and Dr Mannion's submissions.

Mr Karet's submission - the period specified in Article 7(1) should begin when notification of the grant of a marketing authorization is published

10 As I have already indicated, Mr Karet sought to persuade me that the Regulation gives an applicant six months after the date when the grant of a marketing authorization is notified to the public, rather than six months from the actual date of the authorization, to apply for a certificate. Mr Karet set the scene by reminding me that although Article 6 of the Regulation requires that a certificate shall be granted to the holder of a patent protecting a product or his successor in title, sometimes the patent holder may not be holder of the marketing authorization for that product. Indeed this is the situation in the present case; the relevant patent is held by the applicant but the marketing authorization was granted to Solvay. However, Mr Karet made it clear at the hearing that he sought to establish a principle based on general considerations rather than on the actual circumstances of the present application. Nevertheless, the relevance of Mr Karet's submission to the present application was clear enough. His aim was to persuade me that the window of six months for filing an application for a certificate should be shifted to start and end on dates later than those determined by a start date corresponding to the actual date of grant of a marketing authorization. If the start date were taken to be the date on which the grant of a marketing authorization was published in the London Gazette, the present application, filed on 25 September 1997, would after all

have been filed within the required six month period.

Publication of the grant of market authorizations in the London Gazette

11 When developing his submission, Mr Karet referred me to pages 4816 and 4817 of the London Gazette published on 23 April 1997. These pages list various veterinary marketing authorizations issued under the Veterinary Medical Products Regulations 1994. Among them on page 4817 are the marketing authorizations 13162/4000, 13162/4001, 13162/4002 and 13162/4003 for difloxacin with their common date of 19 March 1997. Mr Karet pointed out that for difloxacin the delay between the grant of the authorizations and their notification in this issue of the London Gazette had been five weeks. Mr Karet went on to draw my attention to other examples where the delay was greater, for example on page 4816 a product of Cyanamid (UK) Ltd had a date of authorization of 10 January 1997. Mr Karet also highlighted two entries on page 4817, which relate to products of Rhone Merieux Ltd, whose date of authorization is stated as 4 December 1997. Mr Karet suggested that the reference to "4th December 1997" (in a publication dated 23 April 1997) was a typing error and that the date quoted should have been "4 December 1996". No evidence or documents were provided to support Mr Karet's supposition on this point.

A purposive interpretation of Article 7(1)

12 Against this background Mr Karet urged me to interpret the Regulation purposively and to recognise that there must be a proper period for an applicant to know that he is in a position to apply for a certificate and to make the necessary arrangements for the application. Mr Karet observed that it is very straightforward for an applicant who is the holder of both the patent and the marketing authorization, works on a single site in the United Kingdom and has easy access to the London Gazette. On the other hand, in real life situations where the applicant is not the marketing authorization holder, applying for a certificate could be more complex. This led Mr Karet to propose that the Regulation should take account of such real life situations and deal fairly and equally with all arrangements of patent holder and marketing authorization holder.

13 In support of his proposal Mr Karet drew my attention to *Biogen Inc. v. Smithkline Beecham Biologicals SA* [1977] RPC 833. In this case Biogen Inc ("Biogen") was the holder of European patents for inventions used in the production of vaccines against Hepatitis-B. Smithkline Beecham Biologicals SA ("SKB") produced and marketed a Hepatitis-B vaccine under licence not only from Biogen but also from the Institute Pasteur. SKB held Belgian marketing authorizations for the vaccine but refused to provide copies of these authorizations to Biogen. Biogen was therefore unable to satisfy the requirement of Article 8(1)(b) of the Regulation, which requires that:

"**ARTICLE 8**

Content of the application for a certificate

1. The application for a certificate shall contain:

(a) .....

(b) a copy of the authorization to place the product on the market, as referred to in Article 3(b), in which the product is identified, containing in particular the number and date of the authorization and the summary of the product characteristics listed in Article 4a of Directive 65/65/EEC or Article 5a of Directive 81/851/EEC;

(c) ....."

14 Faced with this situation Biogen brought an action against SKB before the Tribunal de Commerce, Nivelles. The Tribunal in turn referred the following questions to the European Court of Justice ("the Court"):

"1. In the event that the holder of the basic patent or his successor in title is a person other than the holder of the authorization to place the medicinal product concerned on the market, is the latter obliged to provide the patent holder on request, or, where appropriate, several patent holders when they so request, the "copy" of that authorization which is referred to in Article 8(1)(b) of Council Regulation (EEC) No. 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products?

2. 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?

3. Regard being had to the wording of Article 6 of the Regulation No. 1768/92, may the holder of the authorization to place the medicinal product on the market refuse to give the holder of a basic patent or his successor in title the copy of that authorization referred to in Article 8(1)(b) of the Regulation and thereby deprive him of the possibility of completing his application for a supplementary protection certificate?

4. May the relevant administrative and/or government authority which granted the authorization to place the product on the market or is the depositary of an original or a copy of the said authorization refuse to supply a copy to the holder of the basic patent or patents concerned or to his successor in title or may it decide, arbitrarily or subject to certain conditions, whether it is advisable to provide or communicate such copy with a view to its being used to support an application for a supplementary protection certificate under the provisions of Council Regulation (EEC) No 1768/92 of 18 June 1992?"

The Court answered the first and third questions at paragraph 38 of its judgment as follows:

"..... the Regulation does not require the holder of the marketing authorization to provide the patent holder with a copy of that authorization, referred to in Article 8(1)(b) of the Regulation."

When considering the fourth question the Court observed at paragraphs 44 and 45 that:

"44 In that regard, it must be borne in mind that the purpose of the requirement

imposed by Article 8(1)(b) of the Regulation to include a copy of the marketing authorization with the application for a supplementary protection certificate is to identify the product and verify that the time limit for submitting an application and, where applicable, the duration of the supplementary protection are observed. It is therefore a formal requirement whose purpose is to demonstrate the existence of an authorization to place the product on the market as a medicinal product.

45 Where the basic patent and the marketing authorization are held by different persons and the patent holder is unable to provide the competent national authorities with a copy of that authorization, granted by the authorities of a Member State, in accordance with Article 8(1)(b) of the Regulation, the application for a certificate must not be refused on that ground alone. By simple cooperation, the national authority granting the certificate can obtain a copy of the marketing authorization from the national authority which issued it ..... . If that were not the case, the entitlement to a certificate conferred by Article 6 of the Regulation on the basic patent holder would be rendered nugatory."

and at paragraph 47 of its judgment the Court concluded:

"47 The answer to the fourth question must therefore be that, where the basic patent and the authorization to place the product on the market as a medicinal product are held by different persons and the patent holder is unable to provide a copy of that authorization in accordance with Article 8(1)(b) of the Regulation, the application for a certificate must not be refused on that ground alone."

The Court considered the second of the four questions before it considered the first, third and fourth questions but Mr Karet did not address me on this particular aspect of the *Biogen* case and I see no need to consider it here because it has no obvious relevance to the matter I must decide.

15 Mr Karet's submission based on *Biogen* was that the Court had adopted a purposive construction by departing from the plain language of the Regulation in order to give a practical result. In Mr Karet's view the Court was not interested in the mechanics of a situation where for some reason there was a defect in an administrative provision. The Court was interested in furthering the aims of the Regulation for the grant of certificates. With this in mind Mr Karet opined that where the time limit falls to be considered under Article 7(1), this provision must be given a purposive construction which takes account of the practicalities of real life situations. Thus, there must be a realistic opportunity for applicants to assess whether a certificate is of interest, is economically worthwhile and is worth the time and trouble of paying up front fees, when set against any return that might come from the protection provided by the certificate. Furthermore, Mr Karet urged me to accept that there must be no discrimination between situations where the applicant and marketing authorization holder are one and the same and where they are different. According to Mr Karet the only way this could be done would be to make the time limit of Article 7(1) apply for a period of six months from the date of publication of notification of grant of a marketing authorization. At this date patent holders, including those who are not holders of marketing authorizations, could be expected to be aware that a certificate might be available to them.

16 At my request Mr Karet with assistance from Dr Mannion clarified a couple of points made in the skeleton about giving patent holders the same opportunity to apply for certificates. The particular points in question arose from statements in the skeleton that:

> "Further, the authorization might be publicised in some Member States later than others. As *Biogen* shows, the interests of the patent holders and those holding authorizations may be directly opposed. Applicants should be afforded the same opportunity to apply throughout the Community - the Regulation requires uniformity within the Community (Recital 6)"; and
>
> "In at least one country of the EU authorisation takes effect from the time it is advertised. That provides the full 6 month application period to the holder of the basic patent. It would be odd if the different regimes for the granting of authorisations led to an uneven availability of SPCs in the Community. The Regulation must be read to avoid that happening".

17 On the first of these points Mr Karet and Dr Mannion explained that in some Member States it may take even longer than in the United Kingdom to publish details of authorizations after they have been granted. Therefore, applicants in those Member States would be at a disadvantage in comparison to applicants in other Member States. Mr Karet clarified the argument very succinctly by stating that there should be "a level playing field for every applicant in every country".

18 On the second point Mr Karet confirmed that the "at least one country" was Italy where the authorization to market a medicinal product takes effect from date when the grant of the authorization is published. In other words the date of authorization corresponds to the date when notification of the authorization is published. Under this system of marketing approval, even if Article 7(1) of the Regulation is given its plain meaning so that the start of the six month period runs from the date of grant of an authorization, applicants inevitably get six months from the date of publication of the grant of an authorization, in which to apply for a certificate. Mr Karet questioned why the period for filing an application for a certificate in the United Kingdom might be only one month when in Italy the full six month period is available. However, Italy was the only Member Stated mentioned by Mr Karet and Dr Mannion as providing a period for filing an application for a certificate, which effectively runs from the date of publication of the grant of a marketing authorization. Dr Mannion suggested that there is insufficient case law around Europe to know if the approach taken by Italy would be adopted by other Member States. Mr Karet went further by suggesting that if I accepted his submission on this matter, other Member States might follow.

Assessment of Mr Karet's submission

19 On the basis of Mr Karet's submission, as supplemented by Dr Mannion, it seems that if the six month period specified in Article 7(1) is taken to run from the date of grant of an authorization, some patent holders might have a shorter effective period than others, in which lodge an application for a certificate. For the purposes of this decision when I refer to the "effective period" for lodging an application, I mean that portion of the six months remaining when a patent holder could be aware, as the result of publication of the relevant information, that a marketing authorization of interest has been granted. I can also see that some applicants

might consider a system, such as the one in Italy, where the effective period for lodging an application might be the full six months for all applicants, more favourable than one where the effective period for lodging an application is effectively reduced due to a time lag between the actual grant of a marketing authorization and its notification to the public. Thus, the first question I must answer is does a purposive interpretation of Article 7(1) require that there should be no discrimination between applicants within the same Member State and between applicants in different Member States to the extent that they all should have an effective period of six months in which to decide whether to lodge an application for a certificate?

Does Article 7(1) require there to be no discrimination between patent holders?

20 Mr Karet came to the conclusion that there should be a level playing field for all patent holders by interpreting Article 7(1) of the Regulation purposively. I must do the same to see if I reach the same conclusion as Mr Karet. Thus, I propose to interpret Article 7(1) by taking account of the text of the Regulation, including its recitals, the jurisprudence of the Court and the travaux preparatoires of the Regulation.

21 I should start by considering the text of Article 7(1), which I have already quoted. When read literally this provision is not in the least obscure. There is also equity to the extent that the six months specified in Article 7(1) applies to all patent holders. However, a purposive interpretation of Article 7(1) requires me to look beyond a literal interpretation before reaching any conclusion.

22 Therefore, I should now turn to the recitals of the Regulation to see if they support Mr Karet's proposition that all applicants should have the same effective period in which to lodge an application. The skeleton refers to Recital 6 which states:

> "Whereas a uniform solution at Community level should be provided for, thereby preventing the heterogenous 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 functioning of the internal market;"

Recital 6 is clearly linked to Recital 7 which states:

> "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;"

Thus, Recital 6 recognises that the heterogenous development of national laws concerning supplementary protection was undesirable and that a uniform solution across all Member States should be provided. Recital 7 goes on to explain that the uniform solution should be achieved by the creation of a supplementary protection certificate granted under the "same conditions" by each of the Member States. While these recitals indicate the need for uniformity between Member States in the conditions for granting certificates, I do not see that this extends to making allowances to compensate for the different circumstances of patent holders so that, for example, they all have the same effective period in which to lodge an application for a certificate.

23 The only judgment of the Court drawn to my attention by Mr Karet in the context of his submission, concerning the starting date for the period specified in Article 7(1), was the *Biogen* case. However, the Court's judgment in this case does not help me answer the question whether Article 7(1) requires all patent holders to have the same effective term in which to apply for certificates.

24 I turn finally to the travaux preparatoires of the Regulation in the form of an Explanatory Memorandum which was presented by the Commission with their proposal for the Regulation in 1990. At the hearing Mr Karet drew my attention to the first part of paragraph 46 of the Memorandum, which describes the background to what was at that time Article 6(1) but is now Article 7(1), as follows:

> "46. This Article concerns the time during which the application for the certificate must be submitted and the content of the application. With regard to the time, a period of six months is provided from the date on which the first authorization to place the product on the market in the State concerned was obtained. This solution takes particular account of the interests involved; those of the patent holder who, after having applied for the certificate, may, if he so wishes, forgo the certificate if his product proves to be unsuccessful on the market; and those of third parties who have every interest in knowing as early as possible whether or not the product concerned will be protected by a certificate once the basic patent has expired."

At the hearing Mr Karet suggested that this passage in the Explanatory Memorandum only considered the situation where the basic patent holder and the marketing authorization holder are one and the same person. In my view this passage says nothing about the status of the patent holder in relation to the market authorization. In any case, I cannot see anything in this passage to indicate that as a matter of principle there should be the level playing field, as described by Mr Karet, so that all patent holders have the same effective period to lodge applications for certificates.

25 Thus, from a consideration of the Regulation, including its recitals, and its travaux preparatoires, I do not believe that Article 7(1) requires equality in the sense proposed by Mr Karet. However, when I consider Article 7(1), particularly in the light of the travaux preparatoires, I am drawn to the view that the period of six months from the date of marketing authorization was intended to provide sufficient time for any patent holder, irrespective of his circumstances, to lodge an application for a certificate. Thus, some patent holders might be in a position to lodge applications earlier than others but this is of no importance. What is important is that all who want to apply for a certificate should have the opportunity. Of course this begs the question whether six months from the date of marketing authorization is long enough in practice to achieve this aim and certainly Mr Karet sought to persuade me that it is not.

Does six months from the grant of marketing authorization allow sufficient time to lodge an application?

26 Thus, when interpreting Article 7(1) I should consider whether a period of six months from the grant of a marketing authorization is long enough to give a patent holder an opportunity to lodge an application for a certificate irrespective of whether he also holds that marketing authorization. On this question I am conscious of the Court's judgment in the *Biogen* case

which was referred to by Mr Karet, The Court in *Biogen* took a purposive view when answering the fourth *Biogen* question, and observed at paragraph 44 of its judgment that the requirement, imposed by Article 8(1)(b) of the Regulation, is a formal one whose purpose is to demonstrate the existence of an authorization to place the product on the market as a medicinal product. This led the Court to suggest that where the applicant was unable to meet this formal requirement, it could be met in another way, and to conclude that an application for a certificate must not be refused on this ground alone. If that were not the case, the entitlement to the certificate conferred by the Regulation on the basic patent holder would be rendered nugatory.

27 At the hearing Dr Mannion envisaged a situation where a patent holder could be denied the opportunity to lodge an application within six months from the grant of an authorization because the advertisement of the authorization came too late, possibly even after the expiry of the six month period. However, neither Mr Karet nor Dr Mannion identified any instances where this had happened in the United Kingdom or elsewhere. This is perhaps an appropriate point to note that in their submissions Mr Karet and Dr Mannion did not seek to establish that publication of relevant details in the London Gazette provided the only avenue for someone to discover the grant of a marketing authorization if the holder of that authorization chose not make this information public. I would need to return to this point if I otherwise accepted Mr Karet's submission. For the moment at least I will proceed on the basis that a patent holder who is not also the holder of a marketing authorization, would not be aware of the grant of the authorization until details were published in the London Gazette.

28 I can now turn to the issue of the London Gazette published on 23 April 1997. Whatever the true situation might be concerning the products of Rhone Merieux Ltd, I can see from this issue of the Gazette that for most of the veterinary products listed, there was a delay between the stated date of their authorization and the advertisement of the grant of the authorization. For some of the products the delay was more than three months and this might result in a patent holder having a effective period of less than three months in which to lodge an application for a certificate. Mr Karet's argument was that there must be a realistic opportunity for the applicant to assess whether a certificate is of interest, is economically worthwhile and is worth the time and trouble of paying up front fees. Mr Karet did not quantify what a realistic opportunity would be in terms of months, weeks or days other than to propose that all patent holders should benefit from the same effective period of six months. It seems to me that the actual process of applying for a certificate is no more than a formal matter. It is not like applying for a patent where considerable thought and effort are required in the drafting of a description and claims. Therefore, I do not think it would be an exaggeration to say that an application for a certificate could be prepared in less than a day. Indeed I note from the witness statements of Mr Ward and Mr Mandel that the present application was filed on the same day that Mr Walters of Wyeth Laboratories received instructions to make it. Even if an essential piece of information is not to hand at the time the application is prepared, this will not cause any particular problem because the Regulation allows an opportunity to rectify irregularities after an application has been filed. However, as Mr Karet pointed out, a patent holder will want to assess whether there is business case for having a certificate. Mr Karet suggested that the patent holder needs to make this assessment before deciding whether to lodge an application for a certificate. I recognise that such an assessment could take longer than the part of a day which I have suggested is all that is required to prepare an application, but is it essential to make this assessment before lodging an application? In my view it would not be unreasonable to expect a patent holder to make such an assessment after the application is lodged, particularly if time was tight. I note this is what the Commission envisaged in paragraph 46 of

its Explanatory Memorandum when settling on a period of six months from the date of grant of a marketing authorization after taking account of the interests of third parties. In the passage from this paragraph, referred to by Mr Karet and quoted above, the Commission states (my emphasis):

> "This solution takes particular account of the interests involved; those of the patent holder who, **after having applied for the certificate, may, if he so wishes, forgo the certificate if his product proves to be unsuccessful on the market**; ....."

Therefore, in my opinion there is nothing to prevent a patent holder lodging an application as soon as he becomes aware of a relevant marketing authorization as the result of a notification in the London Gazette. Moreover, I am not persuaded that any of the delays between the grant of marketing authorizations and their notification in the issue of the London Gazette published on 23 April 1997, which was used by Mr Karet as an illustration, are such that the effective period for lodging an application would be so short as to make it impossible for a patent holder to lodge an application.

A uniform solution at Community level

29 A purposive interpretation of Article 7(1) requires more than taking account of just the interests of patent holders who are not also the holders of the relevant marketing authorizations. I must consider the broad purpose of Article 7(1) in the context of the Regulation as a whole. I have already referred to Recitals 6 and 7 which establish the principles that there should be a uniform solution at Community level and that certificates should be granted under the same conditions by each Member State. I note that neither Mr Karet nor Dr Mannion were able to identify any Member State, Italy included, where Article 7(1) is applied so that the six month period runs from a date other than the date of grant of a marketing authorization. Thus, a purposive interpretation of Article 7(1), based on Recitals 6 and 7, indicates that this Article should be given the meaning which does not undermine what at the moment appears to be a uniform solution at Community level.

The interests of third parties

30 Another matter which requires consideration when interpreting Article 7(1) purposively, emerges from the paragraph 46 of the travaux preparatoires mentioned above. From this paragraph it is clear that the interests of third parties were a factor taken into consideration when settling an appropriate period for lodging an application. In particular, it was recognised that third parties have every interest in knowing as early as possible whether or not the product concerned will be protected by a certificate once the basic patent has expired. I see this as indicating that patent holders should be given enough time to lodge an application but no more than is needed because otherwise it would impinge on the legitimate interests of third parties. I have already concluded that a period of six months from the date on which a marketing authorization was granted provides an adequate opportunity for patent holders to lodge applications for certificates. Thus, any interpretation of Article 7(1) which would give patent holders more than six months after the grant of a marketing authorisation, would run contrary to the principle that third parties should know as early as possible whether a product will be protected by a certificate.

Conclusion

31 Overall I am not persuaded by Mr Karet's submission that on a purposive interpretation the period specified in Article 7(1) should begin when notification of the grant of a marketing authorization is published. This submission was constructed on two pillars. The first was that a level playing field should be provided so that all patent holders have the same effective period in which to lodge an application. I have found no support for this proposition in the Regulation, including its recitals, the jurisprudence of the Court or the travaux preparatoires of the Regulation. On the other hand, I did conclude that one of the principles underlying Article 7(1) is that the period specified should give patent holders sufficient time to lodge their applications for certificates. This had a bearing on the second pillar of Mr Karet's submission, which was that a period of six months from the grant of a marketing authorization would not always provide enough time to lodge an application. Thus, according to Mr Karet it was necessary to interpret Article 7(1) in a manner which does not render the entitlement to a certificate nugatory. However, I was not convinced that limiting the period for filing applications to just six months from the date of grant of the relevant marketing authorizations, would ever lead to an instance where a delay in the advertisement of a marketing authorization would result in a patent holder being denied the opportunity of file an application. In particular, I do not believe that any of the delays illustrated in the issue of the London Gazette which Mr Karet relied on, could reasonably result in an application being filed outside this six month period. Moreover, I found that Mr Karet's proposed interpretation of Article 7(1) ran contrary to the principles that the Regulation should provide a uniform solution at Community level for the grant of certificates and that third parties should know as early as possible whether a product would be protected by a certificate. Thus, after considering Article 7(1) purposively I conclude that the time period of six months should run from the date of grant of the relevant marketing authorization and not from any other later date. As a consequence I find that the present application which was filed on 25 September 1997, was filed late.

Dr Mannion's submission - the period specified in Article 7(1) should be extended at the comptroller's discretion

32 I must now turn to the alternate submission presented at the hearing by Dr Mannion. As I have already mentioned, this submission was that the Regulation, as it extends to the United Kingdom, allows the comptroller discretion to extend the period of six months specified in Article 7(1). In her submission to me Dr Mannion began by referring to Article 18 of the Regulation which states:

"**ARTICLE 18**

Procedure

1. In the absence of procedural provisions in this Regulation, the procedural provisions applicable under national law to the corresponding basic patent shall apply to the certificate, unless that law lays down special procedural provisions for certificates.

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

She explained that because there is no procedural provision in the Regulation itself to deal with extensions of the period specified in Article 7(1), Article 18 directs you to the procedural provisions applicable under national law to the corresponding basic patent, unless there are

relevant national provisions for certificates. Dr Mannion did not explain at the hearing what she understood by the expression "basic patent". However, this expression is defined in Article 1 of the Regulation and for presented purposes a "basic patent" can be regarded as a patent designated for the purpose of obtaining a certificate. In the present case the basic patent is European Patent No. 0131839B for which the relevant applicable law is the Patents Act 1977 ("1977 Act") and the 1995 Rules.

33 The skeleton identified four cases where the authorities in some EU Member States have allowed an application for a certificate to proceed under their national law even though the application was filed late. Dr Mannion referred to only one of these cases at the hearing, but I think it is useful to summarise each of them here. I am aided in this because translations of the relevant decisions were filed before the hearing. Taking the decisions in the order they are presented in the skeleton:

(a) An appeal by *Centocor Inc* for reinstatement of its application for a certificate (SPC Application No. 94 C 0001), which had been filed more that six months after the grant of the basic European patent, was allowed by the Institut National de la Propriété Industrielle (France). In this case the applicant pleaded that its professional representative had made a mistake. The appeal was decided under Article L. 612-16 of the French Intellectual Property Code, which allows reinstatement if an applicant gives a legitimate reason and the direct consequence of the hindrance has been refusal of his patent application or of a request or the loss of any other right or means of appeal.

(b) In the Netherlands the rights in an application (SPC Application No. 940021) by *Health Research Inc.* were re-established by applying Article 17A of the Patents Act 1910 after the applicant had failed to observe the time limit of Article 7(1) of the Regulation. Under Article 17A of the 1910 Act if an applicant, despite having exercised all due care under the circumstances, was unable to observe a time limit, the prior state may be restored at the applicant's request if non-observance of the time limit has had the direct consequence of the loss of any right or means of redress. In this case the failure to observe the time limit was the result of a breakdown in communications between two companies involved with the application when a letter sent by someone in one company was not received by the appropriate person in the other company. The Special Department that heard the appeal found no reason to suppose that the people involved had not exercised the required level of care.

(c) An application for a certificate (0190019-0) by *Pre Jay Holdings Ltd & Woco Investments Ltd* was rejected by the Swedish Patent and Registration Office because the application had not been filed within the period of six months from the day on which the authorization to place the product on the market as a medicinal product was granted in Sweden. The applicant then requested a declaration, according to section 72 of the Swedish Patent Law, that the application had been filed within the time limit. In its decision on this matter the Swedish Patent and Registration Office issued the requested declaration because it was satisfied that the applicant had suffered loss of rights despite taking due care.

(d) *Merrell Pharmaceuticals Inc.* missed the deadline for filing an application in Luxembourg for a certificate (90198) because a critical letter sent to its agent could not be identified with the application due to the omission of references. A request for *restitutio in integrum* was made to and allowed by the Intellectual Property Department

of the Grand-Duchy's Ministry of Economy.

34 Returning to Dr Mannion's submission at the hearing, she went on to consider the applicable national law as it relates to certificates and applications for certificates in the United Kingdom. She referred me to the Patents (Supplementary Protection Certificate for Medicinal Products) Regulations 1992 ("the 1992 Implementing Regulations") and in particular Regulation 5 of these 1992 Implementing Regulations:

> "**Extension of existing provisions of the Patents Act 1977 and the Patents Act 1949 to certificates (Articles 5, 17 and 18)**
>
> **5.** Subject to any rules made by the Secretary of State under section 123 of the 1977 Act relating to certificates, applications for certificates or matters relating to the same, the provisions of that Act and where they continue to apply, the provisions of the Patents Act 1949 and any rules made thereunder in respect of patents, applications for patents, existing patents or existing applications shall, in accordance with the provisions of Articles 5, 17 and 18 of the EC Regulation, extend and apply to, and be taken to make, as appropriate and with the necessary changes, corresponding provision, including corresponding provision relating to fees, forms and to the jurisdiction of and proceedings before the comptroller and the court, for certificates, applications for certificates and matters relating thereto, as they apply to, and make provision for, patents and applications for patents and matters relating thereto."

On the basis of this Regulation Dr Mannion concluded that rule 110(1) of the 1995 Rules was available to allow extensions of the period specified in Article 7(1). Rule 110 of the 1995 Rules allows for the alteration of some time limits prescribed in these Rules. According to paragraph (1) of rule 110:

> "110.-(1) The times or periods prescribed by these rules for doing any act or taking any proceeding thereunder, other than times or periods prescribed in the provisions mentioned in paragraph (2) below, and subject to paragraphs (3) and (4) below, may be extended by the comptroller if he thinks fit, upon such notice to the parties and upon such terms as he may direct; and any such extension may be granted notwithstanding that the time or period for doing such act or taking such proceeding has expired."

I do not believe it is necessary to quote the other paragraphs of rule 110 here. It should be sufficient if I explain that paragraph (2) lists various rules prescribing times or periods which cannot be extended at the comptroller's discretion. Paragraph (3) identifies other rules prescribing times or periods where an extension of one month is available as of right by filing an appropriate form and fee. Paragraph (4) allows extension or further extension at the comptroller's discretion of the times or periods identified in paragraph (3) but again subject to the payment of a fee. The remaining paragraphs are not directly relevant to the matter I must decide here.

35 In Dr Mannion's opinion the alteration of time periods in relation to certificates and applications for certificates defaults to rule 110(1) because neither paragraph (2) nor paragraphs (3) and (4) of this rule make any mention of time limits concerning certificates or applications for certificates. At the hearing I expressed my surprise that Dr Mannion should expect to find any specific reference to time periods relating to certificates in rule 110 because the Patents Rules 1995 are just that; rules for regulating procedures relating to patents and patent applications. If

this rule is to make provision for the alteration of time limits in connection with certificates and applications for certificates, it would need to do so with the changes permitted by Regulation 5 of the 1992 Implementing Regulations. Dr Mannion accepted this and explained that her point was that rule 110(1) should make provision for applications for certificates even though paragraph (1) of the rule limits its application to "times or periods prescribed by these Rules". In other words , Dr Mannion took the view that this restriction in rule 110(1) should be changed so that the rule applies to applications for certificates.

36 Dr Mannion next turned to the principles on which the comptroller normally exercises her discretion to grant extensions of time. She identified an earlier Patent Office decision, *Heatex Group Ltd.'s Application* [1995] RPC 546, as the one primary piece of case law. This is a well known case where a patent applicant decided not to proceed with an application and as a result a request for substantive examination was not filed within the prescribed period. The applicant realised later that this decision had been wrong and sought to extend the period for requesting substantive examination. In considering whether the requested extension should be allowed at the comptroller's discretion, the hearing officer looked at how discretion should be used under the then rule 110(3A), which was the forerunner of the current rule 110(4). In doing so the hearing officer concluded at page 550 lines 31 - 34 that:

> "..... an applicant should not suffer loss of rights through unforeseen circumstances. Put another way, the circumstances leading to the failure must have been set against a continuing underlying intention to proceed with the application or patent."

37 Dr Mannion also made the point that when the Regulation was adopted there was an intention that it would result in harmonisation of supplementary protection throughout Europe. She referred me once again to Recital 6 of the Regulation, which I have already considered in the context of Mr Karet's submission to me. In her view I should recognise that the Member States of the Community came together to iron out pre-existing disparities concerning supplementary protection and in so doing they also assumed that certain laws in the Member States, such as discretion and *restitutio in integrum*, were equivalent. She warned that if I followed the examiner's opinion and held that it was not possible to exercise discretion under rule 110, there would be the potential for all other countries on mainland Europe to allow restitution but the United Kingdom would not exercise discretion in similar circumstances. Mr Karet supplemented Dr Mannion's submission on this point by suggesting that the national laws which are applicable by virtue of Article 18 of the Regulation, must be applied within the context of the Regulation and that any departure from the intent and spirit of the Regulation would be invalid. In his view there was a strong case for saying that the Regulation was never intended to prevent the grant of certificates in some countries if in similar circumstances they would be granted in others. Mr Karet mentioned in this context the Court's judgment in *Yamanouchi Pharmaceuticals Co. Ltd. v Comptroller-General* [1997] RPC 844 but subsequently acknowledged that this case was not on the same point and I agree. Therefore, I do not see the need to refer to it further in this decision.

38 Dr Mannion went on to explain the actual circumstances which led to the present application being filed after 19 September 1997. I have already outlined these circumstances at the beginning of this decision but I think it is worth summarising what Dr Mannion said at the hearing. On the basis of the witness statements made by Mr Ward and Mr Mandel, she explained that the circumstances at the time of the acquisition of Solvay's animal health business by AHP were extremely difficult. As a result the parties each had good reason to understand that the other party was actually filing the application but in Dr Mannion's words the "ball was

accidentally dropped". Dr Mannion stressed that these were unforeseeable circumstances and that the applicant was not at fault when it assumed that the marketing authorization holder, that is AHP, would make the application for supplementary protection on its behalf. Dr Mannion sought to demonstrate that there was an intent to file by referring to corresponding applications which were filed on time elsewhere, and to the urgent steps taken to lodge the present application as soon the oversight had been spotted.

Assessment of Dr Mannion's submission

39 Before I can come to any view about the exercise of the comptroller's discretion in the circumstances of this case, I must first consider whether, as Dr Mannion argued, the comptroller's discretion under rule 110(1) of the 1995 Rules extends to Article 7(1) of the Regulation. Like Dr Mannion, I will start by considering the Regulation and in particular Article 18. I agree with Dr Mannion that this Article requires that procedural provisions under national law should apply in the absence of a procedural provision in the Regulation itself. In my view a provision which allows for extensions of time periods, can be regarded as a procedural provision and as Dr Mannion pointed out, it is not one that is dealt with directly in the Regulation. Therefore, this is one procedure where national law might apply.

40 Having cleared this first hurdle, I can now turn to consider whether there is any provision in UK law which applicable to extend the period specified in Article 7(1). Dr Mannion referred me to the 1992 Implementing Regulations. Regulation 4(2) of these Regulations extends powers under section 123 of the 1977 Act so that rules for regulating certificates and applications for certificates can be made. These extended powers were used to make the Patents (Supplementary Protection Certificates) Rules 1997. However, there is no provision in these Rules, which would allow an extension of any time period in relation to certificates or applications for certificates. On the other hand Regulation 5 of the 1992 Implementing Regulations requires, subject to any rules which have been made for regulating certificates or applications for certificates, that the provisions of the 1977 Act and its Rules concerning patents and applications for patents shall extend and apply to, and be taken to make, as appropriate and with the necessary changes, corresponding provision for certificates, applications of certificates and matters relating thereto, as they apply to, and make provision for, patents and applications for patents and matters relating thereto. Thus, as Dr Mannion argued, I must look to the provisions of the 1977 Act and the 1995 Rules for a provision which can be extended and applied to, and be taken to make, as appropriate and with the necessary changes, provision for extending the period specified in Article 7 of the Regulation.

41 It may have been convenient to legislate for applications for certificates simply by extending the existing provisions of the 1977 Act and its Rules to them under Regulation 5 of the 1992 Implementing Regulations but it creates difficulties when faced with the need to extend these provisions to such applications. In the present case Dr Mannion identified rule 110(1) as the provision which is appropriate with the necessary changes for extending the period specified in Article 7(1). Rule 110 provides for extensions of certain times or periods prescribed by the 1995 Rules but it does not cater, for example, for extensions of times or periods specified in the 1977 Act nor is it directly applicable to extensions of the period of Article 7(1). Thus, in line with Regulation 5 of the 1992 Implementing Regulations, I must consider whether it would ever be appropriate use rule 110 to extend the Article 7(1) period. To answer this question I need to look at the Regulation purposively in the same way as I did when considering Mr Karet's main submission.

42 A good place to start is the Commission's Explanatory Memorandum. It is apparent from paragraph 46 of this Explanatory Memorandum, from which I have already quoted the relevant passage, that the six month period specified in Article 7(1) was chosen because it takes account of the interests involved, including those of third parties who have every interest in knowing as early as possible whether or not the product concerned will be protected by a certificate once the basic patent has expired. However, I do not believe this basic consideration should override the possibility of accommodating the interests of a patent holder who has missed the deadline for lodging an application. Moreover, in my opinion, an extension of the period specified in Article 7(1) in appropriate circumstances would not undermine the objective, stated in Recital 6 of the Regulation, of providing "a uniform solution at Community level". Allowing such extensions would not have the same effect as Member States interpreting Article 7(1) differently. In addition, I can find nothing in the Regulation, its travaux preparatoires or the jurisprudence of the Court to suggest that there was ever an intention that Article 18 should not encompass procedures which can be found in all national patent laws of the Member States, to extend a time period in the Regulation. Thus, I cannot see any reason why extensions of the period specified in Article 7(1) should not be possible. I find support for this view in the cases identified in the skeleton where the authorities in France, the Netherlands, Sweden and Luxembourg have already considered and allowed extensions of this period under their national laws. However, I should make it clear that I do not accept Mr Karet's view that for the purposes of the Regulation the relevant national laws should be applied in a uniform way. Whenever reliance is placed on aspects of national law which are not themselves harmonised, it is inevitable that there may be different outcomes in similar circumstances.

43 The question which now arises is which paragraph of rule 110 is applicable? Dr Mannion stated that the applicable provision is paragraph (1) of rule 110 because Article 7(1) of the Regulation is not listed in rule 110(2). However, as already mentioned, when I questioned her on this point she agreed that this was not surprising because the 1995 Rules do not make specific provision for certificates. Therefore, I cannot come to any conclusion on the applicability of rule 110(1) on this basis. When considering the Regulation purposively, I have already concluded that it would be appropriate to extend the Article 7(1) period in some situations and it follows that this period is not one I would expect to find listed in paragraph (2) of rule 110 as non-extendable. That leaves the question of whether the Article 7(1) period should be extendable at the comptroller's discretion under paragraph (1), as of right under paragraph (3) or at the comptroller's discretion on payment of a fee under paragraph (4) of rule 110. In my view the interests of third parties rule out the possibility of allowing extensions, even very short ones, of the Article 7(1) period as of right. Therefore, I do not believe that the period for lodging a certificate should be extendable under rule 110(3). The periods extendable under rule 110(4) at the comptroller's discretion but on payment of a fee are by and large those that provide some flexibility but nevertheless seek to encourage timely and efficient processing of patent applications and patents. In my view these periods are of a different character to the period of Article 7(1). Therefore, by a process of elimination, I agree with Dr Mannion that the appropriate provision in this case is rule 110(1).

44 Now that I have concluded that the period specified in Article 7(1) is extendable under rule 110(1), I must consider whether I should extend this period based on the facts of this case. The hearing officer's decision in *Heatex* established the basis for exercising the comptroller's discretion under rule 110. In essence, an applicant should not suffer loss of rights through unforeseen circumstances but where, as in *Heatex,* there has been a change of mind, an extension will not be allowed.

45 The witness statements of Mr Ward and Mr Mandel paint a picture of considerable confusion about who had responsibility for lodging the application in the United Kingdom for a certificate for difloxacin. However, in *Heatex* the hearing officer took the view that reasonable care on the part of the applicant should not be a factor when considering restitution of a patent application and I am inclined to the same view in the context of the present case. Despite the obvious confusion about who should lodge the application, I am satisfied that there was always an intention on the part of the applicant to seek supplementary protection for difloxacin in the United Kingdom. The witness statements establish that an application for a certificate had already be made in the Netherlands and that the applicant and AHP both thought the other was monitoring the grant of marketing authorizations for difloxacin in various European countries, including the United Kingdom, with the intention of lodging applications at the relevant times. Thus, in my view, the deadline for lodging the application was missed due to unforeseen circumstances.

46 Before I can come to a decision whether to exercise the comptrollers' discretion and allow an extension of the period specified in Article 7(1), there is one further matter I must consider. Although the hearing officer did not address it directly in *Heatex*, the conduct of the applicant, once a problem has been spotted, should be taken into account before deciding on the exercise of the comptroller's discretion. In particular, any undue delay in addressing a problem could lead to discretion being refused. Bearing in mind the Explanatory Memorandum's emphasis on having a relatively short period for submitting an application for a certificate, I believe that the applicant's conduct is a particularly important consideration here because any undue delay in filing an application for a certificate would run contrary to the aim of the Regulation not to prejudice unfairly the interests of third parties. I must therefore take account of the applicant's conduct in this case. In his witness statement Mr Mandel states:

> "11. That on 25 September 1997 I inquired of Abbott to request confirmation that the UK SPC application had been filed. To my considerable concern Abbott replied that it had not been filed.
>
> 12. That it was only at this time that I realised that the notification system I had thought to be in place was apparently not operating satisfactorily.
>
> 13. That I therefore immediately contacted Abbott by telephone. In the course of our telephone conversation it was agreed that the SPC application should be filed immediately. It was also then agreed that my Company's own in-house European Patents Department at Wyeth Laboratories in the UK would now be used to make the SPC application filing (rather than Abbott's usual patent attorneys, who operated as a private practice) so as to eliminate exposure to further delay.
>
> 14. The SPC application was therefore filed by my Company's UK-based Patents Department by facsimile transmission on 25 September 1997."

In his witness statement Mr Ward states:

> "11. Upon telephone notice of the non-timely filing of the UK SPC application, I proceeded to assist Philip Walters of Wyeth Laboratories (Wyeth) in immediately filing the UK SPC application on September 25, 1997. Wyeth is a UK-based subsidiary of AHP."

Thus, the application was lodged on the same day as the oversight was discovered. In other words there was no delay whatsoever once Mr Mandel realised that the deadline for filing the application had been missed. However, I find it strange that Mr Walters of Wyeth who filed the application on behalf of the applicant made no mention of the late filing in his covering letter dated 25 September 1997. It was left to the examiner to raise the matter in his letter dated 9 March 1998. In response to this and subsequent letters from the examiner, the applicant presented various arguments why the application should be allowed to proceed but it was only in the skeleton that the applicant first sought an extension of time based on rule 110(1) of the 1995 Rules. So far as I am aware the applicant has never explained why the late filing of the application was not acknowledged at the outset but I do not think that I should let this detract from the fact that the application was lodged immediately the missed deadline had been noted. I therefore accept that the applicant acted without undue delay so as not to prejudice unduly the legitimate interests of third parties.

Conclusion

47 I have concluded that the comptroller has discretion to extend the period specified in Article 7(1) of the Regulation under rule 110(1) of the 1995 Rules. I have also concluded that the late filing of the present application was due to unforeseen circumstances and that the applicant acted extremely quickly to remedy the situation. Therefore, I allow Dr Mannion's request for an extension until 25 September 1997 of the period for lodging the present application. Since this is the date on which the application was actually filed, the application is deemed to have been filed on time and may now be examined for compliance with the other requirements of the Regulation.

Terms

48 Rule 110(1) allows the comptroller to impose terms when exercising her discretion to extend a time period but I do not think it is necessary in this case since the application was filed only a few days late and it was advertised in the normal manner on 22 October 1997. The very short extension I have allowed would not in my view prejudice the interests of any third party. It has taken a great deal longer to resolve this issue but again I am satisfied that any interested third party would have been under notice from the outset that the application might be allowed to proceed.

Overall conclusions

49 I have considered the interpretation of Article 7(1) purposively and decided that the present application for a certificate for the product difloxacin was filed late. However, I have concluded that the six month period of Article 7(1) may be extended at the comptroller's discretion under rule 110(1) of the 1995 Rules when an application is filed late due to unforeseen circumstances and the applicant acts promptly to rectify the situation. Applying these conclusions to the present case, I am satisfied that the application was filed late due to unforeseen circumstances and that the applicant acted immediately to address the situation. Thus, I allow the applicant's request under rule 110(1) of the 1995 Rules to extend the period for filing the present application to 25 September 1997, the date when the application was actually filed, so that it can now proceed. My decision to allow this extension is not subject to any terms because in my view the circumstances of this case do not demand them.

Appeal

50 Although I have allowed the applicant's request under rule 110(1) of the 1995 Rules, I am conscious that I did not accept the applicant's argument that in principle the period specified in Article 7(1) of the Regulation should begin when notification of the grant of a marketing authorization is published in the relevant Official Gazette. It seems possible that the applicant may wish to appeal this latter aspect of my decision. Thus, as this decision is not on a matter of procedure, any appeal should be lodged within six weeks.

Next steps

51 I remit the application to the examiner to determine if it meets the other requirements of the Regulation necessary for the grant of a certificate.

Dated this 25 day of July 2002

R J WALKER
Deputy Director, acting for the comptroller

THE PATENT OFFICE