COUNCIL REGULATION (EEC) NO. 1768/92

IN THE MATTER OF Application No. SPC/GB/99/012 in the name of Novartis AG and University College London, and Application No. SPC/GB/00/013 in the name of Novartis AG and Institute of Microbiology and Epidemiology

DECISION

The background and issue

1 Novartis AG and the University College London filed an application (SPC/GB/99/012) for the grant of a Supplementary Protection Certificate ("certificate") on 15 March 1999. They identified the medicinal product which they sought to protect, as "Basiliximab" and gave the date of its first marketing authorization in the United Kingdom as 9 October 1998. In line with a footnote on the official application form that in some cases an authorization in a State which is not a Member State of the European Union but is party to the European Economic Area Agreement, may constitute a first authorization in the "Community", the co-applicants stated that the first authorization to place Basiliximab on the market in the "Community" had been granted on 7 April 1998 by Switzerland / Liechtenstein under the legal provision:

> "Regulativ über die Ausführung der interkantonalen Vereinbarung über die Kontrolle der Heilmittel vom 25. Mai 1972 (Stand am 23.11.95 und 1.7.98)"

An English translation of this information was not provided.

2 The application was referred to an examiner who wrote to the co-applicants on 10 May 1999. Among other things, the examiner's letter indicated that the latest expiry date for the certificate would be 6 April 2013 on the basis of the information supplied. The co-applicants' patent agent, B.A.Yorke & Co., responded on 10 January 2000 and offered observations concerning the expiry date of the certificate. The agent's view was that the correct date should be 9 October 2013. In a nutshell, the patent agent disputed the examiner's view that the period of supplementary protection should be calculated on the basis of a Swiss marketing authorization which extended to Liechtenstein. According to the agent, the expiry date for the certificate should be calculated on the basis of the later marketing authorization granted on 9 October 1998 by the European Agency for the Evaluation of Medicinal Products ("EMEA").

3 On 19 May 2000 Novartis AG and a different co-applicant (Institute of Microbiology and Epidemiology based in Beijing) filed another application for supplementary protection. This second application was given the number SPC/GB/00/013. The application identified the related medicinal product as "Artemether, Lumefantrin" and stated that the first marketing authorization for this product in the United Kingdom had been granted on 30 November 1999. The application also stated that the first authorization to place the product on the

market in the "Community" was granted in Switzerland / Liechtenstein on 22 January 1999. Once again the relevant legal provision for this authorization was described as:

> "Regulativ über die Ausführung der interkantonalen Vereinbarung über die Kontrolle der Heilmittel"

However, the application was annotated:

> "See the attached comments on the previous authorization in Switzerland which, in our opinion, extends to Liechtenstein but **not** to the rest of the community".

The attached comments reasoned that the period of the certificate should not be calculated on the basis of a marketing authorization in Switzerland, which extended to Liechtenstein.

4 Upon examination of this second application the examiner once again took the view that the date of the Swiss marketing authorization was relevant to the calculation of the period of the certificate and on this basis calculated that the certificate for Artemether, Lumefantrin should expire on 21 January 2014 at the latest. In response the co-applicants' patent agent, B.A. Yorke & Co., maintained that the relevant first authorization for this calculation should be the authorization granted for the United Kingdom on 30 November 1999, which would give supplementary protection until 30 November 2014.

5 The examination process continued for both applications in the normal manner until the only issue outstanding was the period of supplementary protection available. The examiner remained of the view that the authorizations granted by the Swiss authority but effective in Liechtenstein were relevant to the calculation of this period. However, both sets of co-applicants ("the applicants") did not accept this. Therefore, the matter came before me at a hearing where the applicants were represented by their patent attorney, Mr Phillip Grubb of B.A.Yorke & Co. Mr Grubb was accompanied by Mr Brian Cordery, a solicitor of the firm Bristows. Before the hearing I had the benefit of seeing a skeleton argument provided by Mr Grubb and I thank him for that. The examiner, Mr Jason Bellia, also attended the hearing.

6 I should perhaps add at this stage that the present two applications are not the only ones where there is a dispute between an examiner and an applicant over the relevance of the date of a Swiss marketing authorization to the calculation of the maximum term of a certificate. Proceedings on these other applications are currently stayed pending the outcome of this decision.

Assessment

7 Before considering the issue at hand, it is useful to outline the legal framework underpinning the grant of certificates in the European Union ("EU") and the European Economic Area ("EEA").

Council Regulation (EEC) No. 1768/92

8 I will begin by considering Council Regulation (EEC) No. 1768/92 ("the Regulation") concerning the creation of a supplementary protection certificate for medicinal products, which was adopted on the 18 June 1992. Article 1 of the Regulation provides various important definitions as follows:

"**ARTICLE 1**

Definitions

For the purposes 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."

9 Article 2 of the Regulation sets out what may be the subject of a certificate:

"**ARTICLE 2**

Scope

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

10 Article 3 spells out the conditions which must be met for the grant of a certificate. Here I should point out that Article 3(b) was amended by Council Decision 95/1/EC upon the accession of Austria, Finland and Sweden to the EU on 1 January 1995:

"**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."

As will be apparent when I refer to Article 7 below, the application referred to in the chapeau of Article 3 is an application for a certificate.

11 Articles 4, 5, 6 and 7 concern what is protected by a certificate, the rights conferred, who is entitled to a certificate and the time limits for lodging an application. Of these Articles 4 and 7 are relevant here in that along with Article 2 they indicate the role of an authorization to market a medicinal product in the scheme of things:

"**ARTICLE 4**

Subject-matter of protection

Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorization to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorized before the expiry of the certificate."

"**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."

12 Article 8 lists what is required in an application for a certificate and refers specifically to the authorization referred to in Article 3(b) as well as to the first authorization for placing the product on the market as a medicinal product in the Community:

"**ARTICLE 8**

Content of the application for a certificate

1. The application for a certificate shall contain:

(a) a request for the grant of a certificate, stating in particular:
(i) the name and address of the applicant;
(ii) if he has appointed a representative, the name and address of the representative;
(iii) the number of the basic patent and the title of the invention;
(iv) the number and date of the first authorization to place the product on the market, as referred to in Article 3(b) and, if the authorization is not the first authorization for placing the product on the market in the Community, the number and date of that authorization;

(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) if the authorization referred to in (b) is not the first authorization for placing the product on the market as a medicinal product in the Community, information regarding the identity of the product thus authorized and the legal provision under which the authorization procedure took place, together with a copy of the notice publishing the authorization in the appropriate official publication.

2. Member States may provide that a fee is to be payable upon application for a certificate."

13 Articles 9, 10, 11 and 12 identify the relevant authority with which an application for a certificate should be filed and deal with the grant or rejection of the application by that authority, publication of details of the granted certificate and annual fees which may be payable. I see no need to reproduce these Articles here. I can therefore move on to Article 13 which lies at the very heart of the matter I must decide because it deals with the duration of the certificate:

"**ARTICLE 13**

Duration of the certificate

1. The certificate shall take effect at the end of the lawful term of the basic

patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the market in the Community reduced by a period of five years.

2. Notwithstanding paragraph 1, the duration of the certificate may not exceed five years from the date on which it takes effect."

Thus, the calculation used to determine the duration of a certificate is based on time "lost" under the patent, that is the period between the date on which the patent application was filed and the date of grant of the first authorization to place the corresponding product on the market in the Community.

14 Article 14 is related to Article 13 and deals with the expiry of the certificate:

"**ARTICLE 14**

Expiry of the certificate

The certificate shall lapse:

(a) at the end of the period provided for in Article 13;

(b) if the certificate-holder surrenders it;

(c) if the annual fee laid down in accordance with Article 12 is not paid in time;

(d) if and as long as the product covered by the certificate may no longer be placed on the market following the withdrawal of the appropriate authorization or authorizations to place on the market in accordance with Directive 65/65/EEC or Directive 81/851/EEC. The authority referred to in Article 9(1) may decide on the lapse of the certificate either of its own motion or at the request of a third party."

15 The remaining Articles which deal with invalidity (Articles 15 and 16), appeals (Article 17), procedure (Article 18) and transitional and final provisions (Articles 19 to 23), are not particularly relevant to this decision and I see no need to quote them here. However, I note that like Article 3, Articles 19 and 20 were amended by Council Decision 95/1/EC on the accession of Austria, Finland and Sweden to the EU.

16 So far I have done no more than quote those provisions of the Regulation, which I consider relevant for the purposes of this decision. However, I am mindful that the Regulation is a Community instrument and as such I must take account of the general principles underlying it when interpreting its provisions. I am helped in this by its Recitals. I can take the first five Recitals together (numbering supplied):

"1. Whereas pharmaceutical research plays a decisive role in the continuing improvement in public health;

2. Whereas medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in

Europe unless they are covered by favourable rules that provide for sufficient protection to encourage such research;

3. Whereas at the moment the period that elapses between the filing of an application for a patent for a new medicinal product and authorization to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research;

4. Whereas this situation leads to a lack of protection which penalises 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;"

In my view these Recitals highlight the purpose of the Regulation, which is to encourage the development of medicinal products in the Community by providing patent holders with sufficient protection to cover their investment in research despite the erosion of the effective term of a patent by the time taken to obtain marketing authorization for these products.

17 Recitals 6 and 7 indicate the need for a harmonised solution at Community level to avoid the development of national solutions which could create obstacles to the free movement of medicinal products within the Community:

"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;".

18 Recitals 8 and 9 state:

"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;".

These Recitals are important because they outline the policy for addressing the issues identified in the first five Recitals. In short, there is to be adequate effective protection. This is to be achieved by providing *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*. However, *the certificate cannot be granted for a period exceeding five years*. Moreover, *the protection granted should be strictly confined to the product which obtained authorization to be placed on the market as a medicinal product*. Thus, the Regulation aimed to strike a balance between the interests of patent owners and the other interests at stake, such as those of public health, when settling the scope and the period of protection under a certificate.

19 From Recitals 6 to 9 and Article 13 it can be seen that the manner of calculating the duration of certificates for the same medicinal product is a simple one with the aim of preventing the grant of certificates having different durations in different EU Member States. However, from the outset this simplicity has resulted in a degree of rough justice when the marketing authorization dates for one and the same medicinal product differ from one Member State of the EU to another. This is because by granting certificates of the same duration, the later an authorization is granted in a particular Member State, the shorter the effective period of protection under the patent and certificate will be there. To some extent the establishment of the EMEA which provides access to a centralised procedure of marketing authorization, has addressed this issue but some products are still authorized by national authorities and so may be granted marketing authorizations on different dates in different Member States.

20 The remaining Recitals 10 to 13 concern transitional arrangements and I do not believe I need to consider them here.

The EEA Agreement

21 On 2 May 1992 Austria, Finland, Iceland, Norway and Sweden, as Member States of the European Free Trade Association ("EFTA"), signed an Agreement on the European Economic Area ("the Agreement") with the then twelve Member States of the Community. This Agreement entered into force on 1 January 1994. Since 1 January 1995 Austria, Finland and Sweden have participated in the Agreement as Member States of the EU. Later the same year on 1 May 1995, Liechtenstein became a Contracting Party to the Agreement. Switzerland is not party to the Agreement, although it is a Member of EFTA.

22 The objectives and principles of the Agreement are set out in its Articles 1 to 7 and of these I consider Articles 1 and 7 to be particularly relevant to the matter I must decide:

"***Article 1***

1. The aim of this Agreement of association is to promote a continuous and balanced strengthening of trade and economic relations between the Contracting Parties with equal conditions of competition, and the respect of the same rules, with a view to creating a homogeneous European Economic Area, hereinafter referred to as the EEA.

2. In order to attain the objectives set out in paragraph 1, the association shall entail, in accordance with the provisions of this Agreement:

(a) the free movement of goods;

(b) the free movement of persons;

(c) the free movement of services;

(d) the free movement of capital;

(e) the setting up of a system ensuring that competition is not distorted and that the rules thereon are equally respected; as well as

(f) closer cooperation in other fields, such as research and development, the environment, education and social policy."

"***Article 7***

Acts referred to or contained in the Annexes to this Agreement or in decisions of the EEA Joint Committee shall be binding upon the Contracting Parties and be, or be made, part of their internal legal order as follows:

(a) an act corresponding to an EEC regulation shall as such be made part of the internal legal order of the Contracting Parties;

(b) an act corresponding to an EEC directive shall leave to the authorities of the Contracting Parties the choice of form and method of implementation."

23 Common rules concerning intellectual, industrial and commercial property are addressed in Article 65(2) of the Agreement:

"***Article 65***

1. .....

2. Protocol 28 and Annex XVII contain specific provisions and arrangements concerning intellectual, industrial and commercial property, which, unless otherwise specified, shall apply to all products and services."

24 Protocol 28 to the Agreement deals with matters concerning the substance of protection, exhaustion of rights, Community Patents, semiconductor products, international conventions, negotiations concerning the General Agreement on Tariffs and Trade, mutual information and consultation, transitional provisions and competence. Of these matters, the most relevant to this decision seem to be substance of protection (Article 1) and exhaustion of rights (Article 2). Article 1(2) requires the Contracting Parties to adjust their legislation on intellectual property so as to make it compatible with the principles of free circulation of goods and services, and with the level of protection of intellectual property attained in Community law. Article 2(1) requires that to the extent that exhaustion is dealt with in

Community measures or jurisprudence, the Contracting Parties shall provide for such exhaustion of intellectual property rights as laid down in Community law.

25 The introduction to Annex XVII on Intellectual Property states:

> "INTRODUCTION
>
> When the acts referred to in this Annex contain notions or refer to procedures which are specific to the Community legal order, such as:
>
> - preambles,
> - the addressees of the Community acts,
> - references to territories or languages of the EC,
> - references to rights and obligations of EC Member States, their public entities, undertakings or individuals in relation to each other, and
> - references to information and notification procedures,
>
> Protocol 1 on horizontal adaptations shall apply, unless otherwise provided for in this Annex."

26 Protocol 1 on horizontal adaptations which is mentioned in Annex XVII, opens with a statement that the provisions of the acts referred to in the Annexes to the Agreement shall be applicable in accordance with the Agreement and Protocol 1, unless otherwise provided in the respective Annex. The Protocol then goes on to set out various adaptations, the first of which is:

> "1. INTRODUCTORY PARTS OF THE ACTS
>
> The preambles of the acts referred to are not adapted for the purposes of the Agreement. They are relevant to the extent necessary for the proper interpretation and application, within the framework of the Agreement, of the provisions contained in such acts."

The eighth adaption concerns references to Territories:

> "8. REFERENCES TO TERRITORIES
>
> Whenever the acts referred to contain references to the territory of the "Community" or of the "common market" the references shall for the purposes of the Agreement be understood to be references to the territories of the Contracting Parties as defined in Article 126 of the Agreement."

For completeness I should quote Article 126(1) of the Agreement which identifies the

Contracting Parties to the Agreement:

"***Article 126***

1. The Agreement shall apply to the territories to which the Treaty establishing the European Economic Community and the Treaty establishing the European Coal and Steel Community is applied and under the conditions laid down in those Treaties, and to the territories of the Republic of Austria, the Republic of Finland, the Republic of Iceland, the Principality of Liechtenstein, the Kingdom of Norway and the Kingdom of Sweden."

Article 126 goes on to deal with the application of the Agreement to the Åland Islands which need not concern me here.

27 Returning to Annex XVII on Intellectual Property, it was amended by Annex 15 to Decision of the EEA Joint Committee No. 7/94 of 21 March 1994. One of the amendments was to add a new point 6 which in turn was adapted by a Decision of the EEA Council No. 1/95 of 10 March 1995 on entry into force of the Agreement for Liechtenstein. Point 6 currently applies the Regulation to the Agreement as follows:

"6. **392 R 1768:** Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ No L 182, 2.7.1992, p.1).

The provisions of the Regulation shall, for the purposes of the present Agreement, be read with the following adaptations:

(a) in Article 3(b) the following shall be added:

"; for the purpose of this subparagraph and the Articles which refer to it, an authorization to place the product on the market granted in accordance with the national legislation of the EFTA State shall be treated as an authorization granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC, as appropriate.";

(b) Article 19(1) shall be replaced by the following:

"1. Any product which on 2 January 1993 is protected by a valid patent and for which the first authorization to place it on the market as a medicinal product within the territories of the Contracting Parties was obtained after 1 January 1985 may be granted a certificate.

In the case of certificates to be granted in Denmark, in Germany, in Finland and in Norway, the date of 1 January 1985 shall be replaced by that of 1 January 1988.

In the case of certificates to be granted in Belgium, in Italy and Austria, the date of 1 January 1985 shall be replaced by that of 1 January 1982.";

(c) the following paragraphs shall be added to Article 19:

"3. If a basic patent in an EFTA State lapses, due to the expiry of its lawful term, between 2 January 1993 and the date of entry into force of this Regulation under this Agreement, the certificate shall take effect only with respect to the time following the date of publication of the application for the certificate. However, Article 13 shall apply as to the calculation of the duration of the certificate.

4. In the case of paragraph 3, the application for a certificate shall be lodged within two months of the date on which the Regulation enters into force in the EFTA State concerned.

5. A certificate applied for in accordance with paragraph 3 shall not prevent any third party who, between the lapse of the basic patent and the publication of the application for a certificate, in good faith has commercially used the invention or made serious preparations for such use, to continue such use.".

(d) In addition the following shall apply:

In view of the patent union between Liechtenstein and Switzerland, Liechtenstein shall not deliver any supplementary protection certificates for medicinal products as laid down in this Regulation.""

The basis of the examiner's objection

28 Now that I have set out the legal framework underlying the grant of certificates both within the EU and the EEA, it is useful to consider why the examiner took the view he did on the question of the expiry dates for the certificates sought by the applicants. The examiner summarised his reasons in letters dated 27 June 2002 to the applicants and I can do no better than quote from them:

"Article 8(1) of Regulation 1768/92 sets out the content of the application for a certificate. In particular Article 8(1)(b) and 8(1)(c) require:

"(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) if the authorization referred to in (b) is not the first authorization for placing the product on the market as a medicinal product in the Community, information regarding the identity of the product thus authorised and the legal provision under which the authorization procedure took place, together with a copy of the notice publishing the authorization in the appropriate official publication."

The date of the first authorization for placing the product on the market as a medicinal product has a bearing on Article 13(1) which relates to the duration of the certificate and states:

"1. The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the market in the Community reduced by a period of five years."

Basically the point at issue is whether Swiss authorizations 545901 01 *(sic)* and 54630 01 should be taken into account in the calculation of the term of SPC/GB/00/013 and SPC/GB/99/012 respectively. In my view they should.

My reasons for this view are predicated on the adaptation of Article 8(1)(c) and Article 13(1) by Protocol 1 on horizontal adaptations of the EEA Agreement. Protocol 1 indicates how the adaptation is to be made when it states:

"The provisions of the acts referred to in the Annexes to the Agreement shall be applicable in accordance with the Agreement and this Protocol, unless otherwise provided in the respective Annex. The specific adaptations necessary for individual acts are set out in the Annex where the act concerned is listed."

One of the Annexes to the Agreement, specifically Annex XVII, relates to intellectual property and one of the acts referred to in that Annex is Regulation (EEC) No.1768/92, therefore Protocol 1 applies to the Medicinal Products Regulation. Paragraph 8 of Protocol 1 states that:

"Whenever the acts referred to contain references to the territory of the "Community" or of the "common market" the references shall for the purposes of the Agreement be understood to be references to the territories of the contracting parties as defined in Article 126 of the Agreement."

Therefore references to "Community" in Regulation 1768/92 are for the purposes of the EEA Agreement understood as references to the territories of the contracting parties to the Agreement.

Both Article 8(1)(c) and Article 13(1) contain references to "Community" and so for the purposes of the EEA Agreement these references should be understood as references to the territories of the contracting parties. Since it acceded to the EEA on 1 May 1995 these territories have included Liechtenstein.

It is my view that the Swiss authorizations 545901 01 *(sic)* and 54630 01, which relate to the products identified in your applications, should be regarded as the first authorizations in the EEA by virtue of their effect in Liechtenstein. The simultaneous effect of a Swiss authorisation in both Switzerland and Liechtenstein arises from a provision in Liechtenstein law, specifically Section 7(2) of the Drug and Medications law of which I enclose an excerpt."

The applicants' submission at the hearing

29 At the hearing Mr Grubb began his submission to me by explaining that the two medicinal products in these cases are not major products but nevertheless a loss of ten months or six months of supplementary protection taken over the whole of the EU could well cost the applicants tens of millions of euros. He also informed me that the majority (if not all apart from the Netherlands) of EU Member States now adopt the same position as the examiner in these cases. In short, Liechtenstein is an EEA Member State, Swiss marketing authorization applies to Liechtenstein and therefore a Swiss marketing authorization can be the first in the EEA. Mr Grubb pointed out that it would cost the research-based pharmaceutical industry hundreds of millions of euros over the next couple of decades, if this position were maintained. However, Mr Grubb thought that the stance adopted by the examiner and by most EU Member States was seriously flawed because it fails to take into account the unique dual status of Liechtenstein simultaneously as a Member of the Customs Union or Zollfereine with Switzerland and also as a EEA Member State. In his view a Swiss marketing authorization affects Liechtenstein only in its capacity as a Member of the Swiss Customs Union, and not in its capacity as a Contracting Party to the Agreement. Mr Grubb's submission to me at the hearing was based on three separate lines of argument:

(i) Decision No. 7/94 of the EEA Joint Committee established an EEA version of the Regulation which is applicable only to the EEA/EFTA Member States, by allowing a marketing authorization in an EEA/EFTA Member State to form a basis for a certificate according to Article 3(b) of the Regulation, even though the authorization was not one in accordance with either of the relevant EEC Directives specified in that Article. However, Article 13 is not adapted by Decision No. 7/94 because this Article does not refer to Article 3(b), and so a marketing authorization in an EEA/EFTA Member State cannot be used as the starting point for calculating the duration of a certificate;

(ii) irrespective of whether Protocol 1 to the Agreement operates as maintained by the examiner, the Regulation has no effect on Liechtenstein in view of the EEA Council Decision No. 1/95 which exempts Liechtenstein from the obligation to deliver certificates as laid down in the Regulation. In other words, the EEA version of the Regulation does not extend to Liechtenstein and so Article 13 cannot be affected by some deemed marketing authorization in Liechtenstein; and

(iii) a marketing authorization approved in Switzerland and extended to Liechtenstein is not an approval to put the product on the market in the EEA, but only one to put the product on the market in Liechtenstein in its capacity as a Member of the Swiss Customs Union. As a consequence there is no free movement of medicinal products, covered only by a Swiss marketing authorization, between Liechtenstein and the other EEA Member States.

At the Hearing each of these arguments was considered in some detail and I will deal with them in turn.

Is a marketing authorization in an EEA/EFTA Member State relevant for the purposes of Article 13 of the Regulation?

30 Decision No. 7/94 of the EEA Joint Committee adds to Annex XVII to the Agreement the requirement that the Regulation should be read with the following adaptation to Article 3(b) (my emphasis):

> "; for the purpose of this subparagraph **and the Articles which refer to it**, an authorization to place the product on the market granted in accordance with the national legislation of the EFTA State shall be treated as an authorization granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC, as appropriate.";

Various Articles in the Regulation refer back to Article 3(b) and all of these concern the procedure for applying for a certificate. Article 13 which concerns the duration of the certificate, is not one of them. On this basis Mr Grubb argued that although Decision No. 7/94 established an EEA version of the Regulation for the EEA/EFTA Member States, which enabled authorizations granted in accordance with the national legislation of these States to form the basis for certificates, it did not provide a mandate for treating such authorizations as "an authorization granted in accordance with Directive 65/65/EEC or Directive 81/851/EEC" for the purposes of determining the duration of a certificate according to Article 13.

31 Mr Grubb sought to reinforce his argument that Decision No. 7/94 established an EEA version of the Regulation which is applicable only to the EEA/EFTA Member States, by referring me to a decision of the Netherlands Industrial Property Office in connection with an application for a certificate for a medicinal product corresponding to "Basiliximab". Shortly before the hearing Mr Grubb supplied a letter from the Netherlands Office in which the relevance of the Swiss authorization was considered. According to a translation of this letter, also provided by Mr Grubb, the Netherlands Office took the view that there are two distinct versions of the Regulation, one which is applicable to EU Member States and another which is applicable to the non-EU EEA Member States, in other words to the EEA/EFTA Member States. The Netherlands Office based this view on the effect of Decision No. 7/94 which applied the Regulation to the EEA/EFTA Member States, which initially included Austria, Finland and Sweden, and the effect of the later Council Decision 95/1/EC which amended the Regulation on accession of Austria, Finland and Sweden to the EU. The Netherlands Office considered that amendment of the Regulation on accession of Austria, Finland and Sweden to the EU would not have been necessary if the EEA version already regarded these States as "Community" States in accordance with Protocol 1 to the Agreement.

32 In yet further support for his view that there are two distinguishable versions of the Regulation, Mr Grubb drew my attention to *Yamanouchi Pharmaceuticals Co. Ltd. v. Comptroller-General of Patents, Designs and Trade Marks (Case C-110/95)* [1997] RPC 844 ("*Yamanouchi*") and in particular the Opinion of Advocate General Fennelly. I do not believe I need consider here the facts of the *Yamanouchi* case because the point made by Mr Grubb does not hang on them. It is the Advocate General's references in his Opinion to "the EEA version of the Regulation" and in particular his comments concerning this version at paragraphs 29 to 33 of his Opinion, which Mr Grubb considered relevant (my emphasis):

> "29. The applicants further argue that, unlike Article 3, Article 19 does not require that the basic patent be valid at the date of the application, in order to demonstrate

that Article 19 cannot be read subject to Article 3. This argument begs, rather than resolves, the question of whether Article 19 is a material, or merely a temporal, derogation from the remainder of the Regulation. It adds nothing to the other arguments of the applicants I have already rejected. Rather it draws further attention to the anomaly which would thereby be created. **Such anomalies are carefully avoided in the EEA version,** which I will now discuss.

30. **The applicants have sought to rely on the EEA version of the Regulation set out in paragraph 5 of Annex 15 to Decision No. 7/94 of the EEA Joint Committee.** None of the parties to the present proceedings addressed the issue of whether it is appropriate to interpret a measure based on the EEC/EC Treaty in the light of a later measure which was based on an international agreement concluded by the Community, the Member States and a number of third countries. In my view, resort to such a technique of interpretation should be approached with caution; even if the provisions in question had been identical, the differences in character between the EEC/EC Treaty and the EEA Agreement are notorious.

31. **Here the applicants are relying on certain amendments made to the text of the Regulation with a view to applying it as part of the common rules which apply to products and services by virtue of Article 65(2) of the Agreement. They rely in particular on the fact that the EEA version of the Regulation** contains specific provisions covering the situation where the patent expires before an application under Article 19 is made. From this they conclude that '[in] the EEA version, Article 19 *must* operate independently of Article 31[, and that it] follows that the same applies in the case of the EC version'; the fact that the (original) EEC version contains no such provisions is dismissed as 'not material'.

32. This argument seems to be based on a misunderstanding of the legal effect and function of the amendments in question. Article 19(1) **of the EEA Regulation** provides in effect that an SPC may be granted in the EFTA States for products protected by a valid patent on 2 January 1993 and for which a marketing authorization has been granted after 1 January 1985. Under Article 19(2), applications for such transitional EFTA-SPCs must be made within six months of the coming into force **of the EEA Regulation**, on 1 July 1994 (Article 3 of Decision No. 7/94 of the EEA Joint Committee). Article 19(3) provides for the special situation of products in respect of which the basic patent has expired **between the coming into force of the EEC Regulation and that of the EEA Regulation**; an SPC may be granted for such products, in accordance with Article 19(1), but only with effect from the date of publication of the application for the certificate (Article 19(3)) and only if the application is made within two months of the entry into force **of the EEA Regulation** (Article 19(4)). These provisions therefore seek at the same time to harmonise the arrangements regarding SPCs in all the EEA Member States, while avoiding any retroactive effect for SPCs granted for products whose basic patent had expired before the entry into force **of the EEA Regulation** (Article 19(3)), and safeguarding the interests of third parties acting in good faith after the basic patent had expired (Article 19(5)).

33. The applicants' submission that Article 19 **of the EEA Regulation operates independently of Article 3 of the same Regulation** is therefore, in my view,

completely unfounded, **and their suggested interpretation of the EEC Regulation** in the light of these provisions must be rejected."

33 My understanding of Mr Grubb's position was that he does not dispute that before Decision No. 7/94 of the EEA Joint Committee came into force, the expiry date of a certificate in an EU Member State was properly determined under Article 13 of the Regulation on the basis of the date of the first authorization to place the product in question on the market in the Community. Therefore, the question I must answer is what impact did Decision No. 7/94 have on the duration of a certificate in an EU Member State, such as the United Kingdom?

34 To answer this question I need to consider the effect of Decision No. 7/94. As an act referred to in this Decision at Point 6 of Annex 15, the Regulation became binding upon all Contracting Parties to the Agreement by virtue of Article 7 of the Agreement. More particularly, in accordance with Article 7(a) of the Agreement, as an act corresponding to an EEC Regulation, it became part of the internal legal order of the Contracting Parties who at that time were the then twelve EU Member States and the EFTA Member States of Austria, Finland, Iceland, Norway and Sweden. However, extension of the Regulation to embrace the EEA/EFTA Member States, required some adaptation of the Regulation. Point 6 of Annex 15 requires that the Regulation should be read with certain specific adaptions for the purposes of the Agreement. In addition, Protocol 1 on horizontal adaptations to the Agreement requires that whenever acts refer to the territory of the "Community", the references shall for the purposes of the Agreement be understood to be references to the territories of the Contracting Parties as defined in Article 126 of the Agreement unless otherwise provided for in the respective Annex. No such other provision exists in Point 6 of Annex 15 and so it would appear that this aspect of Protocol 1 should apply to the EEA version of the Regulation but this is disputed by the applicants and is something I must decide.

35 Looking at the specific adaption of the Regulation made by Point 6 of Annex 15 and relied on by Mr Grubb to indicate that a marketing authorization in an EEA/EFTA Member State cannot be taken into account when determining the date of the first authorization to place the product on the market for the purpose of Article 13, I do not dispute that textually the adaptation to Article 3(b) of the Regulation does not extend to Article 13. However, it is well established that Community and international law should not be interpreted literally and that the correct approach to interpretation is a teleological one. On this point I also note that Protocol 1 on horizontal adaptations allows me to refer to the preamble of the Regulation to the extent necessary for the proper interpretation and application of the Regulation within the framework of the Agreement. Thus, could it be that on a teleological interpretation, the authorization referred to in Article 13 is one in accordance with either of the relevant Directives? If this were the case, it might be equally appropriate to interpret the adaptation of Article 3(b) of the Regulation by Decision No. 7/94 as extending to Article 13 so that a marketing authorization in an EEA/EFTA Member State should be treated as one in accordance with an appropriate one of the Directives for the purpose of determining the duration of a certificate.

36 As already noted there are a number of Articles in the Regulation, which include specific references to the authorization "referred to in Article 3(b)". However, there are other Articles, similar to Article 13(1), which simply refer to "the authorization" or "the first authorization", and there is even one Article (Article 14(d)) which refers directly to

authorization(s) "in accordance with Directive 65/65/EEC or Directive 81/851/EEC" so bypassing any cross-reference to Article 3(b). In my view it would help with the interpretation of Article 13 to consider how the unqualified references to "the authorization" should be interpreted in these other Articles. Thus, I propose to consider Article 4 of the Regulation, which deals with the subject matter of protection (my emphasis):

> "....., the protection conferred by a certificate shall extend only to the product covered by **the authorization to place the corresponding medicinal product on the market** and ....."

as well as Article 13(1) (my emphasis):

> "The certificate shall take effect ..... for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of **the first authorization to place the product on the market** in the Community ....."

37 A teleological interpretation requires that I should have regard to the objectives of the Regulation and for this I turn to its Recitals. Recital 3 identifies the issue addressed by the Regulation as one where there was an insufficient period of effective protection under patents for medicinal products due to the period that elapsed between the filing of an application for a patent for a new medicinal product and the authorization to place the product on the market. The solution emerges from Recital 7 and involves the creation of a supplementary protection certificate relating to a medicinal product for which marketing authorization has been granted. More particularly, according to Recital 8, the holder of both a patent and a certificate should be able to enjoy an overall maximum of fifteen years exclusivity from the time the product in question first obtains authorization to be placed on the market in the Community. Finally, Recital 9 recognises all the interests at stake by strictly confining the protection granted to the product which obtained authorization to be placed on the market as a medicinal product. In all these Recitals no emphasis is placed on the legal basis of the authorization which lay at the heart of the issue addressed by the Regulation, of the authorization on which the solution was based, or of the authorization which provided the basis for respecting all interests at stake. Furthermore, I note that the European Court of Justice ("ECJ") in the *Yamanouchi* case which Mr Grubb drew to my attention, recognised a connection between the authorizations referred to in Article 3(b) and Article 4 at paragraph 26 of its judgment (my emphasis):

> "26. On the contrary, **it is the authorization referred to in Article 3(b) of the regulation which confers entitlement to the certificate. That principle is borne out by Article 4, according to which the protection conferred by the certificate extends only to the product covered by the marketing authorization in respect of the corresponding medicinal product.** Entitlement to the certificate is strictly linked, therefore, to the existence of a marketing authorization granted in the Member State in which the application is submitted and to the date of that application."

38 Thus, I am led to conclude that the legal basis of "the authorization" which is referred to in Article 4, and of "the first authorization" which is referred to in Article 13(1), should not be distinguished from that of the authorization referred to in Article 3(b). As a consequence all these authorizations should be treated as being in accordance with either

Directive 65/65/EEC or Directive 81/851/EEC as with the authorization mentioned in Article 3(b). On the same basis it is also my view that a teleological interpretation of the Regulation, as specifically adapted for the purpose of the Agreement by Decision No. 7/94, should not distinguish "the first authorization" referred to in Article 13(1) of the Regulation from one granted in accordance with either of the relevant Directives or one granted in accordance with the national legislation of an EEA/EFTA Member State and treated as an authorization in accordance with the appropriate Directive. It follows that although the textual adaptation to Article 3(b) does not extend to Article 13 for the purposes of the EEA version of the Regulation, I am unable to accept the inference Mr Grubb draws from this, that is an authorization, granted in accordance with the national legislation of an EEA/EFTA Member State, cannot be used to determine the duration of a certificate.

39 However, in case I am wrong in this, I should consider how Article 13 might be interpreted if, as Mr Grubb argued, an authorization, granted in accordance with the national legislation of an EEA/EFTA Member State, cannot be treated as one in accordance with either of the relevant Directives for the purposes of Article 13. As I have already noted, the authorization referred to in Article 13(1) is not specifically described as one which has been granted in accordance with one or other of the relevant Directives. Thus, on an alternative view, this might mean that a marketing authorization not complying with either Directive could nevertheless provide a proper basis for calculating the duration of a certificate. At the hearing I sought Mr Grubb's view on this matter but apart from recognising it as an issue I must address, he was unable to help me.

40 I will begin my consideration of this alternative view of Article 13 by looking at the purposes of the authorizations referred to in Articles 3(b) and 13(1). I am assisted in this by the judgment of the ECJ in the *Yamanouchi* case from which I have already quoted paragraph 26. At paragraphs 23 to 26 the ECJ states (my emphasis):

> "23 As is apparent from Article 13, the condition imposed by Article 19(1) in respect of the first marketing authorization in the Community is necessary only for the purposes of determining the duration of the certificate, Thus, Article 8(1)(a)(iv) and (c) and Article 9(2)(e) of the regulation lay down an obligation to provide information concerning the first marketing authorization in support of an application for a certificate, in order to ensure that the competent industrial property authority receiving the application has available to it the information needed in order to determine the duration of the certificate. Article 11(1)(e) provides that that information is to appear in the notification of the grant of the certificate which is published for the information of the public.
>
> 24 However, the effect of Articles 8(1)(a)(iv) and (b), 9(2)(d) and 11(1)(d) is that the first marketing authorization in the Community is not intended to take the place of the marketing authorization provided for in Article 3(b) of the regulation, that is to say, the authorization granted by the Member State in which the application is submitted; instead, it constitutes a further condition applying in the event that the latter authorization is not the first authorization to place the product on the market as a medicinal product in the Community. **The first marketing authorization in the Community therefore serves a purely temporal purpose**.

25. By referring to the first marketing authorization in the Community, the regulation is designed to exclude the possibility that, in Member States in which there has been significant delay in the grant of authorization to place a given product on the market, a certificate can still be granted even though that is no longer possible in the other Member States in which the authorization in question has been granted before expiry of the deadline. The regulation is thus intended to prevent the grant of certificates whose duration varies from one Member State to another. In those circumstances, Article 19(1) cannot be construed as meaning that the existence of an authorization in the Member State in which the certificate is sought is of no relevance.

26. **On the contrary, it is the authorization referred to in Article 3(b) of the regulation which confers entitlement to the certificate.** That principle is borne out by Article 4, according to which the protection conferred by the certificate extends only to the product covered by the marketing authorization in respect of the corresponding medicinal product. Entitlement to the certificate is strictly linked, therefore, to the existence of a marketing authorization granted in the Member State in which the application is submitted and to the date of that application."

Thus in summary, the first marketing authorization in the Community has **a purely temporal function** for calculating the duration of a certificate, whereas the authorization referred to in Article 3(b) **confers entitlement** to the certificate and defines the extent of protection conferred by a certificate.

41 I should now turn to consider the temporal nature of the first marketing authorization in the Community. Once again I am drawn to Recital 3 which explains that when the Regulation was adopted, the time taken to obtain marketing authorization for a medicinal product was such that the period of effective protection under the patent was insufficient to cover the investment put into research. As already mentioned, Recital 8 states how this issue was to be addressed. The solution was to provide a certain maximum period of exclusivity to the holder of both a patent and a supplementary protection certificate, running from the time the medicinal product in question first obtained authorization to be placed on the market in the Community. In other words, the duration of the supplementary period of exclusivity was to depend on when the patent holder was first allowed to market the medicinal product in the Community and so begin to recover the investment put into research. Recital 8, like Article 13(1), is silent concerning the legal basis under which the authorization should be granted, and I can see no overriding reason on this alternative view of Article 13 why the first authorization in the Community must be one in accordance with Directive 65/65/EEC or Directive 81/851/EEC. It should then not be significant nor surprising that Decision No. 7/94 did not adapt Article 13 of the Regulation, along with Article 3(b) and the Articles which refer to it, so that a marketing authorization granted in accordance with the national legislation of an EEA/EFTA Member State shall be treated as one granted in accordance with the appropriate Directive for the purpose of calculating the duration of a certificate. On this alternative view of Article 13 it is my opinion that any authorization which is granted in accordance with the national legislation of an EEA/EFTA Member State and which allows the patent holder to begin recovering the investment in the patented medicinal product, could be used as a basis for determining the duration of a certificate.

42 Mr Grubb's submission was also that there is an EEA version of the Regulation which is

applicable only to the EEA/EFTA Member States, and in *Yamanouchi* Advocate General Fennelly certainly did refer to "the EEA Regulation" and "the EEC Regulation". As a matter of Community and international law it seems to me that there are two versions of the Regulation which exist side by side. As Community legislation, the EEC version is binding on all EU Member States and I do not believe that Mr Grubb sought to persuade me otherwise. On the other hand the EEA version is part of the internal legal order of all EEA Member States (with the exception of Liechtenstein due to the exemption allowed by Decision No. 1/95 of the EEA Council) by virtue with Article 7(a) of the Agreement. From this I must conclude that the EEA version is applicable to EU Member States and EEA/EFTA Member States alike and not just to the EEA/EFTA States, as Mr Grubb argued. Moreover, unlike Mr Grubb, I do not accept that amendment of the EEC version to accommodate Austria, Finland and Sweden on their accession to the EU has any significance for the interpretation of the EEA version. At the time of accession of these States to the EU, the EEC version would have been part of their so-called *acquis communautaire,* despite their existing legal obligations under the EEA version, and the amendment of the EEC version to take account of this *acquis* carries no implications for how references to the "Community" in the Regulation should be interpreted in the context of the Agreement.

43 Indeed, if I accepted Mr Grubb's submission that EU Member States should apply only the EEC version and that the EEA version, which was specifically adapted for EEA/EFTA Member States, should apply only to these States, it would in my view lead to a situation at odds with at least one of the principles underlying the Regulation. In considering Mr Grubb's submission I am drawn once again to Recital 8 of the Regulation. This Recital recognises that the duration of the certificate should be such as to provide adequate effective protection with the holder of both a patent and a certificate being able to enjoy an overall maximum of fifteen years exclusivity from the time the medicinal product in question first obtains authorization to be placed on the market. If I follow Mr Grubb's line of argument, the EEC version of the Regulation would operate for the EU Member States as it did at its outset with the first marketing authorization for a medicinal product in the Community being used to ensure that certificates granted in EU Member States have the same duration. Any earlier marketing authorization in an EEA/EFTA Member State would be disregarded for this purpose. Consider now how the EEA version of the Regulation would operate for the EEA/EFTA Member States alone. Mr Grubb did not expand on this at the hearing but in line with his argument, I will take it that the EEA/EFTA Member States cannot be regarded as "Community" States for the EEA version, despite the adaptation provided for in Protocol 1 to the Agreement. Therefore, the duration of a certificate in any EEA/EFTA Member State would be calculated by applying Article 13 of the Regulation on the basis of the first marketing authorization in the Community, that is in an EU Member State. What then would be the consequence if a marketing authorization had been granted in an EEA/EFTA Member State before the first marketing authorization in any EU Member State? It is easier to answer this question by considering a specific example. Take a situation where a marketing authorization for a medicinal product was granted in an EEA/EFTA Member State nine years after the patent application was lodged but the first marketing authorization in any EU Member State was granted after ten years. Calculated on the basis of the first marketing authorization in the EU, the duration of a certificate in any EU Member State or any EEA/EFTA Member State would be the maximum five years permitted by Article 13(2). This result is important because as stated, for example, by the ECJ in the passage from *Yamanouchi* I have quoted above:

> "The regulation is thus intended to prevent the grant of certificates whose duration

varies from one Member State to another."

However, in the EEA/EFTA Member State where the marketing authorization was granted after nine years, the holder of the patent and certificate would enjoy sixteen years of exclusivity from the time the medicinal product obtained marketing authorization in that State. This is one year more than the period of exclusivity under the patent and certificate recognised by the Regulation as adequate and effective. Thus, if the Regulation were applied without taking account of marketing authorizations granted in EEA/EFTA Member States, this principle on which the Regulation was founded would be undermined. On the other hand if the reference to the territory of the "Community" in Article 13(1) of the Regulation is taken to refer to the territories of all EEA Member States in line with Protocol 1 to the Agreement, a first marketing authorization in an EEA/EFTA Member State could be used as the basis for calculating the period of a certificate in any EEA Member State. This would lead to a situation wholly consistent with the principles of the Regulation where all certificates granted in the EEA would have the same duration and the period of exclusivity under a patent and certificate would never exceed fifteen years.

44 Therefore, on the basis of either of my alternative interpretations of Article 13, I cannot accept Mr Grubb's submission that a marketing authorization for an EEA/EFTA Member State should be disregarded for the purpose of calculating the duration of a certificate in an EU or EEA/EFTA Member State. Moreover, if the EEA version of the Regulation is to satisfy the principles on which it is based, I believe that it must be applied uniformly by all EEA Member States. I also consider that the amendment of the EEC version of the Regulation on accession of Austria, Finland and Sweden to the EU has no significance whatsoever for the way references in the Regulation to the territory of the "Community" should be read in the context of the EEA version. Thus, I can only conclude that Protocol 1 should apply to Article 13(1) of the EEA version of the Regulation so that the first marketing authorization in the EEA should be the basis for calculating the duration of a certificate granted in any EEA Member State.

45 In the event that this was to be my conclusion in response to his first line of argument, Mr Grubb relied on his second and third arguments to persuade me that Liechtenstein's status as an EEA Member Sate was a special one and as a result an authorization to market a medicinal product in Liechtenstein should not have a bearing on the duration of certificates in other EEA Member States. I will now consider these further arguments.

Does Liechtenstein's exemption from the obligation to grant certificates mean that a first marketing authorization in Liechtenstein has no bearing on the duration of certificates granted in other EEA States?

46 The skeleton argument provided by Mr Grubb prior to the hearing explains that Liechtenstein is unique among the EEA Member States in that it does not grant its own patents or certificates. Thus, Annex 10 to Decision No. 1/95 of the EEA Council contains the adaptation that Liechtenstein shall not deliver any certificates for medicinal products as laid down in the Regulation. However, this adaptation does not address whether a marketing authorization to place a medicinal product on the market in Liechtenstein has a role to play in the operation of the Regulation for the rest of the EEA. According to Mr Grubb this was not spelt out in Decision No. 1/95 because the Regulation simply does not apply to Liechtenstein. Mr Grubb took the view that since Liechtenstein was excluded from the EEA version of the Regulation, the corollary was that Liechtenstein should be irrelevant to the operation of the

Regulation. Therefore, a marketing authorization to place a medicinal product on the market in Liechtenstein should have no bearing on the operation of the Regulation in other EEA Member States.

47 Following Decision No. 1/95, supplementary protection certificates for medicinal products became available in Switzerland from September 1995. Some time later still a Decision of the EEA Joint Committee No. 59/97 of 31 July 1997 amended Annex XVII to the EEA Agreement to include Regulation (EC) No. 1610/96 concerning the creation of a supplementary protection certificate for plant protection products. Once again Liechtenstein was exempt from delivering these supplementary certificates. However, the amendment also spelt out that:

> "....., certificates for plant protection products delivered by Switzerland shall take effect in Liechtenstein as from the entry into force of the relevant legislation in Switzerland."

Mr Grubb took this as delivering a clear message that so far as supplementary protection certificates are concerned, the system operating in Liechtenstein is separate from and independent of that operating within the rest of the EEA.

48 From what Mr Grubb told me at the hearing it seems that the Swiss provisions, relating to supplementary protection for medicinal products as they extend to Liechtenstein, are in line with the Regulation, except that the duration of a Swiss supplementary protection certificate is calculated on the basis of the first authorization to market the medicinal product in Switzerland. On this basis Mr Grubb made the point in his skeleton that if a Swiss marketing authorization is granted later than the first in the EEA (and less than ten years from the patent filing) for the same medicinal product, the Swiss supplementary protection certificate would expire after any granted in an EU Member State, Norway or Iceland. In other words, the duration of the Swiss supplementary protection certificate is not shortened in view of an earlier approval in the EEA. Mr Grubb then posed the question "Why should certificates within the whole Community be shortened in view of an earlier approval in Switzerland, which although extending to Liechtenstein has no effect whatsoever in the EU?"

49 It is clear to me that Decision No. 1/95 removes from Liechtenstein an obligation under the Agreement to grant certificates under the EEA version of the Regulation. Thus, there is no entitlement in Liechtenstein to a certificate under this version of the Regulation. However, it is important in my view not to confuse this issue of entitlement with the purely temporal matter of calculating the duration of certificates. Because Decision No. 1/95 does not address this latter matter in the context of Liechtenstein's position as a Contracting Party to the Agreement, I believe that I must look once more to the principles upon which the Regulation and the Agreement were founded to decide if a marketing authorization effective in Liechtenstein should be used as a basis for determining the duration of a certificate elsewhere in the EEA.

50 I have already noted from a consideration of Recitals 6 and 7 that the Regulation aims to provide a uniform solution by ensuring that certificates are granted in each Member State under the same conditions, so as to avoid the creation of obstacles to the free movement of medicinal products. From Article 1(2)(a) of the Agreement and Article 1(2) of Protocol 28 to the Agreement it is clear that the free movement of goods is also of central importance to the Agreement. Therefore, when interpreting the provisions of the EEA version of the

Regulation I should aim to do so in a way which does not create barriers to the free movement of medicinal products within the EEA. In my view, keeping in mind the provision of the Agreement (Article 2 of Protocol 28) which deals with exhaustion of intellectual property rights, the duration of certificates is one aspect of the Regulation which has implications for the free movement of medicinal products, for example generic medicinal products. Closely related to this and as recognised by the ECJ in *Yamanouchi*, the Regulation is intended to prevent the grant of certificates whose duration varies from one Member States to another. This objective is achieved by calculating the duration of certificates for the same medicinal products on the basis of a common date, which in turn leads to certificates expiring on the same date where the associated patents also expire on a common date. It is against this background that I should examine the implications of using the date of the first authorization to market a medicinal product in Liechtenstein as a basis for calculating the duration of certificates elsewhere in the EEA.

51 If a Swiss marketing authorization effective in Liechtenstein was granted before any marketing authorization elsewhere in the EEA and if this authorization was recognised by all EEA Member States as providing the basis for calculating the duration of certificates, certificates granted for Liechtenstein and in the rest of the EEA would expire on the same date. In my opinion, this would sit well with the aim of safeguarding the free movement of goods within the EEA because there would be no certificates in force after that date to prevent the free circulation of generic equivalents. On the other hand, as Mr Grubb pointed out at the hearing, supplementary protection in Liechtenstein, based on a Swiss marketing authorization, could expire after certificates for the same medicinal product in the rest of the EEA when the Swiss marketing authorization was granted after the first in the EEA. The example provided by Mr Grubb shows that reliance on the first marketing authorization anywhere in the EEA (Liechtenstein included) as the basis for calculating the duration of certificates in all EEA Member States, apart from Liechtenstein, could lead to situations which would create obstacles to the free movement of medicinal products between Liechtenstein and the rest of the EEA. However, Mr Grubb's submission that a Swiss marketing authorization which has effect in Liechtenstein, should never be used as a basis, leads to an equally unsatisfactory outcome because Swiss supplementary protection extended to Liechtenstein would sometimes expire on a different date from that of certificates granted in other EEA Member States for the same product. Thus, the solution proposed by Mr Grubb also does not sit comfortably with the aim of avoiding the creation of obstacles to the free movement of goods within the EEA. It seems to me that by exempting Liechtenstein from the obligation to grant certificates under the EEA version of the Regulation, an anomaly has been created where the aim of the Regulation to avoid the creation of obstacles to the free movement of medicinal products, cannot be satisfied fully. At the hearing Mr Grubb suggested that in view of this apparent anomaly, it would not be useful for my decision to turn on the point that all certificates within the EEA (including Liechtenstein) should expire on the same date. I agree since I do not see how I can reach any clear conclusion on this basis one way or the other.

52 There remains Recital 8 of the Regulation which I considered when assessing Mr Grubb's first line of argument. There I took the view that the Regulation aims to provide a period of exclusivity to the holder of both a patent and a certificate which runs from the time the patent holder is permitted to begin recovering the investment made in a medicinal product. For the EEA version of the Regulation I have also already concluded that the period of exclusivity should run from the date of the first marketing authorization in the EEA. If Liechtenstein were the first EEA Member State in which the patent holder could start recovering the

investment put in to research, why should a marketing authorization effective in Liechtenstein not be the basis for calculating the duration of certificates in other EEA States?

53 At the hearing Mr Grubb urged me not to lose sight of the fact that the Regulation is intended to benefit the research based pharmaceutical industry, as established by Recitals 1 to 5, but if Liechtenstein with its 32,000 inhabitants were put on an equal footing with Germany, a major part of the benefit to come from the Regulation would be lost. In Mr Grubb's view this could never have been the intention. I accept that the Regulation was introduced for the benefit of the research based pharmaceutical industry but this objective should not be viewed in isolation. Importantly, Recital 9 indicates the need to balance this benefit against other interests at stake, such as those of public health, when settling the maximum period of protection under a certificate. Moreover, as I have already observed above, the simplicity of the system for calculating the duration of certificates results in a degree of rough justice and I can find no suggestion that the size of the market for medicinal products is something I should take into account when considering whether a first marketing authorization in a particular EEA Member State should be the basis for calculating the term of a certificate. Therefore, I am not persuaded that the relatively small market for medicinal products in Liechtenstein has any bearing on the matter I must decide. Indeed, nothing in Mr Grubb's argument convinces me that the date, on which a patent owner can begin to recover in the EEA the investment made in the medicinal product, should not be the date used for calculating the duration of a certificate. I cannot then agree with Mr Grubb that the provision in Decision No. 1/95, which removes entitlement to certificates in Liechtenstein under the EEA version of the Regulation, means that an authorization to market a medicinal product in Liechtenstein should not be used for calculating the duration of certificates in other EEA States.

Should a marketing authorization in Liechtenstein which precludes export of a medicinal product to other EEA Sates, be used to calculate the duration of certificates in the other States?

54 Finally I come to Mr Grubb's third line of argument which he described as his strongest at the hearing. Although Mr Grubb suggested that no sound conclusion could turn on the point that all certificates within the EEA should expire on the same date so as to safeguard the free movement of medicinal products, he stressed that the aim of the Agreement to respect the free movement of goods provides the key to the matter I must decide. In Mr Grubb's opinion, it was of no consequence that supplementary protection for a medicinal product in Liechtenstein might expire on a different date from certificates in the rest of the EEA. This was because the export of medicinal products, covered by a Swiss Marketing authorization, from Liechtenstein to the rest of the EEA is not allowed.

55 At the hearing I questioned Mr Grubb about the legal basis for this prohibition on the export of medicinal products with a Swiss marketing authorization from Liechtenstein to other EEA Member States. He thought that the relevant provisions might be part of the Liechtenstein law dealing with the authorization of medicinal products but was not certain at the time of the hearing. In view of this uncertainty, I allowed Mr Grubb a month to investigate the matter further and I invited him to supplement his arguments with a written submission when he was more certain of his ground.

56 Authorization to place medicinal products on the market in Liechtenstein can be obtained in two different ways. The first way involves obtaining a marketing authorization in Switzerland

which is extended to Liechtenstein by the operation of the Liechtenstein Heilmittelgesetz ("HMG"). The other way is an autonomous national approval procedure which involves applying for marketing authorization to the relevant authority in Liechtenstein under the Liechtenstein Arzneimittelgesetz ("AMG"). After the hearing the AMG and its translation were filed at Mr Grubb's request by Dr Kathryn Nicholls who is a patent attorney with the firm of patent agents, Mewburn Ellis, and a little while later Mr Grubb supplied a copy of the HMG and its translation. In an accompanying letter, dated 26 September 2002, Mr Grubb explained:

> "As discussed during the Hearing, the Arzneimittelgesetz contains provisions (articles 43 and 44) which place restrictions on the export to Switzerland of medicinal products marketed in Liechtenstein as a result of approval according to the AMG. Such restrictions, necessary to maintain the dual marketability system, have to be imposed by Liechtenstein, since there are no customs controls imposed by Switzerland on goods entering from Liechtenstein, the two countries being part of a customs union (Zollverein).
>
> It will be seen that the HMG contains no corresponding restrictions on the export to other EEA countries of medicinal products marketed in Liechtenstein as a result of approval in Switzerland. This is because there are customs controls on the borders of the Swiss/Liechtenstein Zollverein with EEA countries such as Austria, and these countries are therefore able to control imports of such products directly. Thus the lack of free movement of such goods between Liechtenstein and other EEA countries is not based on any Liechtenstein law, but on the provisions of Annex 2 of the EEA Council Decision 1/95 and Chapter XIII of Annex II of the EEA Agreement, as set out in Dr Büchel's letter of 6 August, 2001."

57 The letter from Dr Büchel, which Mr Grubb referred to in his letter of 26 September 2002 and which he had supplied with a translation before the hearing, was addressed to John Mogg, Director General of the European Commission. At the hearing Mr Grubb described Dr Büchel's letter as setting out the position of the Liechtenstein Government. However, the copy of the letter which Mr Grubb supplied, has no letter heading, is not signed and the only clue it gives about the identity of Dr Büchel comes at the end of the letter where Dr Büchel gives his title as "Chair of the EEA Committee". Nevertheless, since Mr Grubb relies on Dr Büchel's letter for an explanation of the basis for the lack of free movement of medicinal products authorised under the HMG between Liechtenstein and the other EEA States, I think it is useful to quote the relevant part of Dr Büchel's letter here. Dr Büchel begins by referring to Decision No. 1/95 which excludes Liechtenstein from granting certificates under the EEA version the Regulation, and continues:

> "This special rule of the EEA law regarding supplementary certificates in Liechtenstein is a consequence of the system of the so called parallel marketability that is laid down in Annex 2 to the EEA Council's Decision 1/95 and that applies to all product categories of Annex II to the EEA-Agreement, i.e. also to medicinal products (Chapter XIII of Annex II to the EEA-Agreement): "On Liechtenstein's market, Liechtenstein may apply to products falling under the legal instruments listed in this Annex Swiss technical regulations and rules that arise from its regional union with Switzerland parallel to the provisions for the implementation of the legal instruments to which this Annex refers. In the case of exports from Liechtenstein into the area of the other parties to this Agreement, stipulations in this Agreement or in other

referenced legal instruments regarding the free circulation of products only apply to products complying with the legal instruments referred to in this Annex."

The area of Liechtenstein (and only Liechtenstein) is consequently at the intersection of two economic areas. For this reason, Liechtenstein also created two different legal foundations for the grant of marketing authorizations for medicinal products, i.e. on the one hand the Medicinal Products Code (Heilmittelgesetz, HMG) for authorizations with effect for the economic area of Switzerland-Liechtenstein, and on the other hand the EEA-Pharmaceutics Code (Arzneimittelgesetz, EEA-AMG) with effect for the EEA. Considering their validity, the corresponding authorizations are - according to the above-mentioned Decision 1/95 - limited to the respective economic and effective areas, and legal consequences created by the authorizations shall therefore be judged and treated separately. This is the consequent result of applying the system of parallel marketability, according to which medicinal products, which are approved on the basis of Article 7(2) of the Medicinal Products Code (HMG), do not have to comply with the relevant legal instruments of the EEA-Agreement but only with Swiss regulations and standards. Against this background, the only possible consequence is that the effects of such "Swiss marketing authorizations" are limited to the economic area Switzerland-Liechtenstein.

Even in practice, no problems arise for the remaining economic areas of the EEA with this grant of the "parallel marketing authorization" for medicinal products in Liechtenstein's economic area - as well as for other products of Annex II EEA-Agreement - since Liechtenstein prevents the circumvention of the circulation rules with the aid of a market supervision and control system."

58 The adaptation to Annex II to the Agreement made by EEA Council Decision No. 1/95 is not quite as quoted in the translation of Dr Büchel's letter. The paragraph added by this Decision reads:

"For products covered by the acts referred to in this Annex, Liechtenstein may apply Swiss technical regulations and standards deriving from its regional union with Switzerland on the Liechtenstein market in parallel with legislation implementing the acts referred to in this Annex. Provisions on the free movement of goods contained in this Agreement or in acts referred to shall be applicable to exports from Liechtenstein to the other Contracting Parties only to products in conformity with the acts referred to in this Annex."

On checking the acts referred to in Annex II, I note that in Chapter XIII (Medicinal Products) of the Annex, the reference to Council Directive 65/65/EEC was deleted by Decision No. 82/2002 of the EEA Joint Committee. On further investigation I discovered that Council Directive 65/65/EEC had itself been consolidated in and repealed by Directive 2001/83/EC of the European Parliament and of the Council. Nevertheless, Directive 2001/83/EC requires that references to Directive 65/65/EEC shall be construed as references to Directive 2001/83/EC. I also discovered that a reference to this consolidating Directive 2001/83/EC had ben inserted in Chapter XIII of Annex II to the Agreement by Decision No. 82/2002 of the EEA Joint Committee. Thus, it does appear that the provisions on the free movement of goods contained in the Agreement were and are still only applicable to exports from Liechtenstein of medicinal products which have been authorized in Liechtenstein under its AMG law. The medicinal products which are the subjects of the applications for certificates

in these cases, were authorized in Liechtenstein under its HMG law and so the provisions in the Agreement on the free movement of goods do not seem to apply to them.

59 Although Mr Grubb described his third argument as his strongest, I am not convinced that it helps me in the matter I must decide. My reasons for taking this view stem from the Regulation itself and in particular Recital 6 which explains the relationship between supplementary protection and the establishment and functioning of the internal market. To recap this Recital makes clear that one of the aims of the Regulation was to establish a uniform system of supplementary protection at Community level and so prevent 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. Thus, as I have already noted above, when interpreting the provisions of the Regulation, I believe that I am bound to try and do so in a way which avoids certificates creating obstacles to the free movement of medicinal products. However, in my view it was not an aim of the Regulation itself to establish the free movement of such products; this would depend on rules in addition to those relating to supplementary protection. Furthermore, I do not believe that the implications for the free movement of medicinal products, which may arise from such other rules, have any bearing on the way I should interpret the Regulation. Thus, it seems to me that the restriction on the export from Liechtenstein to the other EEA Member States of medicinal products, authorized in Liechtenstein under its HMG law, is a matter that solely concerns the technical standards for the grant of marketing authorizations and does not bear on whether or not such an authorization could provide the basis for calculating the duration of certificates in these other EEA Member States. I must therefore dismiss Mr Grubb's third line of argument.

Summary and conclusions

60 I have now considered each of Mr Grubb's three lines of argument and have reached the following conclusions:

(a) Point 8 of Protocol 1 on horizontal adaptations to the Agreement applies to Article 13(1) of the EEA version of the Regulation in such a way that the reference in that Article to the territory of the "Community" should be understood as a reference to the territories of the Contracting Parties to the Agreement. Thus, an authorization to place a medicinal product on the market, granted in accordance with the national legislation of an EEA/EFTA State, is relevant for the purposes of Article 13(1) of the Regulation if it is the first in the EEA;

(b) a marketing authorization, granted by the Swiss authorities but effective in Liechtenstein under its HMG law, can be relevant for the purpose of Article 13(1) of the Regulation even though Annex 10 to Decision No. 1/95 of the EEA Council requires that Liechtenstein shall not deliver certificates for medicinal products as laid down in the Regulation; and

(c) the adaptation to Annex II to the Agreement made by EEA Council Decision No. 1/95, which requires that the provisions on the free movement of goods contained in the Agreement or in acts referred to shall be applicable to exports from Liechtenstein to the other Contracting Parties only to products in conformity with the acts referred to in Annex II, has no bearing on the question whether a marketing authorization in accordance with Liechtenstein's HMG law should be relevant for the

purpose of determining the duration of a certificate in another EEA Member State in accordance with Article 13(1) of the Regulation.

Furthermore, I consider that the examiner was correct to take the view that the Swiss authorizations which relate to the medicinal products identified in the applicants' applications, should be regarded as the first authorizations in the EEA for the purposes of Article 13(1) by virtue of their effect in Liechtenstein. Thus, I find that the latest expiry date of a certificate granted on application number SPC/GB/99/012 should be 6 April 2013 based on the date of Swiss Authorization No. 54630 01and that the latest expiry date of a certificate granted on application number SPC/GB/00/013 should be 21 January 2014 based on the date of Swiss Authorization No. 54594 01.

Appeal

61 This being a decision other than on a matter of procedure, any appeal against this decision shall be filed within six weeks after the date of this decision.

Dated this day of February 2003

R J WALKER
Deputy Director, acting for the comptroller

THE PATENT OFFICE