Intellectual Property Office

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COUNCIL REGULATION (EC) 469/2009
CONCERNING THE CREATION OF A
SUPPLEMENTARY PROTECTION CERTIFICATE
FOR MEDICINAL PRODUCTS

APPLICANT	Genzyme Corporation
ISSUE	Date of the first Marketing Authorisation for SPC/GB/04/031 and Duration of protection under Article 13
HEARING OFFICER	Dr L Cullen

DECISION

Introduction

1 This decision relates to an application which was filed on behalf of Genzyme Corporation (the "applicant") on 25 April 2012 for a six month extension to the period of protection provided by granted supplementary protection certificate (SPC) SPC/GB/04/031.

2 As part of their application, the agent acting on behalf of the applicant included a request for the term of the original SPC to be corrected because they considered that the expiry date of the SPC, 9 March 2019, currently stated on the Certificate of Grant for this SPC is incorrect. This request is the subject of this decision.

Background

3 The original SPC application was filed on 9 September 2004 and accorded number SPC/GB/04/031. It was granted to the applicant on 12 August 2005 and will come into force, subject to payment of the requisite fees, on 5 June 2015, i.e., the day after the basic patent (see below) expires.

4 The product for which SPC/GB/04/031 was granted is *colesevelam hydrochloride* and it is the active ingredient in a medicinal product marketed by the applicant under

the trade name *Cholestagel*[1]. Colesevelam hydrochloride is used to treat high levels of cholesterol in the blood ("hypercholesterolaemia")[2].

5 The application for a six-month extension to the duration of this SPC was made under Article 13(3) of Council Regulation (EC) 469/2009 concerning the creation of a supplementary protection certificate for medicinal products ("the SPC Regulation")[3], on the basis that the applicant had completed all necessary studies and requirements in compliance with an agreed paediatric investigation plan (PIP) and so was entitled to the reward under Article 36(1) of Council Regulation (EC) 1901/2006 on medicinal products for paediatric use ("the Paediatric Regulation")[4].

6 The basic patent upon which SPC/GB/04/031 relies is EP(UK) 0764174 B1, entitled "*Process for removing Bile Salts from a Patient and Alkylated Compositions therefor"*. It was filed on 5 June 1995, with a priority date of 10 June 1994, and was granted on 1 September 1999. The expiry date of the patent in the UK is 4 June 2015.

7 European marketing authorisation EU/1/03/268/001-003 for medicinal product *Cholestagel*, supplied in support of the application for SPC/GB/04/031, has a decision date of 10 March 2004. This marketing authorisation is valid for the UK. I note that Article 4 of this decision reads as follows *(my emphasis added in bold)*:

> "*The **period of validity of the authorization issued will be five years from the date of notification of this Decision**. It shall be renewable under the conditions laid down on Article 13(1) of Regulation (EEC) No. 2309/93.*"

8 This marketing authorisation was modified, in light of an agreed completed PIP, by decision of the European Commission, decision number C(2011)5946, dated 10 August 2011.

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[1] *Cholestagel* is a registered trade mark in the UK

[2] Colesevelam hydrochloride works by inactivating bile salts in the gut and causing them to be removed from the body (in the stool). Bile salts are made from cholesterol in the liver and are normally reused by the body. Colesevelam hydrochloride stops bile salts from being reused and the liver needs to remake more bile salts. In doing so, the liver takes cholesterol from the blood and thus lowers the amount of cholesterol in the blood; for further details see http://www.nhs.uk/medicine-guides/pages/MedicineOverview.aspx?condition=Cholesterol&medicine=Colesevelam%20hydrochloride&preparationColesevelam%20625mg%20tablets.

[3] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the Supplementary Protection Certificate for Medicinal Products, see OJ L 152, 16.6.2009, p 1. As explained in recital (1), this regulation codified and superseded Regulation (EEC) No. 1768/92 concerning the creation of a Supplementary Protection Certificate for Medicinal Products.

[4] For further details on how the reward works under the Paediatric regulation whereby the holder of an SPC can gain an additional six months extension to the duration of protection provided by the SPC for carrying out an approved set of clinical tests to determine efficacy in the paediatric population, see discussion in earlier IPO decisions explaining how the Paediatric regulation works – see BL O/035/09, Merck & Co. Inc, at http://www.ipo.gov.uk/pro-types/pro-patent/pro-p-os/p-challenge-decision-results-bl.htm?BL_Number=o03509&submit=Go+%BB and BL O/096/09, EI du Pont de Nemours & Co at http://www.ipo.gov.uk/pro-types/pro-patent/pro-p-os/p-challenge-decision-results-bl.htm?BL_Number=o09609&submit=Go+%BB.

9 As part of their request for an extension to the period of protection provided by the granted SPC, which the applicant filed on 25 April 2012, they also requested that the term of SPC/GB/04/031 should be corrected. By this the applicant meant that the SPC should expire either on 11 March 2019 or, one day later, on 12 March 2019, and not on 9 March 2019 as currently recorded on the Certificate of Grant for this SPC (and also on the Register[5]). Notification of a change of agent in relation to the basic patent and the SPC was also included with this request.

10 The applicant outlined why the expiry date of the duration of protection provided by the granted SPC should be changed:

(i) The applicant requested that the term of SPC/GB/04/031 should end on 11 March 2019 (before applying the six-month paediatric extension) because the expiry date of the SPC should have been calculated from the date of notification of the relevant marketing authorisation, which was 12 March 2004, and not, as at present, from the date of grant of this authorisation, which was 10 March 2004.

(ii) In addition, the applicant also considered that Article 3(1) of Regulation (EEC, Euratom) No. 1182/71 (the "Euratom Regulation") should be applied when determining the duration of the period of protection provided by SPC/GB/04/031. This would mean that the duration of protection provided by the SPC should end one day later on 12 March 2013. On this basis, the applicant argued that the additional six-month extension to the duration of protection provided by this SPC, as allowed under the Paediatric regulation in this case, should expire on 12 September 2019.

(iii) If the applicant is not correct in relation to (i) above, and the start date of the period of protection provided by SPC/GB/04/031 is 10 March 2004, the applicant still considers that, on the basis of the Euratom Regulation, the expiry date of the period of protection provided by this SPC (before applying the six-month paediatric extension) should be 11 March 2019. Applying the six-month paediatric extension, would give an expiry date for the SPC of 11 September 2019.

The Examiner's View

11 The view of the examiner, first expressed in his examination report dated 23 April 2013, was that the application for the extension to the term of protection of the SPC should be granted. Having considered the written arguments made by the applicant, the examiner's view was that the term of protection should not be corrected but should continue to end on 9 March 2013, and hence any extension would begin from this date. Thus the examiner considered that the six month extension to the term of protection provided by SPC/GB/04/031 should expire on 9 September 2013.

12 In support of his view, he directed the applicant's attention to Article 3(b) and Article 7(1) of the SPC Regulation which both refer to the date of grant and he considered

[5] See entry on IPSUM, the IPO Online Patent Information and Document Inspection Service for this EP patent and SPC number at http://www.ipo.gov.uk/p-find-spc-bypatent-results.htm?number=EP0764174.

that the same should apply to Article 13(1). Recital 9 of the SPC Regulation refers to when the medicinal product "obtains" authorisation and the date of grant could be said to be when the medicinal product "obtains" authorisation. The examiner also pointed out that the SPC Regulation had been amended since the original Regulation 1768/92 and that European legislators had found no need to refer to the date of notification of the medicinal product covered by the marketing authorisation in any of these amendments. The examiner also referred to the judgement of the Court of Justice of the European Union (CJEU) in case C-127/00 *Hässle AB v Ratiopharm GmbH* (hereafter *Hässle*), in which the CJEU concluded that the term "*first authorisation*" should be interpreted consistently to mean the same thing wherever it occurs in the SPC regulation and that this supported his view that the date of grant of the marketing authorisation should determine the term of an SPC.

13 The examiner explained his view that Article 3(1) of the Euratom Regulation did not apply to the SPC term determination in Article 13(1) and 13(2) of the SPC Regulation because the Euratom Regulation required a triggering date, such as X months from date Y, whereas the provisions in Article 13(1) do not set out a period of time but describe instead a way to calculate a period from the interval between two events in time.

The Applicant's View

14 The applicants have requested:

(i) that the duration of the SPC is rectified under Article 17(2) of Regulation (EC) No 1610/96[6], which under recital (17) of that regulation applies *mutatis mutandis* to the SPC Regulation[7]. The applicants argue that where the SPC Regulation refers to the "*date of grant of the authorisation*" (such as in Article 13) it should be interpreted as meaning "*date of notification*" and that any SPC term should be calculated from this date of notification; and

(ii) that the term of the SPC be extended, under Rule 107(3) of the Patents Rules 2007 (as amended) because of the irregularity of not using the Euratom Regulation when calculating the SPC term.

15 Following the examiner's report of 23 April 2013, the applicant wrote on 4 June 2013 requesting a hearing to discuss extending the SPC term. The applicant set out provisions of the Treaty Establishing the European Community and the Danish text of the SPC Regulation in support of their argument that the SPC Regulation should be interpreted as meaning the "date of notification". They also explained why they did not think that a trigger date was required for the Euratom Regulation to be applicable.

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[6] Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products. Article 17(2) of this regulation reads: "*The decision to grant the certificate shall be open to an appeal aimed at rectifying the duration of the certificate where the date of the first authorization to place the product on the market in the Community, contained in the application for a certificate as provided for in Article 8, is incorrect."*

[7] Recital 17 reads "*Whereas the detailed rules in recitals 12, 13 and 14 and in Articles 3 (2), 4, 8 (1) (c) and 17 (2) of this Regulation are also valid, mutatis mutandis, for the interpretation in particular of recital 9 and Articles 3, 4, 8 (1) (c) and 17 of Council Regulation (EEC) No 1768/92*"

16 The applicant wrote again on 13 June 2013 setting out the basis for the term of the SPC to be amended and again on 21 June 2013 setting out that the marketing authorisation was dated 10 March 2004, dispatched from the European Commission on 11 March 2004 and received by the applicant on 12 March 2004, which is the date of notification for this authorisation listed in the Official Journal of the European Union. Following the hearing, in a letter dated 14 August 2013, the applicant provided, as requested at the hearing, further information about how the European Commission determines when the marketing authorisation is delivered and received by its holder.

The Issues to be decided

17 The matters at issue came before me to be decided at an oral hearing at the IPO on 27 June 2013 following a request from the applicant in their letter dated 4 June 2013 The applicant, Genzyme Corporation, was represented by Dr Mike Snodin of Potter Clarkson LLP. Also present were the examiner, Dr Jason Bellia, and my assistant for the hearing, Ms Mary Taylor.

18 There are two issues to be decided: (i) what date does the Marketing authorisation take effect for the purposes of the SPC Regulation: and (ii) does the Euratom Regulation apply to determine the term of an SPC. I will consider each of these in turn below.

Date of Effect of the Marketing Authorisation

The Relevant Law and its interpretation

19 Article 3(b) of the SPC Regulation provides what authorisation is required to obtain an SPC:

> "(b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate"

20 Article 7(1) of the SPC Regulation sets out the time limit for applying for an SPC:

> "The application for a certificate shall be lodged within six months of the date on which the authorisation referred to in Article 3(b) to place the product on the market as a medicinal product was granted."

21 Article 13(1) of the SPC Regulation provides details of the algorithm used to calculate the duration of an SPC (emphasis added in bold):

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

22 The Treaty establishing the European Community (TEC)[8] provides, at Article 254, that:

> "1. Regulations, directives and decisions adopted in accordance with the procedure referred to in Article 251 shall be signed by the President of the European Parliament and by the President of the Council and published in the *Official Journal of the European Union*. They shall enter into force on the date specified in them or, in the absence thereof, on the 20th day following that of their publication.
>
> 2. Regulations of the Council and of the Commission, as well as directives of those institutions which are addressed to all Member States, shall be published in the *Official Journal of the European Union*. They shall enter into force on the date specified in them or, in the absence thereof, on the 20th day following that of their publication.
>
> 3**. Other directives, and decisions, shall be notified to those to whom they are addressed and shall take effect upon such notification**."

23 The Treaty on the Functioning of the European Union (TFEU)[9] has superseded the Treaty establishing the European Community (TEC). Article 297 TFEU, which has replaced Article 254 TEC, provides:

> "1. Legislative acts adopted under the ordinary legislation procedure shall be signed by the President of the European Parliament and by the President of the Council.
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> Legislative acts adopted under a special legislative procedure shall be signed by the President of the institution which adopted them.
>
> Legislative acts shall be published in the *Official Journal of the European Union*. They shall enter in force on the date specified in them or, in the absence thereof, on the twentieth day following that of their publication.
>
> 2. Non-legislative acts adopted in the form of regulations, directives or decisions, when the latter do not specify to whom they are addressed, shall be signed by the President of the institution which adopted them.
>
> Regulations and directives which are addressed to all Member States, as well as decisions which do not specify to whom they are addressed, shall be published in the Official Journal of the European Union. They shall enter into force on the date specified in them or, in the absence thereof, on the twentieth day following that of their publication.
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> **Other directives, and decisions which specify to whom they are addressed, shall be notified to those to whom they addressed and shall take effect upon such notification**."

[8] See full text of this treaty at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12006E/TXT:EN:HTML

[9] See full text of this treaty at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2012:326:0001:01:EN:HTML

24 The CJEU in case C-127/00, *Hässle,* considered the meaning of the words '*authorisation to place on the market*' in the context of its use in EC Regulation 1768/92 (which has been codified and superseded by the SPC Regulation[2)]. In paragraphs 57-60 of this judgement, the court stated:

> "*57. There is thus nothing to justify the words* 'authorisation to place... on the market' *being interpreted any differently depending on which provision of Regulation No 1768/92 they appear in. In particular, those words cannot be construed as having a different meaning according to whether they appear in Article 3 or Article 19, especially when it is apparent from Article 8(1)(a)(iv) and (c) that the marketing authorisation referred to in Article 3(b) may also be the first marketing authorisation in the Community.*
>
> *58. It follows therefrom that the* 'first authorisation to place ... on the market ... in the Community'*, mentioned in, among others, Article 19(1) of Regulation No 1768/92, must, like the* 'authorisation to place ... on the market' *mentioned in Article 3 of that regulation, be a marketing authorisation issued in accordance with Directive 65/65.*
>
> *59. Secondly, contrary to Hässle's contention, even if the certificate does no more than compensate for the time which elapses between lodging the patent application and the issuing of a marketing authorisation in accordance with Directive 65/65, the protection conferred by that certificate, which extends that conferred by the patent, is not illusory. Furthermore, it is clear from the eighth recital and from Article 13(1) of Regulation No 1768/92 that the duration of the certificate is at least five years shorter than the period which may have elapsed between the patent application and the issuing of a marketing authorisation, which shows that the Community legislature did not pursue at all the objective of compensating in its entirety the loss of effective protection conferred by a patent as a result of lead times required by protected products*.
>
> *60. Thirdly, that interpretation is the only one which can satisfy the requirements of legal certainty. Contrary to the marketing authorisation procedure provided for by Directive 65/65, the other authorisation procedures relied upon by Hässle concerning the fixing of prices or reimbursement for medicinal products are entirely national matters inasmuch as they have not been harmonised at Community level. Consequently, if Article 19 of Regulation No 1768/92 were to be interpreted as referring to such authorisations, the persons covered by that regulation would not be aware of the existence or the nature of other obstacles to the placing of products on the market in the various Member States, thus creating the kind of legal uncertainty which the abovementioned regulation was precisely intended to remedy."*

Analysis and Argument

25 The applicant has requested that the term of the SPC should start on the date of the notification of the marketing authorisation for several reasons. I will consider each of these in turn.

26 Firstly, the applicant referred to paragraph 57 of *Hässle* which provides that wherever the term '*authorisation*' is referred to in the SPC Regulation it has to have the same meaning. The applicant pointed out that this means the references in the SPC Regulation to '*authorisation*' in Article 13(1), Article 3(b) and 3(d) cannot have a different meaning and so must all refer to the same type of authorisation. I agree with the applicant that this is what the Court held in *Hässle*.

27 However, the applicant went on to say that as Article 3(b) refers to "*a valid authorisation having been granted"* then the other references to '*authorisation'* in the SPC Regulation must also mean that the authorisation must be a valid authorisation, e.g., in Article 13(1), Article 3(b) and 3(d). The applicant then referred to Commission Decision C(2004) 856 of 10 March 2004 granting the marketing authorisation for human use of the medicinal product, "*Cholestagel* – colesevelam hydrochloride". Article 4 of this decision states:

> "*The period of validity of the authorisation issued shall be five years from the date of notification of this Decision."*

The applicant argued that this meant that this decision was not valid until it was notified. Therefore, a valid authorisation in Article 3(b) actually means a notified one and, by analogy, a valid authorisation for the purposes of Article 13(1) and Article 3(d) of the SPC Regulation must also mean a notified authorisation.

28 While I agree with the applicants assessment of the decision by the CJEU in *Hässle* that wherever the term '*authorisation'* is referred to in the SPC Regulation, it has to have the same meaning, it does not, in my view, provide any detail or make any reference to whether or not the authorisation was a notified one. The court does indicate that the authorisation referred to is a marketing authorisation issued in accordance with Directive EEC/65/65 which I take to mean an authorisation that meets all the requirements laid down in that Directive and its successors[10]. This is because the issue that the CJEU was asked to provide guidance on in *Hässle* was, as is referred to in paragraph 60 of the judgement, whether any other authorisation steps at national level that are required before a medicinal product can be made available for human use are relevant for the purposes of obtaining an SPC[11].

29 The Court specifically rejected the notion that the SPC Regulation was trying to provide compensation for the whole of the period necessary to get a product onto the market. In paragraph 59 of *Hässle*, the CJEU makes clear that "*the Community legislature did not pursue at all the objective of compensating in its entirety the loss of effective protection conferred by a patent as a result of lead times required by protected product*." Therefore, I do not see that *Hässle* provides authority for the SPC term to start from the date of notification of the marketing authorisation. At best, I consider that this case provides authority for the SPC term to start from the

[10] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use has replaced and superseded Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products

[11] See first question of the three questions referred in *Hässle*. The CJEU dealt with this question in paragraphs 48-79 of the decision. For the purposes of the present decision, the discussion in paragraphs 48-61 in relation to the first part of the first question is most relevant.

date that a marketing authorisation that is compliant with all the requirements of Directive 65/65/EC has been granted[10].

30 Secondly, the applicant made reference to the relevance of Article 254(3) TEC. However, the latter treaty was superseded on 1 December 2009 by the Treaty on the Functioning of the European Union (TFEU). The original marketing authorisation for *Cholestagel* was granted in March 2004 and therefore was granted under the Treaty establishing the European Community (TEC) whereas the amended marketing authorisation was granted in 2011 when the Treaty on the Functioning of the European Union (TFEU) was in force. As noted above, Article 254(3) TEC says that "*Other .... decisions, shall be notified to those to whom they are addressed and shall take effect upon such notification*". By 'other decisions', Article 254(3) means those not covered by Article 254(1) and 254(2). Article 254(1) deals with regulations, directives and decisions adopted in accordance with the so-called co-decision procedure between the Parliament and the Council as set down in Article 251 of this Treaty and Article 254(2) relates to Regulations and Directives of the Council and the Commission directed to "*all member states*". Therefore, neither Article 254(1) nor Article 254(2) relate to decisions of the European Commission which are directed to specific named applicants concerning the grant of a marketing authorisation for a medicinal product.

31 In the current case, there are three decisions from the Commission concerning the marketing authorisation for "*Cholestagel* – colesevelam hydrochloride", each of which indicates clearly that they are addressed to the applicant, Genzyme Europe BV[12], but only one of these, decision C(2004) 856 of 10 March 2004 (see Article 4) refers specifically to the period of validity of the authorisation being five years from date of notification. The interaction between these three decisions was discussed in some detail at the hearing. In the material that the agent provided with the request for extension to the term of the SPC dated 24 April 2012, three extracts from the Official Journal of the European Union (OJEU) were provided. These extracts each relate to the above mentioned decisions concerning the marketing authorisation for *Cholestagel.* The relevant extracts from the OJEU concerning the issuing of the marketing authorisation are shown in Figure 1 (see **A**) and those concerning the modification of the marketing authorisation are shown in Figure 2 (see **B** and **C**).

32 The applicant considers that, when Article 254(3) TEC is taken into account with Article 4 of the decision of the Commission dated 10 March 2004 granting the marketing authorisation, this confirms that marketing authorisation does not take effect on the date of the decision itself but rather at a later date, which is identified as the date of notification, and which occurs at some point in the future after the date of the decision. However, the Commission decision of 23 March 2010 and the Commission decision of 10 August 2011, both of which amend the Commission decision of 10 March 2004, do not contain equivalents of Article 4 of this original decision. Recital (8) of the Decision of 10 August 2011 says that this decision corrects the decision of 23 March 2010 and that it should have retrospective effect to the '*date of notification*' of that earlier decision. When one examines the decision of 23 March 2010, it is not possible to find a specific reference to a date of notification in any of its articles or recitals in the same way as it is in the original decision, dated

[12] See Article 5 of decision C(2004) 856 of 10 March 2004; see Article 2 of decision C(2010) 2008 of 23 March 2010; and Article 3 of decision C(2011) 5946 of 10 August 2011.

10 March 2004, which granted the marketing authorisation in the first place. Thus, in this regard, it would appear that the date of notification is relevant only to the original decision and not the other two later ones. At the hearing, the applicant explained that the decision of 23 March 2011 did not have a date of notification because it relates to a renewal of a marketing authorisation and renewals are worked out from the original decision.

(Published pursuant to Article 12 or Article 34 of Council Regulation (EEC) No 2309/93 (1))

(2004/C 77/02)

— Issuing of a marketing authorisation (Article 12 of Regulation (EEC) No 2309/93): Accepted

Date of the decision	Name of the medicinal product	Holder of the marketing authorisation	Number of the entry in the Community Register	Date of notification
23.2.2004	Ibandronic Acid Roche	Roche Registration Limited 40 Broadwater Road Welwyn Garden City Hertfordshire AL7 3AY United Kingdom	EU/1/03/266/001-002	26.2.2004
23.2.2004	Bonviva	Roche Registration Limited 40 Broadwater Road Welwyn Garden City Hertfordshire AL7 3AY United Kingdom	EU/1/03/265/001-002	26.2.2004
2.3.2004	Advate	Baxter AG Industriestraße 67 A-1221 Wien	EU/1/03/271/001-004	4.3.2004
2.3.2004	Reyataz	Bristol-Myers Squibb Pharma EEIG 141-149 Staines Road Hounslow TW3 3JA United Kingdom	EU/1/03/267/001-007	4.3.2004
10.3.2004	Faslodex	AstraZeneca UK Limited Alderley Park Macclesfield Cheshire SK10 4TG United Kingdom	EU/1/03/269/001	12.3.2004
10.3.2004	Cholestagel	Genzyme Europe BV Gooimeer 10 1411 DD Naarden Nederland	EU/1/03/268/001-003	12.3.2004

A

***Figure 1**: Extract from the Official Journal of the European Union, C 77/2, dated 26 March 2004, showing date of grant and date of notification for* Cholestagel*.*

33 However, if we consider the entries in the OJEU for both of these later decisions we find that a date of notification is listed for each corresponding to a date 2 days after the date of the Commission decision (see **B** and **C** in Figure 2). Thus, although no reference is made to a date of notification in the respective decisions themselves, clearly such a date has been identified for each decision. From this, I consider that decisions, such as these from the European Commission in relation to a marketing authorisation for a medicinal product, each have an identified date of notification as well as an identified date of the decision.

34 In considering the copies of the OJEU that the agent provided, and especially the copy from which Figure 1 above is an extract, I noted that the date of notification could vary between 2 and 4 days from the date of the decision. I pointed out to the agent that there did not appear to be any pattern to this difference, for example, the longer periods of 4 days or 3 days did not always include a weekend, or did not appear to relate to applicants that could be considered to be geographically the most distant. The agent was not able to provide any further explanation at the hearing. In addition, the agent was not able to provide any information as to how the applicant was made aware of the date of notification or how the European Commission was able to determine the date of notification so it could be published in the OJEU. As a consequence, I asked the agent to find out and to provide this further information after the hearing.

— **Modification of a marketing authorization (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): Accepted**

	Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
B	23.3.2010	Cholestagel	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/03/268/001-004	25.3.2010
C	10.8.2011	Cholestagel	Genzyme Europe B.V. Gooimeer 10, NL-1411 DD Naarden, Nederland	EU/1/03/268/001-004	12.8.2011

***Figure 2**: Extracts from the Official Journal of the European Union showing the dates of grant and dates of notification of modifications to the marketing authorisation for* Cholestagel*: (**B**) C 258/1, dated 24.9.2010; and (**C**) C 316/1, dated 28.10.2011].*

35 This information was provided in a letter dated 14 August 2013 and related statutory declaration which included a number of emails from the European Direct Contact Centre, which is part of the European Commission Services responsible for dealing with enquiries and request for information[13]. The Contact centre's email of 11 July 2013 stated:

> *"In accordance with Article 297 of the Treaty on the Functioning of the European Union decisions which specify to whom they are addressed shall be notified to whom they are addressed and shall take effect upon such notification. In practice the Commission decision is sent by the Commission via DHL to the addressee."*

36 As discussed above, Article 297 TFEU replaced Article 254 TEC (which was referred to by the applicant). The final paragraph of both of these provisions is the same and provides that decisions, such as that granting the marketing authorisation for

[13] For further details see http://europa.eu/europedirect/index_en.htm

Cholestagel, which are addressed to a specific addressee, "*shall be notified to those to whom they are addressed and shall take effect upon such notification*".

37 In a further email dated 30 July 2013 the European Direct Contact Centre stated that "*the Commission receives the information as regards the proof of delivery from DHL*". From this I am satisfied that the date of notification of the marketing authorisation is the date on which the holder of the marketing authorisation receives into his hand as it were confirmation that he has been granted a marketing authorisation. It is the date on which the applicant actually knows of the Commission Decision and thus the date occurs some few days after the grant of the marketing authorisation. This actual date is determined by the time it takes to deliver the authorisation to the entity to which it is specifically addressed and to have this delivery confirmed by the courier delivering it – at present this is DHL.

38 In each European Commission decision dealing with a marketing authorisation, the first page of the decision which contains the reasons and explanation for the decision, usually indicated by the starting phase 'having regard to', always makes reference to the relevant Treaty. As discussed above, decision of C(2004) 856 of 10 March 2004 refers to TEC and C(2010) 2008 of 23 March 2010 and C(2011) 5946 of 10 August 2011 refer to TFEU. I consider this to be an indication that the decision has to have regard to the relevant provisions of the respective Treaty which, as discussed above, include Article 254 TEC, now superseded by Article 297 TFEU. Thus the decision of the European Commission granting a marketing authorisation does not come into effect until the date of notification. In the present case, the marketing authorisation for *Cholestagel*, which was granted on 10 March 2004, was notified to the applicant, Genzyme Europe BV, on 12 March 2004, as confirmed by entry in the OJEPO (see Figure 1 above).

39 Recital 9 of the SPC Regulation refers to "*exclusivity from the time the medicinal product in question first obtains authorisation*" and Article 13(1) of the SPC Regulation provides for the term of the SPC to start from the "*date of the first authorisation*." I note, in addition, the argument made by the examiner in relation to the recitals and articles of the SPC regulation, referring only to a '*granted*' marketing authorisation [see, for example, in Article 3(b), Article 7(1) and 7(2)] and to the '*date of authorisation'* of the marketing authorisation [see, for example, Article 8(1)(iv)(b) and 8(1)(iv)(c), Article 9(d) and 9(e)]. I also note his argument that, despite a number of opportunities to amend the SPC Regulation since it first came into force in 1992, no reference to a date of notification as being relevant to deciding when a marketing authorisation takes effect has ever been included into this regulation. While, this is true as far as it goes, I have to take account of the fact that the overriding nature of Article 297 TFEU (and its predecessor treaties and relevant articles referred to above) means that a decision of the European Commission granting a marketing authorisation to a specific holder does not become valid and take effect until the date of notification. Thus, the holder is considered not to know his marketing authorisation has been granted and has valid legal effect until they actually receive it on the date of notification.

40 When applying for an SPC the applicant must, according to Article 8 of the SPC Regulation, include a copy of the marketing authorisation for the medicinal product which comprises the product that the SPC is being applied for. The applicant cannot do so until it receives a copy of the decision granting the marketing authorisation

and, as explained above, the applicant does not receive this until the date of notification. Thus the earliest that the applicant can apply for an SPC is the date of notification and not the date of decision of grant of a marketing authorisation.

41 Therefore, it appears to me that on the basis outlined above, the term of the SPC should be calculated from the date of notification of a European marketing authorisation. For the sake of clarity, I would like to reiterate that this conclusion relates only to European marketing authorisations and does not affect practice in relation to SPCs based upon UK national marketing authorisations granted by the Medicines and Healthcare products Regulations Agency ("MHRA").

Relevance of EURATOM Regulation

The Relevant Law and its interpretation

42 Recitals 9 and 10 of the SPC Regulation read *(my emphasis added in bold)*:

> *"(9) The duration of the protection granted by the certificate should be such as to provide adequate effective protection. For this purpose, the holder of both a patent and a certificate should be able to enjoy* ***an overall maximum of 15 years of exclusivity from the time the medicinal product in question first obtains authorisation*** *to be placed on the market in the Community."*
>
> *(10) All the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector should nevertheless be taken into account.* ***For this purpose, the certificate cannot be granted for a period exceeding five years****. The protection granted should furthermore be strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product."*

43 Article 13 of the SPC Regulation includes the following provisions:

> *"1. The certificate shall take effect at the end of the lawful term of the basic patent for* ***a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the Community, reduced by a period of five years****.*
>
> *2. Notwithstanding paragraph 1, the duration of the certificate may not exceed five years from the date on which it takes effect.*
>
> *3. The periods laid down in paragraphs 1 and 2 shall be extended by six months in the case where Article 36 of Regulation (EC) No 1901/2006 applies. In that case, the duration of the period laid down in paragraph 1 of this Article may be extended only once."*

44 Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time limits ("the Euratom Regulation") comprises the following statement of reasons and recitals which read as follows;

> *"THE COUNCIL OF THE EUROPEAN COMMUNITIES,*

Having regard to the Treaty establishing the European Economic Community, and in particular Article 235 thereof;

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Article 203 thereof;

Having regard to the proposal from the Commission;

Having regard to the Opinion of the European Parliament;

Whereas numerous acts of the Council and of the Commission determine periods, dates or time limits and employ the terms "working days" or "public holidays";

Whereas it is necessary to establish uniform general rules on the subject;

Whereas it may, in exceptional cases, be necessary for certain acts of the Council or Commission to derogate from these general rules;

Whereas, to attain the objectives of the Communities, it is necessary to ensure the uniform application of Community law and consequently to determine the general rules applicable to periods, dates and time limits;

Whereas no authority to establish such rules is provided for in the Treaties;"

45 Article 1 of this regulation outlines the general area of application of this regulation.

"Article 1

Save as otherwise provided, this Regulation shall apply to acts of the Council or Commission which have been or will be passed pursuant to the Treaty establishing the European Economic Community or the Treaty establishing the European Atomic Energy Community."

46 After Article 1, this regulation arranges the remaining articles into two chapters. Chapter I is entitled 'Periods' and Article 3(1) from this chapter reads as follows:

"Article 3

(1). Where a period expressed in hours is to be calculated from the moment at which an event occurs or an action takes place, the hour during which that event occurs or that action takes place shall not be considered as falling within the period in question.

***Where a period, expressed in days, weeks, months or years is to be calculated from the moment at which an event occurs or an action takes place, the day during which that event occurs or that action takes place shall not be considered as falling within the period in question**.*

(2).....
(3).....
(4).....
(5).....

47 Chapter II of this regulation is entitled 'Dates and Time Limits' and Article 4 and Article 5 from this chapter read as follows:

Article 4

(1). Subject to the provisions of this Article, the provisions of Article 3 shall, with the exception of paragraphs 4 and 5, apply to the times and periods of entry into force, taking effect, application, expiry of validity, termination of effect or cessation of application of acts of the Council or Commission or of any provisions of such acts.

(2). Entry into force, taking effect or application of acts of the Council or Commission — or of provisions of such acts — fixed at a given date shall occur at the beginning of the first hour of the day falling on that date.

This provision shall also apply when entry into force, taking effect or application of the afore-mentioned acts or provisions is to occur within a given number of days following the moment when an event occurs or an action takes place.

(3). Expiry of validity, the termination of effect or the cessation of application of acts of the Council or Commission — or of any provisions of such acts — fixed at a given date shall occur on the expiry of the last hour of the day falling on that date.

This provision shall also apply when expiry of validity, termination of effect or cessation of application of the afore-mentioned acts or provisions is to occur within a given number of days following the moment when an event occurs or an action takes place.

Article 5

(1). Subject to the provisions of this Article, the provisions of Article 3 shall, with the exception of paragraphs 4 and 5, apply when an action may or must be effected in implementation of an act of the Council or Commission at a specified moment.

(2). Where an action may or must be effected in implementation of an act of the Council or Commission at a specified date, it may or must be effected between the beginning of the first hour and the expiry of the last hour of the day falling on that date.

This provision shall also apply where an action may or must be effected in implementation of an act of the Council or Commission within a given number of days following the moment when an event occurs or another action takes place."

48 The Court of Justice of the European Union (CJEU) in case C-139/73 *Einfuhr- und Vorratsstelle für Getreide und Futtermittel v Firma Eurgen MÜNCH* (hereafter "*Einfuhr*") considered what is the concept of a 'period' and what is the concept of a

'time limit' as laid out in the Euratom Regulation and how these are applied to European legislation[14]. The CJEU said in paragraph 4 of this decision:

> *"The context of Article 3 [of the Euratom Regulation] shows that the concept of a period is to be taken to mean an interval of time expressed in hours, days, weeks, months or years without reference to a specified date or event."*

The CJEU also said, in relation to Articles 4 and 5 of the Euratom Regulation that these provisions which relate to dates and time limits:

> "*are concerned with actions which must be effected at a specified date or within a specified time following a given date or event."*

Analysis and Argument

49 The applicant has requested that the term of protection provided by the SPC should be extended in light of the relevance of the Euratom Regulation to the calculation of SPC term.

50 The applicant considers that, as the SPC regulation is a piece of European legislation and the Euratom Regulation sets out the general basis on which time limits and periods are to be dealt with in such legislation, then Article 3 of the Euratom Regulation applies to the setting of time periods in the SPC regulation. The agent argued that the practical result of this provision of the Euratom Regulation is that for all Directives and Regulations of the EU, time periods specified in days, weeks, months or years run from the day after the event takes place which requires this time period to be applied, the so-called 'triggering' event. The agent considers that Article 13(1) and 13(2) of the SPC regulation, which describe how to calculate the duration of an SPC, must be understood in the context of recitals 9 and 10 of this regulation. Recital 9 refers to the fact that the exclusive protection offered by the SPC regulation is a '*maximum of 15 years of exclusivity*' and recital 10 says that the maximum period of protection provided by a supplementary protection certificate (SPC) cannot exceed 5 years. The applicant considers that the need to make sure that the applicant gains 15 years of exclusivity is the most important consideration as, in their view, this is what delivers on the overall purpose of the SPC regulation – to compensate the patent holder and the holder of the marketing authorisation for the time lost while gaining approval for the medicinal product to be placed on the market for human use.

51 In applying the Euratom regulation to recital 9, the applicant considers that this means that the 15 years of exclusivity would run from day after the European MA was notified, i.e., first hour of the day on 13 March 2004, until last hour of the day 12 March 2019.

52 The relevance of the Euratom regulation was discussed in some detail at the hearing. The applicant considers that recital (9) and Article 13(1) and 13(2) relate to a period, i.e. 15 years, according to Chapter I of the Euratom regulation and hence Article 3 of that regulation applies. However, Article 13 does not refer to a time

[14] This case concerned a preliminary reference from the German Courts concerning the determination of the deadline by which an application for a so-called 'carry-over payment' had to be made in relation to wheat held in stock under specific European legislation.

period in the way that recital (9) does. Instead it describes how to work out the duration of a certificate based on the calculation of a "*period ...elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the market in the Community*" to provide the period of exclusivity referred to in recital (9). Thus, it would appear that Articles 4 and 5 of the Euratom Regulation which relate to actions which must be effected at a specific date or within a specific time following a given date or event might be more relevant than Article 3.

53 The agent argued that Articles 4 and 5 of the Euratom Regulation are not relevant because they relate to "*acts of the Council or Commission*" and talk about dates "*fixed at a given date*" and "*at a specified date*" respectively. The applicant appeared to argue at the hearing that, in the context of these articles, "*acts*" meant legislation such as directives or regulations which include reference to a date or time period or time limit in the articles of the acts themselves. Thus the acts covered by Article 4 and Article 5 are only those of the Council and Commission which include provisions that, when they come into force, relate to things that must be carried out by a specific date or within a specific time period, before or after some triggering event mentioned in the Act itself or if they indicate that something must go out of force either on a specific date or within a specific time period, again which is included in the Act itself. The agent considered that these Articles are only relevant to "*an unambiguous date specified in the Act".*

54 The agent suggested that the decision of the Commission to grant a marketing authorisation, which he considers is the relevant triggering event, required for Article 3 of the Euratom Regulation to apply (and that then requires you to work out when the 15 year period of exclusivity will begin and finish) is not 'legislation' and therefore, not an "*act*" covered by Articles 4 and 5 of this Regulation.

55 However, Article 1 of the Euratom Regulation provides that, unless as otherwise provided, this regulation applies to "*acts of the Council or Commission which have been or will be passed pursuant to the Treaty*". This is an inclusive provision which I take to mean that the Euratom Regulation applies to all acts of the Council or Commission unless there is a specific provision in such an act which indicates that it does not.

56 Although the agent considered that "*acts*" covered by Article 4 and 5 therefore had no relevance to the calculation of an SPC's term using Article 13 of the SPC regulation, he considered that Article 3 of the Euratom Regulation is relevant in this scenario because it refers to the general approach to be taken in all European legislation when it is necessary to calculate a period "*from the moment at which an event occurs or an action takes place*". The SPC regulation mentions a specific time period in recital 9 (15 years) which is triggered by the grant of the marketing authorisation. In this situation, the agent considers that the date of notification of the marketing authorisation (MA) is the event that triggers the time period. Article 3 of the Euratom Regulation applies to deciding what day this 15 year period starts and what day it finishes. Thus, the 15 year period of exclusivity for the active ingredient in *Cholestagel* should begin on the day after the 'triggering event' (date of notification of MA) occurs and expires on the same date 15 years hence (see Article 3(2)(c) of Euratom Regulation).

57 The applicant considers that their approach would ensure that the SPC term in this case is the maximum 15 years exclusivity allowed. This approach is also supported, in their view, by the Explanatory Memorandum, dated 11 April 1990, for a Council Regulation (EEC) concerning the creation of a supplementary protection certificate for medicinal products[15] said:

> "*The duration of the protection given by the certificate is set in such a way as to enable it to afford actual overall protection similar to that in other sectors of technology. This period is set at 16 [now 15] years in the proposal. However, it is set as a function of the first marketing authorisation in the Community, which means a loss to industry in countries in which the authorisation is granted much later*. "

58 The agent considers that it is not necessary to carry out the calculation of the SPC term of protection provided for in Article 13 of the SPC Regulation because, applying a teleological interpretation to ensure the delivery of the overall objective means that all one has to do is to ensure that the period of 15 years of exclusivity referred to in recital (9) is delivered. The overall objective of the SPC regulation, in the view of the applicant, is to compensate patentees by giving them a period of exclusivity on the market to make up for time lost gaining authorisation for the medicinal product. The applicant did not consider that recital (10) had an impact on this entitlement because it relates to the maximum duration of an SPC certificate which recital (9) will provide. Thus the period in recital (9) was all that had to be calculated and therefore Article 3 of the Euratom Regulation should be applied.

59 I consider that there is a contradiction in this reasoning. If Article 3 of the Euratom Regulation applies to the SPC regulation in the manner that the agent describes, then I cannot see how Article 1 of this regulation does not also apply to the decision of the Commission to grant a market authorisation – the event that triggers the calculation of the time period. I do not consider that the Euratom Regulation can only apply to some acts of the Commission but not others – a decision of the Commission to grant a marketing authorisation to a specific applicant which takes effect on a specific date is, in my view, an act of the Commission. Such acts are covered by the Euratom Regulation. The Euratom Regulation dates from 1971 and the Treaty establishing the European Economic Community to which it refers has been superseded by a number of subsequent treaties, the current being TFEU, and as we have already discussed above, acts of the Council and the Commission will include decisions of the Commission to grant a marketing authorisation to a specific applicant. I find it difficult to understand how "*acts*" in Article 1 of the Euratom Regulation can be interpreted broadly so as to include such a decision of the Commission but, in Articles 4 and 5 of this regulation, the same word should be interpreted narrowly so as to mean something different. As is clear from the approach taken by the CJEU in *Hässle* discussed above, the same interpretation should be placed on the same term when it is used in a number of provisions in the same piece of EU legislation unless there is a specific requirement or exclusion not to do so.

60 Furthermore, the applicant argues that the overriding purpose of the SPC regulation is to compensate patentees by giving them a maximum period of exclusivity on the

[15] Com(90) 101 final SYN 255, see paragraph 14 on page 9

market of 15 years. Recitals 9 and 10 refer to what the maximum period of exclusivity should be, but as recitals they are describing what the articles in the regulation that follow these recitals are designed to achieve. Article 13 delivers the objective set out in recitals (9) and (10), thus I cannot see how one can separate the recital from the article that is designed to deliver the same objective. This is what I consider is the effect of what the agent is asking me to do – to ignore Article 13 and apply recital (9) to determine a period of 15 years exclusivity. Also, I consider that recitals (9) and (10) represent two different ways to arrive at the same goal one based on the marketing authorisation and one based on the patent. By this I mean that the 15 years of exclusivity referred to in recital (9) is made up of (a) the remaining protection provided by the patent once the marketing authorisation has taken effect and (b) up to a total of an additional five years further protection provided by the SPC which takes effect once the patent protection has expired. Taken together, these provide a period of 15 years of exclusivity from the date that the MA takes effect and provides an SPC with a term of protection of between 0 and 5 years to deliver this. I consider that this emphasises the fact that, as the explanatory memorandum for this Regulation describes[16], an SPC is a *sui-generis* right that sits at the interface of the patent and regulatory approval systems.

61 Thus, I do not accept that you can use the 15 year period referred to specifically in recital (9) of the SPC Regulation as a means to say that I can apply Article 3 of the Euratom Regulation to determine when this 15 year period actually starts and ends, while at the same time, saying that Article 3 of the Euratom Regulation does not apply to the article in the SPC regulation, Article 13, that delivers the objective referred to in this recital. Article 13 of the SPC regulation is the operative part of the regulation, i.e., provides the rule that is to be followed, whereas recital (9) is part of the reasons why the regulation is needed. Thus, Article 13 cannot be ignored when taking account of the objective set out in recital (9).

62 The nature of the type of time period to which the Euratom regulation applies was discussed in light of the CJEU decision in *Einfuhr* (C-139/73). The applicant did not consider that this decision had any relevance to the calculation of when the 15 year period of exclusivity began and finished and hence the expiry date of an SPC. He indicated that nothing in this decision would impact on his view of the relevance of Article 3 of the Euratom Regulation to the calculation of the duration of the SPC based on recital (9) of the SPC regulation. The duration of the SPC was a period of time that had to be calculated once a specific event had occurred – the triggering event was the grant of the MA – and the 15 year period of exclusivity would begin on the day after the MA had taken effect. Thus only Article 3 could apply to the period as defined in Article 13(1). I do not agree with this analysis. Article 13 of the SPC Regulation does indeed provide for the calculation of a period of time – the term or duration of the SPC. However, this period of time is not a period expressed as so-many hours, days, weeks, months and/or years that is specified in an Article in the SPC regulation and which must be calculated after a specific event occurs. I consider that there are other Articles in the SPC regulation which are examples of time periods which occur before or after a specific event or date, e.g., Article 7(2) concerning the application for a certificate or Article 20(a)-(l) concerning the various additional arrangements relating to enlargement of the Community. Article 13 is, in my view, different, because it relates to a working-out the time that has elapsed

[16] Com(90) 101 final SYN 255, see paragraph 20 on page 12

between two events, i.e., the period of time between the date of application for the patent and the date that the marketing authorisation takes effect, and this calculated time period which is limited to a maximum value of 5 years in turn takes effect after a different but related (third) event takes place, i.e., the expiry date of the patent. This calculation uses an algorithm which refers to certain events but not to a specific period of time in years, weeks, months or days that is calculated after a specific triggering event. Thus, I do not consider that Article 13 relates to a time period of the type to which Article 3 of the Euratom Regulation applies. I consider that *Einfuhr* supports this conclusion because it indicates that Article 3 of the Euratom Regulation does not apply when the period is calculated by reference to certain events. This article provides a concept of a time period that means "*an interval of time expressed in hours, days, weeks, months or years without reference to a specified date or event*". In my view, and in contrast to that of the agent, calculation of the duration of the certificate using the algorithm in Article 13 is not subject to Article 3 of the Euratom Regulation.

63 It also appears to me that Article 13 does not relate to a date or time limit covered by Articles 4 and 5 of the Euratom Regulation either. Article 13 of the SPC regulation does not just relate to an action that must be effected at a specific date or within a specific time following a given date or event but instead it relates (as already discussed above) to working out the time that has elapsed between two events, reducing it by a period of 5 years, comparing this outcome to a maximum and then identifying a third event from which the calculated time period will take effect.

Conclusion

64 Taking account of all of the above, I conclude, that a marketing authorisation to place a medicinal product on the market in the Community granted according to the relevant European legislation[10], takes effect not on the date of decision by the European Commission, but rather, on the date that this decision is notified to the applicant for the marketing authorisation. Thus, the calculation of the duration of an SPC based upon such a European marketing authorisation should take account of the date of notification of the decision by the European Commission to grant the relevant marketing authorisation and not the date of the decision itself. According to the OJEU, the date of notification for the marketing authorisation for *Cholestagel* was 12 March 2004, 2 days after the date of grant.

65 I also conclude that the Euratom Regulation does not apply to recital (9) and Article 13 of the SPC regulation. I do not consider that the time period in recital (9) provides a basis for not taking account of the calculation of the duration of the SPC required in Article 13. I do not think that the Euratom Regulation applies to the algorithm in Article 13 of the SPC Regulation because the algorithm is not a period expressed in hours, days or weeks that falls to be calculated following a specific triggering event. Instead, Article 13 relates to working-out the time that has elapsed between two events (the period of time between the date of application for the patent and the date that the marketing authorisation takes effect), which is limited to a maximum time value (5 years) and takes effect after a third event takes place, i.e., the expiry date of the patent. I do not, therefore, consider that there is an irregularity on the part of the Office that needs to be rectified under Rule 107(3) of the Patents Rules 2007 (as amended).

66 As a consequence of my conclusion above in relation to the date of notification of the marketing authorisation for *Cholestagel*, the date of expiry of SPC/GB/04/031 for *colesevelam hydrochloride*, based on this date and the date of application for the basic patent, is 11 March 2019. The six-month extension to the SPC under Council regulation (EC) 1901/2006 would thus commence on 12 March 2019 and expire on 11 September 2019. Therefore, under Article 17(2) of Regulation (EC) No 1610/96, which applies *mutatis mutandis* to the SPC Regulation, the expiry date of SPC/GB/04/031 should be rectified.

67 I remit the application back to the examiner to make the necessary arrangements to rectify the expiry date of the term of protection provided by this SPC.

Appeal

68 Any appeal must be lodged within 28 days

Dr L Cullen

Deputy Director, acting for the Comptroller