PRACTICE NOTICE

Calculation of the duration of a Supplementary Protection Certificate

Issue

1. This Practice Notice outlines a change in practice of the Intellectual Property Office (IPO) as regards the calculation of the duration of a Supplementary Protection Certificate (SPC) where the first authorisation in the Community is one granted by a decision of the European Commission.

Introduction

- Article 13 of Council Regulation (EC) 469/2009 concerning the creation of a supplementary protection certificate for medicinal products ("the SPC Regulation") sets out how the duration of an SPC may be calculated. Article 13(1) provides that the duration is calculated having regard to the "date of the first authorisation to place the product on the market in the Community", and Article 13(2) provides that the duration of an SPC may not exceed 5 years.
- 3. In the situation where the earliest authorisation is one granted by a decision of the European Commission following a favourable opinion from the European Medicines Authority (EMA), it has been the IPO's practice that the date of the first authorisation in the Community, for the purposes of Article 13(1) of the SPC Regulation, is the date of grant by the European Commission of this European authorisation.

The Practice Change

- 4. In decision BL O/418/13 (Genzyme Corporation) the hearing officer determined that the duration of the SPC should be rectified¹ because the date of the first authorisation in the Community, for the purposes of Article 13(1) of the SPC Regulation, should be the date of notification.
- 5. The date of notification is the date that the applicant for the marketing authorisation is notified of the decision by the European Commission to grant the marketing authorisation and this is the date from which the granted authorisation takes effect. This date is recorded in the Official Journal of the European Union (OJEU). The date of notification is often a few days later than the date of grant of the marketing authorisation. As a consequence, when Article 13(1) is applied the duration of the SPC based on the authorisation date may be correspondingly longer (unless it exceeds the limit of 5 years provided for in Article 13(2)).

¹ Under Article 17(2) of Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products (which recital 17 applies to the SPC regulation).

6. We will now calculate SPC duration in accordance with this decision. This may also affect the dates, but not the duration, of related paediatric extensions².

The Procedure

7. This change will affect applications for SPCs, granted SPCs and paediatric extensions to SPCs.

SPC Applications

- 8. To amend a SPC application you should:
 - a. write to the comptroller, for the attention of the examiner, either when a response to an official action comes due, or in a separate letter; and
 - b. provide the number of the SPC and a copy of the relevant entry in the Official Journal of the European Union (OJEU) which shows the date of notification of the European marketing authorisation entered at item 8 of Form SP1.
- 9. The IPO will acknowledge receipt and notify you of the amended maximum expiry accordingly.

Granted SPCs

10. To rectify the term of a granted SPC you should:

- a. write to the comptroller, for the attention of the examiner; and
- b. provide the number of the SPC and a copy of the relevant entry in the Official Journal of the European Union (OJEU) which shows the date of notification of the European marketing authorisation entered at item 8 of Form SP1.
- 11. The IPO will issue a corrected version of the SPC certificate and extension certificate as necessary; publish the correction in the Patents Journal; and amend the Register entry for the basic patent to reflect the change.

Paediatric Extensions

- 12. To amend the dates of an extension you should mention the extension when you write to the IPO about the granted SPC or application.
- 13. The IPO will then ensure the necessary steps are taken to amend the dates in line with our practice set out above.

Further Information

Decision BL O/418/13 is available on the IPO website at http://www.ipo.gov.uk/O41813.pdf

² Under Article 13(3) of the SPC Regulation and Article 36 of Regulation (EC) No 1901/2006

Enquiries

Any enquiries about this notice should be sent to:

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20 November 2013

Patents Practice Change

Practice change: Ceasing to issue Patents Form 10 reminder letter

We have changed our practice so that, as of 1 July 2014, if you have not requested substantive examination (by filing Patents Form 10) we will no longer send you any reminders. More information on this change in practice can be found at www.ipo.gov.uk/p-pn-form10.

How to request substantive examination

You may request and pay for substantive examination online by using our web filing service at <u>www.ipo.gov.uk/p-apply-online-sfdchecklist</u>.

Alternatively Patents Form 10 may be downloaded at <u>www.ipo.gov.uk/p-formsfees</u>.

More information on requesting substantive examination can be found on our website at <u>www.ipo.gov.uk/p-subexam</u>.

The British Library - Recent Additions to the Library

The following transcripts of High Court Decisions have been received at the British Library.

Plaintiff(s) & Defendants(s)	Date Of Hearing	SRIS code No.
HTC Corporation -and- Nokia Corporation	28, 29 November 2013	C/158/13
Adaptive Spectrum and Signal Alignment Inc -and- British Telecommunications Plc	23 rd to 25 th October 2013 30 th to 1 st November 2013 5 th November 2013	C/159/13

Patent Cooperation Treaty (PCT) Fees

Changes in fees payable under the Patent Cooperation Treaty (PCT)

Notice is given that the fees (chapter 1) payable in connection with applications filed under the Patent Cooperation Treaty at the UK Intellectual Property Office (RO/GB) are changed with effect from **01 January 2014.**

Transmittal Fee:	£75
Search Fee:	£1582
International Fee:	
(a) For the first 30 sheets	£914
(b) For each sheet over 30	£10
Restoration for Restoration of Priority	£150
Reductions For E – FILING	
Electronic filing (not being in character coded format)	£138
Electronic filing (being in character coded format)	£206
Fees for preparation of priority document	£20

WITHDRAWING PATENT APPLICATIONS

This notice seeks to inform applicants and practitioners of the method the Intellectual Property Office recommends for withdrawing patent applications.

Background

Any request to withdraw an application is always an important action and is dealt with as quickly as possible in the Office. However, quick action in the Office becomes *crucial* when a withdrawal request is received for an application which is soon to be published. We of course wish to avoid erroneous publication.

Ways of withdrawing applications

Withdrawal of a patent application can be made by:

- emailing withdraw@ipo.gov.uk
- faxing the Office on 01633 817777
- writing to the Office

We **highly recommend** that the email option be used, as this will ensure that the request is dealt with quickly by a dedicated team of staff. Full details of this service can be found at <u>http://www.ipo.gov.uk/p-direction-withdrawal.htm</u>.

Notifying the Office of withdrawal in time to prevent publication

An application for withdrawal in time to prevent publication must be received in this Office by $\underline{23:59}$ on the day before preparations for publication are complete (the *PPC date*). The official letter notifying applicants of the PPC date for their application will only be received 2 or 3 days prior to the PPC date. That leaves a very short time in which to notify the Office of withdrawal. If the email message or written notification is not received by $\underline{23:59}$ on the day before the PPC date, it will be too late to prevent publication.

Therefore the earlier applicants and practitioners can make decisions about withdrawal and notify the Office, the better.

Further guidance on withdrawal of patent applications can be found at: <u>http://www.ipo.gov.uk/p-withdraw.htm</u>

If you have any queries about this notice, please contact:

or

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Patent Publication Enquiry Service

The Patents Publication Enquiry Service <u>www.ipo.gov.uk/patent/p-find/p-find-publication.htm</u> enables you to search for, view and download newly published, granted and corrected GB patents. Patents are added on a weekly basis on the day of publication (usually every Wednesday).

The following types of GB published documents are available:

Document code A – for the published "A" application.

Document code A8 – for the corrected front page of a published "A" application (changes to bibliographical data only).

Document code A9 – for the complete re-issue of a published "A" application (as a result of a correction).

Document code B – for the granted 'B' specification.

Document code B8 – for the corrected front page of a granted "B" specification (changes to bibliographical data only).

Document code C - for complete re-issue of a granted "B" specification (as a result of a correction or amendment).

If you have any queries regarding this notice please contact Emma Callaghan - Tel: 01633 614876, or via e-mail: <u>emma.callaghan@ipo.gov.uk</u>

Provision of Information from the Intellectual Property Office

On-Line Web Services

A number of **free** services are available via our web site which is located at **www.ipo.gov.uk**.

esp@cenet

This service provides an interface to the published patent application databases of the Intellectual Property Office, the European Patent Office and other European national patent offices, as well as access to the PCT database of published patent applications. A full copy of the specification, claims and drawings may be viewed if available.

Designs Image Search

This service provides access to images of UK registered designs along with bibliographic information.

Trade Mark Text

This service provides searches for trade marks matching/starting with specified text.

Trade Mark Proprietor

This service provides searches for trade mark proprietors.

Trade Mark Classification Index

The index serves as a guide to the classes of goods and services to specify when applying for Trade Mark registration. With over 70,000 terms, the index shows which class to put each term in.

Legal Decisions

This service provides the text of reasoned decisions issued by the office since the beginning of 1998.

Status Information

This service provides the status information for Patents, Supplementary Protection Certificates, Trade Marks and Designs.

Other Services

The Status Information and further information can also be obtained on paper from the office. Some of the information available is shown below, along with the relevant prices.

Patents	Request for uncertified copy from file or register	£5
Designs	Request for uncertified copy of extract	£5
Trade Marks	Request for uncertified copy from file or register	£5

<u>Note</u> Trade Marks & Designs: The cost is £5 per file copied, though we reserve the right to quote for our actual costs where particularly large files are involved.

General Cost, per page, of faxing information

£1 (plus VAT)

Payment

Deposit accounts: Customers may charge orders against their account with the Office. In such cases the deposit account number should be quoted on the order.

Credit and debit cards: Payment can be made using the following credit and debit cards:Visa, MasterCard,American Express, Switch,Maestro(only if the card is issued by a UK Bank) and Solo.

Cheque: These should accompany any order, be crossed "Account Payee Only" and made payable to "The Intellectual Property Office". Payments from overseas must be in sterling drawn on a UK clearing bank.

Orders

Post: Sales, Concept House, Cardiff Road, Newport, South Wales NP10 8QQ

e-mail (Deposit Account Holders only): sales@ipo.gov.uk

Telephone (Deposit Account Holders and payments by credit and debit card only): +44(0)1633 813651

Fax (Deposit Account Holders and payments by credit and debit card only): +44(0)1633 817777.