You can count on us: UK IPO agrees to award longer term to some SPCs

Mike Snodin explains why a decision on supplementary protection certificates by the UK Intellectual Property Office is good news for drug innovators.

By way of a practice notice issued on 20 November, the UK Intellectual Property Office formally announced a change in the way that it calculates the term of certain supplementary protection certificates (SPCs) that are based upon EU centralized marketing authorizations (MAs) for drugs.

In essence, the UK IPO has accepted the argument first proposed by this author in 2011 in *Scrip Regulatory Affairs* That is, the UK IPO has changed its practice such that when SPC term is determined by the date of a centralized MA, then the date ascribed to that MA should not be that of the European Commission's decision to issue the MA but rather the (later) date of notification of that decision to the applicant.

Because of the way that SPC term is calculated, a later MA date can lead to longer SPC term. However, the UK IPO's change of practice will only lead to additional term in the UK for those SPCs where:

(a) the earliest MA in the European Economic Area is a centralized MA issued by the commission; and
(b) less than 10 years have elapsed between the date of filing of the patent upon which the SPC is based and the date of the commission's decision to grant an MA.

Thus, not all SPC proprietors or applicants will benefit from this change of practice. However, a significant number will. For example, of the SPC applications filed in the UK in 2013 prior to issuance of the practice notice, over 40% stand to gain additional days of term.

In total, it is believed that over 140 human or veterinary medicinal products could benefit from longer exclusivity as a result of the change of practice in the UK.

For those granted and pending SPCs that are affected, the additional term now available in the UK is likely to be only a few days (typically in the region of two to four days). However, this author has identified numerous pending and granted SPCs in the UK for which the additional term would be longer than this, even in excess of one week (or, in one instance, in excess of two weeks).

Background

SPCs are a unique form of protection that are available in Europe for (mixtures of) active ingredients that are patent-protected and authorized for sale according to certain specified directives (including Directive 2001/83/EC on medicines for human use). For many innovative medicinal products, SPCs will represent the "last man standing" in terms of absolute (or highly significant) barriers to generic market entry. Thus, the protection afforded by SPCs is often of great commercial significance, as is the determination of the precise date of expiry of SPC protection.

> The protection afforded by SPCs is often of great commercial significance, as is the determination of the precise date of expiry of SPC protection

This author had previously argued that the majority of patent offices across Europe were adopting an incorrect approach to the calculation of the term of SPCs based upon centralized MAs. This is because the standard practice of almost all offices is to calculate SPC term upon the basis of the date of issue of the commission's decision to issue a MA, rather than the (later) date of notification of that decision to the MA applicant.

This standard practice is not only inconsistent with the accepted approach to the calculation of the duration of another IP right (data exclusivity) but is also at odds with the fact that each centralized MA is only valid from the date of notification.

With this in mind, this author sought to challenge this standard practice by filing a request for correction of the term of a granted SPC (SPC/GB04/031, to colesevelam hydrochloride, which is the active ingredient in Genzyme's cholesterol-lowering product Cholestagel).

This correction request was filed simultaneously with a request for a six-month extension of that SPC, based upon the completion of clinical trials in the pediatric population in accordance with an agreed paediatric investigation plan.

Decision of the UK IPO

In a decision issued on 22 October, subsequent to a hearing at which this author argued the applicant's case, the hearing officer of the UK IPO accepted the argument that the relevant date of a centralized MA is the date of notification of that MA.

Consequences for the UK

Following the ruling in the Genzyme case, the UK IPO has now formally confirmed its new approach to the calculation of SPC term, based upon notification dates of centralized MAs.

Positive action will be required by SPC applicants or proprietors to benefit from the additional term. That is, the UK IPO will not automatically correct SPC term but will instead only act upon requests from proprietors or applicants.

It seems that, where they are justified, requests for correction of SPC will be granted by the UK IPO. However, it would seem prudent for rights holders not to delay in requesting correction of term, in order to ensure that the public (including generics competitors) are provided sufficient notice of the later SPC expiry date in the UK.

Other countries

To the knowledge of this author, the only other country to have adopted the same approach as the UK IPO to the calculation of SPC term is Belgium. Thus, at this time, there is significant disharmony across Europe that can only be resolved either by other national patent offices coming into line with the UK IPO's new practice or by the Court of Justice of the European Union providing a ruling on this issue.

It remains to be seen whether the involvement of the CJEU can be avoided by other national offices following the UK IPO's lead. What may be persuasive in this regard is the UK IPO's recent track record in reaching conclusions relating to SPC term that have eventually been rubber-stamped by the CJEU. That is, in connection with revolutionary concept of negative term SPCs, which also touches upon the issue of the duration of SPC protection, the UK IPO was the first office to accept another hypothesis put forward by this author that was ultimately confirmed by the CJEU.

In any event, this development represents good news for innovators as, for many products, even a few days' additional protection in the UK could bring significant benefits.

Mike Snodin is a senior attorney and head of pharma and nutrition at Avidity IP, a UK-based firm of European patent and trade mark attorneys. Email: mike.snodin@avidity-ip.com.

References for this article are available online at www.scripregulatoryaffairs.com