Patent Focus

Researched and written by Genericsweb

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Practicalities of paediatric extensions to the Supplementary Protection Certificate

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INTRODUCTION

The Paediatric Regulation[1] entered into force on 26th January, 2007. The regulation aims to facilitate the development and accessibility of medicinal products for use in the paediatric population by introducing a number of obligations, incentives and rewards for conducting the necessary clinical trials to assist in evaluating such use.

In short, all applications for marketing authorisation of new medicinal products and for those relating to new indications, new pharmaceutical forms and new routes of administration of existing, authorised medicinal products need to include the results of all studies performed and details of all information collected in compliance with an agreed Paediatric Investigation Plan (PIP) or alternatively, a decision to waive the product or class of products or defer the studies must have been reached by the European Medicines Agency (EMEA).

Where an applicant for marketing authorisation has included the results of an agreed PIP, one such reward/incentive for complying with the above is that the holder of a Supplementary Protection Certificate (SPC), or a patent which qualifies for the granting of one, shall be entitled to a 'six-month extension of the period referred to in Articles 13(1) and 13(2) of Regulation (EEC) No 1768/92'. Article 13 of the referred SPC regulation is set out in Box 1 for reference purposes. The six-month SPC extension is available for new and existing medicinal products, even if the results of the PIP do not give rise to any additional indications; furthermore, the protection afforded by the SPC is not limited to any paediatric indications authorised as a result of the PIP. The net result is that generic competitors can expect market entry dates for certain products to be pushed back by up to six months.

This is not recent news; however, the time is drawing near when the practicalities of complying with this regulation in the industry become clearer, and the inevitable variation in interpreting the regulation by different member states begins to take effect.

The general reading of the relevant regulations seems to be fairly logical, but when looking at specific circumstances a few options emerge for interpreting them differently, with vastly differing results in terms of the protection offered to innovators.

One of the earlier products that we may see benefit from the paediatric SPC extension is Merck's Losartan. For example the UK SPC is due to expire in early September 2009, thus Merck has to apply for paediatric extension with the UK Patent Office by 1st March, 2009 based on the rules stating that the application has to be made six months before expiry of the original SPC term. In order to do so, Merck clearly needs to have completed

Box 1: Article 13 Regulation (EEC) No. 1768/92.

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.
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.

the necessary studies outlined in the PIP and have received a positive opinion from the Paediatric Committee, which they may take up to 60 days to issue according to the regulation. The SPC application then needs to be evaluated by the patent office and a decision made on its validity before the original SPC term expires, but also timely enough for potential generic entrants to be able to plan any potential launch. This is a fairly straightforward case in that a patent with an existing SPC has a possibility for paediatric extension but it demonstrates that both the Paediatric Committee and the relevant patent office need to act in a very efficient and timely manner to ensure that the rewards of conducting the studies can be realised by the MA holder.

COMPLEX SCENARIOS

Let us turn our attention to some more complex scenarios where a patent that protects a product that is the subject of a PIP is not necessarily eligible for an SPC extension of term under normal circumstances, that is, where it is questionable whether the patent is one which 'qualifies for the granting of an SPC' as required by the Paediatric Regulation.

An SPC is usually awarded if the period that elapsed between the application date of the patent and the first marketing authorisation date in the EU is more than five years (subject to meeting other criteria). In the Losartan case above, the patent was eligible for an SPC with a term of approximately two years based on the seven years that elapsed between filing the patent and receiving marketing authorisation in Sweden. A six-month extension to this term is clearly within the scope of the regulation.

Snodin and Miles[2] outlined three scenarios that may occur when the time that elapses between patent application and marketing authorisation is less than five years, and in particular between 4½ and 5 years. Essentially, the three scenarios depend on whether the patent office in each member state is willing to grant a negative or zero SPC on a patent so that it may ultimately qualify for a six-month extension.

For example, another Merck product Sitagliptin first gained EU approval on 21st March, 2007. It is protected by a patent that was applied for on 5th July, 2002 resulting in a normal expiry date of 5th July, 2022. After the Paediatric Regulation came into force, Merck applied for an SPC with the UK Intellectual Property Office. Based on the 4 years and 8½ months that elapsed between patent filing and first marketing authorisation one would expect that no SPC extension would be granted. However, the Office granted an SPC that has a maximum expiry date of 22nd March, 2022, 3½ months before the patent on which it is based expires.

The UK Intellectual Property Office clearly took a view in accordance with Miles and Snowdon's Model A that an SPC is eligible to be granted in the situation where the subsequent grant of a paediatric extension would have an effect on the monopoly

period. In this case, the grant of a paediatric extension would result in monopoly protection ending on 22nd September, 2022.

Subsequent to this decision, there was an attempt to appeal that failed. Without studying the file wrapper for this application, one can only imagine that this appeal was an attempt to force the Intellectual property office to grant a zero term SPC (Miles and Snow Model C) so that six months Paediatric Regulation reward could be added to the end of the normal patent term, giving a valuable extra 3½ months monopoly protection.

Of course, one cannot assume that this interpretation will apply throughout the EU. Indeed, the Greek patent office has responded to a similar SPC application by granting it with a zero term, that is, the expiry date of the SPC is the same as the expiry date of the underlying patent, thus a Paediatric SPC extension would result in monopoly protection for this product until 6th January, 2023.

In contrast to these advantageous decisions to Merck, the patent offices in both Portugal and Slovenia have rejected similar applications for an SPC with a zero or negative term. In these cases the monopoly protection will expire on 5th July, 2022. This results in the situation where a product that receives first EU marketing authorisation between 4½ and 5 years from the patent application date will actually receive a shorter product monopoly period than one that receives authorisation more than five years after patent application (Miles and Snow Model B).

The lessons from the Sitagliptin example are ones that we have been forced to learn many times before — despite attempts to harmonise intellectual property rights in the EU it is still necessary to investigate patent and SPC protection thoroughly in each member state to determine the possible launch dates.

The questions to be asked of this legislation can become far more confusing and will no doubt be tested by innovator companies and, if successful, challenged by competing generic manufacturers. For example, where an innovator has chosen not to file an SPC prior to the introduction of the Paediatric Regulation because there was seemingly no benefit, would the innovator be able to apply for an SPC now in those countries where a zero or negative term might be granted? The answer is probably no because no transitional period was incorporated into the regulation for filing of such SPCs. Is this fair on those that have possibly missed out in six months monopoly protection? Perhaps not, but certainly the lack of a reward to the innovator in these cases will provide little incentive to facilitate the development and accessibility of medicinal products for use in the paediatric population.

Confusion of how this regulation may be interpreted is compounded by the different ways in which SPCs are granted throughout EU (this will be the subject of a later article). Some questions for the more legally minded to ponder over may be:

- If more than one SPC has been granted in respect of a particular product in a given EU member state (something that is not uncommon), can the paediatric extension apply to each of the existing SPCs?
- If a Paediatric SPC extension is granted, is the scope of protection restricted to the subject matter of the patent or any product for which the PIP was devised? (This is particularly relevant where the SPC is granted on a process or polymorph patent and is also pertinent to the original SPC term.)

Such questions can only be answered fully by the courts in each of the member states and ultimately by the ECJ, but in the meantime the situation regarding the rewards for many PIPs and the dates that generic competitors can provide the public with cheaper access to these medicines will remain uncertain.

Notes

1. Regulation (EC) No. 1901/2006 of the European Parliament and of the Council of 12th December, 2006. Available from http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-1/reg_2006_1901/reg_2006_1901_en.pdf.
2. Making the Most of Paediatric Extensions, RAJ Pharma, July 2007, www.rajpharma.com.