Topical, authoritative and business-critical coverage of pharmaceutical and medical device regulatory affairs

SCRIP
Regulatory Affairs

SCRIP Regulatory Affairs
provides you with topical, authoritative and business-critical coverage of the latest developments in pharmaceutical and medical device regulatory affairs.
www.scripregulatoryaffairs.com

SCRIP Regulatory Affairs

Difficult Questions, Important Answers: The Latest Case On SPCs

Mike Snodin discusses the basis of, and possible answers to, some challenging questions on the law governing supplementary protection certificates that have recently been referred to the Court of Justice of the European Union.

Can a Treaty of Accession for a country that becomes a member state of the EU validly contain transitional provisions that retroactively modify (e.g., shorten the duration of) rights granted in that country prior to accession?

This question represents the fundamental basis of the latest case (C-572/15, *F. Hoffman-La Roche*) on supplementary protection certificates (SPCs) for pharmaceuticals to be initiated at the Court of Justice of the EU[1].

This article discusses the questions posed in C-572/15, as well as two alternative approaches to answering those questions. It also notes that when the CJEU's judgement is issued it could be particularly well timed for the purposes of SPC law. It could also have a much broader impact, through clarification of the scope and applicability of several general principles of EU law.

Background

SPCs under EU law

SPCs provide an additional period of protection beyond normal patent expiry for active ingredient(s) present in certain authorised medicinal products.

An SPC is a stand-alone right that is granted, on a country-by-country basis, where (on the date of application) there is both a valid patent and an in-force marketing authorisation (MA) for the active ingredient(s) in question.

SPCs for medicinal products are governed by EU legislation (Regulation (EC) No 469/2009), which allows for both the validity and duration of SPC protection to be determined according to harmonised rules.

According to the case law of the CJEU[2], a "normal" (i.e., unextended) SPC can remain in force only until the *earlier* of:

(a) 15 years from the first MA in the European Economic Area for a medicinal product containing the active ingredient(s) in question; and
(b) five years from expiry of the patent upon which the SPC is based.

For many SPCs, this means that the date of the first MA in the EEA is crucial to the determination of SPC duration.

SPCs under pre-accession, national law in Estonia

Before Estonia acceded to the EU on May 1, 2004, the national law of that country contained provisions that enabled the filing and grant of SPCs.

Whilst the provisions of the pre-accession SPC law in Estonia were no doubt drafted with the EU legislation in mind, those provisions will also have differed from the EU legislation in some important respects. One such difference will have been the manner in which the duration of SPC protection was calculated. That is, instead of being calculated by reference to the first MA in the EEA, the duration of pre-accession SPCs in Estonia will have been calculated by reference to the (typically later) first MA in Estonia.

Because of how the duration of pre-accession SPCs in Estonia was calculated, the duration of a significant proportion of those SPCs will have been longer than that of equivalent SPCs filed in other countries that were member states of the EU at that time.

Transitional Provisions Of The Treaty of Accession

The 2003 Treaty of Accession[3] (i.e., that for the Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovenia and Slovakia) amended the SPC legislation of the EU by insertion of the following wording:

> *This Regulation shall apply to supplementary protection certificates granted in accordance with the national legislation of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Malta, Poland, Slovenia and Slovakia prior to the date of accession*

This wording now forms Article 21(2) of Regulation 469/2009 (which governs SPCs for medicinal products) and Article 20(2) of Regulation 1610/96 (which governs SPCs for plant protection products).

These transitional provisions appear unambiguous in applying EU law to SPCs that, prior to accession, had been granted under national law. However, if taken at face value as applying to the calculation of SPC duration, those provisions could have the effect of shortening the duration of SPCs granted under pre-accession, national law.

This is because, as mentioned above, the term awarded under pre-accession laws in countries such as Estonia will, for a significant proportion of SPCs, be longer than the duration calculated under EU laws.

Questions Referred to the CJEU

Case C-572/15 relates to the issue of how duration should be calculated for an SPC granted in Estonia prior to the accession of that country to the EU. The questions referred to the CJEU in that case are as follows[4].

1. Must Article 21(2) of Regulation No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (codified version) be interpreted as shortening the duration of a supplementary protection certificate issued in a member state which was issued under national law before the accession of the state in question to the EU and whose duration in relation to an active substance, as stated in the supplementary protection certificate, would be longer than 15 years from the time when the first marketing authorisation in the Union was granted for a medicinal product consisting of the active substance or containing it?
2. If the answer to the first question is in the affirmative, is Article 21(2) of Regulation No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (codified version) compatible with European Union law, in particular the general principles of European Union law on the protection of acquired rights, the principle of the prohibition of retroactive effect of law, and the Charter of Fundamental Rights of the European Union?

Difficult Questions

If the CJEU answers question 1 in the affirmative, then this would lead to the *retroactive* shortening of the duration of

various SPCs granted under pre-accession, national law in the Czech Republic, Estonia, Croatia, Cyprus, Latvia, Lithuania, Malta, Poland, Romania, Slovenia and Slovakia.

It is very difficult to see how such a retroactive effect result would comply with important principles of EU law regarding legal certainty, including those mentioned specifically in question 2. This is not least because there are strong reasons to doubt that such retroactive effect is strictly necessary (i.e., justifiable on grounds that are more important than the preservation of legal certainty).

For example, in Article 21(1) of Regulation 469/2009, the opposite approach (i.e., **no** retroactive applicability) was adopted in respect of pre-accession, national SPCs granted in Austria, Finland and Sweden. In the light of the fact that different approaches have been taken by the legislators at different times, an argument of strict necessity for only one of those approaches would appear to be doomed to failure.

With the above in mind, the CJEU may well be keen to answer "no" to question 1. But how can the CJEU reach that answer when the wording of the relevant transitional provisions is seemingly unambiguous in providing retroactive effect?

A Possible, "Gentle" Solution

The view of this author is that one possible solution to the above conundrum may emerge from careful consideration of what is meant by "the Community" in Article 13(1) of Regulation 469/2009 (i.e., the provision governing SPC term).

In straightforward terms, "the Community" means member states of the EEA (which includes the member states of the EU, plus Norway, Iceland and Liechtenstein). However, this is not the end of the story, as the membership of the EEA changes with time.

Taking this latter consideration into mind, this author believes that there is a strong argument for permanently ascribing a particular meaning of "the Community" for each SPC application. For example, "the Community" could:

(I) take the **permanent** meaning of the list of countries that were member states of the EEA *on the date that the MA relied upon was issued*; and

(II) for those countries determined not to be on the list mentioned in point (I) above, be replaced by references to the country in which the MA relied upon was issued.

In this context, the MA relied upon would be the earliest MA taking effect in the country where the SPC application was filed, namely the MA supporting the SPC application under Article 3(b) of Regulation 469/2009.

With respect to CJEU case C-572/15, this solution would provide a neat way of answering "no" to question 1. This is because "the Community" for the Estonian SPC application in question would not include Estonia. Following point (II) above, references to "the Community" (including in Article 13(1)) would then be replaced by references to "Estonia" – meaning that the national SPC would retain the term that it was originally granted under national law.

The Nuclear Option

There is no explicit basis in the legislation for the interpretation of "the Community" proposed above. Nevertheless, there certainly are grounds for defending it as a common-sense interpretation that, with respect to the duration of SPC protection, ensures the preservation of legal certainty.

However, it is important to acknowledge that the retroactive effects of the above-mentioned transitional provisions extend beyond calculation of the duration of SPCs. That is, the retroactive application of the EU legislation may also modify (to a greater or lesser extent, depending upon the country in question) determinations of scope and/or validity of SPCs granted under pre-accession, national law. As they would also pose challenges in connection with the preservation of legal certainty, such retroactive effects would appear to be equally undesirable as the curtailment of SPC duration.

For this reason, the CJEU may instead prefer to take a much more radical approach, namely to find the relevant transitional provisions of the 2003, 2005 and 2012 Treaties of Accession to be invalid.

This alternative approach would have the advantage of finality, thereby avoiding the need for further references to clarify issues such as:

- the effect of the transitional provisions on the scope and/or validity of an SPC; or
- the meaning of the word "*granted*" in the transitional provisions (i.e., whether those provisions have any effect upon SPC applications that were filed but not yet granted at the time of EU accession).

Conclusions

There are other possible answers to the questions posed in C-572/15. Although difficult to justify in the view of this author, such alternative answers could even effectively confirm that, for some or all pre-accession SPCs, EU legislation indeed has retroactive effect (including on calculation of SPC duration).

In this respect, it remains to be seen whether, when providing its judgement (most likely by mid-2017 at the latest), the CJEU will choose either of the "gentle" and "nuclear" options discussed above. Whatever happens, the CJEU's judgement is certain to contain important learning points for individuals tasked with drafting EU treaties and secondary legislation.

The European Commission is currently considering a review of the SPC legislation of the EU[5,6], so the above-mentioned learning points could well emerge at a particularly opportune time. However, the potential impact of the CJEU's judgement may extend well beyond the sphere of SPC law. This is because it could provide important clarification on the scope and applicability of one or more general principles of EU law, such as the protection of acquired rights and/or the principle of the prohibition of retroactive effect of law. For this reason, and unusually for a case involving SPCs, C-572/15 may well attract many close observers.

References

1. *InfoCuria, C-572/15, F. Hoffman-La Roche, website accessed Jan.20, 2016, http://bit.ly/20567PF*
2. *Snodin, M, Every cloud has a silver lining: Portugal's loss may be the UK's gain, Scrip Regulatory Affairs, June 20, 2014*
3. *Treaty of Accession, provisional version published April 16, 2003, www.europarl.europa.eu/enlargement_new/treaty/default_en.htm*
4. *InfoCuria, Request for a preliminary ruling from the Riigikohus (Estonia) lodged on 2 November 2015 – F. Hoffmann-La Roche AG v Accord Healthcare OÜ, (Case C-572/15), website accessed Jan. 29, 2016, http://bit.ly/1PyGWzh*
5. *EU Wants Report On Fitness Of Supplementary Protection Certificate System, Scrip Regulatory Affairs, Jan 27, 2016*
6. *European Commission, Study on the legal aspects of the supplementary protection certificates in EU, Dec. 15, 2015, http://bit.ly/1WMItY8*

Mike Snodin is the founder and director of Park Grove IP, a UK-based patent attorney firm that provides advice to companies in the chemical, pharmaceutical and life sciences fields. The views expressed in this article are the personal views of the author. Email: mike.snodin@parkgrove-ip.com.

