

CASE COMMENTS

THE LATEST CASE ON SPCs: THE CJEU RULES IN FAVOUR OF CHAOS

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When the Riigikohus (Supreme Court) of Estonia referred questions to the Court of Justice of the EU (CJEU) in Case C-572/15 (*F. Hoffmann-La Roche*), the stage appeared to be set for a very interesting outcome. This is because it appeared that the CJEU would need to decide either to uphold the validity of (a plain reading of) a provision of primary EU law, or to instead interpret that provision in a manner consistent with a number of important, general principles of EU law.

The CJEU's judgment of 5 October 2016 in *F. Hoffmann-La Roche*¹ will therefore be a huge disappointment to many observers. This is not only because the court effectively 'ducked' issues relating to principles of EU law but also created huge uncertainty (and likely financial loss) for the holders of pre-accession SPCs in certain EU Member States.

Facts

SPCs and Their Term

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

Under EU law, the latest possible expiry date for a 'normal' (that is, unextended) SPC protecting an active ingredient, or combination of active ingredients, is 15 years from the first marketing authorisation (MA)² in the European Economic Area (EEA) for a medicinal product containing the active ingredient(s) in question.³

Prior to their accession to the EU, certain Member States (including states that acceded to the EU in 2004, 2007 or 2013) provided SPC protection under different (national) laws. Crucially, those national laws required SPC term to be calculated by reference to the first national MA in the country in question, as opposed to the first MA in the EEA.

For many pre-accession SPCs, calculating term using the first *national* MA (instead of the first MA in the EEA) leads to a significantly later expiry date.

EU Accession Treaties

The 2003, 2005 and 2011 Treaties of Accession⁴ all refer to Acts of Accession that contain transitional provisions stipulating the application of EU law to pre-accession SPCs. These transitional provisions are reflected in Article 21(2) of Regulation 469/2009, which provides that:

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

The purported *retroactive* application of EU legislation to pre-accession SPCs represents a marked departure from the approach taken for SPCs in earlier accession states. The transitional provisions for those states, as reflected in Article 21(1) of Regulation 469/2009, were:

with regard to Austria, Finland and Sweden, this Regulation shall not apply to certificates granted in accordance with their national legislation before 1 January 1995. (emphasis added)

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1) See <http://bit.ly/2dPRgZr>.

2) In the light of the CJEU's decision in *Neurim* (Case C-130/11: <http://bit.ly/2e2Wa8g>), this should be interpreted as the first *relevant* MA.

3) M. Snodin, 'Every cloud has a silver lining: Portugal's loss may be the UK's gain', *Scrip Regulatory Affairs*, 20 June 2014.

4) <http://eur-lex.europa.eu/collection/eu-law/treaties-accession.html>.

Questions Posed to the CJEU

With respect to the treatment of pre-accession SPCs, it is unclear why divergent approaches were taken in the pre- and post-millennium Acts of Accession. However, what is clear is that the purported *retroactive* application of the new (EU) legal standard to SPCs granted under a different (national) law generates serious issues in connection with legal certainty and the protection of legitimate expectations.

These issues came to the fore in connection with an SPC in Estonia for Xeloda® (capecitabine). That SPC was granted several years prior to Estonia's accession to the EU, and validly awarded a term calculated by reference to an Estonian MA. Nevertheless, the question arose as to whether Estonia's subsequent accession to the EU, and the consequent application of Article 21(2) of Regulation 469/2009 to pre-accession SPCs, required the term of the Xeloda® SPC to be recalculated (that is, shortened), based upon an earlier MA for capecitabine in the EEA.

In the light of the difficulty of interpreting the transitional provisions in a manner consistent with general principles of EU law, the Riigikohus (Supreme Court) of Estonia referred the following questions to the CJEU.⁵

(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?

Decision

As it often does, the court elected to answer the questions out of order.

Question 2

The CJEU declined to answer the question of compatibility of Article 21(2) with general principles of EU law. In this respect, the court held that it did not have jurisdiction to rule on the validity of a provision that derives from an agreement (an Act of Accession) that represents primary EU law.

In reaching this conclusion, the court referenced its earlier case law,⁶ and reiterated its view that primary EU law, such as the provisions reproduced in Article 21(2), 'may not be suspended, amended or repealed otherwise than by means of the procedures laid down for the revision of the original Treaties'.

Question 1

Having decided that it was unable to address the potentially worrying consequences of upholding the validity of Article 21(2), the court essentially answered question 1 in the affirmative.

In doing so, the court explicitly stated that the term of the SPC concerned should be calculated by reference to the first MA in the EEA (a Swiss MA), instead of by reference to the MA in Estonia.

Commentary

Surprising Elements of the Judgment

For the SPC that was at issue in *F. Hoffmann-La Roche*, following the CJEU's judgment leads to a maximum term expiring almost three years earlier than the term originally awarded under pre-accession law in Estonia.

5) *F. Hoffmann-La Roche AG v Accord Healthcare OÜ* (Case C-572/15; <http://bit.ly/1PyGWzh>).

6) *LAlSA and CPC España v Council* (Cases C-31/86 and C-35/86; <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A61986Cj0031>).

Surprisingly, the court asserted that ‘there can be no question of retroactive application’ of EU law in connection with this recalculation of SPC term.

In justifying this position, the court firstly pointed to established case law holding that:

- (a) new (substantive) rules of EU law apply immediately to the future effects of a situation which arose under the old rules; and
- (b) from the date of accession of a new Member State, the provisions of EU law apply under the conditions laid down in, for example, the relevant Act of Accession.

The court then pointed out that the SPC in question only took effect at the end of the lawful term of the basic patent, which was after the date of accession of Estonia to the EU.

In the first of two quite astonishing omissions, the court did not consider whether the conclusion on retroactivity would have been different if (as would have been perfectly possible) the SPC *had* been in force upon the date of accession.

National SPCs in force on the date of EU accession (in certain 2004 and 2007 accession states) will now have expired. Nevertheless, the retroactive recalculation of the duration such SPCs could still have important legal implications, for example in connection with payments made under licence agreements.

The second omission of the court was the failure to consider the implications of its ruling for SPC validity (as opposed to SPC term). In this respect, *possible* consequences of the decision in *F. Hoffmann-La Roche* include invalidity of:

- (i) all pre-accession SPCs, for failure to comply with Article 3(b) (on the grounds that the national MAs relied upon were granted neither under the requisite EU rules nor under rules deemed to be equivalent to them); or
- (ii) those pre-accession SPCs for which application of EU legislation leads to a recalculated term of less than minus six months.⁷

It is impossible to argue that there is no retroactivity in invalidating SPCs (under EU rules) that were perfectly valid when originally granted (under pre-accession, national rules). Therefore, in failing to directly address this possibility, the CJEU has placed itself in a very difficult position. It has also generated huge uncertainty for the holders of pre-accession SPCs.

What Else Could the Court Have Done?

As troubling as the gaps in the CJEU’s reasoning may be, the most disturbing aspect of the judgment in *F. Hoffmann-La Roche* was the court’s refusal to apply principles of EU law that serve to provide legal certainty.

Given the importance of such principles, SPC holders may be left wondering why the CJEU did not choose to deploy the one weapon that it holds in its arsenal for tackling provisions stemming from primary law, namely *interpretation* of those provisions.

In this respect, it appears to this author that it is perfectly possible to interpret Article 21(2) in a manner that does not contravene important principles of EU law (such as the protection of acquired rights). This could be achieved, for example, by:

- observing that, as Member States of the EU and/or the Council of Europe, the signatories to the Acts of Accession were all bound to uphold the right to (the protection of) property enshrined in Article 1 of Protocol 1 to the European Convention on Human Rights (ECHR) and Article 17 of the Charter of Fundamental Rights of the EU; and
- assuming that, as a result of the obligations placed upon the signatories to uphold that right, they could not have intended to enter into an agreement that led to its violation.

If the CJEU had followed this course, Article 21(2) could then have been interpreted so that it applied EU rules to pre-accession SPCs only when doing so did not breach important principles, including those of Article 1 of Protocol 1 to the ECHR.

⁷ The CJEU’s ruling in *Merck Sharp & Dohme* (Case C-125/10: <http://bit.ly/2ezZWYg>) arguably only confirms the validity of SPCs having either a positive term or a term between zero and minus six months.

In its prior case law,⁸ the court has shown itself capable of considering context (for example, objectives pursued by EU law) when interpreting the effects of other provisions deriving from accession treaties.⁹ It is therefore unclear why the court failed to do the same for Article 21(2).

Even if there were good reasons for adopting a 'plain' interpretation of Article 21(2), the view of this author is that the court could still have reached a conclusion that preserved legal certainty. Indeed, this author has previously suggested¹⁰ an interpretation of Article 13 of Regulation 469/2009 that would have avoided retroactive curtailment of the duration of pre-accession SPCs.

As Article 21(2) is a transitional provision, it will eventually cease to have practical effects. Indeed, a significant percentage of pre-accession SPCs will have already expired. Nevertheless, SPCs affected by the judgment in *F. Hoffmann-La Roche* may well include some that are (or at least were) particularly valuable. It is therefore possible that the holders of those SPCs will seek alternative ways of addressing the issue of non-compliance of Article 21(2) with EU legal norms.

Possible Remedy

When the Riigikohus inevitably confirms the CJEU's judgment on the effects of Article 21(2), the SPC holder will have exhausted 'all domestic remedies' against what, in the view of this author, represents a clear violation of important legal principles (such as the protection of legitimate expectations).

Whilst this will no doubt be a huge disappointment for many SPC holders, it does clear the way for a possible action at the European Court of Human Rights (ECtHR). The case law of the ECtHR includes precedents for applying ECHR Protocol 1, Article 1 to the protection of *intellectual* property,¹¹ including in circumstances where there is merely a legitimate expectation of obtaining an IP right.¹² It also includes a precedent for finding a violation of Protocol 1, Article 1 in circumstances where property has been taken without payment of an amount 'reasonably related to its value',¹³ and

even for holding an individual state responsible for entering into treaty commitments that violate the ECHR.¹⁴

Thus, whilst it is uncertain whether a claim to the ECtHR would be successful, it appears to this author that the holders of pre-accession SPCs that have been effectively invalidated by the CJEU's judgment (or had their term either wholly or partly eliminated) would have little difficulty in demonstrating that the provisions of Article 21(2) of Regulation 469/2009 violate the principles of Article 1 of Protocol 1 to the ECHR.

Whether any holders of pre-accession SPCs decide to pursue such actions remains to be seen. In the view of this author, one potential attraction of pursuing (and succeeding in) such actions would be to establish a precedent that would help to ensure that, at least in Europe, there is an effective remedy against the destruction of the value of intellectual property rights *via* international agreements that change the legal order. Indeed, such a precedent could help to ensure that obligations under the ECHR (including the protection of legitimate expectations) are taken seriously in the upcoming negotiations for the 'Brexit' agreement between the EU and the United Kingdom.

Summary

The CJEU's judgment in *F. Hoffmann-La Roche* will be a huge disappointment to the holders of pre-accession SPCs in the countries listed in Article 21(2). This is because the judgment raises serious concerns in both the short and the longer term.

Concerns in the short term are likely to focus upon negative effects of the judgment upon the value of many pre-accession SPCs, as well as the question of whether the countries listed in Article 21(2) will be liable for entering into treaty commitments that appear to violate the ECHR.

On the other hand, longer term concerns may arise around the issue of whether signatories to the ECHR will take their obligations more seriously when concluding future international treaties (such as the likely 'Brexit' agreement) that could also have an impact upon acquired intellectual property rights.

8) Article 19(1) of Regulation 1768/92 (now obsolete) is discussed in *Kirin Amgen v Lietuvos Respublikos valstybinis patentu biuras* (Case C-66/09: <http://bit.ly/2dLOSrG>) and Article 19a(e) of Regulation 1768/92 (now Article 21(1) of Regulation 469/2009) is discussed in *Synthon v Merz* (Case C-195/09: <http://bit.ly/2dKQMoz>).

9) The 1994 and 2003 Accession Treaties.

10) M. Snodin, 'Difficult Questions, Important Answers: The Latest Case on SPCs', *Scrip Regulatory Affairs*, 1 February 2016.

11) *Smith Kline and French Laboratories Ltd v Netherlands* (1990) 66 DR 70.

12) *Anheuser-Busch Inc. v Portugal* (ECHR, Application no 73049/01): [http://hudoc.echr.coe.int/eng?i=001-78981#{"itemid":\["001-78981"\]}](http://hudoc.echr.coe.int/eng?i=001-78981#{).

13) *Maurice v France* (Application no 11810/03): [http://hudoc.echr.coe.int/eng#{"itemid":\["001-70445"\]}](http://hudoc.echr.coe.int/eng#{).

14) *Matthews v United Kingdom* (Application no 24833/94): <http://www.webcitation.org/5lWx37qMR>.