News and Views

The European Commission submits its views in an important case for SPCs to biologics

Summary

To the knowledge of Park Grove IP, *Pharmaq v Intervet* (E-16/14) is the first case from any of the European Free Trade Association (EFTA) states of Iceland, Liechtenstein and Norway to seek clarification from the EFTA Court on the law relating to Supplementary Protection Certificates (SPCs).

The case is potentially of huge importance to those seeking (or holding) supplementary protection for biological active ingredients in European Union (EU) or EFTA Member States. This is because it raises fundamental questions relating to the breadth of protection provided by an SPC to a biological product, and may well lead to an opinion from the court that could influence the extent to which such SPCs can be enforced against the producers of "copycat" (i.e. biosimilar or "me too") biological products.

The case will also be of great interest to those seeking SPC protection for products for which early (i.e. prior to marketing authorisation) access has been granted to a limited number of individuals, for example under "emergency" conditions (such as in the event of a serious epidemic disease) or on a named patient or compassionate basis. This is because the EFTA court has been asked to provide an opinion on whether early supply of a veterinary medicinal product under "emergency" conditions prevents SPC protection from being obtained based upon a later marketing authorisation (MA) for the product.

The EFTA Court will only provide a non-binding opinion. Moreover, that opinion is one that the Court of Justice of the EU (CJEU) would be free to ignore if asked to rule on the same or similar issues. In this respect, whilst the opinion of the EFTA Court will be important (and potentially persuasive for future cases in the EU), the most interesting aspect of the case is the fact that observations have been submitted to the Court by parties that include the European Commission (EC) and the Government of the United Kingdom.

Both the EC and the UK Government submitted arguments that are generally supportive of the conclusion that early access to medicinal products should not hinder the grant of SPC protection based upon a later MA. However, whilst the UK Government did not comment upon the crucial questions relating to SPC scope, the EC has proposed answers that may have profound (and, in part, undesirable) implications.

The EC's proposed answers could lead to both harsh results for innovators and/or prolonged uncertainty for producers of "copycat" biological products. Parties having a stake in either innovative or "copycat" biological products may therefore wish to develop, and advocate to national governments and the European Commission, alternative solutions to the problem of SPC scope for biological products that lead to:

- a fairer result for innovators; and
- more (and earlier) certainty on freedom to operate.

The background to the *Pharmaq v Intervet* case and to the above comments and conclusions is provided in more detail below.

SPCs and the EFTA Court: Background

An SPC is a stand-alone form of intellectual property in Europe that provides an additional period of exclusivity for certain products that suffer significant regulatory delays prior to marketing - i.e. certain human or veterinary medicinal products, or so-called Plant Protection Products (agrochemicals and the like).

SPCs are available in Member States of the EU. However, they are also available in Switzerland (CH) and the EFTA Member States, namely Iceland (IS), Liechtenstein (LI) and Norway (NO).

Although not identical, the SPC laws in IS, LI and NO have close ties to the EU laws governing SPCs. This is because IS, LI and NO form part of the European Economic Area (the EEA, which defines the territorial extent of the EU's internal market).

In the EU, the Court of Justice of the EU (CJEU) serves as the final arbiter for clarification of the law on SPCs. However, for SPC cases arising in IS, LI or NO, that role is awarded to the EFTA Court.

Unlike the CJEU, the EFTA Court does not issue binding judgements but instead issues only non-binding opinions. Nevertheless, given the close connections between the SPC laws of EU and EFTA Member States, opinions issued by the EFTA Court could well be seen as persuasive by national patent offices and courts in the EU. Such an opinion could even be viewed as persuasive by the CJEU - although that Court would be free to reach completely different conclusions if asked to rule on the same or similar issues.

Pharmaq v Intervet (E-16/14): Background

The dispute between Pharmaq AS and Intervet International BV relates to an SPC granted in Norway for a vaccine for use in preventing a disease in salmon. The facts behind the dispute are highly complex and raise a number of tricky questions. The court hearing the case (the Oslo District Court) therefore sought clarification from the EFTA Court on the interpretation of the provisions of SPC law that are decisive for settling the dispute.

Whilst the questions posed to the EFTA Court are quite specific (in view of the facts of the case), they raise issues that could easily be expressed in broader terms. As a result, the opinion of the EFTA Court could well have implications for a wide range of other SPCs, and in particular SPCs for biological products. When expressed in broad terms, the most important questions raised by the *Pharmaq v Intervet* case can be framed as follows.

1. Medicinal products can sometimes be supplied to users prior to the grant of a marketing authorisation (e.g. under officially sanctioned, special exemptions that can be used, particularly in "emergency" situations). If that happens, does this prejudice the grant of SPCs that are based upon the marketing authorisation?

2. If the answer to question 1 is yes, can an SPC be based upon the (earlier, officially sanctioned) supply to users instead of upon the marketing authorisation?

3. Can the "product" for an SPC be defined as encompassing variants of the authorised medicinal product (e.g. a different strain of the same virus)?

4. If the answer to question 3 is yes, does the scope of protection of the granted SPC encompass all such variants that: (i) fall within the "product" definition; and (ii) that were protected by the basic patent?

In terms of the regulatory provisions governing pre-MA supply of medicinal products, it may be possible to draw distinctions between the principles applying to human medicinal products (e.g. supply on the grounds of compassionate use) and those applying to veterinary medicaments (e.g. special approval exemptions that are applicable in the event of serious epidemic diseases). Indeed, the observations submitted by the UK Government stress the importance of drawing such distinctions. Nevertheless, it is easy to see how the EFTA Court could answer questions 1 and 2 above in a manner that could have implications for both human and veterinary medicinal products alike.

Further, the EFTA Court's opinion on questions 3 and 4 will attract particular interest from the manufacturers of biosimilars. This is on the

grounds that no court in Europe has yet provided a ruling on the issue of:

- whether SPCs to innovative biological products can validly encompass structurally similar (but non-identical) variants of the innovator's authorised product; or
- whether the authorisation route used for the similar biological product makes any difference to the question of SPC infringement (i.e. if it matters whether authorisation of the similar product relied in part upon clinical data submitted in respect of the innovator's product).

Recent Developments

On 27 January 2015, the EFTA Court held a hearing in the *Pharmaq v Intervet* case. Although the court has not yet issued its decision (this can perhaps be expected within about 1 to 6 months), its deliberations will be aided by a Report for the Hearing that was prepared by a judge (Páll Hreinsson) acting as Rapporteur for the case.

A copy of the Report may be found at the following link.

http://www.eftacourt.int/uploads/tx_nvcases/16_14_RH_EN_01.pdf

Discussion

The Report prepared by Judge-Rapporteur Hreinsson is very significant. This is because, although the judge does not present his own conclusions on the questions referred, he summarises the arguments made by the parties to the case and other parties who have filed observations. Indeed, it is the identities of the other parties (the UK Government, the EFTA Surveillance Authority and the European Commission) and the nature of their submissions that makes the report particularly significant.

Whilst the observations of the EFTA Surveillance Authority are largely aligned with those of the plaintiff (Pharmaq AS), those of the UK Government are restricted to the kind of issues raised by questions 1 and 2 above. However, it is the observations (including proposed answers) submitted by the Commission that make for the most interesting reading.

With regard to the issues raised in questions 1 and 2 above, the Commission proposes the following answer.

"*Articles 2, 3(d) and 13(1) of the SPC Regulation should be interpreted to the effect that they* ***do not preclude the granting of an SPC*** *on the basis of a marketing authorisation granted subsequent to safety and efficacy testing in accordance with Directive 2001/82 where this marketing authorisation is preceded by a licence, based on Article 8 subparagraph 1 of Directive 2001/82,* ***provided that the period, if any, during which that licence gives the medicinal product in question essentially full market access is not compensated for when the duration of the SPC is determined****. Whether there has been full market access under the licence is a question of fact to be assessed by the national court*" (emphasis added).

Thus, the Commission proposes that the grant of early (pre-MA) access to medicinal products:

- should not affect the *validity* of SPC protection based upon a later MA; but
- may affect the calculation of the *duration* of the SPC – though only in circumstances where the early access amounts to "essentially full market access" (which is a question of fact to be determined in each case).

Further, the Commission's observations on the important issues raised by questions 3 and 4 above contain the following comments.

"*where an allegedly infringing strain is* ***marketable under the marketing authorisation covering the patented strain and is a therapeutic equivalent to the latter****, the allegedly infringing strain is clearly covered by that marketing authorisation for the purposes of Article 4 of the SPC Regulation*" (emphasis added).

The observations then conclude with the following, proposed answer.

"*Article 4 of the SPC Regulation should be interpreted to the effect that the scope of protection conferred by a supplementary protection certificate extends to a specific strain of a virus covered by the basis patent but not referred to in the marketing authorization for a virus vaccine relied on for the purposes of Article*

3(b) of the SPC Regulation ***only if the specific strain constitutes the same active ingredient as the authorised medicinal product. A supplementary protection certificate is invalid to the extent that it is granted a wider scope***" (emphasis added).

Thus, the Commission appears to be proposing that:

(i) it is the identity of the allegedly infringing product (and not the manner in which it is authorised) that is decisive for whether the product is encompassed by the scope of an SPC; but

(ii) to fall within the scope of an SPC, the allegedly infringing product has to constitute "*the same active ingredient as the authorised medicinal product*" which, in the case of a virus vaccine, means that the allegedly infringing strain must be "*marketable under the marketing authorisation covering the patented strain*" and be therapeutically equivalent to the patented strain.

Whilst the holders of SPCs to biological medicinal products will welcome the Commission's views on point (i) above, their views on point (ii) may cause some concern. This is because it is currently unclear which biosimilar or "me too" biological products the courts could decide are "*the same active ingredient as the authorised medicinal product*".

The Commission has indicated that the question of whether one active ingredient is "*the same*" as another is a question of fact that is to be determined in each case. However, adopting this standard for assessing the scope of SPC protection would lead to a great deal of uncertainty for both innovators and the producers of "copycat" (biosimilar or "me too") biological products.

This is because it seems likely that it will only be possible for either the innovator or the manufacturer of the "copycat" product to obtain an *opinion* on whether the innovator's SPC protection is capable of hindering the marketing of that product when the "copycat" product in question has (at the very least):

- been manufactured according to the final (commercial) process for obtaining that product;
- been assessed by regulators at least to an extent sufficient to enable an International Non-proprietary Name (INN) to be assigned to the product; and
- had its structural and therapeutic characteristics compared to those of the innovator's product.

Moreover, given the total absence of any guidance from the case law, it is perfectly possible that different parties will obtain diverging opinions on the same product and/or that a national court will reach a completely different opinion.

Indeed, at this point, it is not clear how many (and what type of) changes can be made to a biological active ingredient before it would no longer be regarded by the courts as being "*the same*". For example, even relatively small changes to the amino acid sequence of a protein, peptide or antibody, or to the glycosylation pattern of a glycoprotein, *may* lead to the resulting product being awarded a different INN by regulators. However, even in those circumstances, it may still be arguable in some cases that structurally related products having different INNs are therapeutically equivalent to one another – even though regulatory authorities may treat the products as being distinct.

With this in mind, the standard proposed by the European Commission for a virus vaccine (that an allegedly infringing strain must be "*marketable under the marketing authorisation covering the patented strain*") seems unduly restrictive in view of the case law of the CJEU (*Farmitalia*, C-392/97) that indicates that an SPC will only serve its purpose if it encompasses the active ingredient not only in its marketed form but also in therapeutically equivalent forms that are protected by the basic patent.

If the Commission's views are adopted by the courts in Europe, this could well lead to a harsh result for the innovators of biological products, wherein the additional period of protection provided by an SPC is incapable of preventing the marketing of a "copycat" product that fell within the scope of the basic patent upon which the SPC is based. This would arguably represent a result that is contrary to one of the fundamental purposes of the SPC legislation, which is to provide "*adequate effective protection*" that enables innovators to cover the

investment put into the research and development of innovative medicinal products.

Action Points

As the EFTA Court is now in possession of all of the information and arguments upon which it will base its opinion, there is little that can be done to further influence the outcome in the *Pharmaq v Intervet* case. However, it is important to remember that the CJEU (as well as the national courts of the EU member States) will not be bound by the opinion of the EFTA Court.

In this respect, the answers proposed by the European Commission in the *Pharmaq v Intervet* case show that there is much that needs to be done to persuade the Commission (as well as the national governments of the EU Member States) that a more practical solution is required for the issue of SPC scope for biological products. Moreover, in the absence of a strongly-advocated alternative solution that is both plausible and workable, there is a significant risk that the kind of solution proposed by the Commission will be the one adopted by all courts in Europe.

As discussed above, the European Commission's current views could lead to a harsh result for innovators of biological products. It could also lead to prolonged uncertainty (up to a late stage of development) over freedom to operate for "copycat" biological products. Parties having a stake in either innovative or "copycat" biological products would therefore appear to have a common interest in formulating and advocating an alternative solution for the scope of SPCs to biological products that strikes a fair balance between the provision of:

(a) an appropriate breadth of supplementary protection for innovators (in order to enable costs to be recouped and to incentivise further research and development); and

(b) a clear boundary for the limits of supplementary protection, which boundary can ideally be determined at an early stage – i.e. before significant investment is made in a "copycat" (biosimilar or "me too") biological product.

Parties having a stake in either innovative or "copycat" biological products may therefore wish to develop, and advocate to national governments and the European Commission, such an alternative solution. Although SPC protection may not represent the only possible solution to the problem of achieving a fair balance between (a) and (b) above, it represents the most effective tool that is currently available in Europe.

In the light of the above, please contact Mike Snodin (mike.snodin@parkgrove-ip.com) if you would like our assistance in developing or advocating alternative solutions to the problem of SPC scope for biologics. Please also contact Mike if you would like our advice on any other matter.