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SPCs for biologics – guidance on product definitions, scope and validity from the EFTA Court in *Pharmaq v Intervet* (E-16/14)

The EFTA Court has provided some much needed guidance regarding the scope and validity of SPCs for biologics, but the language used may concern innovators. It remains to be seen whether the CJEU will agree with the EFTA Court's approach.

The SPC Regulation (469/2009/EC) has been the subject of extensive analysis and numerous referrals to the CJEU. However, there is still relatively little guidance regarding what is the scope of protection provided by an SPC and what is the significance of the definition of the "product" in the SPC in relation to its scope and validity. Uncertainty regarding the range of products that may be covered by an SPC and the optimum product definition in an SPC application is particularly acute for biologics. With the increasing number of biologics coming off patent and facing biosimilar competition, these issues are of great interest to the biopharmaceutical industry. The recent judgment of the Court of Justice of the European Free Trade Association States (EFTA Court) in *Pharmaq AS v Intervet International BV* (E-16/14) provides important guidance for the EFTA states and perhaps some clues about how the CJEU will address these issues when it is asked to consider them, as it inevitably will.

Background

The EFTA Court fulfils a role similar to the CJEU for Norway, Iceland and Liechtenstein. These states are not members of the EU, but they are members of the EEA, and the EEA agreement incorporates the SPC Regulation. Judgments of the EFTA Court are not binding on the CJEU or courts in non-EFTA states, but in the absence of guidance from the CJEU on the particular issues considered by the EFTA Court in this case, its judgment may turn out to be persuasive in these states. Notably, the European Commission has taken the time to make submissions in this case, which emphasises its potential significance across Europe.

Pharmaq AS and Intervet International BV had developed vaccines against viral pancreatic disease in salmon using different inactivated virus strains. Pharmaq sought a declaration before the Oslo District Court that a Norwegian SPC held by Intervet does not cover the virus strain in the Pharmaq vaccine, or that the SPC is invalid. The SPC in question is based on a marketing authorisation for the specific strain used by Intervet, but the SPC was granted with a broader product definition that encompasses the Pharmaq strain. The Oslo District Court asked the EFTA Court to consider whether the scope of protection for an SPC can cover not only the specific strain included in the relevant medicinal product, but also other strains covered by the basic patent and the SPC product definition, and whether an SPC is valid if it is granted with a product definition that is not limited to the authorised strain.

The EFTA Court was also asked to consider the validity of the SPC in light of earlier marketing of the Intervet vaccine under special approval exemptions, prior to the full marketing authorisation used for the SPC application. The exemptions are used in rare circumstances to allow provisional supply of products in the event of serious diseases and this aspect of the judgment is not discussed here.

Context

The questions addressed by the EFTA Court are significant because practice regarding how a product should be defined in an SPC application and the resulting scope of a granted SPC is not settled. Article 4 of the SPC Regulation states that "the protection conferred by a certificate shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market", but as in the present case, many SPCs are granted with product definitions that encompass other products in addition to the authorised product. Also, the scope of protection provided by SPCs, in particular in relation to biologics, has

not been clearly defined in the case law. Currently, the entry of biosimilars to the market generally respects innovators' SPCs covering reference products, but it has not been confirmed that an SPC for a reference product will necessarily always cover a biosimilar. The CJEU held a number of years ago in *Farmitalia* (C-392/97) that an SPC "is capable of covering the product, as a medicinal product, in any of the forms enjoying the protection of the basic patent", which suggests that a broad interpretation of Article 4 is appropriate. However, Farmitalia related to a small chemical entity and there is doubt whether the reasoning in *Farmitalia* can be transposed to complex biologics.

Judgment and comment

In its judgment, the EFTA Court apparently approves the reasoning in *Farmitalia* as relevant to complex biologic products, such as the vaccine compositions at issue, and the Court repeats the observation in *Farmitalia* that an excessively narrow interpretation of Article 4 would allow medicinal products that are "therapeutically equivalent" to the product protected by the SPC to enter the market. The Court felt this approach would frustrate the purpose of the SPC Regulation (paragraph 86 of the judgment). These comments should be reassuring for biologics innovators because they suggest that biosimilars, which generally must be "therapeutically equivalent" to a reference product, will be covered by an SPC. However, the Court then turns to Article 4 itself and provides a final answer to the questions using more narrow language: "the scope of protection conferred by a supplementary protection certificate extends to a specific strain of a virus covered by the basic patent, but not referred to in the marketing authorisation ... only if the specific strain constitutes the same active ingredient as the authorised medicinal product and has therapeutic effects falling within the therapeutic indications for which the marketing authorisation was granted" (answer 2 of the judgment). This answer appears to suggest that the Court considered an SPC to cover products not referred to in the marketing authorisation only if the products constitute the same active ingredient, without any reference to products that are "therapeutically equivalent". It is unclear what variation or modification might cause a biologic to no longer be considered "the same active ingredient". Nevertheless, despite the relatively narrow language used, it appears that the Court intended to imply that useful scope around the authorised product should be acknowledged, because the Court asserted that "It is not relevant whether a medicinal product based on such other strain would require a separate marketing authorisation". This is significant, because it suggests that follow-on products cannot be distanced from an SPC by obtaining a new marketing authorisation, which was a suggestion made by Pharmaq and the EFTA Surveillance Authority.

The part of the judgment referring to "the same active ingredient" appears to be based on submissions made by the European Commission. However, the European Commission additionally submitted that if an allegedly infringing strain is marketable under the marketing authorisation for the SPC and is a therapeutic equivalent of the authorised product, then the allegedly infringing strain is clearly covered for the purposes of Article 4 (paragraph 78 of the judgment). This aspect of the European Commission's submissions does not appear to have been followed by the Court, but the European Commission's submissions will nevertheless be of interest, especially outside of the EFTA states.

The Court also uses strong language in its comments regarding the validity of SPCs granted with product definitions that are broader than the marketing authorisation. The Court concludes that: "A supplementary protection certificate is invalid to the extent it is granted a wider scope than that set out in the relevant marketing authorisation." Taken out of context, this conclusion will be a concern to many SPC proprietors who might have been granted SPCs with apparently broad product definitions. However, this aspect of the judgment does not include detailed reasoning and it may not have been the Court's intention to suggest that SPCs with broad product definitions are invalid or partially invalid, rather than merely partially unenforceable. Indeed, the Court's comment regarding SPC validity is possibly inconsistent with its comments regarding SPC scope. The Court did not indicate that the product definition used for an SPC is relevant when interpreting its scope, and so perhaps an overly-broad product definition cannot render an SPC invalid. If the Court's comment is read as indicating that an SPC is unenforceable beyond the active ingredient set out in the marketing authorisation, this is more consistent with the Court's other findings.

The Court's judgment is, of course, focussed on the issues as they relate to the specific inactivated virus vaccine products that were under dispute, and the Court's reasoning is not detailed enough to indicate how broadly the statements should be applied. It is also difficult to predict to what extent the Court's position will be followed by other courts. Nevertheless, the judgment is an important addition to SPC jurisprudence, especially in the current absence of guidance from the CJEU on these points.

Authors: Camilla Balleny & Ian MacLeod

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