# Does an SPC for a Biological Product Cover a Biosimilar?

To what extent will a Supplementary Protection Certificate (SPC) for a biological product be considered to encompass closely-related alternatives such as biosimilars? This question will become increasingly important as more and more biological medicinal products, and their competing biosimilars, enter the marketplace. We expect to see the issue arise before the national courts of the EU and the UK, and ultimately – at least for EU member states – the question is likely to require a referral to the CJEU. Until that happens, however, arguably the best available guidance is that provided by the EFTA court in 2015, in its judgment E-16/14 (Pharmaq v Intervet), subsequently applied in 2016 by the Norwegian Court of Appeal. This briefing provides an analysis of Pharmaq v Intervet as well as our conclusions and recommendations for those seeking SPCs for biological products across Europe.

In December 2016 the Norwegian Court of Appeal handed down its decision in Pharmaq v Intervet[1], which concerns the validity of Intervet's SPC for a viral vaccine for preventing pancreatic disease (PD) in salmonid fish. Questions relating to this case had been considered by the EFTA Court[2] in its judgment E-16/14[3], having been referred by the Oslo District Court. The advice of the EFTA Court was subsequently interpreted by the District Court who found in favour of Intervet3, with the December 2016 decision concerning Pharmaq's appeal.

The case is of general interest in that it relates to the extent to which an SPC for a biological product may be considered to encompass closely-related alternatives such as biosimilars. The guidance of the EFTA court was that an SPC is invalid due to non-compliance with Article 4 of the SPC Regulation[4], to the extent that it has been granted with a wider scope than that set out in the relevant Marketing Authorisation (MA). However, the EFTA Court also proposed that an SPC for a viral vaccine could extend to cover a specific strain of virus encompassed by the claims of the patent but not mentioned in the MA, provided said strain constitutes the "same active ingredient" as the authorised product, and has therapeutic effects within the same indications for which the MA was granted.

Applying this guidance, the Oslo District Court had found in a majority decision that the competing products of Pharmaq and Intervet did constitute the "same active ingredient", thus holding in favour of Intervet. However, reconsidering the EFTA Court's guidance in the light of new evidence before it, the Norwegian Court of Appeal has now overturned that earlier decision.

Claim 1 of Intervet's patent explicitly recited the deposited virus strain (of type SAV-1) that was used in its own vaccine. However, the claim referred also to "closely-related strains which share similar genotypic or phenotypic characteristics". In proceedings relating to the patent, the virus strain (of type SAV-3) used in Pharmaq's competing product was found to infringe the claim by virtue of this "closely-related" feature. Intervet's MA specifically describes the deposited strain used in its own product. Nonetheless, when applying for an SPC from the Norwegian Patent Office, Intervet stipulated a definition of the product which precisely mirrored the wording of claim 1 of the patent, thus including the reference to "closely-related strains".

The Norwegian Patent Office was evidently concerned that this product definition was broader than that provided by the MA, and thus problematic under Article 4 of the SPC Regulation. There is some suggestion that the examiner's preference would have been to limit to closely-related strains of the SAV-1 type, but he found no basis for this interpretation in the patent. Therefore, recognising a legitimate concern that an SPC limited solely to the deposited strain could be easily circumvented, the Office awarded Intervet the benefit of the doubt – in the knowledge that Pharmaq were bringing a legal challenge to the SPC and that the question would ultimately be decided in the courts.

The proceedings before the Court of Appeal spent a considerable amount of effort interpreting the EFTA Court's guidance, and the extent to which Intervet's and Pharmaq's products might be considered to constitute the same active ingredient. As part of their argumentation, Intervet relied upon the decision of the CJEU in C-392/97 (Farmitalia)[5]. This long-standing decision established that where a patent claims a chemical compound and the marketing authorisation specifies a particular salt, the SPC is interpreted to cover alternative salts and esters of the same compound, which are in principle therapeutically equivalent. It has been argued (including by Intervet) that similar reasoning should apply for closely-related biological products in order for the purpose of the SPC Regulation to be met.

The Norwegian Court of Appeal recognised the importance of Farmitalia in establishing that the purpose of the SPC Regulation would not be satisfied if therapeutically equivalent salts and esters were not covered by an SPC for a small chemical entity. They also recognised the desirability of establishing a corresponding definition for biological medicinal products which, in line with Farmitalia, prevents third parties from escaping the scope of an SPC by making only minor changes to an active ingredient that otherwise remains therapeutically equivalent. However, they noted that Farmitalia provides limited guidance for biological products (unsurprisingly given the age of that decision) and the Court was concerned also to balance the scope of protection of SPCs for such products against the other objectives of the SPC regulation. In particular the aim that improvements to medicinal products should not be kept off the market to the detriment of human or veterinary health. Much of the Norwegian Court of Appeal's decision is thus spent grappling with these conflicting pressures.

They found what they considered to be helpful guidance in a 2009

judgment of the Dutch Appellate Court submitted by Pharmaq, referred to as the "Yeda judgment" (2000809060/1/H3). In that judgment, the Dutch Court upheld the decision of the Dutch Patent Office to grant an SPC only in respect of the specific active ingredient Adalimumab (a monoclonal antibody) mentioned in the relevant MA, despite the patent claims encompassing other antibodies specific for the same target. Yeda had argued that the other antibodies would be expected to have the same therapeutic effect as Adalimumab, and pointed to Farmitalia as supporting grant of an SPC with a broader product definition. The Dutch Court found that it was not proven that other antibodies would have the same therapeutic effect, and furthermore that even closely related biological medical products are qualitatively different to salts and esters of a chemical product. The Dutch Court noted that even minor differences in a biological product could be significant for the quality, safety and efficacy of the said product.

The Norwegian Court of Appeal adopted much of the same reasoning, stating that for there to be a different active ingredient, the difference between two products must be expressed such that there is a practical and appreciable effect on the quality, safety and efficacy of the medicine in question. Intervet argued that any such difference must be systematic, consistent and significant in order for two products to be found different. The Court expressed some doubt that a "significant" standard was too high a threshold, but did not need to consider this further since, on the evidence before it, they found that Pharmaq's product was systematically, consistently and significantly more efficacious against SAV-3 infection than Intervet's product.

Having reached this conclusion, the Norwegian Court of Appeal decided that Intervet's SPC was invalid for lack of compliance with Article 4 of the SPC Regulation. The Court noted that this is not a ground for invalidity under Article 15 of the SPC Regulation, and thus was obliged to define Article 15 as "not exhaustive" in order to make their decision. Interestingly, the Court also felt that they had no legal basis to amend the SPC to provide a compliant product definition, even though the guidance from the EFTA Court appeared to suggest such an option. The EFTA Court's guidance was that an SPC would be invalid to the extent that it covers anything other than the authorised product.

It remains to be seen whether the CJEU and/or other national courts will adopt similar reasoning. Nonetheless, we offer the following conclusions and recommendations:

1. Applicants should be alert to the risk involved if the definition of the product in a granted SPC could be interpreted as broader than the authorised medicinal product – a definition that is made too broad in an attempt to capture biosimilars may result in loss of the entire SPC if it proves impossible to amend after grant. In our experience, however, most national offices will insist that the product definition in an SPC application is limited to the INN of the authorised product before grant.
2. The EFTA court confirmed the approach of the CJEU in Farmitalia, extending SPC protection for an authorised small molecule drug to cover "therapeutically equivalent" salts and esters of the same compound. However, although we think most courts are likely to recognise a need to apply a similar principle to (more complex) biological products, such that protection is not absolutely limited to the authorised product, it appears likely that (as the EFTA court did) they will find it difficult to apply Farmitalia directly. The precise scope of protection for biosimilars therefore remains unclear, but we would expect some reliance on the concept of "therapeutic equivalence". Evidence of a lack of systematic, consistent (and significant) difference in quality, safety and efficacy is likely to be available from any biosimilar marketing authorisation process, and may help to establish that a biosimilar should fall within the scope of an SPC.
3. Where possible (bearing in mind patent claim scope and time limits) consider applying for a separate SPC based on your own patent and a biosimilar competitor's marketing authorisation. Such an application could use a narrow product definition directed specifically to the competitor's authorised biological product. As such, the theoretical risk in 1 and the uncertainty regarding scope in 2 will not apply.

**Footnotes**

1. Case number 15-170539ASD-BORG/01 and 15-204605ASD=BORG/01 – English translation of decision available here.
2. Similar status to the CJEU for matters referred by the national courts of the EFTA states: Norway, Iceland, Switzerland and Liechtenstein.
3. Judgment E-16/14 (Pharmaq v Intervet) – English language version available here.
4. Article 4: Within the limits of the protection conferred by the basic patent, 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 and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate. Full regulation available here.
5. C-392/97 (Farmitalia) – full decision available here.

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