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Client Alert

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EFTA Court Rules on Key SPC Issues

The supply of a medicinal product without a marketing authorisation under national provisional permissions of use does not generally prevent an SPC

The scope of protection of an SPC for a virus may be broader than the specific virus strain mentioned in the marketing authorisation

Today, the EFTA Court ruled on two important SPC issues that were raised in the *Intervet* case (E – 16/14). The case concerns, on the one hand, the supply of a veterinary vaccine without a marketing authorisation ('MA') under successive national provisional permissions of use in order to fight a serious epizootic disease, and, on another hand, the scope of an SPC granted for a virus.

In essence, the Court decided that:

(1) The supply of a vaccine without MA under Article 8 (1) of Directive 2001/82, i.e. under a national provisional permission of use in the event of a serious epizootic disease and in the absence of a suitable medicinal product, does not constitute an administrative authorisation procedure in the meaning of Article 2 of the SPC Regulation. Such supply therefore does not generally amount to placing the product on the market as a veterinary medicinal product for the purposes of Article 2 of the SPC Regulation.

(2) The scope of protection conferred by an SPC extends to a specific strain of the virus covered by the basic patent but not referred to in the MA, only if that specific strain (i) constitutes the same active ingredient as the authorised medicinal product and (ii) has therapeutic effects falling within the therapeutic indications for which the MA was granted. It is for the national court to determine whether those criteria are met.

This decision is important for two main reasons. First, like Directive 2001/82, Article 5 of Directive 2001/83 on medicinal products for human use allows the Member States to permit the supply of a medicinal product without MA in order to satisfy patients' therapeutic needs. Compassionate use programs are based on Article 5. A decision that would have generally denied an SPC because of a supply under national provisional permission of use would have jeopardized compassionate use programs and any form of supply of a medicinal product before the grant of a MA. Second, it confirms that the principles set out by the Court of Justice of the European Union (CJEU) in the *Farmitalia* case also apply to biological substances or at least to viruses.

The EFTA Court is the equivalent of the CJEU for matters referred by the national courts of the three EFTA countries (Iceland, Liechtenstein, Norway).

Supply of a medicinal product without MA under national provisional permissions of use

In the early 2000s, pancreas disease (PD) virus started spreading in Norway and Ireland, killing thousands of salmons in fish farms. Intervet was working on an experimental vaccine against PD, so many veterinarians and fish biologists requested the competent health authority to allow the supply of that vaccine to their fish farms in order to fight PD.

Normally, a medicinal product may be placed on the market only after having been granted an MA. However, Article 8 (1) of Directive 2001/82 on veterinary medicinal products allows the Member States to permit provisionally the use of a vaccine without an MA in the event of serious epizootic diseases and in the absence of a suitable medicinal product. The veterinarians' and fish biologists' requests were based on the national rules implementing Article 8 (1). Both the Norwegian and Irish authorities allowed the supply of the vaccine, and such provisional permissions of use were granted until a 'full' MA was granted in August 2011.

Intervet filed an SPC application in Ireland, Norway and the UK. The UK patent office rejected the application as it considered that a provisional MA granted in May 2005 was the first MA in the UK. The Norwegian patent office granted an SPC, and Pharmaq, one of Intervet's competitors, initiated a lawsuit to obtain the invalidity of the SPC. According to Pharmaq, the product is not eligible for an SPC under Article 2 of the SPC Regulation because the supply of the vaccine under the national provisional permissions of use has amounted to placing the product on the market before the MA. The national court referred the issue to the EFTA Court.

The EFTA Court ruled that:

- A product is only eligible for an SPC if, before being placed on the EEA market as a veterinary medicinal product, it obtained an MA pursuant to an administrative authorisation procedure as laid down in Directive 2001/82, including in particular safety and efficacy testing. This authorisation procedure includes authorisations granted in exceptional circumstances pursuant to Article 26(3) of Directive 2001/82.

- In contrast, the supply of a medicinal product on the basis of Article 8 (1) of Directive 2001/82, does not constitute an administrative authorisation procedure as specified in Article 2 of the SPC Regulation.

- Article 8 (1) is an exemption to the MA system set out in Title III of Directive 2001/82 and thus does not require the same safety and efficacy testing as the MA procedure and does not entitle the company to market the product but only to supply it, to the extent necessary to combat the disease in question. Consequently, such supply does not generally amount to placing the product on the market as a veterinary medicinal product for the purposes of Article 2 of the SPC Regulation.

To the argument that the product was supplied in quantities comparable to those under an MA, the Court replied that a provisional permission of use does not entail placing the product on the market because of the restrictions on supply set forth in Article 8 (1), and that it is for the national court to determine whether the permissions granted for Intervet's vaccine were actually based on Article 8 (1).

Scope of protection of an SPC for a virus

The SPC granted by the Norwegian patent office was defined more broadly than the specific virus strain mentioned as active substance in the MA. Pharmaq claims that such an SPC is invalid because it covers more than the active ingredient contained in the medicinal product.

The EFTA Court decided that:

- Article 4 of the SPC Regulation entails that the use of a medicinal product which has not been authorised by the MA may not be covered by an SPC. Consequently, an active ingredient whose therapeutic effects do not fall within the therapeutic indications of the MA may not give rise to the grant of an SPC.

  - The SPC allows its holder to oppose the marketing of another medicinal product containing the same active ingredient with a therapeutic effect falling within the same therapeutic indication. Otherwise, it would be possible for medicinal products which were, in principle, therapeutically equivalent to that protected by the SPC to compete with the latter. Such a result would frustrate the purpose of the SPC Regulation, which is to ensure the holder of the basic patent of exclusivity on the market during a given period extending beyond the period of validity of the basic patent (compare, to that effect, *Farmitalia*, cited above, paragraph 18).

- The product definition in the SPC granted to Intervet covers the specific strain of the SPD virus. The SPC is based on the Norwegian MA granted for "Salmonid pancreatic disease (SPD) virus strain F93-125, > 70% RRP", so the SPC prevents the marketing of medicinal products containing "Salmonid pancreatic disease (SPD) virus strain F93-125, > 70% RRP".

- Intervet may prevent Pharmaq from marketing its vaccine, provided it contains the same active ingredient with a therapeutic effect that falls within the therapeutic indications for which the MA has been granted to Intervet. It is for the national court to determine whether Pharmaq's virus strain constitutes the same active ingredient with the same therapeutic indication as Intervet's vaccine.

- It is not relevant whether a medicinal product based on another strain would require a separate MA.

This part of the decision is confusing because the EFTA Court uses the term 'same' active ingredient and does not explain the conditions under which a virus strain can be considered the same as another virus strain; this is left to the national court to determine. Nevertheless, the Court sets the principle that two virus strains may be the same active ingredient (depending on the facts) for SPC purposes, which implies that genetic differences among virus strains are not sufficient to make them different active ingredients.

Viruses being biological substances, the EFTA Court ruling could apply to other biological substances as well.

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