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Judgment in Case E-16/14 *Pharmaq AS* v *Intervet International BV*

PLACING ON THE MARKET OF A VETERINARY MEDICINAL PRODUCT AND THE VALIDITY AND SCOPE OF A SUPPLEMENTARY PROTECTION CERTIFICATE

In a judgment delivered today, the EFTA Court answered the questions referred to it by *Oslo tingrett* (Oslo District Court) on the interpretation of Articles 2, 3 and 4 of Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products ("the SPC Regulation").

Pharmaq AS and Intervet International BV have both developed a vaccine against viral pancreatic disease in salmonid fish. Between 2003 and 2011, Intervet sold its vaccine to fish farmers in Norway under "special approval exemptions" as provided for in Norwegian law. It also supplied the vaccine in Ireland under a corresponding scheme. In 2005, Intervet was granted a provisional marketing authorisation in the United Kingdom and eventually obtained a Norwegian marketing authorisation in 2011 for a period of five years.

In anticipation of the expiry in 2015 of the basic patent, Intervet applied for and was granted a supplementary protection certificate ("SPC") in Norway on the basis of its Norwegian marketing authorisation. In the SPC, the provisional marketing authorisation granted in the United Kingdom in 2005 is regarded as the first marketing authorisation in the EEA. Pursuant to Article 13 of the SPC Regulation, the effective protection under a combined patent and SPC may not exceed 15 years from the time of the first marketing authorisation in the EEA, and an SPC may not be granted for more than five years. Therefore, the validity of the SPC has been fixed until 2020.

By its action before *Oslo tingrett*, Pharmaq seeks a declaration that the SPC is invalid, since any product placed on the market before receiving a marketing authorisation falls outside the scope of the SPC Regulation because the patent holder has not suffered any loss of its period of exclusivity. Pharmaq argues that this appears to be the case for Intervet, which could sell its vaccine on the basis of the special approval exemptions in Norway and similar schemes under Irish law and on the basis of the UK provisional marketing authorisation, which it claims not to constitute a marketing authorisation within the meaning of the SPC Regulation. On the other hand, Intervet argues that the commercial exploitation of the medicinal product starts with a marketing authorisation, defined as an unconditional right to place a medicinal product on the market immediately.

The Court found that an SPC for a veterinary medicinal product may be granted in an EEA State on the basis of a marketing authorisation obtained in that State pursuant to an administrative authorisation procedure under Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products ("the Directive"), which includes in particular testing the safety and efficacy of the product. However, under the first paragraph of Article 8 of the Directive, in the absence of a suitable medicinal product, EEA States may provisionally allow the use of

immunological veterinary medicinal products without a marketing authorisation in the event of serious epizootic diseases. Such action does not constitute an administrative authorisation procedure and does not generally constitute a placement on the market.

The determination of whether the Norwegian "special approval exemptions" or the corresponding Irish scheme, and the UK provisional marketing authorisation were issued pursuant to an administrative authorisation procedure or pursuant to a provisional procedure under the first paragraph of Article 8 of the Directive depends essentially on the assessment of the facts in the national proceedings, which is a matter for the national court.

Pharmaq alternatively claims that the scope of protection of the SPC must be deemed not to include its vaccine, since it cannot be extended to cover strains of the virus other than that included in the medicinal product and covered by the basic patent. Intervet argues that the SPC only ensures an effective protection under the SPC Regulation if it covers not only the specific form of the active ingredient contained in the authorised medicinal product, but also the other forms of that active ingredient which are covered by the basic patent and that are therapeutically equivalent to the specific form contained in the authorised medicinal product.

The Court found that the scope of protection conferred by an SPC 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. It is not relevant whether a medicinal product based on such other strain would require a separate marketing authorisation. The appreciation of such elements is a matter of fact which is to be determined by the referring court.

The full text of the judgment may be found on the Internet at: www.eftacourt.int.

This press release is an unofficial document and is not binding upon the Court.