

## Memo

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To EPLAW Patent Blog  
From Advokatfirmaet Grette DA  
Re The Borgarting Court of Appeal's judgment in case no. 10-103765ASD-BORG/03: Pharmaq AS vs. Intervet International B.V. and Intervet Norge AS

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### **THE BORGARTING COURT OF APPEAL'S JUDGMENT: PHARMAQ AS VS INTERVET INTERNATIONAL B.V. AND INTERVET NORGE AS**

On 22 December 2011 the Borgarting Court of Appeal rendered its decision in the case between Pharmaq AS (hereafter Pharmaq), and Intervet International B.V. and Intervet Norge AS (hereafter Intervet) regarding Intervet's patent NO 317547.

NO 317547 concerns an isolated biological material in the form of a virus used in the development and production of vaccine against a disease affecting farmed fish, such as Atlantic salmon. The disease affects the fish pancreas and is called pancreatic disease. Biological materials are, in accordance to Norwegian law and its international obligations, considered patentable and qualify as an invention as long as certain requirements are fulfilled.

Intervet claimed victory in a legal battle with rival pharmaceutical company Pharmaq. Intervet has a patent, NO 317547, on the inactivated virus vaccine against pancreatic disease for intraperitoneal injection in Atlantic salmon. This is the only approved vaccine against the devastating disease that is available on the market.

Intervet filed a patent application in 1995, and was granted the Norwegian patent NO 317547 in 2004. Pharmaq challenged the validity of NO 317547 in the Patent Office, but was unsuccessful.

Eventually, Pharmaq developed a vaccine against the same disease, and then initiated legal actions against Intervet, claiming that NO 317 547 was invalid and/or to obtain a declaratory judgment of non-infringement. Thus, the case concerned the validity, scope and possible infringement of Intervet's patent NO 317547.

An important question for the Court was the determination of the scope of protection of the patent-in-suit, especially in view of the fact that the parties' vaccines were developed from different subtypes of the same virus.

The question was whether Pharmaq's SAV 3 – virus strain (ALV 405) is an embodiment covered by Intervet's patent NO 317547. The disagreement is related to whether or not Pharmaq's SAV 3 – vaccine strain, in the patent sense, is a "closely related strain" that has

“genotypic and/or phenotypic characteristics” similar to those of the deposited strain- If SAV 3 – including Pharmaq’s virus strain – is closely related to the deposited SAV 1-strain and reacts serologically with convalescent anti-FPDV-serum or antiserum formed against the deposited virus strain, Pharmaq’s virus strain will be covered by the patent.

The Court discussed whether Pharma’s virus strain is closely related to the deposited virus strain, but could not find sufficient basis for a conclusion that the scope of protection of the patent is limited to viruses that are physically derived from the deposited strain.

The Court applies a restrictive approach to the basis for examination of the validity of the patent as well as the scope of the patent protection. The patent specification supports a relatively strict interpretation of the claims, and held that the genotypic and phenotypic qualities must be very similar if the patent is to include a virus. Nevertheless, the Court states that the patent specification cannot be interpreted as if the virus has to be physically derived from the deposited material. If the patent specification were to be interpreted narrowly, it should have been expressed more clearly.

Usually, SAV 1 and SAV 3 cause a late and atypical CPE in cell culture compared with other viruses. Pharmaq claimed that their SAV 3 – strain caused CPE faster in cell culture than other SAV, and accordingly differs phenotypically from other SAV 1 and SAV 3. The Court notes that this is not substantiated.

The Court finds that both SAV 1 and SAV 3 have great similarity in the ability to induce symptoms in Atlantic salmon, and states that there will not be possible to state anything definite about any differences in virulence between virus strains belonging to respectively SAV 1 and SAV 3.

Further on, the Court finds that there can be no clear scientific conclusions concerning difference in efficacy. In the choice between several alternatives of interpretation the Court found that the patent had to be given the widest protection so that it covered all subtypes of the virus. The Court determined that the relevant genotypic and phenotypic traits were found to be very similar. Therefore, the Court found that the SAV 3–virus is covered by the patent.

However, the Court does not rule out that degree differences in vaccine efficacy may be significant as a factor in an overall assessment in other cases, where there are doubts of whether the patent is too broad in relation to its inventive contribution.

The Court emphasizes that the least far-reaching patent protection would mean that Intervet’s patent would be worth almost nothing and not protect the invention as intended. According to the Court, the importance of the invention of NO 317547 was found to weigh more than the patent protection challenges competitors face when developing vaccines based on the virus. This is justified by the fact that the implemented isolation of the virus was a major breakthrough for research and development of vaccines for salmon diseases. It is also of importance that patent protection is to reward the inventive effort.

The Court concluded that Pharmaq committed patent infringement in the production vaccine doses based on SAV 3. In accordance to this, Pharmaq has no right to put vaccines based on this subtype on the market.

The Borgarting Court of Appeal’s judgment confirms a decision from 2008 by the Norwegian Patent Office, as well as the Oslo District Court’s judgment from 2010, on the validity of the same patent, which were also decided in Intervet’s favour.