BORGARTING COURT OF APPEAL

JUDGMENT AND RULING

Handed down: 19 December 2016

Case no.: 15-170539ASD-BORG/01 and 15-204605ASD-BORG/01

Judges:

Appeal Judge	Espen Lindbøl
Appeal Judge	Tonje Vang
Extraordinary Appeal Judge	Hans O. Kveli

Lay judges:

Senior Researcher	Siri Mjaaland
Professor	Trond Øivind Jørgensen

Appellant	Pharmaq AS	Mr Gunnar Meyer Ms Ida Elisabeth Gjessing
Respondent	Intervet International B.V.	Mr Eirik Wensell Raanes

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No limitations on publication

The main question in the case applies to the validity of the Norwegian supplementary protection certificate granted to Intervet International B.V. by the Norwegian Industrial Property Office in January 2014.

Introduction

Norway is the world's largest producer of farmed salmon, featuring about 1 000 fish farms. In addition, Norwegian aquaculture includes the farming of rainbow trout and wrasse. Fish farming brings together a large number of individuals in tanks or cages, and where it is a challenge to prevent the spread of infectious matter due to high fish density. For that reason, effective measures to fight disease are of great importance for the economy and sustainability of the industry.

Effective vaccines mean that the industry has good control of bacterial infections among farmed salmon, while viral diseases continue to represent formidable challenges to fish health and welfare. There are currently several viral diseases that lead to reduced health in farmed salmon and, together, they represent a serious challenge, financially as well as in terms of loss of reputation. Virus epidemics are particularly challenging since there is a lack of robust preventive measures, e.g. in the form of good vaccines, or means of treatment to control these diseases.

Pharmaq AS (Pharmaq) is a veterinary pharmaceutical enterprise specialising in fish health. The company is headquartered in Overhalla in Nord-Trøndelag County, and is part of a leading international animal health company, Zoetis Inc.

Intervet International B.V. (Intervet) is a large veterinary pharmaceutical enterprise. The company is headquartered in Boxmeer in The Netherlands, and is a part of a leading international animal health company, MSD Animal Health Inc.

Intervet was the holder of Norwegian patent NO 317 547 (the basic patent), which provided protection *inter alia* against the virus that causes Pancreas Disease (PD), in salmonids. The patent also covered closely related virus strains with similar genotypic and and/or phenotypic characteristics, described in more detail below in patent claim no. 1.

Intervet has marketing authorisations in several EEA Member States for a vaccine against PD, based on the virus strain F93-125 (SAV-1), made from PD-infested fish in Ireland. The vaccine strain is deposited with the European Collection of Cell Cultures, under Deposit number V 940 90 731. The vaccine is marketed under the trademark Norvax Compact PD, and is currently also offered in a multi-component vaccine that Intervet sells in Norway.

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Pharmaq has also developed a vaccine against PD. It is based on a virus isolated from PD-infected fish from Norwegian waters, and is known as virus strain ALV405 (SAV-3).

On 22 December 2011, Borgarting Court of Appeal handed down a judgment in a case between Pharmaq and Intervet, where the main question involved the validity of Intervet's patent. By virtue of the judgment, an injunction directed at Pharmaq's vaccine was granted, since it was considered to constitute infringement of Intervet's patent, which the Court of Appeal found to be valid at the same time.

Intervet's patent expired on 17 October 2015. In a letter dated 15 January 2014, the Norwegian Industrial Property Office granted Intervet a supplementary protection certificate, SPC/NO no. 2011024 (the SPC), under Chapter 9a of the Patents Act, cf. the EEA Agreement's Annex XVII, section 6 (Council Regulation no. 1768/92) of 18 June 1992 (the SPC Regulation), extending the product's protection period. The notice from the Norwegian Industrial Property Office stated that the extension applied from the expiry of the patent's protection period and up to 6 June 2020, but the parties agree that the correct expiration date is 6 May 2020.

Pharmaq made it known in a letter dated 17 February 2014 to the Norwegian Industrial Property Office that a petition for a nullity ruling on the SPC was being filed with the Oslo District Court, cf. §86, third subsection, first and second sentences, of the Patent Regulations.

The writ from Pharmaq against Intervet had already been filed on 16 August 2013. In the lawsuit, Pharmaq contended *inter alia* that before the ordinary marketing authorisation existed, Intervet had supplied vaccines under schemes involving special approval exemptions in Norway and AR16 licences in Ireland, so that the conditions for granting extended protection periods were not satisfied. Pharmaq's main argument was that since Intervet had actually sold its vaccine on the market since 2003 almost unimpeded, the purpose of the SPC rules regarding extended protection time was not satisfied. Pharmaq filed a claim for relief with the District Court, requesting that the SPC be declared invalid, alternatively, that it be declared that the use of Pharmaq's vaccine did not in any event represent infringement of the SPC.

Intervet's main argument before the District Court was that the SPC was fully valid, and that Pharmaq's vaccine represented an infringement of the SPC. Intervet referred to the fact that under certain circumstances, it is warranted to grant special approval exemptions, e.g. in the case of a serious epizootic diseases. The condition for granting such special authorisations was satisfied for the fish disease PD. Intervet contended further that the special authorisations did not grant the company the right to freely exploit the product commercially through active marketing or sales.

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For the Court of Appeal, the case also raises general questions about what can be considered bringing a veterinary medicinal product on the market under the SPC Regulation, and what constitutes a marketing authorisation under the Regulation, as well as about what bearing the product description in the marketing authorisation has on the SPC's scope of protection.

The SPC Regulation, EEC no. 1768/92, in a nutshell

Once granted, a patent can be maintained for up to 20 years from the date on which the patent application was filed, cf. §40, first subsection, of the Patents Act.

The SPC Regulation introduced an opportunity for patentees in EU Member States to get the period of protection for a patented medicinal product extended by up to five years, so that the total protection period of the patent and the supplementary protection certificate can be a maximum of 25 years. The rules encompass medicinal products for human use as well as veterinary medicinal products. The regulations are covered by the EEA Agreement, and became an integral part of Norway's legal obligations under the EEA as from 1994.

The background for the scheme of supplementary protection certificates is that it normally takes a long time from the time a patent is granted until a medicinal product receives a marketing authorisation. Without a marketing authorisation, it is not legal to sell a medicinal product in the EEA area. Time elapses before a medical drug is allowed to be placed on the market due to requirements for clinical studies to be carried out, along with other documentation requirements to comply with the rules laid down in Directive 65/65/EEC or Directive 81/851/EEC for medicinal products for human use and veterinary medicinal products, respectively. The directives were later superseded by Directive 2001/83 and Directive 2001/82, respectively.

Submitted documentation is to corroborate that the product complies with the regulations' requirements for quality, safety and efficacy. The time it takes to satisfy the documentation requirements can mean that the patentee is prevented from trading in the medicinal product for large parts of the time during which the patent protection applies. A supplementary protection certificate is intended to compensate for the time that elapses and thereby to help ensure that the pharmaceutical industry invests in the development of new products to benefit human and veterinary health in the EEA.

The certificate applies from the expiry of the basic patent and ceases to apply 15 years from the date on which the first marketing authorisation was granted within the EEA, but limited up to five years from the expiry of the basic patent. Thus, the calculation of the SPC's duration depends on when the product obtained its first marketing authorisation within the EEA. This applies regardless of which EEA Member State the SPC was granted in, so that the certificate will expire at the same time in all

EEA Member States in which the SPC was granted.

The SPC Regulation was incorporated into the EEA Agreement, Annex XVII, Section 6 of the EEA Joint Committee's resolution no. 7/94, 21 March 1994, ("supplementary agreement") and was implemented into Norwegian law by reference in the new §62 a) to the Patents Act.

SPC Regulation (no. 1768/92) was later superseded by Regulation (EEC) 469/2009. At the time of the judgment, the latter has not yet been implemented into Norwegian legislation, but the Court of Appeal cannot see that this is of importance for understanding the provisions that the Court is to apply in the case in suit.

Virus, PD and vaccine

Virus

Viruses are microorganisms that depend on a host cell to be able to reproduce (replicate). As long as a virus is outside of a living cell, it has none of the functions that characterise a living organism. This changes when the virus gets into a cell with the help of specific surface molecules (receptors) on the surface of the cell. The virus then takes over the cell's production system for the synthesis of new virus particles. This usually leads to the cell dying or disintegrating (cytopathogenic effect). Viruses can therefore be viewed as "intracellular parasites".

A virus consists of an inner core of DNA (nucleic acid, genome), surrounded by a shell (capsid) made of protein, and there may be a membrane on the outside of the shell. Depending on the virus type, the nucleic acid is either DNA or RNA, single-stranded or double-stranded. The PD virus is a single-stranded RNA virus.

Viruses are classified by family, genus and species based on morphology/shape, virulence (the virus' ability to cause disease), the antigenic serological determinants/epitopes (the part of the protein recognised by the immune system), in addition to gene sequence. The PD virus belongs to the genus Alphavirus in the family Togaviridae. All subtypes of salmonid PD virus (SPDV) are distinguished from all other Alphaviruses and can be defined as a separate species.

Pancreas disease (PD)

Salmonid Alphavirus (SAV) is, as of today, responsible for the most severe virus infections in the fish-farming industry because they cause PD in Atlantic salmon in Norway, Ireland and Scotland, and sleeping disease in rainbow trout in France. In 1976, Nelson et al. detected the disease in Scottish salmon and the pathogen (the virus) was subsequently genetically characterised by sequencing in 1999.

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The disease was later detected in Ireland and Norway.

The Norwegian outbreaks increased steadily from 1997 to 2003, followed by a steep epidemic increase from 2005 to 2008. Since then, the number of outbreaks has remained more constant at about 100 to 140 per year. The average costs of a PD outbreak add up to tens of millions of NOK when an outbreak occurs about nine months after putting one million smolt to sea.

There is no fully optimised prevention or treatment for PD. The effect of vaccination is controversial, but vaccinated fish have shown somewhat lower mortality, milder pathological changes and therefore experience less infection pressure in the cages.

Clinical signs of PD in salmon are reduced appetite, emaciation, and abnormal swimming activity, in addition to the fish tolerating physical handling poorly, often with an increased tendency towards sudden death ("sudden death syndrome"). The histopathological picture is characterised by varying degrees of haemorrhages and necrosis in the pancreas, heart and muscles of the skeletal system. These changes can vary a lot and are related to the duration of the interval between infection and the histological analyses. In Norway, PD generally occurs from Rogaland County to Trøndelag. PD is a year-round disease, but with the highest incidence from April to September.

There are six variants (genotypes/subtypes) of Salmonid Alphavirus, SAV 1-6, which cause PD in salmon. SAV-2 and SAV-3 have been detected in Norway. SAV-3 epidemics have been known ever since 1995. SAV-2, which first appeared in 2012 along the coast of Møre, has since been detected annually at about 40 locations. The Norwegian Veterinary Institute refers to infections with SAV-2 and SAV-3, respectively, as "two PD epidemics" in Norway. SAV-3 epidemics are generally limited to western Norway, while SAV-2 occurs primarily in Møre and Trøndelag. The two epidemics also occur at slightly different times, with SAV-3 occurring most frequently in June – July, while SAV-2 dominates in September – November.

In the 1990s, it was assumed that PD in salmon in Norway was caused by the same virus that had been isolated from infected salmon in Scotland and Ireland. Subsequent sequencing studies conducted by Weston (1999) and Hodneland (2005) showed that PD in the UK was caused by another genotype (SAV-1), compared with the Norwegian isolates (SAV-2 and SAV-3).

Immune responses against virus infections

The virus' surface proteins enable the virus to infect a host cell, and thus a host organism. Binding to molecules on the surface of the cell (receptors) activates the mechanisms that give the virus access to the cell. In response to a virus infection, the host induces an immune response. This

involves many different white blood cells, leucocytes/lymphocytes, which work together to fight the virus infection. The production of antibodies is an important part of this, both neutralising and non-neutralising. Neutralising antibodies work by preventing the virus from binding to the cell's receptors. Non-neutralising antibodies can fight a virus infection by binding to virus-infected cells and thereby killing the cells before they manage to produce more virus particles (antibody-dependent cell- mediated cytotoxicity; ADCC). Alternatively, virus-specific antibodies can lead to an increase in the admission of virus particles to phagocytic cells (PC-mediated phagocytosis), which thereby inactivates the virus intracellularly. In addition to the production of antibodies, there are also specialised cells that recognise the virus-infected cells and kill them through membrane-to-membrane contact (cytotoxic killer cells).

Vaccines

The principle of vaccination is to simulate a weak infection and thereby prepare the host, so that upon the subsequent onset of a genuine infection, the foundation has been laid for a strong immune response.

The antibodies produced after a vaccination contribute to immunity and provide increased protection against a new infection against the same virus as the one used in the vaccine (same set of epitopes). If the epitopes presented at the time of infection differ from the virus strain used for the vaccination, the immune response against the virus could be changed and/or be reduced. A good vaccine response also depends on the extent to which the host (the salmon) recognises and is able to induce good immune responses against the vaccine antigens.

The vaccines involved in this case consist of chemically inactivated virus particles (the F93-125 isolate and the ALV405 isolate), with an adjuvant (excipient) – i.e. an oil emulsion that enhances the effect of the vaccine.

Intervet's PD patent

As mentioned above, viruses do not occur in a pure form in nature, so viruses can be subject to patenting when rendered in isolation from their natural environment, provided the general terms and conditions for patenting are satisfied. Intervet's patent referred to a method for making and isolating a PD virus, as well as using a PD virus in an inactivated form for making a vaccine.

In 1994, the inventors McLoughlin and Nelson succeeded in growing (propagating) PD virus, and thereby managed to isolate the virus. The British patent application was filed on 18 October 1994 by Akzo Nobel, who had acquired the rights from the inventors. The rights to exploit the patent were subsequently transferred to Intervet.

The Norwegian patent application was, as mentioned earlier, filed on 17 October 1995, and was the starting point for the duration of the now lapsed basic patent. The application in Norway was granted on 15 November 2004. The European patent application was filed on 13 October 1995 and granted on 8 October 2003. The European patent application involved rights to both the biological material and the method for isolating the virus. After final processing by the European Patent Office and the Norwegian Industrial Property Office, respectively, the approved patent claims were almost identical, except for certain linguistic subtleties.

The patent claims in Intervet's Norwegian patent are worded as follows:

1. A virus which when injected intraperitoneally at a titre of $10^{3.5}$ TCID50 into Atlantic salmon post-smolts held in sea water at 14°C causes the fish to develop symptoms of pancreatic disease, w h e r e i n
   (a) said virus is the virus strain as deposited at ECAVCC under Deposit number V94090731 or closely related strains which share similar genotypic and/or phenotypic characteristics to said deposited virus strain,
   (b) said virus reacts serologically with covalescent anti-FPDV antiserum or antiserum raised against the deposited virus strain V94090731.

2. Viruses according to claim 1 substantially free of other viral or microbial material.

3. A vaccine to combat fish pancreas disease, said vaccine comprising a virus according to claim 1 or 2.

4. The vaccine according to claim 3 comprising an attenuated or inactivated from of said virus according to claim 1 or 2.

5. A diagnostic reagent for fish pancreatic disease, said reagent comprising an antibody capable of binding selectively to a virus as claimed in claim 1 or 2.

6. The diagnostic reagent according to claim 5 having a marker, a chromophore, a fluophore, a heavy metal, an enzymic label, or an antibody label.

7. The diagnostic reagent according to claim 5 or 6 in immobilised form.

8. A method of isolating a virus according to claim 1 or 2, said method comprising
   (a) identifying fish suffering from pancreas disease,
   (b) co-cultivating affected tissues with Chinook salmon embryo cells,
   (c) passaging the co-cultivated cells through Chinook salmon embryo cells,
   (d) isolating the virus particles.

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9. The method according to claim 8 in which the affected tissues are the pancreas or kidney, and co-cultivation with Chinook salmon embryo cells is undertaken for approximately 28 days.

10. A method of diagnosing fish pancreas disease, said method comprising the following steps:
(a) contracting a test sample with a diagnostic reagent according to any of claims 5 to 7 to produce a reagent complex;
(b) an optional washing step; and

(c) determining the presence, and optionally the concentration, of said reagent complex and thus the presence or amount of virus in the test sample.

11. The method according to claim 10 wherein the test sample is a blood sample or a sample of the water in which the fish has been contained.

In the patent case between the parties, which was decided in the final judgment of the Borgarting Court of Appeal of 22 December 2011, Pharmaq only disputed the validity of patent claims 1-4.

Supplementary protection certificate SPC/NO No. 2011024

In mid-January 2014, the Norwegian Industrial Property Office granted Intervet a supplementary protection certificate for the following product:

> Salmon pancreatic disease virus which, when injected intraperitoneally in a titrated concentration on 103.5 TCID50 in Atlantic salmon, post-smolt, in seawater at 14°C, causes the fish to develop symptoms of pancreatic disease, where: (a) said virus is the virus strain as deposited at ECACC under Deposit number V94090731 or closely related strains which share similar genotypic and/or phenotypic characteristics to said deposited virus strain, and (b) said virus reacts serologically with covalescent anti-FPDV antiserum or antiserum raised against the deposited virus strain V94090731 and (c) said virus is an inactivated form.

The SPC is commensurate with the basic patent's claim 1 and comprises, according to the wording, closely related strains that share similar genotypic and phenotypic characteristics to said deposited virus strain.

The Norwegian Industrial Property Office was in doubt about the stipulation of the scope of protection, which is corroborated by email correspondence between the case officer at the Norwegian Industrial Property Office and Intervet's patent attorney. An email from the case officer to the patent attorney sent on 14 January 2014 states the following:

> We could actually have gone either way, as you are no doubt aware. Our in-house virus expert disagrees strongly with the decision.
> ---
> We would have liked to limit the certificate to apply only to wording that refers to SAV-1, but there are not grounds for this in the patent application. So this is where we are struggling, if we grant for the deposited strain only, it will be very easy to circumvent the protection conferred by the certificate and the certificate will be worthless. We have decided to give the applicant the benefit of the doubt. Then the lawsuit can deal with the final decision.

Pharmaq had submitted observations on Intervet's SPC application. At the time of the decision, it was thus clear that Pharmaq would test the validity of a certificate with a scope of protection in compliance with the decision.

Procedural history

Pharmaq's writ was filed with the Oslo District Court on 16 August 2013, even before the SPC was issued by the Norwegian patent authorities. In Intervet's reply of 5 September 2013, a claim for relief was lodged, requesting that the case be rejected due to a lack of legal standing.

However, the SPC was granted by the Norwegian Industrial Property Office in January 2014, before the District Court had taken a position on the question of dismissal. During the preparatory proceedings, the District Court opted to submit certain questions of interpretation in the case to the EFTA Court, pursuant to §51a of the Courts Act. The Court of Appeal will revert to the questions and the EFTA Court's opinion.

In the pleading of 15 April 2015 to the District Court, Intervet submitted a petition for a prohibition pursuant to §56a, second sentence, of the Patents Act, requesting that Pharmaq be prohibited from manufacturing, offering for sale, putting on the market or using, etc. vaccines against pancreas disease in fish, based on virus isolate ALV405, or from introducing or possessing the product with such intent. cf. Article 5 SPC Regulation cf. §62a, first subsection, of the Patents Act.

In the pleading and reply of 20 April 2015, Pharmaq refuted the counterclaim and filed a new claim in the alternative regarding compulsory licensing if the Court were to conclude that Pharmaq's vaccine infringed on the SPC, cf. §59a of the Patents Act. The District Court decided on 16 April 2015 to divide the main hearing. Intervet's counterclaim and Pharmaq's claim in the alternative were divided into separate hearings, cf. §16-1 of the Dispute Act.

On 25 August 2015, Oslo District Court handed down a judgment in the first part of the case, with the following conclusion of judgment:

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> The Court finds for Intervet International BV.
>
> The decision regarding costs will remain pending until the decision that concludes the case before the District Court.

After a separate hearing, the Oslo District Court subsequently rendered a judgment on 15 October 2015 with the following conclusion of judgment:

> Pharmaq AS is prohibited from manufacturing, offering for sale, putting on the market or using viruses and vaccines against pancreas disease in fish based on virus isolate ALV 405, or from introducing or possessing the vaccine with such intent, during the period of validity of supplementary protection certificate NO 2011024.
>
> Pharmaq AS is ordered to pay Intervet International B.V.'s costs, including expenses for expert lay judges and the court fee, NOK 12 096 765.91 – twelve million ninety-six thousand seven hundred and sixty-five Norwegian kroner and ninety-one øre. The time limit for performance is two – 2 – weeks from service of this judgment.

Pharmaq appealed the case to the Borgarting Court of Appeal. During the preparatory proceedings, Pharmaq withdrew the claim regarding compulsory licensing under §59a of the Patents Act, so the District Court's decision of 15 October 2015 is legally binding as regards this claim. The Court of Appeal pronounced this part of the case closed.
Immediately prior to the appeal proceedings before the Court of Appeal, Intervet petitioned for an interlocutory injunction, requesting that Pharmaq be prohibited from manufacturing, putting on the market, etc. a vaccine based on the ALV405 virus isolate. In the reply, Pharmaq did not object to an interlocutory injunction being handed down without further administrative procedure. Accordingly, on 6 September 2016, Borgarting Court of Appeal handed down a ruling with the following conclusion:

1. Pharmaq AS is prohibited from manufacturing, offering for sale, putting on the market or using viruses and vaccines against pancreas disease in fish based on virus isolate ALV 405, or from introducing or possessing the virus and vaccines with such intent, during the period until the Court of Appeal renders a judgment in the main hearing between the parties.

2. Costs are not awarded

For more details pertaining to the particulars of the case, reference is made to the District Court's judgment, the Borgarting Court of Appeal's judgment of 22 December 2011 in the patent case and the Court of Appeal's comments below.

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The appeal proceedings were held over 15 court days during the period from 11 October – 3 November 2016 in the Borgarting Court of Appeal Building.

Mr Gunnar Meyer and Ms Ida Elisabeth Gjessing appeared as legal counsel on behalf of Pharmaq, cf. §3-1, second subsection, second sentence of the Dispute Act. Mr Lars Erik Steinkjer appeared as co-counsel. Also present from Pharmaq were Corporate Counsel Nils Arne Grønli, Senior Researcher Marit Rode and Ms Sally Malian (*sic*).

Mr Eirik Wensell Raanes appeared as legal counsel for Intervet. Mr Magnus Hauge Greaker appeared as co-counsel. Mr J.J.L. Mestrom appeared on behalf of Intervet. In addition, Petter Frost, Managing Director of MSD Animal Health Innovation AS (the Norwegian subsidiary of Intervet Holding B.V.) and Mr Roald Kaus (*sic*) appeared on behalf of Intervet.

Twenty witnesses were examined. For more about the presentation of evidence, reference is made to the court record.

In short, the appellant, **Pharmaq AS**, argued that:

The supplementary protection certificate is invalid, and there are several alternative grounds for invalidity. First, the product falls outside the scope of the SPC Regulation, as defined in Article 2 of the Regulation. Article 2 must be understood to mean that, under the directives referred to in the provision, products traded before a marketing authorisation is granted fall outside the provision.

The British preliminary marketing authorisation granted in 2005 cannot be considered a marketing authorisation under Article 2 of the Regulation.

The objective of an SPC is to ensure sufficient patent protection to promote research and the development of new medicinal products. This is accomplished by compensating the patentee for the time spent on safety and efficacy studies before being granted a marketing authorisation.

Intervet has not experienced any delay or obstacles to the sale of the vaccine product on the market such as those for which the SPC Regulation is intended to compensate. Intervet has traded the vaccine almost freely throughout the EEA, without conducted time-consuming studies to document safety and efficacy in compliance with the ordinary requirements for being granted a marketing authorisation.

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The scheme of special approval exemptions and the Irish AR16 licences entailed that the PD vaccine has in actual practice been traded almost freely in the EEA market since 2003. Sales have been substantial. Norvax Compact PD vaccines were traded for about MNOK 600 from the time before Intervet was granted the first ordinary marketing authorisation in August 2011. Even if the UK preliminary marketing authorisation from 2005 were to be considered the first authorisation to trade the product in the EEA, Intervet had a turnover prior to that time that entails that the product had been "placed on the market" in the sense of the Regulation. Thus, the product has been almost freely available on the market through sales. Permission was also given in Norway to advertise the vaccine in respect of the industry and veterinarians, and it has been proven that Intervet took advantage of this on a large scale. The product has been one of the most traded medicinal products within the aquaculture industry in Norway.

There is no requirement that Intervet must have had full market access to be considered to have exploited the invention commercially. If the SPC were upheld, Intervet would be compensated with an extended protection period for time they have not lost, at variance with the objective of Article 2. It is only sales in emergency situations, as mentioned in Article 8 of Council Directive 2001/82, that do not preclude the granting of an SPC. The problem with PD infection has not been serious enough in either Ireland, Norway or UK for the conditions for permission under Article 8 to have been satisfied.

Article 8 is not correctly implemented in the Norwegian Medicinal Products Regulation. The AR-16 licences granted under Irish rules do not correctly implement Article 8 either. The Directive must be considered exhaustive for regulating the opportunities the Member States have for granting emergency permissions. The special approval exemptions were not issued for the type of emergency situation that falls under Article 8. This exception is limited to serious cases of epizootic diseases where there are no appropriate medications. Even though PD is a serious disease for the aquaculture industry, it has not been epizootic in any Member State.

The SPC must in any event be found invalid since the certificate was granted at variance with the conditions in SPC Regulation Article 3 d) cf. b). Intervet's marketing authorisation in Norway from 2011 was not the first authorisation to put the product on the market in the sense of Article 3 d). The special approval exemptions in Norway and Ireland must be seen as national authorisations to place the product on the market. Consequently, the application for a certificate was filed too late.

The scope of the SPC as granted was also specified too broadly. The scope of protection for an SPC is strictly limited to the product covered by the marketing authorisation, cf. Article 4. In the case in suit, there are two different active ingredients. Pharmaq's vaccine is a complex biological medicinal product in itself, constituting a separate genetic subtype and another virus strain that is

different from Intervet's product. The protection that Intervet can claim is limited to the active ingredient in Intervet's vaccine, which is, SAV-1, strain F93-125. Intervet's SPC was granted at variance with Article 4, as it reflects the entire scope of the patent claim, and it is not limited to the product that was approved for being placed on the market.

If the Court were to conclude that the SPC covers other virus strains, under any circumstances, it is argued that the strains are not therapeutic equivalents. Pharmaq's vaccine has been proven to have a significantly better effect than Intervet's vaccine. Pharmaq and Intervet both carried out challenge trials with the two vaccines after the District Court's judgment was rendered. In Pharmaq's view, the results of the trials corroborate that the vaccine based on the virus strain ALV405 clearly show better vaccine efficacy than Intervet's vaccine. The fact that the scope of protection is too broadly specified must lead to the SPC being found invalid. In the alternative, the Court must find that Pharmaq's vaccines based on ALV 405 do not constitute infringement of the SPC.

Pharmaq argues in the alternative that the Norwegian Medicines Agency's decision to grant Norvax Compact PD a special approval exemption on 29 August 2003, must be considered the first authorisation to bring the product on the market under SPC Regulation, Article 3d) cf. b). The marketing authorisation of 11 August 2011 was thereby not the first authorisation to bring the vaccine on the market in Norway, and the SPC application should therefore have been rejected as being filed too late when received, cf. the six-month deadline in Article 7 no. 1. In consequence, the SPC must be found invalid.

Pharmaq AS submitted the following claim for relief:

As regards validity and scope of protection:

Primarily:

> Norwegian supplementary protection certificate SPC/NO 2011024 is found invalid.

In the alternative:

> Manufacturing, offering for sale, bringing on the market, or using vaccines against pancreas disease in fish, based on vaccine strain ALV 405, or introducing or possessing vaccines for such purpose, do not constitute infringement of SPC 2011024.

As regards the claim for an injunction pursuant to §56a the Patents Act:

> The court finds for Pharmaq AS

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As regards the interlocutory injunction:

The petition is not granted.

In all events:

Intervet International B.V. is ordered to compensate Pharmaq AS for its legal costs for the District Court and the Court of Appeal.

Briefly, the respondent, **Intervet International B.V.,** has submitted the following:

The SPC is validly granted and there are neither judicial nor factual grounds for finding it invalid, as the District Court correctly surmised. Intervet also essentially agrees with the District Court's reasons for the result.

The SPC was not granted at variance with Article 2 of the Directive. The special approval exemptions and the AR16 licences were granted on the basis of national rules that implement Article 8 of the Council Directive relating to Veterinary Medicinal Products. Thus, the authorisations cannot mean that the product is excluded from the scope of the Regulation.

Even though the authorisations were not considered to have been granted on the basis of national rules which implement the Council Directive relating to Veterinary Medicinal Products, the product does not fall outside the scope of the Regulation. Any mistakes made by the Norwegian authorities cannot in any case be allowed to affect Intervet's rights under the SPC Regulation.

A product cannot be considered to have been placed on the market in the sense of the SPC Regulation before the patentee has had free legal access to immediate and unconditional commercial exploitation of the product. That is not the case here. Special approval exemptions can only be applied for by and granted to veterinarians or fish health biologists. The scheme is based on strong societal interests where consideration for fighting a serious disease situation is given priority, and is administered only to animals the veterinarian has in his practice. The authorisation is limited to allocated vaccine quotas and is granted for a specific period of time. The special approval exemptions in Norway and AR16 licences in Ireland did not, therefore, give Intervet access to free commercial exploitation of the product, and cannot mean that the product can be considered to have been "placed on the market" in the sense of the Regulation.

Pharmaq's point of view implies that medicinal product manufacturers will have to consider refusing to supply medicinal products under special approval exemptions in order not to disqualify themselves from getting a subsequent SPC. This could lead to a situation in which

medicinal product manufacturers refrain from supplying medicinal products under special approval exemptions in critical disease situations, something that is at variance with the most important social considerations that justify the rules for special approval exemptions.

Also, it cannot be decisive for the assessment whether an applicant has supplied the product on a large scale or a small scale. Such a state of law would be impossible to practise, be unpredictable and inconsistent with the objective of having clear and uniform rules in this area.

The SPC Regulation is to ensure an effective protection period for commercial exploitation of the product and it is intended to compensate for the time that elapses from the time a patent application is filed until a marketing authorisation is granted. The SPC Regulation would not fulfil its purpose if deliveries under special approval exemptions were to exclude them from later being granted an SPC.

Deliveries and sales under special approval exemptions, which took place after the marketing authorisation was granted in the EEA and before the UK PMA was granted in 2005, are, under any circumstances, irrelevant for the question of whether the product is covered by the SPC Regulation. The traded value of the PD vaccines prior to the preliminary marketing authorisation in 2005 totalled only MNOK 6, an amount that did not give a sufficient yield on the investments in the development of the vaccine.

Intervet disputes further that special approval exemptions are to be considered the first authorisation to place the product on the market as a medicinal product under Article 3d) of the SPC Regulation. The authorisation to which this provision refers, is the first to freely place the product on the market and must be an authorisation granted in compliance with Council Directive 2001/82. National systems for special approval exemptions are governed by national legislation, which varies from Member State to Member State, and they cannot form the basis for an application for and the granting of an SPC. Intervet cannot under any circumstances be subject to prejudice if a Member State has implemented or applied the EEA regulations incorrectly.

The SPC covers the specific strain of PD virus (inactivated) that makes up the vaccine covered by the marketing authorisation, as well as other strains of the same PD virus (inactivated) covered by the basic patent. Strains of the PD virus will have similar genotypic and phenotypic characteristics. The insignificant biological variations that will be present because this is biological material will not affect the general characteristics of the virus. Vaccines based on different variants of the PD virus have the same therapeutic effect, and are directly competing commercial products. The SPC gives no genuine protection for the patentee if it is limited to the specific embodiment of the PD virus, as indicated on the product characteristics. The different strains of the PD virus are not other products pursuant to Article 4 SPC Regulation.

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The purpose of the product definition in the SPC Regulation is to give effective protection for the medicinal product developed on the basis of the basic patent. The definition of 'product' in the sense of the SPC Regulation is not determined exclusively by the active ingredients that constitute the vaccine to which the marketing authorisation applies. In our case, the basic patent's description gives a reasonable scope of protection

Only where there is proof of systematic, consistent and significant differences between the vaccine products, can there be talk of different active ingredients, cf. Article 4. Pharmaq has not submitted evidence that this is the case. Quite to the contrary, existing research material and challenge trials that have been carried out show that the vaccine based on isolate ALV405 does not afford better protection against PD infection than Intervet's vaccine. The two challenge trials performed after the District Court's judgment was rendered do not justify the claim that Pharmaq's vaccine is more efficacious against PD infection.

The SPC is thus valid as granted by the Norwegian Industrial Property Office. Pharmaq's PD vaccine will constitute infringement of the SPC, meaning it provides a basis for an injunction under §56a of the Patents Act.

If the appeal is dismissed, both the claim and the grounds for securing the claim are established as probable, so that the conditions are satisfied for granting an interlocutory injunction until the Court of Appeal's judgment is legally binding, cf. claim for relief, point 2.

Intervet International B.V. has submitted the following claim for relief:

1. The appeal is dismissed.

2. Pharmaq AS is prohibited from manufacturing, offering for sale, putting on the market or using viruses and vaccines against pancreas disease in fish based on virus isolate ALV 405, or from introducing or possessing the virus and vaccines with such intent, until a legally binding judgment has been rendered in the case.

3. Intervet International B.V. is awarded costs for the Court of Appeal.

The **Court of Appeal** has arrived at a different result from the District Court, and finds the supplementary protection certificate invalid since the scope of protection goes further than what ensues from Article 4 of the SPC Regulation. Given the grounds for the result on which the Court of Appeal bases its findings, it is not necessary for the Court to take position as to whether invalidity can also be justified by the certificate also being at variance with Articles 2 and 3 of the SPC Regulation.

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Application of law – certificates' scope of protection

The term of protection for a patent is 20 years, calculated from the date on which the patent application was filed in the State in question, as established by law in Norway under §40, first subsection, of the Patents Act. For medicinal products, the time it takes before a product is brought to market could decrease the effective protection time for the patent significantly. Accordingly, a regime to extend the protection of a product was introduced, i.e. the SPC Regulation.

In the Preamble to the SPC Regulation, Council Regulation (EEC) NO1768/92 of 18 June 1992, concerning the creation of a supplementary protection certificate for medicinal products, the background for the SPC rules is expressed as follows:

> Whereas at the moment the period that elapses between the filing of an application for a patent for a new medicinal product an authorisation to place the medicinal product on the market makes the period of effective protection under det patent insufficient to cover the investment put into the research;

The point of stimulating the development of new drugs by granting protection against competing products after the period of patent protection must nonetheless be balanced against other general considerations that are at cross purposes, expressed in the Preamble as follows:

> Whereas all the interests at stake, including those of public health, in a sector as complex and sensitive as the pharmaceutical sector must nevertheless be taken into account; whereas, for this purpose, the certificate cannot be granted for a period exceeding five years; whereas the protection granted should furthermore be strictly confined to the product which obtained authorisation to be placed on the market as a medicinal product;

The SPC Regulation establishes a supplementary protection certificate system for medicinal products that have been granted a marketing authorisation. As mentioned, the scheme is designed to stimulate investment in research and development that leads to new medicinal drugs that benefit public health in the Member States. Meanwhile, the rules are not intended to unreasonably impede the development and sale of new, competing products that benefit public health in the EEA area. It is consideration for the opportunity to develop new, improved products that justifies that the protection an SPC affords is to be "strictly limited" to the product that is allowed to be placed on the market as a medicinal product.

The SPC regulations ensure a medicinal product satisfactory protection for a period of time in excess of the period of patent protection, which is 15 years from the date on which the first marketing authorisation is granted for the medicinal product in the EEA, but nonetheless, so that

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protection under the SPC cannot exceed five years, cf. Preamble, points 7 and 8.

The scope of the Regulation is governed as follows in Article 2:

> "Any product protected by a patent in the territory of a Member State and subject, prior to being placed on the market as a medicinal product, to an administrative authorisation procedure as laid down in Directive 65/65/EEA1 or Directive 81/851/EEA may, under the terms and conditions provided for in this Regulation, be the subject of a certificate."

The more detailed terms for the issue of a certificate are governed by Article 3:

> A certificate shall be granted if, in the EEA Member State in which the application referred to in Article 7 is submitted:
>
> (a) the product is protected by a basic patent in force;
> (b) a valid authorisation to place the product on the market as a medicinal product has been granted in accordance with Directive 65/65/EEA or Directive 81/851/EEA, as appropriate;
> (c) the product has not already been the subject of a certificate;
> (d) the authorisation referred to in b) is the first authorisation to market the product as a medicinal drug.

The EEA Agreement's Annex XVII, point 6, determines that, for the purposes of the EEA Agreement, Article 3, letter b) of the SPC Regulation, a marketing authorisation granted by an EFTA Member State can be considered a valid marketing authorisation. Thus, the regulations have been adapted for the EEA.

The object of the certificate, including the scope of protection, is thereby regulated as follows in 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 authorized before the expiry of the certificate."

According to the wording of this provision, the certificate's product protection cannot be extend further than the protection conferred by the basic patent, and it encompasses only the product covered by the marketing authorisation for the corresponding medicinal product. The Court of Appeal will revert to the more detailed understanding of Article 4 for our case.

Intervet's Norwegian marketing authorisation was granted by the Norwegian Medicines Agency on 18 August 2011 for "Norvax Compact PD vet. injection fluid, emulsion Intervet, MT no. 10-7431". The authorisation was granted pursuant to the Act relating to medicinal products of 4 December 1992 no. 132 and the Regulations governing medicinal products of 18 December 2009

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no. 1839, §5-8, and applied for five years. Point 2 of the product characteristics "Qualitative and Quantitative Composition", which is attached to the marketing authorisation, specifies the medicinal product's "Active Substance" as:

> Salmon pancreas disease virus (SPDV) strain F93-125,≥ 70% RPP*
> *RPP: relative percentage protection in a laboratory potency test in Atlantic salmon

According to the wording in Article 4, the scope of protection for the SPC is, as mentioned, limited to the "product" that will be covered by the marketing authorisation for the corresponding medicinal product. Article 1 of the SPC Regulation stipulates definitions. Article 1 b) establishes that "product" for the purposes of this Regulation shall be understood as:

> the active ingredient or combination of active ingredients in a medicinal product.

The active ingredient in the marketing authorisation is specified only as "Salmon pancreas disease virus (SPDV) strain F93-125". The SPC certificate granted to Intervet confers a scope of protection also covering "closely related strains which have genotypic and phenotypic characteristics similar to said deposited virus strain". The marketing authorisation is defined only as covering strain F93-125 (SAV-1), while the certificate encompasses somewhat more; i.e. also closely related strains, which have genotypic and phenotypic characteristics similar to the deposited virus strain.

The question the Court of Appeal must decide is whether the product for which extended protection has been granted coincides with the product – the active ingredient – covered by the marketing authorisation. Whether the SPC as granted falls within the scope of protection allowed by Article 4 cf. Article 1 b, must be decided based on an interpretation of what the same "active ingredient" is in the sense of the Regulation.

Intervet has argued that the scope of protection cannot be decided from an isolated linguistic understanding of "the product", but must be supplemented by other sources of law, in particular by reflections on the purpose and case law. Intervet's main contention is that the scope of protection for biological medicinal products must go further than to be strictly limited to the product definition in the marketing authorisation in order for the SPC scheme to have any genuine importance at all for biological medicinal products. The District Court agreed with that view, and stated an opinion about this (page 36, first paragraph):

> For a vaccine that is based on inactivated whole-virus particles, as in this case, however, with an interpretation of the term "product" based on the language, one could end up with an illusory protection. The strain of vaccine is strictly defined in the documentation associated with the marketing authorisation to ensure consistency in the production of

vaccines, cf. witness Dr. Rhona Banks, (Veterinary Biologicals Consultant, RA-Elect Ltd, UK). Accordingly, this definition does not take into account whether there may be other virus particles that can have the same mechanism of action. With an interpretation of the language based on the marketing authorisation, it would thereby have been possible for a competitor to make a new product based on a different isolate of an identical or similar virus, without implying a breach of the SPC protection. In their effect, such vaccines would have been equivalents, and thus comparable to generic vaccines covered by the SPC protection. This distinction appears to lead to an unreasonable result.

The Court of Appeal agrees with the District Court in that the point of ensuring that the SPC scheme takes on genuine importance also for biological medicinal products, indicates that the scope of protection is not limited to a strict interpretation of the wording of the product designation in the marketing authorisation. This consideration must nevertheless be weighed against other considerations, especially that the SPC protection should not be given such a broad scope that other, improved medicinal products are kept off the market to the detriment of human or veterinary health in the EEA.

The District Court decided during preparatory proceedings to submit the case before the EFTA Court, cf. §51a of the Courts Act. The questions referred to the understanding of the SPC regulation Articles 2, 3 and 4:

1. Concerning Article 2 of the SPC Regulation, has a product been placed on the market as a medicinal product in the EEA before it has been granted marketing authorisation in accordance with the procedure for administrative authorisation laid down in Directive 81/851/EEC (or Directive 2001/82/EC) when delivery of the product has taken place in accordance with:
   (i) 'special approval exemptions' granted by the State Medicines Agency to veterinarians and fish health biologists pursuant to Section 3-6 or 3-7 of the Norwegian Regulation of 22 December 1999, alternatively Sections 2-6 or 2-7 of the Norwegian Regulation of 18 December 2009, or
   (ii) what are known as 'AR 16 licences' granted by the Irish Department of Agriculture, Food and the Marine pursuant to the Irish Statutory Instrument No 144/2007 European Communities (Animal Remedies) Regulations 2007 part III 'Exceptional authorisation', point 16?
2. If question 1 is answered in the affirmative, is such a product outside the scope of the SPC Regulation and is an SPC granted on the basis of such a product therefore invalid?

3. Concerning the interpretation of Article 2 of the SPC Regulation, should a marketing authorisation granted for a veterinary medicinal product pursuant to Article 26(3) of Directive 2001/82/EC be deemed to constitute an administrative authorisation pursuant to Directive 81/851/EEC (or Directive 2001/82/EC) within the meaning of Article 2?

4. a) Do special approval exemptions pursuant to Section 3-6 or 3-7 of the Norwegian

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Medicines Regulations of 1999 (FOR-1999-12-22-1559) or Section 2-6 or 2-7 of the Norwegian Medicines Regulations of 2009 (FOR-2009-12-18-1839) constitute valid authorisation to place the product on the market as a medicinal product within the meaning of Article 3(b)?

b) Do special approval exemptions pursuant to Section 3-6 or 3-7 of the Norwegian Medicines Regulations of 1999 (FOR-1999-12-22-1559) or Section 2-6 or 2-7 of the Norwegian Medicines Regulations of 2009 (FOR-2009-12-18-1839) constitute a first authorisation to place the product on the market as a medicinal product in Norway within the meaning of Article 3(d)?

5. When the medicinal product is a virus vaccine, can the scope of protection under the SPC cover not only the specific strain of virus that is included in the medicinal product and covered by the basic patent, but also other strains of the virus that are covered by the basic patent?

   In answering this question, is it of significance whether:
   a) such other strains have an equivalent therapeutic effect to the virus strain included in the medicinal product or whether the therapeutic effect is not immediately equivalent?
   b) a medicinal product based on such other strain will have to be the subject of a separate marketing authorisation with requirements for documentation of safety and effect?

6. If an SPC has been granted with a product definition that is not strictly limited to the specific strain of the virus authorised to be placed on the market as a medicinal product:

   a) will such an SPC be valid, or

   b) will the SPC be valid; such, however, that the scope of protection under Article 4 does not extend beyond the specific virus strain authorised to be placed on the market as a medicinal product?"

The EFTA Court handed down its advisory opinion in the case on 9 April 2015 with the following conclusion:

1. Under Regulation (EEC) No 1768/92, a supplementary protection certificate for a veterinary medicinal product may be granted in an EEA State on the basis of a marketing authorisation granted in that State pursuant to the administrative authorisation procedure set out in Title III of Directive 2001/82/EC, including the procedure for authorisation in exceptional circumstances under Article 26(3) of that directive. Such a marketing authorisation constitutes a valid authorisation and, where appropriate, may also constitute the first authorisation to place the product on the market as a veterinary medicinal product within the meaning of Article 3(b) and (d) of Regulation (EEC) No 1768/92.

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Permissions granted on the basis of the first paragraph of Article 8 of Directive 2001/82/EC do not constitute a marketing authorisation within the meaning of Regulation (EEC) No 1768/92. That derogating provision strictly limits the use of the measures permitted under it, stating that it applies only in the event of serious epizootic diseases, in the absence of suitable medicinal products and after informing the EFTA Surveillance Authority of the detailed conditions of use.

The determination of whether "special approval exemptions" or "AR 16 licences", granted respectively by Norwegian and Irish authorities between 2003 and 2011, and the provisional marketing authorisation granted in the United Kingdom in 2005 were issued pursuant to national provisions implementing the first paragraph of Article 8 or Article 26(3) of Directive 2001/82/EC depends essentially on the assessment of the facts in the national proceedings, which is a matter for the national court.

2. Pursuant Article 4, Regulation (EEA) no. 1768/92, 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 for a virus vaccine relied on for the purposes of Article 3(b) of Regulation (EEC) no. 1768/92, only if the specific strain constitutes the same active ingredient as the approved 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 national court.

   A supplementary protection certificate is invalid to the extent it is granted a wider scope than that set out in the relevant marketing authorisation."

Point 2 of the opinion from the EFTA Court specifies that it is decisive in respect of the product protection in Article 4 that it refers to the same active ingredient that is in the approved medicinal product. The assessment of whether this is the case must, according to the opinion, be determined by the national court of law. In other words, the Norwegian Industrial Property Office cannot issue an SPC to Intervet that covers vaccines that do not have the same active ingredient as that in the approved medicinal product. The requirement for the same medical indications mentioned in the opinion is not appropriate as a delimitation criterion in our case.

In our case, the question of whether a certificate has been granted that is limited to the "same active ingredient" as in the approved medicinal product, must be decided based on an interpretation of the language seen in the context of other sources of law, where case law and the purpose of the SPC rules are key.

Intervet has placed emphasis on the Farmitalia judgment (case C-392/97) to support its contention that the "same active ingredient" must be interpreted so that the purpose of granting sufficient protection is satisfied when the scope of protection is established.

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The judgment referred to a patent for a chemical compound where the marketing authorisation specified a salt of the chemical compound. The question was whether the SPC Regulation also encompasses the free base, and salts and esters of the same compound, which can potentially have different properties when used in a medicinal product.

The European Court of Justice assumed that the product designation in Article 1 b), that specifies "the active ingredient or combination of ingredients in a medicinal product", must be interpreted in compliance with purpose of the regulation, cf. paragraphs 18–22 of the judgment. The European Court of Justice's decision assumes that if the certificate only provides protection against competitors making use of the product in the form mentioned in the marketing authorisation (salt), the purpose of the SPC Regulation will not be satisfied, because competitors, unimpeded by the certificate, would be able to sell therapeutically equivalent products, cf. in particular, paragraphs 29 and 35.

The judgment attaches importance to the purpose of the Regulation in establishing the concept of product for generic medicinal products, but in the Court of Appeal's opinion, the decision otherwise gives limited guidance for understanding the term "the same active ingredient" used in biological medicinal products.

The decision in the "Yeda judgment" rendered by the Dutch appellate court Raad van State (Judgment 200809060/1/H3), on 19 August 2009, is, in the opinion of the Court of Appeal, more illustrative of the issue in our case.

The decision deals with a biological active ingredient, "Adalimumab". The judgment was presented to the Court of Appeal as translated to English by Sworn Translator Frank Scholl.

The basic patent covered a number of monoclonal antibodies, including Adalimumab, but the marketing authorisation was limited to the latter antibody. The Dutch patent authorities' (OCNL) decision to grant the SPC solely for the API described in the marketing authorisation – "Adalimumab", was upheld by the courts.

In 2005, the Dutch patent office OCNL granted an SPC to the Yeda Research and Development Company Ltd. (Yeda) that was limited to the company's medicinal product "Adalimumab", a monoclonal antibody aimed at the human cytokine TNFa (Tumor Necrosis Factor Alpha) and with a medical anti-inflammatory effect.

Yeda filed a case in 2009 against OCNL in the Dutch District Court, claiming that the certificate should also cover other monoclonal antibodies against TNFa, given that they had a medical effect which corresponded to the one described in the marketing authorisation for Adalimumab. Yeda argued that the company was entitled to be granted an SPC with a broader coverage than for the

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product/medicinal product covered by the marketing authorisation. The other monoclonal antibodies were covered by the basic patent. Yeda referred *inter alia* to the fact that in the Farmitalia case, an SPC with broader coverage than what was given in the marketing authorisation was allowed, in that also salts of the active ingredient (mentioned in the basic patent) were considered to be covered by Farmitalia's SPC.

The Dutch appellate court rejected Yeda's appeal. The appellate court found in favour of OCNL, stating that there were no grounds for derogating from the description given in the marketing authorisation, and that it was correct to grant an SPC just for Adalimumab and not for other monoclonal antibodies covered by the basic patent. The Court also found it not proven that other monoclonal antibodies against TNFa would have the identical therapeutic effect as Adalimumab. The Court found that the Yeda case was different from the Farmitalia judgment in that the aforementioned covered a biological medical medication that was qualitatively different from salts of a chemically active substance with an identical medical effect.

The judgment states in points 2.5.3 and 2.5.4:

> Likewise, it is also not accepted by medical science that related biological medicines generally have one and the same effect.
>
> ---
> In view of the molecular complexity of the monoclonal antibodies, it cannot be excluded that a minor difference could have significant effects on the quality, safety and efficacy of the medicine in question.

The Court also referred to the fact that a monoclonal antibody (such as Adalimumab) is a given protein consisting of a unique series of amino acids (1330) and with a complex structure making it difficult to predict whether it will have a completely identical (medical) effect as other antibodies against TNFa.

The Dutch appellate court also referred to research data in which a number of monoclonal antibodies against TNFa (including Adalimumab) were tested, and with somewhat divergent results with a view to medical effect against TNFa. This involved minor differences, but the appellate court underlined that even minor differences could be significant for the quality, safety and efficacy of the medicinal product in question.

In the Court of Appeal's view, the Yeda judgment is based on the Farmitalia judgment's broader interpretation of the API in the marketing authorisation for a chemical medicinal product not being immediately transferable to biological medicinal products.

The Court subsequently concluded as much in point 2.5.5:

> The District Court rightly ruled that this case, where it concerns a biological medicine, differs considerably from the situation referred to in the Farmitalia ruling and that OCNL therefore did not have to see any reason to deviate from the description of the active substance in the marketing authorisation in the product description in the certificate granted to Yeda. Yeda's argument fails.

The Court of Appeal's understanding of the judgment is that, in the context of a biological medicinal product, as opposed to the Farmitalia case, there are not sufficient grounds to derogate from the description of the active substance described in the marketing authorisation. This is because even minor differences in the antibody could have significant effects on the quality, safety and efficacy of the medicine in question.

The Court of Appeal finds, after balancing of the conflicting interests that the SPC scheme is intended to protect, that the main consideration is to protect against competition from equivalent variants, and that minor differences in the active ingredient do not mean that one is outside the SPC's scope of protection for a biological product. On the contrary, the rules will not be of any genuine practical importance for biological medicinal products. In the view of the Court of Appeal, it is, however, not clear how the limits on the scope of protection for biological medicinal products ought to be established.

The Court of Appeal assumes as a point of departure, that for there to be a different "active substance", the difference between the products must at least be expressed in such a manner that it has a practical and appreciable effect on the quality, safety and efficacy of the medicine in question. In our case, it is the difference in vaccine efficacy that is the topic for assessment.

Intervet has argued before the Court of Appeal that the differences between the vaccine products must be systematic, consistent and significant for the SPC as granted in our case to be found invalid. The Court of Appeal agrees that such a legal starting point can lead to a reasonable and balanced assessment of the conflicting interests by the SPC Regulation. The Court of Appeal is not convinced that the threshold should be set as high as "significant" before deeming a substance to be a different active ingredient.

As our case stands, it is not necessary for the Court of Appeal to take a position on this question.

In any event, based on an overall assessment of the existing research data and other evidence, the Court of Appeal is convinced that Pharmaq's vaccine is systematically, consistently and significantly more efficacious against SAV-3 infection than Intervet's vaccine.

The Court of Appeal has therefore determined that the Norwegian Industrial Property Office has

granted Intervet an SPC with a scope of protection that is inconsistent with Article 4 of the SPC Regulation.

Below, the Court of Appeal will explain the results of the evidence in more detail.

In general about the assessment of evidence

The assessment of evidence is the result of an overall assessment of the scientific and other evidence presented to the Court of Appeal, and where the Court, based on the evidentiary requirements of civil law, shall accept the most probable facts as proven. The parties themselves have based their arguments on the two vaccines having the same antigenic content in the experiments and analyses that were presented to the Court of Appeal during the appeal proceedings. The Court of Appeal is using the same facts as the basis for its assessment of the evidence.

In assessing whether there are systematic, consistent and significant differences in efficacy between the two vaccines, the Court of Appeal will initially mention the different methods used in the case in suit for comparing virus strains and vaccines.

Virus neutralisation tests

Virus neutralisation tests are appropriate for detecting the production of antibodies that bond to antigen structures, and are involved in how the virus bonds to a receptor on a host cell. The antibodies block this bond and thereby prevent that the virus from infecting the cell (neutralisation).

One way to detect and quantify virus-neutralising antibodies is to set up a dilution series of antisera, which is subsequently mixed with virus particles before these are added to an appropriate culture of host cells. The neutralisation titre (TCID50) is read as the serum dilution in which just 50% of the cells in the culture are infected (cytopathogenic effect).

By comparing antisera from fish that have been immunised or infected with different viruses, e.g. subtypes F93-125 and ALV405, it is possible to compare whether a type of virus has stimulated the formation of antibodies that cross react (wholly, partially or not at all) with both subtypes.

The parties have presented results from several neutralisation tests in their arguments before the Court of Appeal.

Challenge trials; testing of vaccines

In the case in suit, challenge trials are vaccine trials performed under controlled conditions

where one measures vaccine efficacy in vaccinated fish after they are infected with a live virus. Infection can be accomplished either by the injection of infectious matter (virus) into each individual fish or by fish-to-fish contagion ("cohabitant infection"), where certain fish are injected with a strong dose of virus. The virus reproduces and is transferred through the water to the vaccinated fish (the cohabitants). Cohabitant infection is the closest one can come to the type of infection to which the fish are exposed in the field.

In our case, three challenge trials were conducted, two of which were new for the Court of Appeal.

Field challenges; vaccine trials in the field

Field challenges are safest method for investigating the quality, safety and efficacy of vaccines. Such studies cover a large number of locations and vaccinated fish in their natural environments. Field challenges are time-consuming and costly.

One field challenge was carried out in the case in suit, to which the Court of Appeal will revert.

The Court of Appeal's assessment of vaccine efficacy

Genetic differences/similarities between SAV subtypes

Salmon Alphavirus has a single-stranded RNA (+) genome and the first gene information came to light in 1999 when Weston et al. sequenced parts of a PD virus. In a comparison with other Alfa virus genomes, it appeared to belong to a separate species of *Togaviridae*. Subsequent sequencing of a number of PD viruses in isolation from epidemics from *inter alia* Norway, Ireland and Scotland, showed that the SAV virus could be further divided into six distinct genotypes/subtypes; hence the enumeration SAV 1-6.

All the SAV viruses (1-6) are closely related, with roughly 90% sequence homology. Converted into amino acid sequences (what the genes code for), there is roughly 95% similarity between SAV 1-6, and this also applies to SAV-1 and SAV-3, which are discussed in this case. The genetic distance between SAV-1 and SAV-3 has led to the hypothesis that both subtypes are derived from a common precursor 200 to 500 years ago.

The SAV genome codes for two continuous gene products, which are subsequently divided into four non-structural proteins (nsP1-4) and five structural proteins (capsid protein, E1, E2,E3 and 6K).The surface proteins E1, E2 and E3 are bound to each other (heterodimers/homodimers) and

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form so-called "spikes" on the surface of a virus. These structures primarily serve as carriers of the virus-specific antigen determinants/epitopes. The E2 protein is of special interest with its three exposed domains (A, B and C), which are probably carriers of the most important antibody-binding structures/epitopes discussed in this case.

The E2 molecule is bonded to the virus' cell membrane through the E1 protein, with the A, B and C domains pointing outward. The protein is comprised of 438 amino acids. The sequencing of E2 in SAV-1 (F93-125) and SAV-3 (ALV405) show differences in 22 amino acid positions (5%) between the two isolates. Several of the differences are located on the surface of the E2 molecule and can in principle affect the structure of the antibody-binding epitopes and, as a result, the antibodies' ability to bond to E2 (affinity/avidity). In addition, there are some differences of significance for the virus' ability to bind to receptors on a host cell and therefore for the virulence of the virus in an organism.

In the opinion of the Court of Appeal, the PD viruses SAV-1 and SAV-3 have major genetic similarities. However, they are sufficiently different, both genetically and in the structural proteins, that these two subtypes can to some extent appear to be two different virus antigens.

Immunological differences between SAV viruses/epitopes

Salmon express an "immunological memory" almost like that of mammals, i.e. the antibody specificity produced during a first-time infection (or vaccination) with an antigen/pathogen gives an immunity and additional protection against second-time infection by the same pathogen. Reduced vaccine efficacy could arise if the virus used in the vaccine differs from the virus that causes the disease, depending on how important the altered antigen structures /epitopes are in the immune response against the virus.

There are many examples to show that minor amino acid differences in the most central surface molecules in a virus can cause significant differences in antigenicity (the ability to induce an immune response). There is some uncertainty about how this works in salmon, which have a greatly reduced antibody (V-gene) repertoire (mainly tetramered IgM), compared with mammals. This may cause significant deviations in connection with an infection.

Of the 22 amino acids that differ in the E2 molecule in F93-125 and ALV405, respectively, there are changes that both introduce (Asn to Asp, Val to Glu) and eliminate (Asp to Ala) charged carboxyl (COO-) groups, and that introduce the hydrophobic amino acid proline (Leu to Pro and Ser to Pro). These are amino acids that are important for proteins' structural properties, and they can therefore potentially lead to significant structural differences in certain epitopes on the E2 molecule of the SAV-1 and SAV-3 subtypes. Such differences can tentatively result in different

antigenicity between the two virus particles.

Pharmaq's expert witness (Richard Engh) uses modelling in his report to show how amino acid differences in the E2 protein from SAV-1 (F93-125) and SAV-3 (ALV405), respectively, lead to significant structural changes, and thus to changes in the antigenic epitopes in the outermost part of the E2 protein (the B domain). The amino acid changes in the E2 protein that are responsible for binding to the host cells' receptors can also have an impact on the virus' virulent (disease-related) properties.

The Court of Appeal's assessment is that the documentation that shows genetic and amino acid differences between isolates of SAV-1 (F93-125) and SAV-3 (ALV405) point in the direction of there being genuine differences between the two isolates in areas/structures that must be assumed to potentially be significant for the salmon's immune response and therefore for its immunity after vaccination.

Neutralisation analyses on the SAV-1 and SAV-3 viruses

The Court of Appeal has been presented with neutralisation analyses carried out by both parties.

The data from such an investigation, carried out for Pharmaq by Inge Tom Solbakk in 2016, shows a distinct tendency for antisera against F93-125 and ALV405 to cross-react to a significant extent (log2 = approx. 7-10). However, a homologous antiserum against F93-125 indicates a somewhat elevated response (log2 = 10), compared with a heterologous response against ALV405 (log2 = 8).

Conversely, antisera against ALV405 show no significant preference for homologous or heterologous virus. These data indicate that the neutralising determinants on F93-125 and ALV405 particles are sufficiently similar to stimulate and bond to the neutralising antibodies with roughly the same efficiency.

It is, however, important to bear in mind in this reflection that virus neutralisation tests are an "end point" analysis, i.e. the analysis is based on a dilution of a polyclonal antiserum. In such a diluted antiserum, only a few antibody specificities will be present. What will be decisive for the analysis will be either the antibody specificities that are in the highest concentration, or those that have the highest bond strength (affinity/avidity) in relation to the epitopes. Thus, virus neutralisation tests measure only a limited range of epitopes on the receptor-binding structure, and do not give a complete picture of the virus' overall antigenic structure. Neither the non-neutralising antibodies nor the neutralising antibodies that are only efficacious in an undiluted serum (*in vivo*) and binding to their corresponding epitopes are measured in such a test.

The neutralisation experiments presented in Court indicate that the pre-dominant neutralising

epitopes are sufficiently similar and cross react to a great extent. The non-neutralising antibodies and any cellular mechanisms are, however, not taken into account. Laboratory analyses such as virus neutralisation only say something about the antigenic properties of a few epitopes. Consequently, these analyses are not sufficient to say anything about the importance of the complete set of epitopes and thus the effect of the vaccination. The importance of the virus neutralisation data produced in a field situation, after vaccination with SAV-1, or possibly SAV3, is, in the Court's assessment, uncertain.

Challenge trials

The District Court found it probable that there is a difference in the protective effect afforded by the two vaccines, but the majority of the Court found that the data were insufficient to say anything about whether or not this constituted significant differences. Two new challenge trials were carried out after the District Court's judgment was handed down, one by each of the parties.

The purpose of the three different challenge trials has been to compare the effect of vaccines (administered in different doses) based on ALV405 (SAV-3) versus F93-125 (SAV-1) after infection with a SAV-3 isolate under controlled conditions.

In Pharmaq's challenge trial carried out in 2010 (PD 006.16 ES), the injection of infection (high contagion; defined dose) was used as a model. The same method was applied in Pharmaq's second challenge trial in 2016 (PD 028 ES).

Intervet carried out one challenge trial, in 2016. It was based on cohabitant infection, i.e. adding PD-infected fish that were used as the infection model. In general, this is considered a more natural infection model.

In addition to testing and comparing the incidence of infection among the sampling fish, histopathological examinations were carried out on the heart and pancreas for proof of the infection-related development of pancreas disease (PD).

Both parties have carried out statistical analyses of the data from the challenge trials.

An expert witness for Pharmaq, Peder Jansen, has written a report that analysed all the data from the two challenge trials conducted by Pharmaq in 2010 and 2016, respectively. He has analysed all the material together using a method known as logistic regression. In addition, Jansen has considered/re-analysed all the data from Intervet's challenge trial performed in 2016 in a separate supplementary report.

Intervet's challenge trial was analysed statistically by Intervet's expert witness, Mathieu Josef Hubert Hoeimakers. He carried out paired comparisons of data as grounds for his analysis, which the Court of Appeal does not consider to be the most conclusive analytical method for the trials.

The Court of Appeal applies Jansen's statistical method for processing the data as the basis for its assessment, so that the data from the challenge trials are assessed as a whole to determine the veracity of the challenge trials.

It can therefore be concluded that both of Pharmaq's challenge trials showed about two to three times higher probability that fish would test positive for SAV-3 infection after vaccination with F93-125 (SAV-1), compared with vaccine based on ALV405 (SAV-3). The degree of tissue damage found in the fish in the experiment corroborates the differences in protection between the different varieties of vaccines for SAV-1 and SAV-3, and that tissue damage was associated with the degree of virus infection in the trials.

Jansen's report on the data from Intervet's challenge trial indicates that increasing antigen concentration mitigates the probability of infection in the fish, but the same significant differences in vaccine efficacy were found in Intervet's trials as in the Pharmaq trials discussed in the paragraph above.

In the opinion of the Court of Appeal, the three trials show that both the vaccines give good protection against disease at high concentrations of vaccine antigens when carried out under controlled conditions. Upon dilution (titration) of the vaccine concentration, there are nonetheless differences between the two vaccines. As a whole, the data from the challenge trials pull in the same direction; they show that there is a statistically significant difference in vaccine efficacy between the two vaccines. The difference is, in the view of the Court of Appeal, that there is two to three times higher probability of testing positive for the SAV-3 infection when the vaccine is based on the F93-125 (SAV-1) antigen, compared with a vaccine based on ALV405 (SAV-3).

Field challenge

Pharmaq commissioned one field challenge to be carried out, but several factors caused it not to be optimal. Among other things, the number of locations was too low for significant analyses. Accordingly, it is difficult to draw any definite conclusion from the challenge. That being said, the tendency towards systematic differences between the vaccines based on SAV-1 and SAV-3 still appears to be present.

Conclusion – vaccine efficacy

The Court of Appeal's overall assessment of the research data presented and the other evidence is that there are significant differences in vaccine efficacy, and that Pharmaq's vaccine in actual practice has a significantly better effect against SAV-3 infection than Intervet's vaccine. The differences are consistent and systematic. The Court of Appeal's conclusion is, as mentioned, based on an overall assessment, but the two challenge trials conducted after the District Court's judgment was rendered have carried a great deal of weight for the Court's conclusion. Small differences in vaccine efficacy tested under controlled conditions may have a significant effect in the field, where the fish are often stressed and affected by operating conditions and competing infections.

Legal conclusion

In the Court of Appeal's assessment, the SPC as granted goes further than Article 4 allows when it specifies that the scope of protection generally covers "closely related strains which have similar genotypic and phenotypic characteristics as said deposited virus strain."

The Court of Appeal finds that the wording "closely related strains which have similar genotypic and phenotypic characteristics as said deposited virus strain" – is a delimitation that keeps vaccines that are systematically, consistently and significantly more effective against PD infection from being made available on the market. Such a scope of protection runs counter to one of the main purposes of the SPC scheme, i.e. that a certificate should not unreasonably impede the development and sale of medicinal products with documented significantly better efficacy, something that is a legitimate "health policy goal", cf. the Preamble to the SPC Regulation. Thus, reflections on purpose cannot justify an extended interpretation of "the product" for which Intervet has received approval to put on the market in the marketing authorisation, cf. Article 4 cf. Article 1 b).

The Court of Appeal's findings imply that the supplementary protection certificate SPC/NO No. 2011024 stipulates a scope of protection that exceeds what Article 4 allows. The decision is thereby based on an incorrect application of the law.

The effect of the scope of protection goes beyond Article 4

In the view of the Court of Appeal, the incorrect application of the law must lead to the SPC being declared invalid. There are no grounds for the Court itself to adopt a new decision by redrafting the content of the certificate. In the Court of Appeal's opinion, the fact that the consequence must be invalidity in this case also ensues from the EFTA Court's opinion, cf. paragraph 93.In the Court of Appeal's opinion, invalidity must be the sanction in the case, even

though for the wrong specification of the scope of protection, this is not expressly mentioned as an invalidating factor in Article 14 of the SPC Regulation. The Court of Appeal cannot see that Article 14 of the SPC Regulation can be understood to be an exhaustive provision specifying the invalidating factors.

The interlocutory injunction:

Given the Court of Appeal's result, there are no grounds for granting Intervet's request for an interlocutory injunction. Neither the main claim nor the grounds for an injunction are established as probable, cf. §34-2, first subsection, of the Dispute Act.

Injunction under §56a of the Patents Act

The Court of Appeal's result implies that there are no grounds for Intervet's request for an injunction under §56a of the Patents Act either, as the District Court concluded in its judgment of 15 October 2015.

During the preparatory proceedings for the Court of Appeal, Pharmaq withdrew its request for compulsory licensing under §59a of the Patents Act. Based on the District Court's result, the request was not expressed in the conclusion of judgment because an injunction under §56a of the Patents Act would rule out granting permission under §59a of the Patents Act. The Court of Appeal finds it correct to pronounce the closing of this request, which was worded as a separate claim.

Costs

Pharmaq has won the case completely, and is at the outset entitled to be awarded costs in compliance with the general rule in §20-2, first and second subsections, of the Dispute Act.

Exceptions can be made from liability for costs where there are weighty reasons that make this reasonable, and the action was questionable, or was first clarified on the evidence presented after the institution of legal proceedings, cf. § 20-2, third subsection, letter a).

The Court of Appeal has not found the case questionable, but the two challenge trials that the parties carried out after the District Court's judgment have been of key importance for the result. A basic condition for changes in the evidence presented to have consequences for liability for costs is nonetheless that the parties immediately take the consequences of the new or changed facts, cf. Schei, et al., *The Dispute Act*, Annotated edition, 2nd ed., page 710, with further references to case law. This prerequisite is not satisfied, since Intervet has not taken the

consequences of the change in the evidential situation occasioned by the new challenge trials.

The Court of Appeal finds that none of the other exceptions from the general rule regarding liability for costs is applicable, so Intervet must therefore cover Pharmaq's costs for both instances. In deciding the liability for the costs for the District Court, the Court of Appeal has applied its findings, cf. §20-9, second subsection, of the Dispute Act.

Pharmaq's legal representatives have filed a statement of costs in compliance with §20-5 of the Dispute Act.

Costs and the interest claim for processing in the District Court

For the District Court's trial, Pharmaq has claimed a total of NOK 12 909 896 in costs. The amount includes fees for legal counsel, fees for foreign legal counsel, and fees/expenses for expert witnesses. With the addition of the court fee of NOK 38 700 and Pharmaq's percentage of costs for the expert lay judges of NOK 314 860, the total claim is therefore NOK 12 909 986.

Included in the amount is another NOK 442 592, i.e. consequential loss interest of 3% per annum from 29 October 2015 and to the estimated performance date for the Court of Appeal's judgment, i.e. 4 January 2017.

Pharmaq has paid to Intervet adjudicated and instalment costs pursuant to the District Court's judgment with a reservation for claiming the amount repaid with the addition of 3% consequential loss interest. The total amount claimed for reimbursement is NOK 12 705 887, including consequential loss interest of NOK 381 043.10.

The claim for reimbursement includes NOK 69 992.51 in costs awarded to Intervet for the Borgarting Court of Appeal and the Appeals Selection Committee of the Supreme Court in the appeal for access to documentation. Pharmaq lost the case, and in the opinion of the Court of Appeal, does not have a claim for reimbursement from Intervet. After this adjustment, as well as a discretionary adjustment for consequential loss interest on the corrected sum, Pharmaq is awarded reimbursement of NOK 12 630 000 from Intervet.

The total claim for the District Court thereby adds up to NOK 12 909 986 in costs and NOK 12 630 000 in claims for reimbursement.

Costs for the Court of Appeal

The claim for fees for the legal representatives for the Court of Appeal comes to NOK 8 170 262.50, divided into 69.26 hours of time spent prior to filing the appeal, 1787.25 hours

up to the appeal proceedings and 830 hours for work during the appeal proceedings.

In addition, there is a claim for NOK 707 257 in fees and expenses for expert witnesses, NOK 2 582 467 that applies to expenses incurred by Pharmaq for vaccine and neutralisation studies, and other expenses amounting to NOK 666 508.

Total fees and costs for the Court of Appeal come to NOK 12 126 494.50.

The Court of Appeal's assessment of the costs

Intervet's legal counsel has not commented on the statements of costs, or on the reimbursement claim or the interest calculation. Intervet's costs for the District Court and the Court of Appeal are roughly on the same order of magnitude as Pharmaq's.

The Court of Appeal finds that the aggregate costs for trying the case in two instances to be extraordinarily high. This refers to the time spent time by legal representatives on both sides, but also to the overall costs. The overall costs add up to roughly MNOK 50 for trying the case in two instances.

The case involves formidable financial values, and has raised complex factual and legal questions with international ramifications. The Court of Appeal therefore finds, with reservations, that the costs have been necessary owing to the nature of the case and its scope, and accepts the statements of costs.

Intervet is therefore ordered to pay costs to Pharmaq for both instances in accordance with the statements of costs, and with the adjustment the Court of Appeal has made above.

For the Court of Appeal, there will also be costs for the expert lay judges, which Intervet will be ordered to pay in an amount to be fixed in a separate decision. The parties have each paid NOK 250 000 in advance payment to the Court of Appeal as collateral for costs for the lay judges. The court fee for the Court of Appeal is NOK 86 000, which will likewise will be covered by Intervet.

The judgment and the ruling are unanimous.

The decision was not rendered within the deadline laid down in the Act. This was due to the complexity and scope of the case.

Linda Sivesind

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Conclusion:

1. Norwegian supplementary protection certificate SPC/NO 2011024 is found invalid.

2. The court finds for Pharmaq AS in relation to the claim regarding prohibition under §56a of the Patents Act.

3. Insofar as Pharmaq's request to the Court of Appeal for permission under §59a of the Patents Act is concerned, the case is dismissed.

4. The petition for an interlocutory injunction is dismissed.

5. Intervet International B.V. is ordered to pay Pharmaq AS' costs for the District Court, that is, NOK 12 909 986 – twelve million nine hundred and nine thousand nine hundred and eight-six Norwegian kroner.

6. Intervet International B. V. is ordered to reimburse Pharmaq AS NOK 12 630 000 – twelve million six hundred and thirty thousand Norwegian kroner.

7. Intervet International B.V. is ordered to pay Pharmaq AS' costs for the Court of Appeal, that is, NOK 12 126 495 – twelve million one hundred and twenty-six thousand four hundred and ninety-five Norwegian kroner.

8. Intervet International B.V. is ordered to pay the court fee for the Court of Appeal in the amount of NOK 86 000 – eighty-six thousand Norwegian kroner. The costs for the expert lay judges for the Court of Appeal come in addition, in an amount to be stipulated in a separate decision.

9. The time limit for performance for points 5-7 is 2 – two – weeks from the pronouncement of the Court of Appeal's decision.

Espen Lindbøl Tonje Vang Hans O. Kveli

Siri Mjaaland Trond Øivind Jørgensen

The document is in accordance with the signed original
Hans Kåre Hauan, signed electronically.

LINDA SIVESIND OSLO NORGE ENGLISH GOVT. AUTH. TRANSLATION

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