OSLO DISTRICT COURT

JUDGMENT

Delivered: 08.09.2017 in Oslo District Court,

Case nos.: 16-135025TVI-OTIR/01 and 16-141308TVI-OTIR/01

Judge:
District Court Judge Inger Kjersti Dørstad

Lay judges:
Professor Sverre Arne Sande
Professor Johan Kristofer Engblom

The case concerns: Claim that patents NO 334290, 332248 and 333139 are to be ruled invalid

Orifarm Generics AS Orifarm AS	Counsel: Advocate Håkon Bleken, Co-counsel: Advocate Vebjørn Krag Iversen
Orifarm Generics A/S **v.**	
Mundipharma AS	Counsel: Advocate Ida Elisabeth Gjessing, Co-counsel: Advocate Amund Brede Svendsen

No restrictions on publishing

JUDGMENT

The case concerns the validity of the Norwegian patents NO 334 290 (NO 290), NO 332 248 (NO 248), also comprising the submitted alternative sets of claims A and B, and NO 333 139 (NO 139). They are collectively referred to as the patents-in-suit. The patents all concern transdermal patches for the administration of the analgesic drug buprenorphine.

If the Court finds that the patents are valid, there is the question of infringement of the patents.

A claim for compensation has also been submitted in the case, since an interim injunction has been imposed. It has been decided that the proceedings and the adjudication are to be split, so the claim for compensation will not be processed now. The claim will only be of interest if the Court finds the patents to be invalid.

The question of setting aside the ruling of Oslo Court of Execution and Enforcement with regard to an interim injunction of 20 June 2016 shall however be processed here.

The defendant, Mundipharma AS (Mundipharma), is part of the independent associated companies Purdue/Mundipharma/Napp, an international network of companies within pharmaceuticals and pharmaceutical research. One of Mundipharma's products is a transdermal patch for the administration of buprenorphine over a period of seven days. The transdermal patch marketed by the above companies has the commercial name of *Norspan* in Norway, while in certain other countries it is marketed under the commercial name of *BuTrans*. Mundipharma is the holder of the patents-in-suit in the case.

The plaintiffs, Orifarm Generics A/S, Orifarm Generics AS and Orifarm AS (hereinafter collectively referred to as Orifarm), are companies within the Danish Orifarm Group, which sells different kinds of pharmaceuticals to, *inter alia*, the Nordic market. Orifarm is the holder of three marketing authorisations for a transdermal patch containing buprenorphine under the trade name of *Buprefarm*. The marketing authorisations encompass three products of different strengths; 5 micrograms/hour, 10 micrograms/hour and 20 micrograms/hour, respectively.

On the basis of their marketing authorisations, Orifarm planned to enter the Norwegian market with Buprefarm. As a consequence of Orifarm contacting certain wholesalers, Mundipharma petitioned for an interim injunction to stop the import of the products. On 8 February 2016, Oslo Court of Execution and Enforcement (Oslo Byfogdembete) issued a ruling whereby Customs Norway was ordered to uncover and withholds medicinal products covered by the patents. Orifarm was not made a party to the case and was not given the opportunity to state its opinion.

Next, on 17 June 2016 Mundipharma petitioned for an interim injunction to stop Orifarm's sale of Buprefarm. On 20 June 2016, Oslo Court of Execution and Enforcement issued a ruling whereby the petition was accepted. The ruling was issued without Orifarm being given the opportunity to state its opinion.

Nor did Orifarm petition for subsequent oral proceedings. Mundipharma was given until 1 September 2016 to initiate legal proceedings concerning the claim that was the reason for the interim injunction.

On 19 August 2016, Orifarm issued a writ of summons before Oslo District Court, with the prayer for relief that all three patents should be declared invalid and that Mundipharma should be ordered to pay compensation for the loss Orifarm suffered as a consequence of the interim injunction.

Against the backdrop of the time limit that had been stipulated in the interim injunction, Mundipharma issued a writ of summons before Oslo District Court on 31 August 2016, with the prayer for relief that a ban should be issued that corresponded with the one granted by the interim ruling.

The parties agreed that the cases should be joined for joint proceedings, and as a consequence Oslo District Court decided to join the actions for joint proceedings.

Upon agreement between the parties it has also been decided to split proceedings and adjudication before the District Court, meaning that the claim for compensation is postponed.

The main hearing in the case was held from 19 to 28 April 2017. The Court sat with two expert lay judges. Five witnesses were heard, including three expert witnesses, and such documentation was presented as is evident from the court record.

The case has been so demanding that it has not been possible to pronounce the judgments within four weeks after the conclusion of the main hearing; see the Dispute Act section 19-4 (5). This is also related to the fact that the scheduled main hearing was postponed, with the consequence that the case before the Court clashed with other scheduled hearings. The summer holidays have also made it difficult to gather the members of the Court.

Background of the case

Transdermal drug administration means that an active ingredient is applied to the body by passage through the skin of a patient. The field has been described by Mundipharma as a niche field at the priority date of the patents (24 February and 29 September 1997). According to the Norwegian Pharmaceutical Product Compendium (Felleskatalogen), there are currently 18 preparations containing 13 different active ingredients that are administered transdermally in the shape of depot patches commercially available on the Norwegian market. In addition, there are some patches that are used for local treatment - local anaesthesia and anti-inflammatory.

The pharmaceutical product's penetration through the skin is dependent on a number of factors, comprising the molecular weight of the substance to be transferred, its melting point, lipophilic or polar properties, the elimination of the pharmaceutical product in the skin as such, etc. Only a small part of active ingredients display a suitable combination of these properties.

Transdermal administration of buprenorphine was known at the priority date, but there were no commercially available preparations. Buprenorphine was considered a drug it was difficult to administer transdermally due to its high molecular weight. This is also the background of several granted patents that employ different penetration enhancing adjuvants (Hille, Chang Drust).

The solutions in the patents-in-suit are stated to have originated during development and testing of transdermal patches in a project where companies in Mundipharma's network of independent associated companies cooperated with LTS Lohmann Therapie-Systeme GmbH & Co KG (LTS). LTS was, and still is, a central player within the field of Transdermal drug administration.

The patents-in-suit

All three of the patents-in-suit concern a transdermal delivery device that includes buprenorphine for the treatment of pain. A shared feature of the patents is that they according to the patent description make it possible to produce a *medicament that enables reduced plasma concentrations of buprenorphine over a longer period of time than what is possible according to prior art, while at the same time causing effective pain relief* .

NO 332 248 (NO 248)

NO 248 concerns a transdermal delivery device for use with a dosing interval of at least 7 days.

The patent claims are of the following tenor:

> *1.*
> *A transdermal delivery device, which comprises buprenorphine for application in treatment of pain in a patient in a dosing interval of at least 7 days.*
>
> *2.*
> *The use of buprenorphine in the production of the medication for treatment of pain in a patient in a dosing interval of at least 7 days, wherein the said medicament is a transdermal delivery device comprising the aforementioned buprenorphine.*
>
> *3.*
> *A device according to claim 1 or an application according to claim 2, wherein the buprenorphine is the buprenorphine base.*
>
> *4.*
> *A device according to any of the preceding claims or an application according to*

any of the preceding claims, wherein the transdermal delivery device comprises a polymer matrix layer that includes the buprenorphine.

5.
A device according to any of the preceding claims or an application according to any of the preceding claims, wherein the aforementioned polymer matrix layer is a pressure sensitive adhesive reservoir layer.

6.
A device or an application according to claim 5, wherein the layer includes 10 to 95 weight % polymer material, 0.1 to 40 weight % softener and 0.1 to 30 weight % buprenorphine.

7.
A device or application according to claim 5, wherein the polymer matrix layer comprises 10 weight % buprenorphine base, 10 to 15 weight % levulinic acid, approximately 10 weight % oleyl oleate, 55 to 70 weight % polyacrylate and 0 to 10 weight % polyvinylpyrrolidone.

8.
A device or application according to claim 3, wherein the layer is made by drying a mixture containing 1139 g of a 47.83 weight % acrylate polymer solution, 100 g levulinic acid, 150 g oleyl oleate, 100 g polyvinylpyrrolidone, 150 g ethanol, 200 g ethyl acetate and 100 g buprenorphine base.

9.
A device or an application according to any of the preceding claims, wherein the treatment of pain in a patient comprises:
application on the patient's skin of a transdermal delivery device comprising buprenorphine, and maintenance of the transdermal buprenorphine delivery device in contact with the skin of a human patient for at least 7 days, so that the patient continues to receive effective analgesia from the transdermal buprenorphine delivery device.

10.
A device according to any of the preceding claims or an application according to any of the preceding claims, wherein the transdermal delivery device is chosen from among transdermal patches, transdermal plasters, transdermal discs or iontophoretic transdermal devices.

11.
A device according to any of the preceding claims or an application according

to any of the preceding claims, where Tmax occurs from approximately 3 to approximately 5 days after the application of the above-mentioned transdermal device.

.

A device according to any of the preceding claims or an application according to any of the preceding claims, wherein at the termination of the dosing interval, from 68 % to 95 % of the buprenorphine is left in the transdermal delivery device.

Mundipharma has in the course of the case submitted the two following alternative sets of claims:

ALTERNATIVE SET OF CLAIMS A

1.

A transdermal delivery device, which includes buprenorphine for application in treatment of pain in a human patient in a dosing interval of 7 days, where the transdermal delivery device includes buprenorphine base, levulinic acid, oleyl oleate, polyacrylate and polyvinylpyrrolidone.

2.

A device according to claim 1, where Tmax occurs from approximately 3 to approximately 5 days after the application of the above-mentioned transdermal device.

3.

A device according to any of the preceding claims, wherein at the termination of the dosing interval, from 68 % to 95 % of the buprenorphine is left in the transdermal delivery device.

ALTERNATIVE SET OF CLAIMS B

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A transdermal delivery device for application in the treatment of pain in a patient in a dosing interval of 7 days containing a polymer matrix layer that can be obtained by

(i) producing a mixture consisting of:
a) compounds, where the compounds comprise
- 55 weight % polyacrylate
- 10 weight % levulinic acid
- 15 weight % oleyl oleate
- 10 weight % polyvinylpyrrolidone
- 10 weight % buprenorphine base
and b) one or several solvents, and

(ii) drying the mixture to remove the solvent or solvents.

2.
A device according to claim 1, where Tmax occurs from approximately 3 to approximately 5 days after the application of the above-mentioned transdermal device.

3.
A device according to any of the preceding claims, wherein at the termination of the dosing interval, from 68 % to 95 % of the buprenorphine is left in the transdermal delivery device.

NO 248, which was granted on 6 August 2012, is a divisional patent of an application filed on 23 August 2010. The priority dates are 24 February 1997, (US 60/038,919) and 29 September 1997 (US 08/939,068). The parent application is NO 20064395 (granted as patent NO 333 374). The parent application was in turn divisional from the application NO 1994 4087, granted as patent NO 322 515. The priority date of the parent application is essential, since it is the prior art as per the priority date that is the basis for assessing whether the patent is invalid.

The alternative sets of claims were presented in a written pleading of 18 January 2017.

NO 333 139 (NO 139)
Also NO 139 is aimed at a transdermal delivery device for buprenorphine; however, such that the dosing interval is of at least 5 days.

The patent claims are of the following tenor:

1.
A transdermal delivery device, which comprises buprenorphine for application in treatment of pain in a patient in a dosing interval of at least 5 days.

2.
The use of buprenorphine in the production of the medication for treatment of pain in the patient in the dosing interval of at least 5 days, wherein the said medicament is a transdermal delivery device containing the aforementioned buprenorphine.

3.
A device according to claim 1 or an application according to claim 2, in which the buprenorphine is the buprenorphine base.

4.
A device according to any of the preceding claims or an application according to

any of the preceding claims, wherein the transdermal delivery device comprises a polymer matrix layer that comprises the buprenorphine.

5
A device according to any of the preceding claims or an application according to any of the preceding claims, wherein the aforementioned polymer matrix layer is a pressure sensitive adhesive reservoir layer.

6.
A device or an application according to claim 5, wherein the layer comprises 10 to 95 weight % polymer material, 0.1 to 40 weight % softener and 0.1 to 30 weight % buprenorphine.

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A device or application according to claim 5, wherein the polymer matrix layer comprises 10 weight % buprenorphine base, 10 to 15 weight % levulinic acid, approximately 10 weight % oleyl oleate, 55 to 70 weight % polyacrylate and 0 to 10 weight % polyvinylpyrrolidone.

8.
A device or application according to claim 3, wherein the layer is made by drying a mixture containing 1139 g of a 47.83 weight % acrylate polymer solution, 100 g levulinic acid, 150 g oleyl oleate, 100 g polyvinylpyrrolidone, 150 g ethanol, 200 g ethyl acetate and 100 g buprenorphine base.

9
A device or an application according to any of the preceding claims, wherein the treatment of pain in a patient comprises:
application on the patient's skin of a transdermal delivery device comprising buprenorphine, and maintenance of the transdermal buprenorphine delivery device in contact with the skin of a human patient for at least 7 days, so that the patient continues to receive effective analgesia from the transdermal buprenorphine delivery device.

10.
A device according to any of the preceding claims or an application according to any of the preceding claims, wherein the transdermal delivery device is chosen from among transdermal patches, transdermal plasters, transdermal discs or iontophoretic transdermal devices.

11.
A device according to any of the preceding claims or an application according to

any of the preceding claims, where Tmax occurs from approximately 3 to approximately 5 days after the application of the above-mentioned transdermal device.

.

A device according to any of the preceding claims or an application according to any of the preceding claims, wherein at the termination of the dosing interval, from 68 % to 95 % of the buprenorphine is left in the transdermal delivery device.

A transdermal delivery device which comprises buprenorphine for application in treatment of pain in a patient in a dosing interval of at least 5 days.

NO 139 was granted on 11 March 2013 and has the same priority dates as NO 248. NO 2011 1441 is [the] parent application (the patent granted is NO 333 374), which is divisional of NO 2010 1190 (patent granted NO 332 248), which in turn is divisional of the application NO 2006 4395 (patent granted NO 329 734). NO 2006 4395 is a divisional of the application NO 1999 4087 (patent granted NO 322 515).

NO 290

NO 290 concerns a transdermal delivery device with buprenorphine as the active ingredient with a specific composition. The dosing interval is 7 days.

The patent claims are of the following tenor:

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A transdermal delivery device comprising buprenorphine for application in the treatment of pain in a dosing interval of 7 days, wherein the transdermal delivery device includes a layer comprising 10 weight % buprenorphine base, 10 weight % levulinic acid, 15 weight % oleyl oleate, 55 weight % polyacrylate and 10 weight % polyvinylpyrrolidone.

.

A method for the production of the transdermal delivery device for application in the treatment of pain according to claim 1, where the layer may be obtained by mixing 1139 g of a 47.83 weight % polyacrylate solution, 100 g levulinic acid, 150 g oleyl oleate, 100 g polyvinylpyrrolidone, 150 g ethanol, 200 g ethyl acetate and 100 g buprenorphine base until all solids are dissolved, placement of the mixture on a foil so that the coating weight of the dried layer of paste will be 80 g per m2, and removal of the solvents and melting of the levulinic acid by drying of the mixture to obtain the layer.

3.
A method according to claim 2, wherein the polyacrylate solution is a solution of a self-crosslinking acrylate polymer of 2-ethyl hexyl acrylate, vinyl acetate and acrylic acid in ethyl acetate: heptane : isopropanol: toluene: acetylacetonate in a ratio of 37 : 26 : 26 : 4 : 1 as solvent.

4.
A method according to claims 2 or 3, wherein the components are homogenised, the mixture is stirred for about 2 hours, then inspected visually to determine whether all solids have been dissolved before the mixture is placed on the foil.

5.
A method according to any one of the claims 2 to 4, wherein the foil is a 420 mm wide, transparent polyester foil, which may be dissolved again by treatment with silicon and serves as a protective layer.

6.
A method according to any one of the claims 2 to 5, wherein the the drying is done with heated air that is passed over the moist layer.

7.
A method according to any one of the claims 2 to 6, wherein the total amount of buprenorphine comprised in the transdermal delivery device is 10 mg and the active surface area is 12.5 cm².

NO 290 was granted on 27 January 2014 on the basis of a divisional of 26 February 2013 and claims priority from 24 February 1997 (US60/038,919) and 29 September 1997 (US 08/939,068). The parent application is NO 2011 1441 (patent granted NO 333 374), in turn divisional from NO 1994 4087 (patent granted NO 322 515).

The plaintiff, Orifarm AS, has essentially submitted the following:
Orifarm submits that all of the patents-in-suit are invalid. None of the patents-in-suit fulfil the requirement of inventive step and do thus not fulfil the requirements of section 2 of the Patents Act. The ground for patent for all of the patent claims is the dosing time period described in claim 1 of the patents. At the priority date, it is obvious to the skilled person to use transdermal delivery devices for buprenorphine as described in the patents for both 5 and 7 days, and the skilled person would have had a reasonable expectation of success.

At the priority date of the patents-in-suit, several citations existed that describe transdermal delivery devices for buprenorphine for treating pain in patients. From the patent description it can be seen that patches produced in accordance with claim 1 of

WO96/19975 (WO 975 or Hille) were known and preferred, something which may indicate WO 975 to be considered the closest prior art. However, even US 5,240,711 (US 711 or Hille 1) and US 4,956,171 (US 171 or Chang) may be considered the closest prior art, without the Court seeing this to be of any significance for the assessment.

What distinguishes the patents-in-suit from these citations is that the patents-in-suit state dosing intervals of 5 and 7 days, respectively. Against this backdrop, the technical problem that is solved through the patents may be stated to be a suitable and effective further pain treatment by use of transdermal delivery devices for buprenorphine.

The question then becomes whether it was obvious to the skilled person, in light of prior art, to arrive at a dosing interval of 5 and 7 days, respectively, to solve this technical problem. To the skilled person it would obviously be beneficial to replace the patch as infrequently as possible. The skilled person would thus have understood that an extended dosing interval would constitute a more suitable treatment form.

At the priority date there were a number of other citations that described dosage intervals of up to 7 days by use of transdermal administration devices for the administration of other active ingredients than buprenorphine, also for opiates. The skilled person would also be aware that the quantity of active ingredient that remains in the patch would be essential for the duration of the patch. It was further evident from the literature in the field that an effective treatment with buprenorphine is obtained through a transfer of active ingredient from the patch to the skin at a rate of 38 to 54 µg per hour.

Against this backdrop, it would be obvious to the skilled person that the patches that Example 1 in WO 975 describes as containing approximately 10 mg of active ingredient would have sufficient active ingredient to have an effect for a period approaching 7 days.

US 171 further describes in its Example 1 the production of a buprenorphine patch tested in vitro with the use of donor skin from humans. It is stated there that the transfer to skin was maintained for 72 hours and that about 20% of the total quantity of active ingredient then had been administered. This indicates that large quantities of active ingredient (approximately 80%) remained in the patch after 72 hours and that the patch would have sufficient active ingredient for administration beyond 72 hours. US 171 thus also supports the notion that transdermal devices with buprenorphine are suitable for use for extended periods, including periods approaching 7 days. Thus, the skilled person would have had a reasonable expectation that the transdermal delivery devices may have an analgesic effect for up to at least 7 days. As a consequence, the patents lack inventive step and must be ruled invalid; see section 52 (1) of the Patents Act.

In the alternative sets of claims A and B that Mundipharma has submitted, claim 1 of NO 332 248 is limited to a delivery device that comprises certain specified adjuvants. The choice of adjuvants comes across as random and there is nothing in NO 332 248 which

substantiates that anything in particular is obtained through the choice of the specified adjuvants. If NO 332 248 is invalid for lack of inventive step, the alternative sets of claims A and B will also be invalid, as the requirement of inventive step will not be fulfilled. It is further submitted, in the alternative, that the alternative sets of claims A and B do not find sufficient support in the patent application; see section 13 of the Patents Act.

Mundipharma has submitted four prayers for relief in the alternative, linked to the upholding of the alternative sets of claims A and B, and some of the dependent claims in NO 332 248. These prayers for relief in the alternative come across as unfounded; nor have they been submitted during the preparations for the case.

Nor do the other patents-in-suit contain any elements justifying a patent. None of the patents-in-suit fulfil the requirement for inventive step and must as a consequence be ruled invalid in their entirety; see section 52 first subsection (1) of the Patents Act, see also section 2.

As regards the infringement case, the submission that the Court should find against the plaintiff follows from the fact that the patents are invalid. As regards NO 139, NO 290 and NO 248 claims 2, 7, 9 and 10, the submission that the Court should find against the plaintiff follows also from the fact that Mundipharma waived the submission that there is infringement.

Orifarm submits in the alternative that Orifarm's product does not infringe claim 8 of NO 248, since Orifarm's product is not produced by using ethanol as described in claim 8.

It is stated in the ruling of Oslo Court of Enforcement and Execution (Oslo byfogdembete) of 8 February 2016 in case 16-021799TVI-OBYF that the control had a duration of 12 months. As a consequence, the effect of the said ruling has lapsed, which is also in keeping with the information provided in Mundipharma's final pleading. According to the information provided, there are no other rulings either that establish a similar customs control, so it is not necessary for Orifarm to make submissions or any prayer for relief with regard to this.

It is however submitted that Oslo Court of Enforcement and Execution's ruling of 20 June 2016 in case number 16-100798TVI-OBYF must be set aside. If the patents are invalid there is no basis for keeping Orifarm away from the market.

Orifarm has submitted the following *prayer for relief:*

In the invalidity case

Patents NO 334 290, NO 332 248 (including the alternative sets of claims A and B) and NO 333 139, are to be ruled invalid.

In the infringement case

The Court is to find in favour of Orifarm Generics A/S, Orifarm Generics AS and Orifarm AS.

In both cases:

The ruling of Oslo Court of Execution and Enforcement (Oslo byfogdembete) of 20 June 2016 in case number 16-100798TVI-OBYF is to be set aside.

Mundipharma AS is to be ordered to compensate the legal costs of Orifarm Generics A/S, Orifarm Generics AS and Orifarm AS, with the addition of interest on overdue payments from the due date and until payment is made.

The defendant, Mundipharma AS, has essentially submitted the following:
Patents NO 334 290, NO 333 139 and NO 332 248 fulfil the requirements of novelty and inventive step; see section 52 first subsection (1) of the Patents Act, see also section 2.

In the alternative, it is submitted that NO 248 fulfills the requirements of novelty and inventive step if it is limited; see the Patents Act section 52 first subsection last sentence, in accordance with the alternative set of claims A, or a combination of these claims, a limitation to claims 3, 4, 5, 6, 11 and 12 as granted, or a combination of these, the alternative sets of claims B or a combination of his claims, or if the patent is limited to claims 8, 11 and 12 as granted, alternatively a combination of these.

Orifarm has submitted that WO 975 (Rille) is the closest prior art. With this as a starting point, the objective technical problem may in the opinion of Mundipharma be phrased as follows; to produce a suitable and effective relieving pain treatment with transdermal delivery systems for buprenorphine.

With the closest prior art as a starting point, it will not be obvious to the skilled person to arrive at a transdermal buprenorphine patch with a 7-day dosing interval. The average skilled person would not have any reasonable expectation of succeeding with a suitable treatment over a 7-day dosing interval, not even if several citations are combined.

None of the citations mentioned that concern the transdermal delivery of buprenorphine describes any trial with a buprenorphine patch for a time period exceeding 72 hours. Furthermore, the quoted citations do not provide any clinical data on the in vivo effect of transdermal administration of buprenorphine. Studies where cadaver skin is used, sometimes even from animals, have no transfer value when you want to find out how a live human patient will respond to the pharmaceutical. The EPO Opposition Division correctly considered that in vitro permeation studies used in the closest prior art do not predict the in vivo effect in humans. This is especially due to the fact that there is no live skin that can influence the delivery of the pharmaceutical.

Furthermore, it was part of common general knowledge at the priority date that any transdermal administration of a pharmaceutical requires a large excess of the active ingredient in the delivery device. The circumstance that *approximately 20 % of the total amount of the pharmaceutical*

was administered after 72 hours in Example 1 in US 171, would therefore not, as opposed to what is claimed by the plaintiffs, lead the skilled person to believe that the patch could be used for a longer period of time. Quite the contrary; the duration of the trials in prior art that concerned buprenorphine gave an indication that such a formulation would not be effective for more than 72 hours.

During the processing of the application, NIPO first considered NO 248 to be obvious in light of US 177 and US 556, based on the consideration that there was sufficient active ingredient left in the patches for administration over several additional days. Following additional correspondence with the applicant, NIPO accepted the applicant's arguments presented in a letter of 19 October 2011. In the letter, it is explained why the skilled person would not know whether there was sufficient driving force in the transdermal delivery devices in the quoted citations, and that the skilled person thus would not have any reasonable expectation of success in the case of use for 5 or 7 days.

It is further noted that the inventive step of the corresponding European patents (EP 1 731 152 and EP 2 305 194) has been upheld by the EPO Opposition Division. The citations that were invoked by the opponent during the opposition proceedings before the EPO are the same as those Orifarm now invokes in the case at hand. The Opposition Division considered, on the basis of those citations, that the skilled person would not have any reasonable expectation of success when using a transdermal delivery device for buprenorphine used for treatment of pain with a dosing interval of at least 5 days or at least 7 days. Consequently, the most important argument in the writ of summons has been assessed by NIPO and by the EPO Opposition Division during the application processing, and there is nothing substantially new in Orifarm's arguments that means that the Court should adopt a different view of the question.

Orifarm tries to use references to dosing intervals for other active ingredients as evidence in support of its attack on the inventive step of Mundipharma's patent. As established by EPO's Opposition Division in section 5.4.1 of the decision concerning EP 194 and in section 4.7.4 of the decision concerning EP 152, such an approach cannot prevail. As stated by the Opposition Division in paragraph 3 under 4.7.4 in the decision concerning EP 152: *an expectation of success cannot be derived from reports of prolonged dosing intervals for other transdermal delivery systems*. The skilled person would not, based on data concerning a different active ingredient, have tried to use buprenorphine in the patch for 5 or 7 days with a reasonable expectation of success. Firstly, the different properties of the different active ingredients means that one cannot deduce from the fact that one active ingredient can be administered over 7 days that another, different active ingredient can be administered over the same time period. This is described in, *inter alia*, the Australian Journal of Hospital Pharmacy volume 27, no. 6, Optimisation of drug delivery - Transdermal drug delivery (Benson and Prankerd), 1997. As a consequence, the skilled person would not consult documents that concern other active ingredients to clarify whether as 7-day application would be possible.

If the skilled person had consulted documents that describe the administration of fentanyl, US 580 teaches that the administration over a period of 1 to 3 days is preferable, and the skilled person would know that even many years after US 580 became publicly available, no 7-day fentanyl patch had reached the market. The skilled person would therefore not try with a reasonable expectation of success to administer buprenorphine for 5 or 7 days based on information about fentanyl.

As regards the alternative sets of claims, it is submitted that the alternative set of claims A is covered by Example 1 of the application; see p. 47, line 10 – p. 48, line 5, as well as the general part of the description on p. 35, line 13-19. Similar information is found in the parent application on p. 33, lines 16-22. Example 1 is in the parent application rendered on p. 44 lines 14 to p. 45 line 8. The average skilled person would on the basis of the above understand that the statement of amounts is not critical to the working of the invention. Claim set B has similar cover in Example 1 of the application; see p. 47 line 10 to p. 48 line 5.

As regards the infringement case, Mundipharma submits that Orifarm's product encompassed by marketing authorisations no. 15/10645, 15/10646 and 15/10647 infringe patent NO 248 claims 1, 3, 4, 5, 6, 11 and 12, as well as the alternative claim sets A and B. Orifarm has acknowledged such infringement, if the patent were to be upheld with such claims. Mundipharma submits that Orifarm's product will also infringe claim 8 of NO 248 on the basis of the doctrine of equivalence.

A ban is demanded against the offering, sale and use of products encompassed by the above-mentioned marketing authorisations; see the Patents Act, sections 56 a and 3, as well as import and possession for such purposes.

Oslo Court of Enforcement and Execution's ruling of 8 February 2016 in case 16-021799TVI-OBYF has lapsed, and Orifarm's claim that it should be set aside has become void of any object.

Mundipharma has submitted the following *prayer for relief*:

<u>In the invalidity case:</u>

Principally:
The Court is to find in favour of Mundipharma AS

In the alternative:
Patent NO 332 248 is to be upheld with claims 3, 4, 5, 6, 11 and 12 as granted, alternatively a combination thereof.

In the further alternative:
Patent NO 332 248 is to be upheld with claim 1 of the alternative claim set A, alternatively a combination of the claims in claim set A

In the further further alternative:
Patent NO 332 248 is to be upheld with claim 1 of the alternative claim set B, alternatively a combination of the claims in claim set B

In the further further alternative:
Patent NO 332 248 is to be upheld with the dependent claims 8, 11 and 12 as granted, alternatively a combination of these.

In the infringement case:

Orifarm AS, Orifarm Generics AS and Orifarm Generics A/S are to be forbidden to offer, sell and use transdermal patches containing buprenorphine, which is encompassed by the marketing authorisations nos. 15/10645, 15/10646 and 15/10647, and to import or possess such products for such purpose.

In both cases:

The Court is to find in favour of Mundipharma and against the claim to set aside Oslo Court of Enforcement and Execution's ruling of 20 June 2016 in case number 16-100798TVI-OBYF.

Orifarm, Orifarm Generics AS and Orifarm Generics A/S are to be ordered jointly and severally to pay Mundipharma AS' legal costs.

The Court's comments:
Mundipharma's lawsuit with the claim that Orifarm is to be forbidden to sell or apply etc. transdermal patches containing buprenorphine that are encompassed by the company's marketing authorisations, presupposes the existence of one or more valid patents. As a consequence, the Court shall first discuss the validity of the patents.

The invalidity case concerns three patents-in-suit. These are closely related and both parties have in their presentations concentrated on NO 248. The Court shall therefore discuss that patent first. The patent claims are quoted in their entirety in the beginning of this judgment.

Legal points of departure
Section 52 first subsection of the Patents Act provides that a patent may be declared invalid by judgment if, *inter alia*, it has been granted despite the conditions in sections 1 to 2 not being fulfilled (paragraph no. 1); if it concerns an invention that is not sufficiently clearly described to enable a person skilled in the art to carry out the invention (paragraph no. 2); or if the patent has been amended following a petition for a patent limitation in such a way that the patent's scope of protection has been extended (paragraph no. 5).

Pursuant to the Act, the inventor is entitled to be granted a patent when the conditions for a patent exist. It is thus a discretionary assessment determined by statue, where the courts have full right of review.

The decision of the patent claim will however depend on the professional discretionary assessment on the part of NIPO, which indicates that courts should show caution when exercising their judicial review; see [the Supreme Court judgment reported in] Rt-1975 603 (Swingball). The threshold for reviewing the assessments of NIPO will be lowered if it subsequently turns out that NIPO did not take into consideration all relevant information at the time of the application. The scope of NIPO's grounds will also be of significance. Reference is made to Stenvik, Tidsskrift for forretningsjus [Journal of Business Law] 04/1996, in which the following is stated:

> *One may question whether there is reason to attach such importance to the decision that is subject to review. The condition must in any case be that grounds must have been presented that are sufficient to review whether the factual basis of the decision and the application of the law are correct*

The Supreme Court has in Rt-2008-1555 (Biomar) paragraphs 38-40 repeated the principle from the Swingball judgment. The condition quoted above must however still apply.

The Court shall revert to NIPO's decision in the case.

The provisions of the Patents Act are presumed to be fully in line with the provisions of the European Patent Convention (EPC). Pursuant to Article 3 paragraph 4 of Protocol 28 to the EEA Agreement, Norway has a duty to comply with the substantive provisions of the EPC. Norway ratified the EPC in 2007. Consequently, the provisions of the Patents Act must be interpreted in light of the corresponding provisions in the EPC; see [the Supreme Court judgment reported in] Rt-2009-1055 (Donepezil) paragraph 26. The EPC's provisions are interpreted and applied by the bodies of the European Patent Office (EPO). As a result, decisions by the EPO should be taken into consideration for the purpose of interpreting the EPC, and thus also when interpreting corresponding provisions of the Patents Act. Still, the importance to be attributed to a decision by the EPO must depend on an independent assessment and not least on which body of the EPO it was that issued the decision; see Rt. 2008 (Biomar) paragraph 51. There will be particular reason to attach weight to decisions by the Enlarged Board of Appeal, but also decisions by the ordinary Boards of Appeal will be of significance. Administrative practice by the Examination and Opposition Divisions should be taken into consideration only to a limited extent. Reference is made to Stenvik, Patenters beskyttelsesbehov [Patents' Need for Protection] (2001), page 213.

The desire for a uniform interpretation within the entire Convention area suggests that one should also consider relevant decisions by national courts of law in other Convention States. Reference is made to Rt. 2007-1979 paragraphs 45-50, which concerns the significance of case law from national courts of law in other jurisdictions concerning the interpretation of the Brussels Convention / Lugano Convention.

Partly indispositive [i.e., the Court is in part not bound by the parties' dispositions]
By way of introduction it is also mentioned that a case concerning the validity of the patent is indispositive in the direction of declaring the patent invalid, but dispositive in the direction of acknowledging the patent as a valid. In the direction of finding in favour of the defendant party; that is, acknowledging the patent as valid, the parties will thus have a full

right to define the subject matter of the dispute, and the Court must relate to the parties' submissions. Thus, courts will not be bound by the parties' submissions and claims in the direction of declaring a patent invalid, and they will have an independent responsibility for clarifying facts.

Reference is made to Skoghøy, Tvisteløsning [Dispute Resolution], 2nd ed. (2014), page 574, where the following is stated:

> *As another example that for both parties limitations apply to the possibility of making dispositions in a certain direction, one may mention cases concerning the validity of a right under private law that has been obtained by a licence or registration in a public registry of rights. This applies to, for instance, claims for judgment that a change of name authorisation, or a registered patent, trademark, design or plant breeders' right is to be ruled invalid (.....) In the direction of finding against the plaintiff - that is, in the direction of acknowledging the authorisation or registration as valid - the parties to such cases must have full right of disposition. In the direction of ruling the authorisation or registration invalid, such cases must however be considered indispositive.*

Schei et al, Tvisteloven Kommentarutgave [The Dispute Act with Commentaries] 2nd ed. page 403, adopts the same point of view as Skoghøy:

> *Similarly, the parties do not have full right of disposal with regard to a claim for invalidity of, inter alia, an authorisation or registration of rights for certain intellectual property rights etc. see; Skoghøy, Tvisteløsning [Dispute Resolution], pages 530-531. The parties do have full right of disposal of other elements of the case that do not concern the question of validity, for instance whether the right has lapsed, whether it has been waived etc.*

Mundipharma's counsel has submitted that " *Cases concerning the validity of patents are indispositive in the direction of validity but dispositive in the direction of invalidity* , see [the law firm] Advokatfirma Grette's outline for the closing argument presented during the main hearing, page 15. No further grounds for this view have been presented, nor is there any reference to support in any sources, and this view is the opposite of what is argued in legal literature.

Inventive step - the point of departure

Pursuant to section 2 of the Patents Act, patents shall be granted only for inventions which are new in relation to what was known before the filing date of the patent application, and which also differ essentially therefrom. The novelty requirement in section 2 of the Patents Act is not disputed. Orifarm has primarily submitted that the patents-in-suit must be ruled invalid for lack of inventive step.

The requirement of inventive step is expressed in section 2 of the Patents Act in that the invention must "differ essentially" from what was known before the filing date of the patent application. The Court adopts as a starting point the statement by the first judge to cast a vote in the judgment reported in Rt. 2008 page 1555 (Biomar) paragraphs 32-34:

(32) The further particulars of the requirement of differing essentially from prior art may be difficult to specify. In the joint Nordic report on patents of 1964 which formed the basis of patenta acts with largely the same wording in the Nordic countries, the following is said about this on page 127:

> *«Whether the necessary inventive step exists in each individual case, must to a certain degree depend on the discretionary assessment of the patent authority and the courts. It has been discussed whether it would be possible to state objective criteria for the assessment of this question. Many attempts have been made at establishing such subjective criteria, but the committees have not found that it will be possible to state such criteria in the text of an act.»*

(33) In [the Norwegian Official Report] NOU 1976:49 the following is stated in the remarks to section 2 on page 102:

> *«The requirement of inventive step entails that the invention must not only be novel, but must also entail such a development of the art that it cannot be considered to be obvious in relation to what is already known.»*

(34) This wording is highly parallel to the one found in the European Patent Convention (EPC) Article 56 first sentence:

> *«An invention shall be considered to involve an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art.*

With this as a starting point, the Court shall first take a stance on the qualifications of the "man skilled in the art" or the person skilled in the art before proceeding to a review of "the state of the art" at the priority date. Based on this, an assessment of obviousness shall be made.

Description of the person skilled in the art

In the preparatory works of the Act, NU 1963:6 p 127, the following is stated with regard to the person skilled in the art:

> *An invention must thus differ essentially from what must be considered obvious to a man skilled in the art within the field concerned. This refers to what may be considered an average skilled man in the sense of a skilled man who is not in possession of particularly inventive skills, but who on the other hand is fully acquainted with the state of the art at the time in question - the application filing date - and has the capacity to exploit all the known material in a good professional way, comprising also making obvious new constructions."*

NIPO's guidelines, a regulatory framework that is largely harmonised with the European regulatory framework for case processing, describes the "skilled man" as follows in Chapter 4 item 5.6:

> *The skilled man" is to be presumed to be an average practitioner who knows what was common general knowledge in the field at the date in question. The person concerned is also to be presumed to have had access to the entire prior art, in particular the documents mentioned in the examination report, and to have had at his disposal the ordinary means and to have had the skills to do routine work and experimentation. If the problem encourages the skilled man in the field to seek its solution within another technical field, it is the skilled man in the latter field that is qualified to solve the problem.*

The skilled person may be a team, and in the case at hand there is no substantial disagreement with regard to the qualifications this team is to have. Thus, there is agreement that the skilled person here would be like a research/development team in the pharmaceutical industry. Orifarm has described the skilled person to have a background in pharmacy/chemistry and experience with product development within transdermal systems. Mundipharma has described the average skilled person as a team composed of persons working on the transdermal administration of buprenorphine for pain relief, and that the team would probably include at least a clinical pharmacologist and someone with specific knowledge of transdermal administration of pharmaceuticals. The Court agrees with the parties' description of the team that constitutes the skilled person in the case, and agrees with Mundipharma's submission that a clinical pharmacologist should also be included, without presuming that the latter would be of decisive importance for the outcome of the case.

It will thus be this team, referred to as the skilled person, which is the starting point when the problem and solution method is applied. It will also be this team that will be considered when interpreting the citations.

The state of the art/common general knowledge at the priority date
The next question is what is to be considered known to the skilled person in connection with the assessment to be made here.

There is agreement that 24 February 1997 shall be taken as the priority date. Consequently, the inventive step is to be assessed on the basis of the state of the art at that point in time.

In the judgment delivered by Borgarting Court of Appeal LB-2010 – 3684 page 14, the following is stated to be the point of departure:

> *After having assessed the professional background of the skilled man, one must assess what may be considered known to that skilled man. Legal theory does not provide completely unequivocal guidelines on what is to be considered belonging to the knowledge of the skilled man. On the one hand, in Stenvik on page 206, with reference to [the report] NU 1963: 6 page 126 and [the Supreme Court judgment reported in] Rt-1964-1090 (1094), it is specified that the skilled man is presupposed «to have knowledge of everything that was known at the priority date». The same is suggested by the statements in [the Supreme Court judgment reported in] Rt-2008-1555 paragraphs 35-36, where amongst other things there is a reference to the same report page 127, where it is stated that*

it is a skilled man who «is fully aware of the state of the art», although it is «an average skilled man [...] who is not in possession of very inventive skills». On the other hand, on page 210 of the same book, under the discussion of what constitutes common general knowledge [in the field concerned], it is specified that «all kinds of specialty knowledge, typically knowledge to be found in articles and patent documents» fall outside. However, in the same place it is stated that «the content of databases that are easily accessible and commonly used in the field concerned, may be said to be part of common general knowledge».

On the basis of the above, the Court of Appeal finds that the skilled person would have had knowledge of the above-mentioned Finnish article from 1990. It was published in a commonly read journal for those who engaged in pharmacokinetic issues, which was one of the kinds of professional or technical knowledge that the skilled man here would be presumed to master. Although it was not as easy in 1991 to use the Internet to find the above-mentioned article as it is today, it must be presumed that for the skilled man it would have been simple to find the article by giving the librarian for the relevant field some simple keywords, like pain relief and/or cancer treatment and/or opioids and/or oxycodone and the name of other opioids.

The Court presumes that the skilled person within the meaning of section 8 of the Patents Act would not have the same knowledge as for the purpose of assessing inventive step pursuant to section 2. This is evident from EPO case law and also follows from the objective of the said legal provision. The patent description is to publish the invention so that an ordinary skilled person can understand it. The information that follows from textbooks and central articles that skilled persons in the relevant field normally read, will be presumed to form part of common general knowledge in both cases. Patent documents and other more special sources will however fall outside of the skilled person's knowledge within the meaning of section 8, although such information is included in the assessment for the purpose of assessing inventive step.

Transdermal drug administration means supplying a drug from an applied formulation through the skin in order to obtain a systemic therapeutic effect in a patient.

It was known to the skilled person that the skin consists of three layers; epidermis, dermis and the subcutaneous tissue. The epidermis is the top layer. It may in turn be divided into the stratum corneum, which is that non-viable epidermis, and the viable epidermis, which is a more aqueous environment. The dermis makes up the majority of the skin and it is vascularised. Under the dermis there is a subcutaneous tissue, which consists mainly of fat cells.

Drugs that are to be administered transdermally, are administered by penetrating the skin through the epidermis and further into the dermis. In the dermis, the drug may obtain access to the blood vessels and become subject to systemic circulation, thus obtaining a therapeutic effect; in this case, pain relief.

The biggest challenge in transdermal administration is to have the drug penetrate the first layer of the skin, the stratum corneum. This requires a driving force to obtain sufficient transport velocity, also referred to as flux. The driving force is the difference in the concentration of the active ingredient between the outside and inside of the skin.

The physiochemical properties of the active ingredient will be decisive for the flux. Especially important are the substance's molecular weight and octanol/water partition coefficient. It is considered commonly known that the unionised form of a drug generally demonstrates higher penetration rates than the salt form. The flux will also to a certain degree depend on the pharmaceutical formulation. Other circumstances of significance are, amongst other things, temperature, the skin's pH value, as well skin thickness, which may vary from one person to another and depends on where on the body the skin is located. The skilled person will be aware of the different factors that influence the flux rate of a drug. With regard to this, reference is made to the report and statement of the expert witness Dr. Jens Hansen, amongst other things.

The skilled person will be aware that the driving force will be spent over time as the active ingredient moves from the pharmaceutical formulation and through the stratum corneum. Furthermore, the skilled person will be aware that in order to obtain sufficiently driving force it will be necessary with a far larger quantity of active ingredient present in the transdermal system than what will de facto penetrate the skin. A large part of the active ingredient will thus be left after the patch is no longer capable of supplying the drug at the rate necessary to obtain the desired therapeutic effect. The quantity of surplus active ingredient that is necessary to obtain the desired flux will depend on, *inter alia*, the active ingredient and the formulation. This is also something that the skilled person will be aware of.

Most of the studies and patents that have been described in the case, employ different kinds of in vitro test systems. Mundipharma has questioned the extent to which in vitro studies on mouse skin may give the skilled person knowledge of flux through human skin in living patients. The Court notes that at the time it was not uncommon to use mouse skin in trials. In the opinion of the Court, the skilled person would have an expectation that a relationship existed, although the skilled person was also aware that there were differences and that as a consequence it would be necessary to investigate further. The skilled person would know that there is no fixed and accurate correlation, but a good result on mouse skin would give the skilled person a reasonable expectation that a good result could also be obtained with live humans. It was precisely for this reason that mouse skin was used in research. The skilled person would also consider skin from mice to be substantially more penetrable than human skin.

Another model system uses human cadaver skin. Also in that case, the skilled person would presume that even if such trials cannot give exact knowledge, they would provide sound information also about the flux in living humans.

The Court furthermore presumes that the skilled person was aware that drugs that were administered transdermally, could form a depot or reservoir under the skin; see, *inter alia*, Bartek et. al. 1972.

Orifarm has referenced that the skilled person would expect a long terminal half-life to signal longer duration. The Court presumes that at the priority date it was known that different half-lives were observed for different administration paths. The Court can however not see that the absolute value or variation in the statements would lead the skilled person away from or encourage the skilled person into trying transdermal administration of buprenorphine for an extended period of time.

The significance of the fact that a depot of the drug may be formed in the skin which thus may contribute to an extended duration of the patch, has also been a topic in the case at hand. Such a possibility is considered known (see the publications of Pfister and Schefer quoted below). The Court does not consider such a possibility to be decisive for trying the formulation in WO 975 over a 7–day period with the hope of succeeding, nor does the Court find that it would point the skilled person away.

It can also be seen from Dr. Jens Hansen's expert opinion that a number of designs of transdermal systems were known in 1997. The skilled person is thus aware that the fundamental elements of any transdermal system are based upon the drug being dissolved or dispersed in a liquid reservoir or in a polymer matrix that functions as a platform for the release of the drug. There were two main forms of patch; reservoir or membrane controlled patches, and matrix patches. A reservoir patch contains the drug in a gel or a solution, and the supply of the drug is determined by a rate controlling membrane between the drug and the skin. The matrix patch incorporates the drug in a polymer matrix, from which the drug is continuously released into the skin. In the matrix system it is the drug/polymer matrix that controls the release of the drug to the skin; see Dr. Jens Hansen's report. The dose of drug supplied depends on the quantity of drug in the matrix, the surface area of the patch and for how long the patch is attached to the skin.

In 1997 there were a number of transdermal systems on the market, including an analgesic, Durogesic. The said product employed the active ingredient fentanyl. Fentanyl is, like buprenorphine, and opioid, but with a different molecular structure including a lower molecular weight, and other physiochemical and pharmacological properties.

The skilled person would furthermore be aware that in 1997 there were several patches on the market that had a dosing interval; that is, a period of effect, of 7 days. Examples of this are Clondin and Estradiol. Reference is made to Benson and Prankered, Optimisation of Drug Delivery, 1997, pages 444-445. In Table 1; Examples of transdermal delivery products registered in Australia, there are three patches with a dosing interval of 7 days. The table also shows that there were several patches with dosing intervals of 3-4 days (2 times per week). The fentanyl patch (Durogesic) is stated to have a dosing interval of 3 days, but it

is stated in the Gale patent, which concerns fentanyl, that it is described to be be capable of producing an effect for 7 days. The Court shall revert to the Gale patent.

Buprenorphine was used as an analgesic pharmaceutical product parenterally and sublingually at the priority date, but there was no buprenorphine patch on the market in 1997. Several systems for transdermal administration of buprenorphine were however known at the priority date. This also applies to the specific formulation in some of the patent claims in the patent-in-suit. This is stated in the patent description and is not contested in the case at hand.

Patents regarding the transdermal use of buprenorphine (citations)

WO 975 (Rille)
WO96/19975 (WO 975) / D3 in NIPO's processing of the application
WO 975, Hille, was filed on 18 December 1995. The patent states to concern the following: *Transdermal resorption of active substances from supercooled masses.*

The patent describes a transdermal delivery device for buprenorphine and describes a system that improves the drug's skin penetration capability. The patent addresses in particular mechanisms for improving the release of different penetration enhancers (Penetrationsförderer); that is, compounds that facilitate the active ingredient's passage through the skin.

The solution is, according to Hille's patents, to use adjuvants that form supercooled masses, so they remain liquid at room temperature. This improves the release of the penetration enhancing substances from a matrix patch.

In the patent there is a description of the production of 5 different buprenorphine formulations, and they are characterised by the quantity of active ingredient that diffuses through mouse skin in the course of 24 hours in a so-called Franz cell. The formulation with levulinic acid shows the clearly highest penetration rate, and it is this formulation that according to the patent-in-suit surprisingly may be used for pain relief over 7 days.

All the trials were terminated after 24 hours and consequently the patent does not describe any effect beyond 24 hours. The Court does however not find that the skilled person would understand that this must be interpreted to mean that the patch *cannot* be used beyond 24 hours since Hille does not discuss duration or dosing interval.

US 711 (Rille 1)
US 5,240,711 (US 711)
US 711, Hille 1, was filed on 24 September 1992; that is, before the Hille patent mentioned above.

The patent addresses the composition of a transdermal delivery device and describes how the penetration of buprenorphine through human skin can be enhanced, particularly by using a softener in combination with a solvent. The softener can either be higher alcohols, esters of carboxylic acids, diesters of carboxylic acids and [sic] multivalent alcohols.

The patent tests 21 different formulation and states trial data for all formulations based on in vitro trials on mouse skin for 24 hours.

This patent does not carry out tests beyond 24 hours either and does not discuss the issue of how long the patch formulations may work.

US 171 (Chang)

US 4,956,171 (US 171) / D1 in the application documents before NIPO

US 171, Chang, was filed on 21 July 1989; that is, before the Hille patents mentioned above. Also this patent addresses compounds that are to improve penetration through skin in a system with a transdermal delivery device. To solve this problem, Chang uses a double penetration accelerator (dual enhancer) comprising sucrose cocoate and methyl laurate in a transdermal formulation.

The studies mentioned in Chang are in vitro studies on human cadaver skin and concerns trials for 72 hours; that is, 3 days. Chang states that the use of the systems described provide penetration rates that are therapeutically effective for at least 24 hours and for up to 72 hours.

The paragraph on preferred embodiments of the patent states preferred flux rates through human cadaver skin for the same period. It is furthermore stated that by optimising the system, hydromorphone and buprenorphine can be delivered at a constant rate over extended time periods without uncomfortable skin irritation; see 5th column, lines 17- 20.

In the examples, both the reservoir and matrix formulations are used, and examples are given of compositions for the different parts of the patches. The examples contain hydromorphone or buprenorphine and measure a constant flux through human cadaver skin over periods of 72 hours.

In Example 1, a transdermal system is examined that contains a reservoir patch comprising buprenorphine hydrochloride and the above-mentioned penetration accelerators. The trial data state that a flux is obtained that is approximately twice as high as the minimum flux stated in Roy et al U3-1057 (J. Pharm. Sci. 1994). The percentage of the total dose of buprenorphine that is released over 72 hours is stated to be 20%. Consequently, 80% of the active ingredient remained in the patch after 3 days.

A point is also made of the fact that it is the skin and not the formulation itself that limits the rate of release.

Example 3 examines a transdermal system with a matrix patch of the same kind as in the patent-in-suit. It describes that the equilibrium (steady state) flux was mainly constant over the 72-hour period the testing lasted. The flux observed is lower than in Example 1, but still substantially higher than the necessary minimum flux.

US 566 (Drust)

US 5,026,556 (1991) (US 556) / D2 in the application documents before NIPO

Drust also shows a composition of a transdermal delivery system for buprenorphine. The examples in Drust all concern reservoir solutions. Release data are not given and the patent thus says nothing about how long the patch may be expected to work.

US 909 (Sharma)

US 5,069,909 (US 909)

Sharma describes a traditionally designed transdermal system for the administration of buprenorphine to humans. Here too a reservoir solution is used.

The two different formulations are tested in vitro for 48 hours. Sharma states that the penetration rates shown are sufficient to obtain analgesia.

The patent also shows a higher penetration rate for the buprenorphine salt than for the base. However, in the opinion of the Court the skilled person will consider this result to be related to the formulation used and will not read it as an expression of a general teaching.

Other publications

Roy et al U3-1057 (J. Pharm. Sci. 1994)

This publication is based on the Sharma patent mentioned above. The title is: *Transdermal Delivery of Buprenorphine through Cadaver Skin.* It is furthermore stated that *The main objectives of this paper are (1) to evaluate physicochemical properties and solubilities of buprenorphine free base and HCl salt and (2) to evaluate the skin permeation of buprenorphine base and HCl salt through cadaver skin from various vehicle formulations and adhesive matrix patches*.

The skin that was used in the trials was taken from frozen human cadaver skin that was treated to isolate the stratum corneum and viable epidermis (that is, remove deeper skin layers).

In addition to the solubility of buprenorphine base and salts, the melting point and octanol/water partition coefficient are determined. It is also noted that the salt form of buprenorphine is rather lipophilic, and thus considered beneficial for transdermal administration. Large variations in solubility are noted, and the conclusion is presented that it is possible to obtain high solubility also of the base by a careful choice of vehicle. The authors go on to discuss how the base has a higher permeability, but that the salt due to its higher solubility obtains a higher flux that ought to provide a basis for transdermal administration.

Additionally, the effect of different additives to solutions of the base are studied. They show that it is possible to increase the flux by a factor of 8. They also compare the flux of the salt and of the base for a couple of different compositions. Again, it is evident that the salt provides higher flux. As a consequence, the salt is chosen for the subsequent optimisation study. Here, different compositions of the solutions, as well as the addition of penetration enhancers, are examined.

In order to assess to what degree the observed fluxes would be sufficient for an effective preparation, by way of conclusion a theoretical calculation is made of what flux would be necessary. The conclusion is that it should be simple to obtain sufficient flux, since the majority of the reported formulations show fluxes several times larger than the necessary minimum.

The Court notes that even if Roy concludes that the salt gives a higher flux that the base, the skilled person would not get the understanding that the base cannot be used. Reference is made to what is mentioned above under the discussion of Sharma that the skilled person would understand this is related to the specific formulation that is applied here.

Wilding et al U3-1105 (Int.J.Pharm. 1996. 1996)
The title of the paper is: *Pharmacokinetic evaluation of transdermal buprenorphine in man.* The purpose of this study was: *to obtain pharmacokinetic, safety and tolerability data on buprenorphine in healthy subjects following the application of both aqueous- and ethanol-based FTTS and administration of a short intravenous infusion of buprenorphine hydrochloride.*

This is a pharmacokinetic study in humans, 12 persons, where central parameters for drug absorption and metabolism are determined for water- and ethanol-based reservoir systems (FTTS). In addition, possible side effects were observed. As a reference, a short (20 min) intravenous infusion is used. The transdermal administration lasted for 24 hours and the hydrochloride salt of buprenorphine was used.

Wilding shows that the buprenorphine formulations produce analgesic plasma levels in healthy humans. The study teaches that the terminal half-life is of the order of 15 hours after both infusion and transdermal administration. For the transdermal systems,

the plasma concentration increased slowly and in most cases steady state was not reached within the 72 hours the study lasted.

Australian Journal of Hospital Pharmacy volume 27, no. 6 "Optimisation of drug delivery - Transdermal drug delivery" (Benson and Prankerd), 1997

This paper is particularly interesting because it aims at describing the state-of-the-art at a point in time close to the priority date. The difficulties and limitations for transdermal drug delivery are explained under the heading "Limitations of TDD". It is explained that transdermal drug delivery is limited to potent drugs and that attempts at expanding the scope of drugs that can be delivered transdermally by use of penetration accelerators are ongoing. Drugs must have certain physiochemical properties to be suitable for transdermal delivery, and for instance highly lipophilic drugs are difficult to administer because they accumulate in the stratum corneum. It is also stated that skin irritation may be a problem.

The paper also points out the advantages of long dosing times, including once per week, and an orientation is given of products both in Australia and in the rest of the world with a long period of effect, including 7 days. The paper also points out that the patch contains a much larger quantity of active ingredient than what is utilised.

Extract from Therapeutische Systeme (Heilmann), 1984

While Heilmann on the one hand says that the quantity of drug in the system influences the lifespan of the patch, he explains in immediate extension thereof that many transdermal systems will contain a larger quantity of the active ingredient than what is actually administered to the patient, and that this is necessary to maintain the rate of release of the drug.

Transdermal and Topical Drug Delivery systems, Tapash K. Ghosh, William R. Pfister, Su Il Yum, 1997. Transdermal and dermal therapeutic systems: Current status, William R. Pfister

This paper discusses the advantages of long dosage times, including once per week/ 7 days.

The following is stated on pages 52 - 53:

> *One of the primary advantages of TTS is the reduction in dosing frequency from 2 to 4 times a day, typical for oral dosage forms, to 1, 2, or up to 7 patches per week, which results in improved patient compliance.*
>
> .....
>
> *Patients can now wear a single TTS for periods of 12-14h (i.e. NTG), 16-24h (i.e. nicotine and testosterone), 3 or 3.5 days (i.e. scopolamine, estradiol, NETA, fentanyl), or 7 days clonidine, estradiol)*

Additionally, there is discussion of the formation of a depot by lipophilic substances dissolving in the "fat matrix" that surrounds the dead cells in the stratum corneum.

Skin Barrier -Principles of percutaneous penetration, Karger 1996, Schaefer & Redelmeier,

This is another central textbook from the time of the priority date. it discusses, amongst other things, the stratum corneum as a reservoir. The following is stated on pages 162 - 163:

> *The amount of material which is present in the stratum corneum and which is available for absorption is referred to as the stratum corneum reservoir. At the skin surface solvents, vehicles, formulations of any kind or crystalline phases release compounds to the horny layer thus constituting a new stratum corneum-compound phase. This phase, together with residual formulated material which cannot be removed from the surface and its wrinkles by simple wiping or gentle washing, is defined as reservoir from which any further diffusion into the skin takes place. The reservoir is seen to be positioned before the barrier and constitutes its counter piece.*

Patents with a different active ingredient, but with the same therapeutic effect.

US 4,588,580 (US 580) (Gale) (Fentanyl)

US 580, filed on 23 July 1984, describes the administration of fentanyl with a transdermal system. Fentanyl is an opioid with the same therapeutic effect as buprenorphine, but with a different chemical structure.

This patent thus concerns transdermal pain relief with opioid analogues over a 7-day period.
Gale describes different kinds of transdermal administration of fentanyl.
Gale also describes the possibility of constructing a depot of the opioid fentanyl in human skin. For safety reasons it is however not considered desirable.

the administration of fentanyl over 7 days is mentioned in the description and in one of the claims. In the examples, administration for a period of up to 80 hours is discussed. Administration for more than 1 to 3 days is considered to be preferable in US 580. In the introduction the following is stated: *Administration is maintained for at least 12 hours and for up to 7 days with a 1 – 3 day regimen being considered preferable.*

At the priority date, a commercially available embodiment of the invention described in US 580 was on the market. The Durogesic fentanyl patch was intended for use for 72 hours. The product is still on the market.

Further as to the validity of patent NO 332 248

The parties have concentrated their presentations on this patent, and as a consequence the Court shall also use it as a point of departure. The priority date that is to form the basis of the assessment is 24 February 1997.

The patent concerns a transdermal delivery device that comprises buprenorphine for the application in the treatment of pain in the patient in the dosing interval of at least 7 days (claim 1), and the application of buprenorphine in the production of a medication for the treatment of pain in a patient in a dosing interval of at least seven days, wherein such medicament is a transdermal delivery device comprising the above-mentioned buprenorphine (claim 2). In addition there are a number of sub-claims that specify the device or the application according to claims 1 and 2.

Mundipharma has submitted a number of prayers for the relief in the alternative that combine the various sub-claims for the case that the Court were to find claims 1 and 2 to be invalid. Also, two sets of claims in the alternative, A and B, have been presented.

In the assessment of whether the patent is valid, one must take as a point of departure the patent claims and how they are to be understood by a skilled person. The description may serve as guidance. It has not been claimed that all or parts of the patch's formulation is/are inventive. It is only the dosing interval of at least 7 days that is claimed to be inventive. The Court agrees with this starting point. What is new is *a dosing interval of at least 7 days* . The parties agree that this fulfills the novelty requirement in section 2 of the Patents Act and that the question is whether this also fulfills the said provision's requirement of inventive step.

The problem – solution method (problem − solution-analyze)

when assessing inventive step, in practice the so-called problem-solution method (problem and solution approach) is often used. *Problem and solution approach* is used by the EPO. NIPO recommends that it should normally be used, but the procedure is not mandatory. Reference is made to NIPO's Guidelines C, IV, 5.5. NIPO has not applied this method for the processing of patent NO 248. As regards the two other patents-in-suit, correspondence with NIPO has not been submitted and as a consequence the Court is not familiar with it.

Both parties have however in their lines of reasoning used as a point of departure the so-called *problem solution-analyze,* and the Court shall do the same.

The method structures the assessment in three steps, with a view to rendering the assessments as objective and realistic as possible and avoiding hindsight. The first step consists in *identifying the closest prior art,* the one that in practice would constitute the most promising starting point for the invention. The closest prior art must be sought from the same technical field and it must deal with the same technical problem as the invention. Among several

citations in the same field that concern the same problem, the one that has most technical features in common with the invention is chosen.

In step two, the invention is to be compared to the closest prior art, in order to *identify* the *problem* which the invention objectively considered has solved. The problem may have been to obtain greater efficiency, additional effects, better safety etc. If no new or improved efects are obtained, the problem is considered to solely have consisted in producing an alternative constructive solution for obtaining the same effects as in the citation. Producing a random alternative solution, among many possible ones, is often not considered to contain inventive step. If the solution does not solve any problem of a technical nature whatsoever, there will be no inventive step.

The third step consists in assessing whether to the skilled person, starting with the closest prior art, it was obvious to solve the problem in the way that is defined in the patent claims. It may also be formulated as a question whether the skilled person *would* have chosen the patent's solution with a *reasonable expectation* of success.

Closest prior art

Closest prior art
The present analysis takes the closest prior art as a starting point. The patent guidelines identify "the closest prior art" as the combination of features which may be deduced from the one document that provides the best basis for the assessment of whether the invention was obvious.

Reference is also made to the EPO Guidelines for examination, item 5.1 second paragraph, where it is stated that if there are several potential citations that may be characterised as the closest prior art, the assessment must be done on the basis of all alternatives. The assessment of what is the closest prior art must be done in relation to each individual patent claim.

In relation to all the patent claims and the combination of them, including the claims in the alternative, it is the dosage interval of 7 days that might justify the granting of a patent. It is this dosage interval, in the alternative in combination which previously known formulations, that is potentially inventive.

Claims 1 and 2
The assessments with regard to claims 1 and 2 will be identical and the Court takes claim 1 as a starting point. Claim 1 concerns a medicinal product. The product is a "transdermal delivery device"; that is, a device for the administration of a medicinal product to a patient through his skin. For simplicity it may be referred to as a transdermal patch or just a patch. Such a product is previously known through both Chang and Hille et al. Furthermore, the device is to include buprenorphine for application against pain in a patient. This too applies to both Chang and Hille. Claims 1 and 2 do not contain any formulation requirements.

The last claim is a dosage interval of 7 days. This is not found explicitly in either Chang or Hille. Hille performs trials over 24 hours and does not indicate the dosage interval. Chang performs trials over 72 hours and states that the purpose relates to delivery "for extended periods of time". To Chang it is important that the patch is to have a stable effect over an extended period of time.

On the basis of the above, the Court finds that Chang has the most features in common with claims 1 and 2, and that as a consequence Chang is the closest prior art. The Court does however find that the person skilled in the art also would consider Hille and that it would be obvious to combine these two citations.

Claim 3

Claim 3 describes a device or application that follows from claims 1 and 2, but limits the buprenorphine to the base Hille uses the base. Chang uses the salt as a starting point, but in example 3 he adds potassium hydroxide. Independently of whether one uses the base or the salt of the base for the preparation of a solution, an equilibrium will always arise between the salt and the base forms. The percentages of the respective forms will only depend on the pH, in that a low pH produces a preponderance of the salt form, while a higher pH produces a preponderance of the base form. Potassium hydroxide is a basic solution that increases the pH, which causes the patch to largely also contain the base form of buprenorphine despite buprenorphine hydrochloride having been used as a starting point.

Considered in conjunction with the assessment under claims 1 and 2, the Court finds that Chang is the closest prior art also in relation to claim 3. In the same way as with regard to claims 1 and 2, the skilled person will also consider Hille.

Claim 4

Claim 4 is also based on claims 1 and 2, but limits the delivery device to encompassing only a polymer matrix layer. Chang uses a matrix patch in example 3.

Consequently, based on what is presented with regard to claims 1 and 2, the Court finds that Chang is the closest prior art also in relation to claim 4.

Claim 5

Claim 5 is also based on the preceding claims, but limits the polymer matrix layer to a pressure-sensitive adhesive reservoir layer. In example 3, Chang shows a variant where the polymer matrix layer is a pressure-sensitive adhesive reservoir layer.

Consequently, making reference to the above, the Court finds that Chang is the closest prior art also in relation to claim 5.

Claim 6

Claim 6 is also based on the preceding claims. In addition, some formulation requirements are added, especially by stating a softener.

The Court finds that both Hille and Chang can be applied as the closest prior art in relation to this claim. In any case, the skilled person will be able to combine these two patents.

Claims 7 and 8
These claims contain formulation requirements and are based on the formulations found in Hille.

Based on the above, the Court finds that Hille is the closest prior art in relation to these claims, but also Chang may constitute the closest prior art. In any case, it will be obvious to the skilled person to combine them, so it will not be decisive which of these patents is chosen as the closest prior art.

Claims 9 and 10
These claims will be dependent on the other claims. The parties have not processed these claims and the Court finds no reason to do so either.

Claim 11
Here it is stated that Tmax takes place approximately 3 to 5 days after application. This is a consequence of the patch that is used in Hille. In the opinion of the Court, it will be normal for Tmax to occur in the middle of the dosage interval. Consequently, in the opinion of the Court both Chang and Hille may constitute the closest prior art with regard to this claim.

Claim 12
The description in this claim is in agreement with Chang's Example 1. statement in this claim is in line with Chang's example 1.
On the basis of what is mentioned above in relation to claims 1 and 2, the Court thus finds that Chang is the closest prior art in relation to this claim.

The claims in the alternative, claims A and B
These claims are based on the formulations indicated in Hille. On the basis of this, the Court finds that Hille is the closest prior art with regard to these claims. As for the other claims, it will be obvious to the skilled person to combine Chang and Hille.

The objective technical problem
The next stage of the so-called problem-solution analysis is, based on the closest prior art, to determine the problem solved by the patent and which elements in the patent claims that relate to that solution. If it is not demonstrated that the problem described is solved, a more narrow problem must be defined, which in turn will form the basis of the further analysis.

The Patent Guidelines item 5.5.2 describe the technical problem as being *the purpose and the task of modifying or adapting the closest prior art in order to obtain the technical effects that the invention brings about as compared to the closest state of the art*.

In NO 248, an aspect according to the invention is stated to be the production of a transdermal delivery device and an application of buprenorphine in the preparation of a medicament that enable reduced plasma concentrations of buprenorphine over an longer period of time than what is possible according to the state of art, while simultaneously providing effective pain regulation.

The EPO Opposition Division defines the problem in the following ways:

In its decision of 24 July 2009, the Opposition Division states the following:

> *The problem to be solved may be seen in the provision of convenient and further analgesic pain treatment with transdermal delivery systems for buprenorphine.*

In its decision of 22 December 2014, the Opposition Division states the following in item 5.3:

> *The problem to be solved in the light of the closest prior art, whether document D1 or document D11 (D1=Hille and D11=Chang), may be seen in the provision of convenient and effective pain treatment with buprenorphine from a transdermal delivery device.*

In its decision of 3 March 2016, the Opposition Division states the following:

> *The problem solved be the patent-in-suit can therefore be seen as the provision of transdermal delivery devices for the convenient and effective treatment of pain for a period of at least 5 days.*

A differential review must be applied. The question is what technical results are obtained by carrying out the invention that were not obtained by carrying out the solution in the closest prior art. The difference must be assessed for each individual feature. The feature that constitutes the difference between claim and prior art is the 7-day duration. This concerns all of the claims.

Mundipharma has claimed that the problem solved by the patent is *to obtain a convenient and effective pain relief/pain treatment by means of the transdermal administration of buprenorphine*. Mundipharma has in addition submitted that the dosage interval of 7 days cannot be included in the definition of the problem, as it constitutes the solution to the problem.

In the Court's opinion, Mundipharma's statement of the problem is too wide. It does not indicate which technical results are obtained by carrying out the invention which are not obtained by carrying out the closest prior art. This is the case independently of whether Chang or Hille is chosen

as the closest prior art. It has not been demonstrated that Chang and Hille do not indicate *a convenient and effective pain relief/pain treatment by means of the transdermal administration of buprenorphine.*

The Court therefore finds that the objective technical problem must be defined as obtaining a *more* convenient and effective pain relief/pain treatment by means of the transdermal administration of buprenorphine.

The assessment of obviousness

The third and last part of the problem-and-solution approach is to assess whether, with the closest prior art as a starting point, it was obvious to the skilled person to solve the problem in the way defined in the patent claims.

For the purpose of this assessment one shall take into consideration not only what followed from the prior art, but everything that pertained to common general knowledge in the field. The average skilled person is presupposed to have access to everything in the state of the art, but is expected only to use the knowledge that has a certain connection to the problem the invention aims at solving, and which it was reasonable to take into consideration without any knowledge of the invention. There is no set rule as to how many citations the skilled person is presumed to combine, but the more citations it has been necessary to combine to arrive at the invention, the stronger the argument that there is inventive step. The inventive step is to be assessed for the invention in its entirety and must necessarily rely on a discretionary assessment.

The requirement of inventive step is expressed as a requirement that the invention must "differ essentially" from what was already known. This requirement entails that the solution of a technical problem which prior to the filing date was obvious to a person skilled in the relevant field, cannot be patented. There must be a certain leap in the technical development - the invention must differ from what was obvious to an average skilled person. In practice, an invention is considered to have been obvious if the average skilled person would have chosen a solution for which a patent has been sought with a reasonable expectation of success; see 2008 w. [the Supreme Court ruling published in] Rt. 2008 p. 1555 (Biomar). The input of economic resources that lies behind the invention, in terms of
work and other resources spent, is in principle of no significance. Inventive step may well exist even if the invention happened by pure chance, and the invention may be obvious even if it is the result of extensive and qualified work.

The Board of Appeals of the Norwegian Industrial Property Office has described the matter to be assessed as follows:

> *According to established practice, an invention is considered to have been obvious if it must be presumed that a skilled person who was acquainted with the state of the art prior to the filing date, would have tried to solve the problem in the way indicated in the patent claims with a reasonable expectation of success. In the assessment of whether the requirement for inventive step is fulfilled, prior art in its entirety is to be considered, and several citations may be combined.*

Stenvik, Patentrett [Patent Law] page 230, refers that this wording is clearly influenced by European practice, where the so-called ”could-would-approach” has been applied for a number of years.

With regard to this, he notes:

> *The thought behind this way of phrasing the topic subject to discretionary assessment is that one cannot expect that inventions are made as a consequence of random acts or mere curiosity, but that technical development happens on the basis of conscious assessments of the prospects of succeeding with certain modifications of prior art. For an invention to be considered obvious, one must therefore normally be able to establish a specific reason why the skilled person would have chosen precisely the solution for which a patent is sought. There may for instance have been a so-called ”pointer towards the technical solution in the prior art”, or it may be that the solution that is chosen is generally known to produce advantages of the kind obtained through the invention.*
>
> *This conception of the law entails that it will not always be an impediment to patenting that the solution for which patent is sought was ”obvious to try”. It may well happen that technical solutions that present themselves as obvious possibilities, are considered fraught with so much uncertainty that one cannot presume that the skilled person on the basis of rational reasoning would embark upon the necessary research and development project. Even in such cases it is the task of patent law to act as a stimulant to the realisation of new products and methods which would not have been realised without the possibility of a patent, or which would have been realised substantially later.*

So the question is whether it was obvious to the skilled person, with Hille or Chang as a starting point, and with the task of finding a more suitable and effective pain relief by transdermal administration of buprenorphine, to choose the patent's solution; that is, to give a patch as described in the individual patent claims a dosage interval of at least 7 days. This assessment must be performed in relation to the individual patent claims.

The Court shall first assess claims 1 and 2. The claims are interrelated in such a way that it is sufficient to discuss claim 1.

According to its wording, this claim encompasses any transdermal delivery device that includes buprenorphine for application of pain treatment in a patient. As mentioned, it is not in dispute that transdermal patches that include buprenorphine for the application in the treatment of pain were known prior to the patent's priority date. There is agreement that the only thing that is new is that the delivery device is given a duration of 7 days and that it is only this circumstance that may justify the invention being inventive.

Patent claims 1 and 2 are so widely phrased that they will tie up many of the possible solutions. This suggests that the requirement for inventive step, or the threshold, becomes more stringent. An obvious development of prior art would not be inventive, Reference is made to the need to keep options available for public use. This must be assessed objectively. As a point of departure, the inventor's effort is irrelevant.

The requirement of inventive step is intended to prevent patents from restraining rather than furthering technical development; see Ot.prp. [bill draft] no. 36 (1965-1966) page 22.

In this context, reference is also made to paragraph 37 of [the Supreme Court ruling reported in] Rt. 2008 page 1555:
The requirements for obtaining a patent are an expression of a balancing of the fundamental concerns behind the patent institution - the desire to further technical development by protecting the inventor's effort, while simultaneously protecting the general technical development that constantly takes place in society. This has for instance been expressed in the Nordic legal opinion of 1964, page 121 and page 127:

> *The concerns that form the basis of patent law - both the view that the patent is a kind of compensation granted by society to the one contributing something new to the technological development, and the view that society is interested in furthering intellectual innovations by protecting the author in the possession of his invention, enabling him to enjoy the fruits of this activity without fear of infringement by others - suggest going far in terms of novelty requirements, since there cannot be any societal interest in benefiting the one who merely has produced something that skilled persons already know or have been able to obtain knowledge of.*
>
> *Since there is a smooth, gradual transition from the insignificant change or improvement within the skill of art (craftsmanlike change or improvement) of a constructional nature to the important pioneering invention, the question arises of where to draw the line for the patentable invention within this scale. Here, one must balance the concern for the applicant, who wants protection for his ideas, and the concern for the general public, whose possibility of making use of technical aids should only be limited by exclusive rights through patenting in cases where an interest worthy of protection exists.*

There are examples that the very posing of the task has been considered an essential part of the invention. That is not the case here. It can be seen from the referenced literature that the patent concerns a problem of a nature that those skilled in the art were generally focused on solving. A dosage interval of one week was considered an advantage, both to make the medicinal product user friendly and economical to use. Other advantages are also described, like constant plasma values over an extended period of time, which would lead to less side effects.

The skilled person will be aware that in the literature the parties have referred to as the "textbook" in this field, Transdermal and Topical Drug Delivery Systems, Tapash K. Ghosh, William R. Pfister, Su Il Yum, 1997, Transdermal and dermal therapeutic systems: Current status, William R. Pfister**,** the advantages of a patch that does not need to be replaced more than once or twice a week are discussed. There, the fact is mentioned that "multiday patches are being developed" with a reference to earlier literature (Frost and Sullivan 1994). The paper provides a detailed overview of products on the market, including fentanyl. Additionally, on pages 38 and 39, the paper provides a thorough review of the advantages of transdermal administration of drugs, emphasizing in particular long duration, including the patch's possibility of adhering to the skin for 7 days, which may lead to reduced dosing frequency. It is emphasized that patients can attach the patch to the skin under their clothing and may replace it either daily, twice a week or once a week. This is highlighted as perhaps the greatest advantage of transdermal drug delivery.

Information about this was also found in the paper Australian Journal of Hospital Pharmacy volume 27, no. 6, Optimisation of drug delivery - Transdermal drug delivery, Benzon and Prankerd, 1997.

Consequently, the skilled person would consider it a goal to develop a patch that could last for 7 days.

The skilled person would furthermore be acquainted with fentanyl both through the product Durogesic and through the patent linked to it (Gale). In the said patent, a dosage period of 7 days is described. Fentanyl, like what is indicated for the patent in suit, is used for pain treatment in cancer patients, amongst others. Reference is made to the discussion of this above.

With Hille, Chang, Drust, Sharma et al as a starting point, the skilled person would have knowledge of a transdermal patch with the active ingredient buprenorphine for the treatment of pain in patients.

With Chang as a starting point, the skilled person will be aware that such a patch can have a dosage interval of at least 3 days.

As mentioned by way of introduction, as a point of departure courts should display caution in deviating from the Norwegian Industrial Property Office's discretionary assessments, considering the specialist knowledge and broad experience processed by the Norwegian Industrial Property Office; see [The Supreme Court rulings reported in] Rt. 1975 page 603 and Rt. 2008 page 1555. As also mentioned by way of introduction, it must be a condition that the Norwegian Industrial Property Office (NIPO) has set out grounds that are sufficient for a review of whether the factual basis of its decision, as well as its application of the law, are correct.

The Court has not been presented with the complete correspondence between the applicant and NIPO with regard to all of the patents. The Court must however presume that Mundipharma has submitted the most important documents in the case and that they provide a correct picture of the assessments that have been

made by NIPO. It should also be noted that the patent has not been processed by NIPO's Board of Appeals or by the Norwegian Board of Appeal for Industrial Property Rights (KFIR).

In its first statement on the patent application, NIPO concluded that the invention lacked novelty on the basis of Chang (D1), Hille (D3) and Drust (D2). These patents have been reviewed under prior art. NIPO referenced the fact that Chang and Drust both described transdermal delivery systems for the administration of buprenorphine where a controlled release of buprenorphine is obtained for an extended period of time. Since NIPO found that there was no novelty, inventive step was not assessed.

Zacco Norway AS, which replied on behalf of the applicant, made reference to the fact that the citations did not state directly and unequivocally that buprenorphine was applied for a period of 7 days and that as a consequence the novelty requirement was fulfilled.

In its next letter, NIPO states that they have reassessed the case, but reiterate that the claims lack novelty and/or inventive step.
NIPO states the following the letter dated 30 March 2011:

> *D1 describes in Example 1 a transdermal delivery device for the administration of buprenorphine. The device contains 1.8 mg/cm2 buprenorphine (60 mg/cm2 gel containing 3 % buprenorphine on a weight percentage basis). The delivery rate is stated to be 5 µg/cm^2/hr and it is constant over 72 hours. During that period, 20 weight % of the buprenorphine was delivered. This should suggest a transdermal delivery system where the dosage is expected to be maintained for far more than 72 hours (3 days), for instance more than 7 days. Presupposing the same delivery rate, the device would provide a dosage interval of 15 days. D1, column 5, lines 18 – 20, also indicates that the delivery system in accordance with the patent can release buprenorphine at a constant rate over extended periods of time without uncomfortable skin irritations.*
>
> *D2 describes transdermal devices where the parameters stated in column 4 give a delivery of buprenorphine that may be 7 days or more (for instance, 10 mg buprenorphine (within the most preferred range) and a rate of release of 60 µg/hr (within the preferred range) gives a duration of about 7 days. The calculation example stated in their letter only includes the minimum amount of buprenorphine and the highest rate of release. We find that transdermal delivery devices that release buprenorphine for at least 7 days may be deduced from both D1 and D2. There is nothing within prior art that points away from a dosage interval of 7 days. The invention lacks novelty or, in the alternative, inventive step, as pointed out in our previous letter.*

Zacco replies to this in a letter of 29 June 2011, submitting that the application describes a patentable invention and that NIPO's assessments are erroneous. Amongst other things, the following is submitted:

The examples in D1 describe only an application deviation of a maximum of 72 hours. D1 does not state that the patches described may be used for more that 72 hours. D1 would however lead the skilled person away from concluding that the transdermal delivery system described may be used for more than 72 hours, not to mention 7 days, as is described in the patent at hand. In the paragraph that connects columns 4 and 5, it is expressly stated that the patch:
"provides in vitro human cadaver skin flux rates for (...) buprenorphine which are therapeutically effective for at least 24 hours and for up to 72 hours" (emphasis added)

D1 thus teaches the skilled person explicitly that the transdermal systems described therein would bring about therapeutically effective doses for a maximum of 72 hours and not for a more extended period of time.

As regards the opinion of the case-handling officer that the quantity of buprenorphine contained in the patches according to D1 and D2, or the release rates described therein, would make it possible to draw some conclusions with regard to the functional duration of the patch, it should be noted that the results obtained after testing over a period of for instance 3 days (as in D1) cannot accurately predict the results of an application during for instance 7 days. A skilled person would not know whether there was sufficient driving force in the patch to deliver the drug actively over such an extended period. At the priority date, the skilled person would however presume that a far larger excess of buprenorphine in the patch would be necessary to maintain a sufficient concentration gradient as a driving force over a period of 7 days.
The case-handling officer reasons that example 1 in D1 teaches that only 20% of the buprenorphine quantity present is delivered after 72 hours and that this suggests to the skilled person that these patches will continue to provide an effective pain relieving treatment over more extended dosage intervals, including intervals of 7 days or more.

It should be noted that any conclusion that goes beyond what a skilled person and objectively would deduce from prior art, and which instead is based on hindsight, should to be avoided. The presumption of what the skilled person would have anticipated on the basis of prior art, especially D1, does not correctly reflect the understanding of the person skilled within the technology of transdermal delivery systems.

NIPO's next letter is of 27 July 2011. In the letter, NIPO seems to accept the requirement of novelty on the basis of a dosage interval of "at least 7 days". However, NIPO still maintains that the claims are not inventive. The following is stated:

The charactistic feature of the invention at hand and which distinguishes the invention from prior art, is thus the indication of the dosage inerval of "at lest 7 days". Claims 1 and 2 contain no additional features or parameters that indicate how this extended dosage interval is to be obtained. Such features that only describe a desired result, are termed functional features and the generally not to be accepted as they render the claims unclear; see the [Norwegian patent guidelines] PR, C, III, item 4.6. In the current case, where the invention at hand is so close to prior art (see D1 and D2), the invention that is sought protected must be defined in a clearer and more precise way, and through features that are suitable for separating the invention from prior art.

We also maintain that the invention, as defined in the claims, represents an obvious trial in relation to what is described in D1 and D2. We make reference to our arguments in previous letters.

For it to be possible to approve the application, claims must be indicated that a clear and precise and that do not contain functional features. Furthermore, through practical comparative trials it must be shown that the object according to the current invention displays unexpected and advantageous features compared to devices described in D1 and/or D2.

Zacco replies to this in a letter of 19 October 2011. A new set of claims is submitted but it is stated in the letter that claims 1 to 4 are identical. Also, only minor changes have been made in the other claims. It has not been argued in this case that these are to be changes of any significance. Next, arguments are presented against NIPO's stance that the application lacks inventive step. Zacco makes reference to its previous letter. In addition, a comment is made that seems primarily to concern the understanding of the law. The following is stated:

There are clear legal principles about when a reasonable expectation is justified on the basis of prior art. A reasonable expectation of success should not be confused with the more understandable "hope of succeeding". This implies the skilled person's ability to rationally anticipate, on the basis of the knowledge that exists prior to the commencement of the research project, the successful completion of that project. The more difficult it is to predict such a successful outcome, the lower the expectations of success.

Any conclusion that goes beyond what a skilled person objectively would have deduced from prior art, without the benefit of hindsight, should be avoided.

If these principles are applied in the case at hand, they must lead to the conclusion that there was no reasonable expectation of success and that the object of the invention at hand therefore displays inventive step.

> *D2 does not even try to establish any functional duration of the patches that are described. Consequently, any conclusion concerning a functional duration of such a patch is forbidden, since there is no real experimental basis as a point of departure.*
>
> *D1 describes a flux period of up to (but not beyond) 72 hours. Even results obtained from testing over a period of 3 days (as in D1) cannot accurately predict the release rates over a period of 7 days, and in no way and and am just sick effect over at least 7 days. The skilled person would not know whether they would be sufficient propellant force in the patch to deliver drug over such an extended period of time.*

NIPO's next statement is of 16 February 2012. In it, NIPO gives the following assessment of the patentability:

> *We have reviewed the applicant's substantiation of patentability in the previous correspondence in the case, and we have made a new assessment of novelty and inventive step (the Patents Act section 2 first subsection). We have found that what is sought protected fulfils the requirements for patenting. We agree with the essentials of the arguments presented in the correspondence; see, inter alia, your letter of 2011.10.19. Neither D1 and/or D2 leads the skilled person to the invention at hand.*

As can be seen from this, NIPO changes its stance in relation to what it previously has argued in favour of and substantiated in its three previous statements. It is remarkable that this happens without any grounds stated beyond the reference to the applicant's letter. Nor can the Court see that anything new is stated in the patent applicant's last letter. It is thus not possible to see why NIPO changed opinion. Nor does a NIPO performing assessment based on the "problem – solution model" that NIPO normally applies to secure as subjective an assessment as possible of whether there is inventive step; a model that both the plaintiff and defendant have argued that the Court should apply in the case at hand. NIPO here also makes reference to only two citations, D1 which is Chang and D2 which is Drust. The Hille patent, which both parties here believe to be the closest prior art, is not mentioned. It is clear that NIPO was aware of the Hille patent, as it is mentioned in the application and it is mentioned in NIPO's first statement in the case. The decision does however not suggest that NIPO has assessed inventive step in relation to that patent, nor in combination with Chang. Also in Zacco's letter of 19 October 2011 which particular reference is made, the assessment is made only in relation to D1 and D2; that is, Chang and Drust..

It is further noted that NIPO has not expressed how the common general knowledge at the priority date has been assessed, and no assessments has been presented of the skilled person's qualifications. Nor have the individual patent claims been assessed.

In the opinion of the Court, the case is thus stands differently before the Court than it did before NIPO. This also makes it difficult to attach importance to NIPO's decision, as there is no presentation of neither the reasons for their change of opinion nor of what has been assessed and what has been emphasized. NIPO provided far more thorough grounds in its first statements, where the conclusion was that there was no inventive step.

As mentioned, NIPO makes reference only to the applicant's submissions, in particular Zacco's letter of 19 October 2011. In it, it is especially D1 (Chang) that is highlighted and to the extent the applicant choses the closest prior art it must thus be Chang. In the opinion of the Court the teaching of the said patent has however not been presented correctly. The applicant states, even with underlining's, that the patent teaches the skilled person "explicitly" that the transdermal systems described will provide therapeutically effective doses for "a maximum of 72 hours and not for a longer period of time".

In the opinion of the Court, the skilled person will not understand Chang that way. Chang dealt in particular with skin penetration and tested skin penetration enhancers. Chang performs tests for 72 hours. In Example 1, a flux is obtained that is approximately twice as large as a minimum flux stated in Roy, and the part of the total dose of buprenorphine that is released over 72 hours is stated to be 20 %. A point is also made of the fact that it is the skin and not the formulation itself that limits the rate of release. The skilled person will perceive that the patch has an effect for three days and that 80 % of the active ingrident remains. The skilled person will not perceive three days to be the maximum, as claimed by the applicant.

In the above-mentioned letter from the applicant it is also stated that NIPO is wrong in its previous assessments that the quantity of buprenorphine in the patches in D1 and D2, or the release rates described therein, will make it possible to draw a conclusion regarding the patch's functional duration. It is referred that testing after three days "cannot accurately" predict the results in the case of application for 7 days. It is further stated that the skilled person "would not know" whether there was sufficient driving force in the patch to deliver the drug for 7 days. In the Court's view, this is not an expression of a correct standard. It is not a question of whether the skilled person "can accurately predict" or "can know". The question is whether the skilled person "would try with a reasonable expectation of success". Since NIPO makes reference to this letter as a reason to change its stance, it may indicate that NIPO may have adopted an incorrect starting point for its assessment in its last statement.

There are several processes pending before the European Patent Office (EPO) with regard to the validity of the corresponding European patents. There are three decisions by the Opposition Division. The first one found the patent invalid for lack of inventive step. The two other decisions arrived at the opposite result. The desicions of the Opposition Division have been appealed to EPO's appellate body, the Board of Appeal, but have yet to be decided

with regard to the substantive matters. The rulings that exist from the BoA and from the Enlarged BoA concern issues of procedure and have no bearing on the case at hand.

The Court finds that these rulings will be of limited significance to the case at hand; reference is made to what was stated at the outset with regard to the significance of such rulings.

Nor has the Court found any support in the literature presented for there being a general prejudice that would have pointed the skilled person away from an expectation that a buprenorphine patch may have an effect for one week. Nor is there anything pointing the skilled person away from Hille's formulation being capable of having a duration of one week. The skilled person would not consider that the patch's formulation was decisive for the period of effect once the active ingredient had permeated the skin.

The skilled person can of course not be sure, but that is not required under the law. The question is whether the skilled person would have tried with a "reasonable expectation" of success.

There are no indications to suggest that it will not work. In the literature there are also suggestions that one might simply increase the amount of active ingredient, possibly also adjuvants in the same proportion, to obtain a longer period of effect. It will only be by trying that the skilled person will be able to find any possible adjustments that must be made to the formulation to obtain an extended duration, but the Court finds it clear that the skilled person would have done this with a reasonable expectation of success.

Summary in relation to the individual claims:

Claims 1 and 2

These claims contain no formulation requirements. The skilled person will be acquainted with several transdermal systems, also for buprenorphine. The skilled person will have a strong incentive to give the patch an extended period of effect. In particular Pfister and Chang will stimulate the skilled person to doing so. Chang will also give the skilled person a reasonable expectation of success. Reference is made to trials 1 and 3 which show that the patch is stable for 3 days. Example 1 also shows that 80% of the active ingredient remains after 3 days.

Claim 3

The same will apply in relation to this claim. The claim is similar to claims 1 and 2, but is limited to the buprenorphine base. As a point of departure, Chang uses salt, but in example 3 he adds potassium hydroxide, which causes the patch to largely also contain the base form of buprenorphine. Roy also recommends the salt, but the skilled person will first and foremost understand that this is linked to the formulation that is used and would not deter the skilled person from wanting to try the base with a reasonable expectation of success.

Claims 4 and 5

Chang has a formulation that makes it obvious to the skilled person that the patch can last for 7 days. Reference is made to example 1, where 80 % of the active ingredient remains after 3 days. In example 3 it is not stated how much of the active ingredient remains. Chang does however express that the flux is constant; *substantialy constant over 72 hours period*. Consequently, the skilled person would expect a substantial part of the active ingredient to be left in the patch. In any case, the skilled person would presume that the patch's lifespan can be doubled by doubling the thickness of the patch and thus adding more of the active ingredient. The skilled person would thus try a matrix patch as stated in claims 4 and 5, with a reasonable expectation of success.

Claim 6

Claim 6 specifies the levels of two central adjuvants in relation to the active ingredient. These are standard adjuvants for the production of matrix patches that will be known to the skilled person. The amounts indicated are so general that this too will fall within the skilled person's common general knowledge. The Court finds that this claim is not inventive. This is true independently of whether one takes Hille or Chang as a starting point.

Claims 7 and 8

Claim 8 is a specification and expression of a practical application of what is stated in claim 7. The formulation that these claims express are found in Hille and as a consequence will be known to the skilled person. The question is whether the skilled person with a reasonable expectation of success would try to use this formulation with a dosage interval of 7 days.

Hille does not state dosage intervals, but performs trials for 24 hours. It is stated that 38.6 % has been released after 24 hours. The skilled person will have knowledge of skin depots and that this may extend the period of effect. The skilled person will also know that human skin is denser than the mouse skin that has been used in the trials. The skilled person would therefore expect a longer duration in human beings than the 24 hours shown in Hille. It is also noted that it would be obvious to a skilled person without innovative skills to use an existing patch formulation as a starting point. Literature indicates that the active ingredient's composition is of great significance for what formulation should be used. It would therefore be logical for a skilled person without creative skills to take as a starting point Hille's formulation , which is stated to work for buprenorphine.

It is stated that an important problem of having a patch attached to the same place for extended periods of time are immunological reactions. This is something that according to Chang may be remedied by optimisation of the formulation. Such an optimisation is however part of a normal development effort and cannot be considered inventive.

The Court therefore finds that the skilled person would try this formulation which a reasonable expectation that the patch would work for several days. At the same time, the skilled person will know that if it were not to last for 7 days, the duration may be extended by making the patch thicker.

Claims 9 and 10
These claims will be dependent on the other claims and are not inventive.

Claim 11
Here it is stated that Tmax takes place approximately 3 to 5 days after application. If one is to make a 7-day patch, it would be logical that Tmax occurs after 3 – 5 days. This is not inventive in itself This will be true whether one takes as a starting point Chang or Hille as the closest prior art.

Claim 12
The statement in this claim is in line with Chang's example 1. On the basis of what is mentioned above with regard to claims 1 and 2, the Court thus finds that the claim is not inventive. The Court has taken Chang to be the closest prior art, but the same would be true if one were to take Hille as a starting point.

The claims in the alternative, claims A and B
These claims are b These claims are based on the formulations indicated in Hille. ased on the formulations stated in Hille. As a consequence, the Court has taken as a starting point Hille as the closest prior art, but in such a way that it would be obvious to the skilled person to combine Chang and Hille. The claims do not contain any elements that are inventive in themselves. Nor does the Court find that these claims will be inventive when applied to a 7–day patch. With regard to this, reference is made to the assessments made generally in relation to a 7-day patch and to the assessments in relation to claims 7 and 8.

Combination of the claims
None of the claims contains elements that entail a formulation that has inventive step in itself. All elements are found in the Hille patent and the Hille patch. For all claims and combinations of claims, what is new is a dosage interval of at least 7 days. This is not inventive, not even in combination with any of the other claims.

Conclusion
Based on an overall assessment, the Court finds that to the skilled person it was obvious to solve the problem of finding a more effective and suitable transdermal administration of buprenorphine by choosing the solutions indicated in the patent.

For the purpose of this assessment, it has been presumed that the skilled person only has an ordinary skill among technicians or skilled staff within the relevant fields with regard to combining and exploiting available information (prior art) and does not appear as a prominent expert. It has however also been presumed that the skilled person does not consist of a single person, but of a team with such professional background as described above.

It has furthermore been presumed that for this skilled person, normally there must have been concrete reasons for choosing the solution for which a patent is being sought, and that in any case it must

have appeared rational to embark upon the relevant research and development work; see Stenvik page 230-231.

Following the above, the patent is invalid in its entirety. Nor can the alternative claims, submitted in the alternative, make it possible to uphold the patent.

Further as to the validity of patent NO 333 139
The only difference between this patent and NO 248 is that the dosage interval here is set to at least 5 days. Also the description mainly coincides with NO 248. It therefore follows from the discussion above that even this patent is invalid in its entirety.

Further as to the validity of patent NO 334 290
Also this patent largely coincides with NO 248. Also here, the dosage interval is stated to be at least 7 days. The patent differs from NO 248 in some specific requirements for the composition. Reference is made to the patent claims that are quoted in their entirety at the beginning of this judgment. Reference is also made to the fact that in the description it is stated that the composition of the transdermal delivery devices and the kind of system (device) applied, are not considered critical to the invention, as long as the device delivers the active ingredient for the desired time period and at the desired flux rate and/or the desired delivery rate for the transdermal dosage form. As examples of transdermal delivery devices, reference is made to the Hille patch

Also with regard to this patent, it is the time period of at least 7 days for the administration of buprenorphine that potentially might warrant a patent. As a consequence, reference is made to the discussion concerning NO 248. The requirements of composition stated here are not inventive in themselves, nor in combination with a dosage interval of 7 days. Also this patent thus lacks inventive step and must be declared invalid.

Infringement
Following the Court's ruling that the patents in suit are invalid, it is not necessary for the Court to discuss the questions of infringement.. Since the patents have been found invalid, the Court must find in favour of Orifarm in the infringement case.

Setting aside of interim ruling.
Since the patents have been ruled invalid, the Court finds there is no basis for the interim ruling. The ruling of Oslo Court of Execution and Enforcement (Oslo byfogdembete) of 20 June 2016 in case number 16-100798TVI-OBYF is thus to be set aside.

Case costs
Mundipharma has lost both the invalidity case and the infringement case. Both cases have been lost in their entirety and the question of legal costs must be decided pursuant to section 172 of the Civil Procedure Act.

The general rule is that the party losing the case is to be ordered to reimburse the opposite party's legal costs. The Court has considered the exemptions in the second subsection, but finds that they cannot apply.

According to the cost statement from Orifarm's counsel, the total claim for costs amounts to NOK 5,399,865. Of this, NOK 1,078,303 concerns the infringement case and NOK 2,411,759 the invalidity case. Of the total amount, NOK 3,490,062 are lawyers' fees. NOK 978,341 are fees to Onsagers AS Patentkontor. The remainder covers fees for two expert witnesses, as well as expenses, including expenses for interpreting during the main hearing. The cost statement does not include VAT, as a right of deduction exists.

The cost statement has been presented to Mundipharma, who presented remarks to the statement, but they have not been of any significance, considering the outcome of the Court's ruling. By comparison, Mundipharma has presented a fee claim totaling NOK 7,333,967 excl. VAT, of which NOK 5,704,202 concerns the invalidity case and NOK 1,629,765 the infringement case. Thus, this is substantially higher with regard to both the invalidity case and the infringement case.

There are high costs on both sides of the case and the Court has considered whether the claims for costs submitted by the prevailing parties exceed what has been necessary to perform the cases responsibly. The Court notes that the preparations for the case have been extensive. There have been four meetings to prepare the proceedings. The main hearing took place over 7 days, with in part long and intense days in court. The case has been complicated and several expert witnesses have been involved in the case by both parties. The expert witnesses have in part presented differing points of view. Although the Court has not been in doubt as to the outcome, reference is made to the fact that the outcome differs from NIPO's decision. All parties have availed themselves of co-counsels. Considering the scope and complexity of the case, the Court finds that this has been necessary.

Upon an overall assessment, the claimed costs are found to be reasonable and necessary. Consequently, Orifarm is awarded legal costs in accordance with their cost statement.

The court fees shall be paid by Mundipharma AS upon receipt of an invoice from the Court.

In both of the cases, the losing party pays the costs of the expert lay judges in their entirety. The Court does not find that these costs should be split betwen the different individual cases. Both parties have petitioned for expert lay judges and the parties are held jointly and severally liable for the payment of such expenses vis-à-vis the Court. The amount is to be stipulated in a separate court decision.

A claim has been submitted for the payment of interest on late payments after the legal costs fall due. Pursuant to the Enforcement Act section 4-1 third subsection, the legal basis for enforcement of this now follows directly from the Act. This provision was added thorugh the Dispute Act and changed the previous state of the law.

The judgment is unanimous.

CONCLUSION OF THE JUDGMENT

In the invalidity case

Patents NO 334 290, NO 332 248, including the alternative sets of claims A and B, and NO 333 139, are ruled invalid.

In the infringement case

The Court finds in favour of Orifarm Generics A/S, Orifarm Generics AS and Orifarm AS.

In both cases:

The ruling of Oslo Court of Execution and Enforcement (Oslo byfogdembete) of 20 June 2016 in case number 16-100798TVI-OBYF is set aside.

Mundipharma AS is to pay legal costs totaling NOK 5,399,865 – five million three hundred and ninety-nine thousand eight hundred and sixty-five NOK - to Orifarm Generics A/S, Orifarm Generics AS and Orifarm AS jointly within 2 – two – weeks from service of the judgment.

Mundipharma AS is to pay the costs of the Court, including the court fee and the costs of the expert lay judges. The amount is to be stipulated in a separate court decision.

Court adjourned

Inger Kjersti Dørstad

Sverre Arne Sande Johan Kristofer Engblom

Document in agreement with signed original

Oslo District Court 08.09.2017
Maren Sletten-Rambøl

Information about the possibilities of appeal in civil cases is enclosed.