OSLO DISTRICT COURT

[redacted] JUDGMENT

Handed down: 17 June 2016 by the Oslo District Court

Case no.: 15-082184TVI-OTIR/04

Judge:
District Court Judge Knut Hvidsten

Lay judges:
Jukka Rantanen
Sigrid Lise Fossheim

The case refers to: Claim for nullity of a patent.

Teva Norway AS	Mr Gunnar Meyer Co-counsel: Mr Lars Erik Steinkjer
v.	
Boehringer Ingelheim Pharma GmbH & Co KG	Mr Are Stenvik Co-counsel: Associate Attorney Eirik Basmo Ellingsen

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No limitations on publication

JUDGMENT

The case refers to the validity of the Norwegian Industrial Property Office's decision of 15 December 2015, where the defendant Boehringer Ingelheim Pharma GmbH & Co KG (Boehringer), following an earlier administrative limitation, was granted a patent on inhalation capsules made of specific capsule materials with reduced moisture levels, containing the active pharmaceutical ingredient tiotropium.

Boehringer is a company that engages in research-based pharmaceutical development, and is among the 20 largest pharmaceutical groups in the world. The claimant Teva Norway AS (Teva) is part of a global corporation, and the companies in the group comprise the world's largest manufacturer of generic medicinal products. Generic medicinal products are products with the same active pharmaceutical ingredient and in the same amount as original medicinal products, and they are typically brought to market after the expiry of the patent on the original medicinal product. Companies in the Teva Group are also engaged in research-based development of medicinal products.

The active ingredient tiotropium is used for the treatment of chronic obstructive pulmonary disease (COPD). The patent is related to capsules that are filled with this active ingredient in addition to relevant excipients. The capsules are used in an apparatus, an inhaler, which pierces the capsule, and the patient then inhales the contents of the capsule down into the lungs.

Boehringer was granted the original patent with a priority date of 1 June 2001. After Teva filed an action against Boehringer, on 24 August 2015, the company filed an application with the Norwegian Industrial Property Office for administrative limitation with a limited set of claims and a new description. The Norwegian Industrial Property Office decided on 15 December 2015 to limit the patent in accordance with Boehringer's application.
The patent, after limitation, is the subject matter of the lawsuit – and is generally only referred to in the following as the patent in suit.

Tiotropium and patents relating to this active ingredient have led to legal disputes in several European jurisdictions, with Boehringer as one of the parties.

Teva has essentially argued:
Capsules consisting of hydroxypropyl methylcellulose (HPMC) were part of the common general knowledge on the priority date. In addition to an article by Ogura et al., who were employed by one of the world's leading manufacturers of capsules, this knowledge is corroborated by a number of patent applications filed around the priority date. Information about such capsules was also provided at different international conferences, as well as through marketing.

The general moisture level for HPMC capsules is between 3 and 6%, depending on the ambient conditions. A relative humidity between 30 and 60% is within the normal range. As

long as one works with the capsules in normal ambient conditions, there is no inventive drying.

Tiotropium is moisture sensitive, and this was also known prior art on the priority date. Investigations of the sensitivity to moisture would therefore be obvious for the person skilled in the art. Tiotropium was known as a promising active ingredient for the treatment of COPD.

The Court is fully competent to review decisions made by the Norwegian Industrial Property Office. This is no reason to exercise reticence in the review. Among other things, facts are often different for the courts than for the Norwegian Industrial Property Office, and the procedure performed by the Norwegian Industrial Property Office is not subject to the same degree of contradiction as court procedures. The fact that the Norwegian Industrial Property Office accepted Boehringer's application for administrative limitation cannot be ascribed independent importance, and in practice, the Norwegian Industrial Property Office never rejects such applications.

The Court only reviews dependent claims to which submissions are linked. Boehringer has not linked any submissions to the dependent claims. If the independent claims are found to be invalid, dependent claims 9 to 13 will also fall.

The Court is to base its findings on the facts that are most probable.

In assessing the criterion for inventive step, consideration must be given to the need to secure a reasonable public domain for the use of others. The pace of development within the field of pharmaceuticals shows that the threshold for this must not be placed too low. The regular procedure is to use the "Problem and Solution Approach", and the parties agree that this shall be applied. The method is intended to ensure an objective and realistic assessment, without the benefit of hindsight.

For the assessment of the patent in suit, the 'skilled person' would consist of a team, comprised of at least one person with expertise and experience within the formulation of medicinal products for inhalation, in addition to a clinician with expertise and experience of respiratory disorders.

The closest prior art is the individual citation that provides the most promising starting point for the invention. The main criteria for the choice of citations are that they solve the same problem as the invention, and that they share the most relevant and similar technical features. The similarity in the technical problem is a main criterion. An article written by Ogura et al. is the most promising starting point, but even with the article by Casaburi et al. as the starting point, this will mean that the inventive step requirement is not satisfied.

The article by Ogura et al. teaches the skilled person that HPMC capsules can be used for inhalation formulations and that the capsules contain between 2 and 5% water. The use of tiotropium as an inhalation medicinal product as well as the use of lactose as an excipient are two features of the patent in suit that the person skilled in the art cannot infer from the article by Ogura et al. The

technical problem on the basis of Ogura is therefore to identify an active ingredient that can be used as an inhalation medicament in an HPMC capsule.

If the article by Casaburi et al. is considered the closest prior art, it lacks specification of the capsule material and the moisture content of the capsules. The technical problem would then be to find an alternative capsule material for a tiotropium formulation in a dry powder inhaler with lactose as an excipient.

The starting point must be taken in the patent's formulation of the problem, and this refers to the features of the capsule material. Boehringer's formulation of the problem is to provide an improved tiotropium formulation. Such wording of the problem cannot be used as the starting point, since assertions about effects cannot be taken into account if they are not corroborated in the application.

The skilled person would have considered the article by Ogura et al. as relevant, and the article compares HPMC capsules with capsules made of gelatin. It also contains relevant information about the use of medicinal products for inhalation, and the advantage of the capsule having a low moisture content. That the article does not contain detailed information about some features of the HPMC capsule is not a decisive objection, and these conditions are not mentioned in the patent in suit either. Regulatory factors would not have prevented the skilled person from using HPMC capsules.

It is not inventive to select an active ingredient for use in HPMC capsules among several obvious alternatives, and tiotropium was one of several known and well-suited active ingredients. The skilled person would have identified tiotropium, which was one of the most promising active ingredients for the treatment of COPD on the priority date. Using standard preformulation experiments, the skilled person would have arrived at the limited claims in the patent in suit. The effect of moisture content would have been examined, and the skilled person would have concluded that tiotropium is moisture sensitive. Boehringer's subsequent experiments are not relevant, and they are also deficient. The experiments also lead to the solution in the patent claims. Secondary indicia are only of importance where no clear conclusion can be drawn based on the "Problem and Solution Approach". Since HPMC capsules at least have a moisture content of between 4 and 6%, in any event, claims 6 and 7 in the limited patent claims will be obvious.

If one's starting point is in the article by Casaburi et al., the skilled person would be aware of the disadvantages of capsules made of gelatin. Since tiotropium is moisture sensitive, this is a weighty argument to indicate that the skilled person would look for alternative capsule materials that have a lower moisture level. The skilled person would then have found the article by Ogura et al. and thus have inferred the invention.

Boehringer has included arbitrary features in claims 7 and 8, which, for that reason as well, must be found invalid. The limits of 4 and 2% were chosen arbitrarily by Boehringer. In the patent in suit, the problems are described as being to produce a sufficiently stable tiotropium formulation,

and there are no indications that capsules with 6% moisture content do not provide sufficient stability. There is no particular effect to indicate that 4 or 2% add anything beyond being possible moisture levels, and the limit could just as well have been set at other levels. The features do not produce an unexpected or special effect compared with capsules made of same material, and do not contribute to inventive step.

The amendment of the dependent claims does not have the requisite support in the description, and therefore represents unlawful generalisations, cf. §13 of the Patents Act. While the description specifies a moisture level prior to filling, the amended patent claims establish moisture levels that could be before or after filling. Such generalisation is at variance with the Act.

In the alternative, Teva maintains that Boehringer has not established the technical effect as probable. Boehringer maintains that one should take as the starting point a skilled person who is not familiar with HPMC capsules, or who would be highly sceptical to the use of such capsules. Such a skilled person would not find the patent in suit credible, because it speculates without corroborating any technical effect. It does not tally that Boehringer, on the one hand, asserts that it is credible that HPMC capsules would give sufficient stability, but then on the other hand, considers the technical effect in the assessment of inventive step to be satisfied because there is an improvement. Boehringer's description covers all conceivable embodiments without specifying what is preferred, and leaves it to others to figure out which alternatives will work. Accepting this would provide an incentive for broad, speculative patents.

Teva filed the following statement of claim:

1. Norwegian patent NO 332 857 B3, claim 6 with related dependent claims, to be found invalid.
2. Boehringer Ingelheim Pharma GmbH & Co KG to be ordered to cover Teva Norway AS' costs.

Boehringer has essentially argued:

The invention is capsules with reduced moisture content that contain tiotropium. This has resulted in additional stability, with a reproducible constant share of the active ingredient that reaches the lungs. The parties agree that the technical solution is novel, and that the invention is described clearly enough to be worked by a skilled person. This indicates that the invention is also patentable.

Even if HPMC capsules were to have a moisture content of between 3 and 6%, this will not be of decisive importance for the assessment of claim 6. Some capsules will then be over the patent claim's limit with a moisture content of equal to or lower than 5%.

Teva's opinions are based on hindsight.

The Norwegian Industrial Property Office has assessed Boehringer's patented solution twice, and has considered both the article by Ogura et al. and Casaburi et al. as prior art.

The article by Ogura et al. focuses on capsules for oral administration, has no reference to tiotropium or other medicinal products for inhalation and does not lead the skilled person to consider the moisture content in gelatin capsules as a problem for tiotropium.

A great deal of the argumentation presented by Teva relates to Boehringer's original patent, and not to the patent after the administrative limitation. The alleged evidence has been selected and interpreted in the light of knowledge of the invention, and the same applies to formulating the problem and the reasoning. There is no reason to criticise the experiments presented by Boehringer, and Teva has not produced documentation from experiments to corroborate their opinions.

To be granted a patent, an invention must provide a solution to a technical problem. The starting point is that the applicant's information is used. On the filing date, it must be reasonably credible that the invention can be produced and applied, that is, speculation is not enough.

To satisfy the criterion for inventive step, the parties agree that the solution must not have been obvious to a skilled person. Both the discovery and the solution shall be taken into account, and the discovery of a problem that was not obvious, means that the solution was not obvious either. Gelatin was not a known problem for tiotropium, and the opinion was that the use of gelatin capsules was completely satisfactory. The solution to use HPMC capsules and lower the moisture level is then a patentable invention.

In applying the "Problem and Solution Approach", the skilled person must be encouraged to modify or adapt the closest prior art to obtain the same result as the invention. However, there was nothing that would encourage or motivate the skilled person to change capsule material, and reduce its moisture content.

The closest prior art is the article by Casaburi et al., and this is the most realistic starting point. The article is related to the formulation of the active ingredient, which is the central issue. It does not require any technical advances, but it points towards the presence of inventive step.

The technical effect can be corroborated by supplementary evidence, as long as it is covered by or related to the technical problem, which is the case for the evidence Boehringer has presented. Supplementary evidence can only be refused if there are specific indications that cast doubts on the technical effect, but that is not the case for Boehringer's patent claims and description.

A solution that results in a technical effect is not a coincidence. HPMC capsules were not known to provide additional stability for tiotropium formulations.

Objective indicia indicate that there is inventive step because competitors would like to take advantage of the patented solution, the invention has a surprising effect, and due to results from comparative tests.

The skilled person is a practitioner of ordinary skill in the art who addresses the problem solved by the invention, and is in possession of the common general knowledge about the subject area.

Since the article by Casaburi et al. gives the relevant data, it is difficult to see that a clinician would have had any part to play on a team. The key individual in any event would have been a formulation expert. HPMC capsules were not something a skilled person could read about in ordinary manuals or journals. That certain patent applicants had received capsules of this material does not mean that it can be considered part of the common general knowledge.

The skilled person has limited ability to combine information. The person in question is rational, and only makes changes in the prior art if he expects to achieve an advantage.

The problem, and not the solution, determines the identity of the skilled person.

The court must render objective, realistic assessments, without the benefit of hindsight. No citations show a reduction of moisture in the capsules, and it would be hard to explain the combination of the articles by Ogura and Casaburi et al. It could not be predicted that the combination would imply advantages. An article with its primary focus on capsules for oral administration is not particularly compatible with a clinical article on medicinal products for inhalation.

The Court will review the patent after the amendment. Declaring the patent invalid is outside the control of the parties. The Court must therefore review all the patent claims that are alleged to be invalid. In reviewing them, the Court shall be cautious about derogating from the Norwegian Industrial Property Office’s decisions.

As regards the common general knowledge and the prior art, there were several different inhalers in use for medicinal products on the priority date. In addition to choosing the type of inhaler, the skilled person goes through several steps in developing a formulation. This includes selecting and testing excipients, stability tests, optimisation of the powder mixture containing active ingredient and excipients in the case of a dry powder inhaler and the measurement of delivered doses. Testing at reduced temperatures or lower relative humidity is not common. Moisture sensitivity is a general concern in connection with formulation. Gelatin was nonetheless known for helping to protect against ambient humidity, and was not considered a problem. By

establishing ambient equilibrium between the capsule wall and the powder mixture, one avoids transferring moisture to the powder. Protective packaging also counteracts any problems, and having a limited shelf life after being removed from the packaging is common.

Gelatin as a capsule material was well tested, and its properties were well known. All inhalation capsules on the market on the priority date were made of gelatin. As long as the capsules have a moisture content of between 13 and 16%, there is no problem with either static electricity or brittleness. No one recommended keeping to the lower part of this range, and no one suggested reducing the moisture in the capsules.

HPMC was a new and untested material, and there was little information or knowledge available about its properties, nor had it been used in medicinal products for inhalation that had been brought to market. There are a number of documents available containing different information about the moisture content in HPMC capsules. Reproducible production of HPMC capsules with tiotropium and lactose within the scope of the patent claims requires controlled conditions, which do not appear from the prior art.

The skilled person would have assumed that the capsule containing tiotropium, as mentioned in the article by Casaburi et al., was made of gelatin. The patent in suit contains another capsule material, featuring reduced moisture content.

The description of the problem in the patent is an inhalation application with greater stability, high dosage accuracy, good emptying of the capsule and good perforation properties. Boehringer's experiments documented that the problem was solved.

The patent's solution was not obvious. The skilled person takes his starting point in well-proven technology and, based on the article by Casaburi et al., would expect a stable formulation without problems. Tiotropium was not known as a moisture-sensitive active ingredient, something that is corroborated by the fact that it was formulated in an aqueous solution. Reports from different authorities state only that tiotropium is potentially hydrolysable, so it must therefore be protected. Any experiments would have shown that tiotropium is not moisture sensitive.

The moisture content of the gelatin would not have been perceived as a problem, and any challenges with the transfer of moisture could in any event be resolved by using capsules and powder in ambient equilibrium. Neither brittleness nor electrostatic forces are a problem when the moisture content is between 13 and 16%. Investigations would have shown that using gelatin would give satisfactory results, and the skilled person would not expect to achieve advantages by switching capsule materials. The skilled person would not be motivated to use HPMC capsules. There is nothing in the article by Casaburi et al. that points in the direction of the article by Ogura et al. The article by Ogura et al. would not in any case have motivated the skilled person to give closer consideration to HPMC capsules. Any experiments would not have provided motivation to move forward with HPMC capsules.

Nor would the skilled person have been motivated to reduce the moisture level in the capsules, and nothing in the prior art pointed in this direction. Reproducible production requires controlled conditions. There would have been no attempts to solve any stability problems by reducing the moisture content in the capsules, but in other ways.

In the alternative, the invention in claims 7 and 8 is not obvious, inasmuch as a further reduction in the moisture level increases the distance to normal production conditions and entails further advantages.

The article by Ogura et al. is not a realistic starting point for the invention. Nor is the patent obvious with this article as the starting point. It addresses a different problem than the patent, and is not related to tiotropium. The citation has also fewer similarities with the patent than the article by Casaburi et al.

If the article by Ogura et al. were considered the closest prior art, this would have consequences for the formulation of the problem and the identity of the relevant skilled person. It is then difficult to express the problem without including the solution in a manner that is not allowed. The objective technical problem to be solved must then be to improve the capsule, and cannot be related to tiotropium. As regards the skilled person, expertise in medicinal products for inhalation will not be relevant since the issue is the development of capsules. The skilled person will then be a generalist, and the focus will be on medicinal products for oral administration.

The patent has a technical effect, and there was no reason to doubt that the effect was obtained. This is corroborated by the description and the examples of embodiments. Test data is not required, as that applies only where there is specific reason to doubt the data provided by the applicant, and such data normally forms the basis. Teva has not offered evidence to corroborate the contention that the solution was not credible either. The submissions from Teva regarding the lack of inventive step and a lack of credibility are inconsistent.

Boehringer disputes the existence of added matter pursuant to §13 of the Patents Act. The main point is that the capsules are dried, not whether it is done before or after filling them. The changes have support in the description, so the selection is not random.

Boehringer filed the following statement of claim:

1. Judgment to be given in favour of Boehringer Ingelheim Pharma GmbH & Co KG.
2. Teva Norway AS to be ordered to cover Boehringer Ingelheim Pharma GmbH & Co KG’s costs.

The Court sees the case as follows:

The Court will begin with the legal starting points for the review.

The main criteria for being granted a patent are stated in §2, of the Patents Act, where the second subsection, first sentence, is worded as follows:

> "A patent can only be granted 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."
>
> All that has been available to the general public is considered known, whether it is published in writing, a lecture, exploitation or by other means.

The parties agree that the patent in suit satisfies the Act's novelty requirement, and the question in the following is therefore whether the patent differs essentially from what was known on the filing date – usually referred to as the priority date. The requirement that the patent must differ essentially from what was known is often called the inventive step.

The Supreme Court judgment in Rt-2008-1555 (Biomar) contains a more detailed explanation for the criterion for inventive step in §2, first subsection. Paragraphs 32 to 34 state the following:

> "What exactly is inherent in the criterion to differ essentially from the prior art, can be difficult to render more concrete. The joint Nordic patent report from 1964, which laid the foundation for generally identical patent acts in the Nordic countries, discusses this on page 127:
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> > "Whether the requirement for inventive step is satisfied in the individual case must to some extent rest on the discretion of the patent authorities and the courts. Consideration has been given to whether it will be possible to specify objective criteria for assessment of the question. Many attempts have been made to set up such objective criteria, but the committees have not found it possible to state such criteria in the wording of a statute."
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> Official Norwegian Report (NOU) 1976:49 states in the comments to §2 on page 102:
>
> > "The requirement for inventive step means that the invention must not only be new, but it must also entail such development of the art that it cannot be considered to be obvious relative to what is already known."
>
> This mode of expression is largely parallel to what is found in the European Patent Convention (EPC), Article 56, first sentence:
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> > "An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art."

As regards the courts' reviews of decisions from the Norwegian Industrial Property Office, the Supreme Court stated the following in paragraphs 38 to 40 of the same judgment:

> "Accordingly, the decision regarding a patent claim will depend on technical discretion. According to the Act, the inventor is entitled to be granted a patent first when the criteria for being granted a patent are satisfied. This is therefore a question of discretion required by law, where the courts have full opportunity to make a judicial review. The technical nature of the discretion nonetheless requires that the court exercises caution in its judicial reviews. This is clearly expressed in case law, cf. Rt-1975-603, Swingball:
>
> > "I would also mention that the discretionary assessment exercised by the patent authorities pursuant to §2 of the Act must be characterised as discretionary subsumption. The Act does not establish any scope for considerations of expediency in the individual action: Where the requirements for novelty and the inventive step have been satisfied, the applicant shall "have the right to be granted" a patent, cf. §1. As stated, I find that this assessment can be reviewed by the courts. However, I would underscore that there is every reason for the courts to exercise caution in departing from the Norwegian Industrial Property Office's decisions, given the special knowledge and the broad experience possessed by NIPO.
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> The respondent has pointed out that some criticism has been directed at the courts for being especially cautious in reviewing patent cases. It is pointed out that refusals of patents have the Oslo District Court as the mandatory venue, cf. the Patents Act, and that the District Court and the Court of Appeal will be empanelled with expert lay judges. Further, it is believed that these will often include an expert who is even better qualified to deal with the particular needs of the case, compared with the Norwegian Industrial Property Office's staff.
>
> Regardless of whether this is correct *per se*, I would point out that the reason for the courts' caution lies not least in the fact that the Norwegian Industrial Property Office will have extensive experience of where to draw the line for the different criteria for patentability, cf. what I have quoted from Swingball. I do not find grounds for departing from the assumption of the courts' reticence in making a judicial review of the Norwegian Industrial Property Office's decisions, as expressed in the Swingball case."

Teva has argued that the caution the Supreme Court refers to in the judgment should not be assumed when reviewing the Norwegian Industrial Property Office's decisions. Teva has referred in particular to the fact that the Biomar judgment referred the question of the validity of a refusal decision, while in our case, Boehringer has had its patent application granted, so this is a nullity suit. Teva has furthermore pointed out that in actual practice, the Norwegian Industrial Property Office never rejects applications for patent limitations, and that the treatment by the patent authorities is not subject to contradiction from anyone other than the applicant.

As the Court sees it, the same considerations that the Supreme Court points to in the Biomar case also apply to the nullity cases, cf. Arne Ringnes' article "The Supreme Court and Intellectual Property Rights" in Law

Truth Justice, Norwegian Supreme Court's 200th anniversary, p. 878. However, as Ringnes points out, the nullity cases are often in a different position for the Court than for the patent authorities, and the Court must in any event make a concrete, independent assessment of the nullity objections based on the presentation of evidence in the case.

The Court will now move on to explain in more detail the patent in suit, and to place this in the context of the prior art on the priority date. Prior art is a collective term for everything that was known on the priority date.

As mentioned by way of introduction, tiotropium is used for the treatment of COPD. COPD entails that the respiratory passages narrow, so that the patient feels short-winded. So-called bronchodilators, including tiotropium, counteract the narrowing of the respiratory passages. They work by relaxing the musculature that leads to a stricture of the respiratory passages, so that they do not constrict.

Several different types of inhalers can be used for medicinal products administered through the respiratory passages. So-called nebulisers convert liquid medicinal products into aerosol drops that can be breathed in by the patient using a mask or a mouthpiece. Some apparatuses are multi-dose inhalers, which have a collective amount of the medicinal product in the apparatus. The latter gauges and portions out the doses, which are then taken by the patient.

Medicinal products formulated as dry powder are often dispensed in so-called blister packs. These packages store the dry powder composition in small, air-tight cavities, where one cavity equals one dose. Dry powder inhalers are used for such dry powder compositions. In some types of dry powder inhalers, entire blister packs containing several doses are inserted into the inhaler. Each time the patient uses the inhaler, a new cavity in the blister pack is pierced and the dose is inhaled by the patient.

Other medicinal products for use in dry powder inhalers are stored in capsules inside the cavities of the blister pack. The capsules, where one capsule equals one dose, are taken from the package one at a time shortly before use, and placed in the inhaler. The latter pierces the capsule, and then the patient inhales the powder. The patent in suit involves this kind of capsule and this means of taking the medicinal product.

For the development and formulation of medicinal products to be taken through a dry powder inhaler, it is essential be able to reproduce a given dose, enabling the same correct amount of the active ingredient to reach the relevant parts of the lungs. To accomplish this, it is common to use so-called excipients to carry the active ingredient. The way they work is that the active and finely dispersed particles of active ingredient adhere to larger particles of the excipient, mainly due to electrostatic forces, and particles of active ingredient are then released when the patient inhales. After inhalation, the particles of active ingredient break away from

the excipient particles and penetrate the deeper parts of the lungs, while the excipient particles used as carriers remain in the upper parts.

During the formulation work, the testing of physical and chemical stability will be crucial. Physical stability is related *inter alia* to the inhaler being able to reproduce exactly the correct amount of active ingredient to the relevant parts of the lungs. Physical stability depends on the properties of both the active ingredient particles, and the excipient particles. Chemical stability is primarily contingent on the medicinal product's ability to break down, e.g. in the presence of other molecules, such as water or excipient, and to generate new chemical compounds that may have undesirable properties. Depending on type and scope, the chemical decomposition of a given active ingredient could result in reduced medical efficacy and could generate undesirable toxic effects.

It ensues from the prior art that water and moisture may be significant for the product's physical and chemical stability, so these conditions must therefore be taken into account during the formulation work. Moreover, it is prior art that the danger of undesirable electrostatic interactions must also be into account, in particular since such interactions can cause the particles of active ingredient to adhere to the capsule wall, increasing the danger that the patient will not receive a reproducible and correct dose. Moisture also has an impact on interactions between the excipient particles and the active ingredient particles. The amount of water on the surface of a particle thereby affects the electrostatic interactions, and the extent of them. If the active ingredient particles are not released from the excipient particles at the right place in the lungs and at the right time, this can substantially affect the efficacy of the medicinal product.

As regards capsules, gelatin was the most prevalent capsule material on the priority date. It was prior art that gelatin capsules usually had a moisture content of between 13 and 16%. To prevent reactions between water in the capsule material or on the surface of the capsule, and the dry powder composition that contains active ingredient and excipients inside the capsule, it ensued from the prior art that this could be done by trying to achieve the same moisture content in the dry powder composition as in the capsule, so that there would be no exchange of moisture between the capsule and dry powder composition in the capsule.

Further, it was prior art that gelatin capsules become brittle if the moisture content drops to less than 10%, and that it could therefore be advantageous to use materials other than gelatin to make capsules.

Due *inter alia* to the above-mentioned disadvantages of gelatin capsules, developments in the 1990s led to capsules made of HPMC. The core of the disputed part of the patent – in brief – is that the capsule containing tiotropium is made of HPMC, and that the capsule also has a more precisely specified moisture level, which is equal to or lower than 5% in claim 6, lower than 4% in claim 7 and lower than 2% in claim 8.

The parts of the patent in suit that are disputed have the following wording in claims 6 to 13:

> "6. Capsules for inhalation which contain as the inhalable powder tiotropium in admixture with a physiologically acceptable excipient, characterised in that the capsule material used is the cellulose-derivative hydroxypropyl methylcellulose, and has a reduced moisture content as a TEWS or halogen drier moisture content of ≤5% and in that the physiologically acceptable excipient is lactose.
> 7. Inhalation capsules according to claim 6, characterised in that the capsule material has a TEWS- or halogen dryer-humidity of less than 4%.
> 8. Inhalation capsule according to claim 6, characterised in that the capsule material has a TEWS- or halogen dryer-humidity of less than 2%.
> 9. Inhalation capsules according to one of the claims 6 to 8, characterised in that the inhalation powder contains 0.0001-2% tiotropium.
> 10. Inhalation capsules according to claim 9, characterised in that the excipient consists of a combination of coarser excipient with an average particle size of 15-80µm and finer grained excipient with an average particle size of 1-9µm, under which the percentage of finely grained excipient accounts for 1-20% of the total amount of excipient.
> 11. Inhalation capsule according to claim 10, characterised in that tiotropium is present in the form of the chloride, bromide, iodide (*sic*), methane sulphonate, paratoluene sulphonate or methyl sulphonate (*sic*).
> 12. Inhalation capsule according to one of the claims 1-11, for use as a medicament.
> 13. Inhalation capsule according to one of the claims 1-12, for use in the treatment of asthma or COPD."

The Court will move on to an assessment of whether the patent in suit satisfies the criterion for inventive step.

The Norwegian Industrial Property Office's decision dated 15 December 2015 states the following about its assessment of claim 6:

> Based on D4, which the Norwegian Industrial Property Office maintains represents the closest prior art, the objective technical problem can be defined as: How can one produce a capsule containing tiotropium for inhalation that has greater stability and empties better? The existing invention solves the problem by formulating a capsule material that uses the cellulose derivative HPMC where the capsule has a TEWS or halogen drier moisture of ≤ 5%.

> From D5, it is known that HPMC, as opposed to gelatin, does not contain chemical reactive groups. This reduces the probability of potential reactions between a medicinal product and the shell of the capsule. D5 mentions that inhalation systems using gelatin capsules may lead to problems associated with adhesion of powder to the gelatin shell due to static electricity, and that by using HPMC capsules, the problem can be avoided. D5 focuses on capsules for oral use and reports no experiments with HPMC as the capsule material for medicinal products for inhalation. D5 has no reference to the use of tiotropium or other medicinal products for inhalation and says nothing about other problems related to a formulation for inhalation. As regards the chemical stability of the active ingredient, there is nothing in D5 that would lead the skilled person to consider the moisture content of ordinary gelatin capsules to be a problem for tiotropium. In our opinion, a person skilled in the art, when faced with the objective technical problem, would not have arrived at the solution in claim 6 without inventiveness, when he starts from D4 and is aware of the teaching of D5.
>
> The Norwegian Industrial Property Office maintains that invention as set out in the patent claims after the patent limitation satisfies the requirements for novelty and inventive step in §2, first subsection, of the Patents Act.

D4 is an article from November 2000 written by Richard Casaburi et al. (Casaburi), while D5 is an article by Toshihiro Ogura et al. in Pharmaceutical Technology Europe from November 1998 (Ogura). The Court will revert to these articles.

The ordinary procedure in the question of inventive step, and which the parties agree should be applied, is to use the method called the "Problem and Solution Approach". This is a method with three steps, consisting of:

- ascertaining the closest prior art on the priority date
- determining the technical problem to be resolved and
- beginning with closest prior art, assessing whether the invention would have been obvious to the skilled person.

In other words, the first question is to determine the closest prior art on the priority date, which entails identifying the closest available citation. "Citation" is the term used to refer to the individual information carrier, e.g. a document or a product.

The closest prior art is the individual citation that provides the most promising starting point for the invention. Case law from conventions and convention-related case law are important sources of legal authority in the area of patent law, cf. Are Stenvik: Patent law, 3rd edition 2013, page 46. The guidelines from the European Patent Office (EPO) state in point 5.1 the following about the closest prior art:

> "The closest prior art is that which in one single reference discloses the combination of features which constitutes the most promising starting point for a development leading to the invention."

The EPO's precedents are summarised in Case Law of the Boards of Appeal of the European Patent Office, Seventh Edition 2013, where point 3.1 states the following on page 167:

> "In a number of decisions, the board has explained how to ascertain the closest prior art constituting the easiest route for the skilled person to arrive at the claimed solution or the most promising starting point for an obvious development leading to the claimed invention…"

Boehringer has argued that Casaburi is the closest prior art. The article discusses a study of the efficacy and safety of using tiotropium, tested on 470 COPD patients. The study concluded that the material is safe and efficacious. By way of conclusion, the article states that:

> "The results of this study suggest that tiotropium should prove useful as once-daily bronchodilator therapy for COPD."

Tiotropium was developed as a successor to ipratropium, which was used for the treatment of COPD on the priority date. Studies of tiotropium were discussed as early as in 1993 and 1995 in articles by F.P.V. Maesen et al. Boehringer was granted the patent on tiotropium in Norway with priority date 16 September 1989, and subsequently a supplementary protection certificate that expired on 8 September 2015.

Casaburi must be read in the light of the fact that J.A. Van Noord et al. published an article detailing a study on 288 patients, comparing tiotropium and ipratropium, in 2000. The conclusion was that tiotropium, administered daily, was clearly more efficacious than ipratropium administered four times a day. The following is excerpted from the article:

> "These data support the use of tiotropium as first line treatment for the long term maintenance treatment of patients with airflow obstruction due to COPD."

Further, Casaburi must be seen in context with an article by P.J. Barnes from February 2000, which *inter alia* compares tiotropium with ipratropium. The conclusion states:

> "These clinical studies support the animal and *in vitro* studies and show that tiotropium is a potent and long-lasting anticholinergic agent. It is likely to be a useful addition to the therapy of COPD, where once-daily administration may prove to be more convenient and provide more consistent bronchodilation than the currently recommended three- to four-times daily treatment needed for ipratropium."

Prior to the priority date for the patent in suit, tiotropium was also mentioned several times in the publication Scrip Intelligence.

Teva has argued that Ogura is the closest citation. By way of introduction, the article states:

> "Hydroxypropyl methylcellulose (HPMC) capsules are made of plant-derived materials and do not contain components of animal origin, eliminating problems with religious or vegetarian dietary restrictions. Unlike gelatin, HPMC does not have chemically reactive groups, dramatically decreasing the potential for reactions between the drug and the capsule shell. HPMC capsules have a naturally low moisture content, maintain mechanical integrity under extremely low-moisture conditions and are, therefore, ideally suited for use with formulations containing water-unstable drugs."

The article states further that capsules made of gelatin have several disadvantages, *inter alia* since gelatin generally contains 13-15% water. They may therefore be unsuitable for medicinal products that are exposed to water-induced breakdown – so-called hydrolysis – in other words, medicinal products that are sensitive to moisture. This will be elaborated subsequently, where the article mentions medicinal products exposed to hydrolysis due to high moisture levels in the gelatin capsules, and subsequently mentions an attempt using acetylsalicylic acid (aspirin) as a medicinal product with improved chemical stability when dispensed in an HPMC capsule rather than in a capsule made of gelatin. The improved stability is explained by the lower moisture content of HPMC, which is specified as 2 - 5%.

Further, the authors write that certain individuals avoid gelatin for religion reasons, and that this may also apply to vegetarians with dietary restrictions. One of the figures in the article also compares the brittleness of HPMC capsules, capsules made of gelatin and capsules consisting of gelatin and polyethylene glycol (PEG). The results indicate that HPMC capsules show no brittleness, as opposed to gelatin-based capsules, even with a low moisture content of 2% for HPMC capsules. These results corroborate the advantage of using HPMC capsules for moisture-sensitive medicinal products.

Under the heading "Other applications", towards the conclusion of the article, the following is stated:

> "Capsules have also been used as unit-dose containers to administer finely divided powders with specially designed inhalation devices. In the past, such delivery systems have encountered problems, including adherence of the powder to the gelatin capsule because of static electricity and capsule breakage because of the brittleness that results from storage under very low humidity. The HPMC capsule avoids these problems and would be appropriate for use in these situations".

As mentioned, it is decisive for what the Court considers the closest prior art to look at what is considered the most promising starting point for the patent in suit. Based on the above-mentioned review of Casaburi and Ogura, the Court finds that Ogura is the most promising starting point, and will *inter alia*, in the light of the parties' views, explains its point of view in greater detail in the following.

Even though a great deal of Ogura deals with HPMC capsules for oral administration, the Court is of the opinion that the last part of the article in particular, clearly draws the skilled person in the direction of a scope of application for the capsule for use in medicinal products based on dry inhalation.

Generally, the articles in the journal *Pharmaceutical Technology Europe*, where Ogura was published, do not maintain the same professional level and references to scientific documentation as one finds in other, more eminent publications. Further, Ogura does not contain experiments or references to tiotropium or other medicinal products for inhalation. There is, however, reason to mention that several of the expert witnesses presented in the case have published articles in the journal *Pharmaceutical Technology Europe*. The journal also enjoys a substantial readership among formulation experts. In the light of the fact that gelatin had been the prevalent material in capsules for quite some time, a skilled person would find the article and the information in it to be a promising starting point for further efforts. In addition, the Court has no doubt that a skilled person would have taken Ogura into account in his/her work.

In addition to Ogura, there is reason to mention that before the prior date, presentations had been made about HPMC capsules for both inhalation and oral administration at international conferences with a significant number participants, which helped spread information about these capsules. Documentation was also presented in the case to show that HPMC capsules for inhalation were actively marketed not long after the priority date.

That the use of HPMC capsules was known on the priority date is also corroborated by a series of patent applications filed during the period in question that refer to the use of such capsules for inhalation. Boehringer has protested that these applications are not related to capsules, but e.g. to excipients. In the court's opinion, Boehringer's objection is not particularly relevant since the applications corroborate that the use of HPMC capsules for inhalation was prevalent among persons skilled in the art within this field of formulation.

The Court will then move on to the second step in the "Problem and Solution Approach", which is to ascertain the technical problem to be resolved. The problem shall be based on an assessment of the differences between the invention and the closest prior art, where one looks at which technical results are achieved by working the invention that would not have been achieved by working the solution in the closest prior art, cf. Are Stenvik: *Patent Law* (213), page 225. From the Norwegian Industrial Property Office's guidelines, section 5.2.2, the following has been excerpted about this issue:

> "To do this, the application is studied, along with the closest prior art, and the differences with regard to technical features (structural or functional) between the invention and the closest prior art are examined and then said technical problem is formulated. The term "technical problem" refers in this context to the purpose and the task of modifying or adapting the closest prior art in order to achieve the technical effects that the invention produces compared with the prior art.
>
> …
>
> The objective technical problem must not be expressed so that it includes the solution, or parts of the solution, according to the invention of the problem *per se* (see T 229/85, OJ 6/1987, p. 237), and it must also not be expressed too generally."

Teva has maintained that the definition of the problem using Ogura as a starting point is to identify an active ingredient that can be used as an inhalation medicinal product in an HPMC capsule. Boehringer has protested that this definition of the problem contains elements of the solution in the patent, which is not allowed. For its part, the company maintains, as the court understands it, that the wording of the problem is to develop a tiotropium inhalation capsule with greater stability, high dosage accuracy, good emptying of the inhalation capsule and good perforation properties. In this connection, there is reason to mention that the Norwegian Industrial Property Office (NIPO), in its decision of 15 December 2015, articulated the problem as "How to produce a tiotropium inhalation capsule with better stability and emptying".

As the Court sees it, the definition of the problem must have a realistic starting point. When the starting point for the assessment is a capsule of the type mentioned in Ogura, the question to be solved will be to find an active ingredient that can be used as an inhalation medicinal product in such capsules. In the Court's opinion, this definition of the problem does not contain elements of the solution in a way that would disallow it. The Court also does not agree with Boehringer in that definition of the problem based on Ogura must be about the capsule *per se*, and any changes in or improvements to it.
The last step in the "Problem and Solution Approach" is to assess whether the invention, taking Ogura as the starting point, would have been obvious to the skilled person.

The Court will first examine the expertise of the person skilled in the art for assessing the patent in suit.

The skilled person is a fictional figure, an average person with expertise in a subject area, which can be used as a scale. In the Biomar judgment, the Supreme Court discussed the person skilled in the art in more detail, stating the following in paragraphs 35 and 36:

> "The skilled person referred to here is discussed in more detail on page 127 of the Nordic patent report from 1964:
>
> > "An invention must therefore differ essentially from what must be considered to be obvious to a person skilled in the pertinent art. By this, one is referring to what can be considered to be a person of ordinary skill in the art in the sense of a skilled person, who is not in possession of any particular inventive abilities, but who, on the other hand, is fully aware of the prior art on the pertinent date - the filing date - and has the ability to make use of all the known material in a sound technical manner, including also developing obvious new designs."

The Norwegian Industrial Property Office's guidelines, a set of regulations that is largely harmonised with the European regulations for the administrative procedure, describes "the person skilled in the art" as follows in chapter 4, paragraph 5.6:

> "5.6 'Person skilled in the art'"
> "The 'person skilled in the art' should be presumed to be an ordinary practitioner who is aware of what was common general knowledge in the art at the relevant date. He should also be presumed to have had access to everything in the 'state of the art', in particular, the documents cited in the search report, and to have had at his disposal the means and capacity for routine work and experimentation. If the problem prompts the person skilled in the art to seek its solution in another technical field, the specialist in that field is the person qualified to solve the problem."

The same point in the Norwegian Industrial Property Office's guidelines continues as follows:

> "There may be instances where it is more appropriate to think in terms of a group of persons, e.g. a research or production team, rather than a single person. This may, for instance, apply for special fields with advanced technologies such as computers or telephone systems and in highly specialised processes such as the commercial production of integrated circuits or of complex chemical compounds."

Against the above backdrop, the Court is of the opinion that the skilled person in our case is a team. The team would comprise at least one person with expertise and experience in the formulation of medicinal products for inhalation, as well as a clinician with expertise and experience with respiratory disorders. In the Court's opinion, the team would hardly include a person with special knowledge of regulatory issues.

In the following, the team is referred to only as the skilled person, unless it expressly states or is indicated by the context the reference is to one or more individuals on the team.

Boehringer has argued that if the Court uses Ogura as the closest prior art, there must be consequences for the assessment of the skilled person, and that this must then be a skilled person within the development of capsules in general.

The Court does not agree with this. Even if Ogura is the starting point, in the Court's opinion, this will not imply that one has to take its starting point in a different skilled person than the group the Court has discussed above. Thus, the Court finds that a skilled person in the development of capsules is not a realistic starting point for the assessment of the patent in suit.

The Court will then proceed to assess in greater detail whether, on the basis of Ogura, the patent in suit would have been obvious to the skilled person.

The EPO Guidelines state the following about this assessment in point 5.3:

> "In the third stage the question to be answered is whether there is any teaching in the prior art as a whole that would (not simply could, but would) have prompted the skilled person, faced with the objective technical problem, to modify or adapt the closest prior art while taking account of that teaching, thereby arriving at something falling within the terms of the claims, and thus achieving at something falling within the terms of the claims, and thus achieving what the invention achieves (see G-VII, 4).
>
> In other words, the point is not whether the skilled person could have arrived at the invention by adapting or modifying the closest prior art, but whether he would have done so because the prior art incited him to do so in the hope of solving the objective technical problem or in expectation of some improvement or advantage (see T2/83)."

Further, the Case Law of the Boards of Appeal of the European Patent Office, Seventh Edition 2013 has summarised case law as follows in point 7.1 on page 184:

> "In accordance with the case law of the boards of appeal, a course of action could be considered obvious within the meaning of Art. 56 EPC if the skilled person would have carried it out in expectation of some improvement or advantage (T2/83, OJ 1884, 265). In other words, obviousness was not only at hand when the results were clearly predictable but also when there was a reasonable expectation of success (T 149/93)."

The danger of hindsight is mentioned in the guidelines published by the Norwegian Industrial Property Office, where point 5.3.1 emphasises that:

> "It should be noted that an invention which may, at first glance, seem obvious, actually may include an inventive step. After an idea has been articulated, it is often possible to

> demonstrate theoretically how to reach that point through a series of apparently simple steps based on the prior art. However, one must nonetheless be cautious about such analyses that are based on hindsight. It must be borne in mind that the documents presented after the investigation have been produced with knowledge of the alleged invention. In any case, one should try to envisage the prior art as it appeared to the person skilled in the art before the applicant filed the application, that is, a 'realistic' assessment of these and other relevant factors is required."

The question then is whether it was obvious that the skilled person, on the basis of Ogura, would choose the solution in the patent in suit with a reasonable expectation of success. The Court must examine the state of the art before the patent in suit became a factor, that is, the Court must make realistic assessments.

The Court must initially determine whether it would be obvious that the skilled person would have invented tiotropium as an active ingredient for use in HPMC capsules.

Among the most prevalent diseases treated using medicinal products administered using a dry powder inhaler is COPD. In the Court's opinion, it would be obvious to figure this out. A clinician on the team with having expertise and experience with respiratory disorders would have been aware of this, and information about the disease would have been easily accessible.

The question then is whether it is obvious to assume that this would lead the skilled person to tiotropium.

Professor Duncan Geddes testified before the Court that on the priority date of 1 June 2001, there were two known anticholinergics used to treat COPD, ipratropium and oxitropium. Further, it was known that tiotropium would become one of, if not the most promising medication for the treatment of COPD. He also stated that the development of medicaments for the treatment of COPD was relatively limited, so that promising medicaments were noticed. In this context, Professor Geddes mentioned *inter alia* an article by Peter M.A. Calverley from February 2000, where it states that tiotropium was the first new treatment for COPD for many years.

Professor Geddes also mentioned that dry powder compositions through the 1990s were the preferred treatment, rather than e.g. medications in the form of droplets, often using nebulisers. The background for this was *inter alia* that it is easier for the patients to use dry powder inhalers.

Professor Geddes referred to a number of documents from before the priority date, which deal with tiotropium, and these corroborate, in the Court's opinion, the validity of his explanation. In that connection, the Court also refers to the review of Casaburi under the question of the closest prior art.

Against this background, the Court finds that it is obvious that the skilled person would be led to tiotropium.

The question is then whether the skilled person would see any point in using HPMC capsules for the active ingredient tiotropium. On the priority date, the capsules for inhalation that had been brought to market were, as mentioned above, generally made of gelatin. In that connection, Boehringer has argued that the moisture level in gelatin would not generally have been perceived as a problem, and that the transfer of moisture was routinely managed by using capsules and powder with a moisture content in equilibrium with its surroundings.

In the light of Ogura, it is obvious that the skilled person would undertake more detailed examinations of the active ingredient tiotropium to try to determine whether there would have been any point in using HPMC capsules instead of gelatin capsules. The Court points out in particular that Ogura discusses problems with substances that are moisture-sensitive, and challenges related to static electricity.

The Court cannot see that regulatory factors would entail that the skilled person would refrain from more detailed examinations of the use of HPMC capsules. The Court refers *inter alia* to the fact that on the priority date, such capsules had been used among other things for the oral administration of nutritional supplements and medicinal products, and that the risk related to capsules for inhalation would have been limited since these were not to be imbibed, but only serve as packaging for the medicament to be breathed in by the patient after piercing the capsule in the dry powder inhaler. Further, HPMC was used as an excipient in tablets, and the substance was intended to reduce the dissolution rate of the tablets in the stomach by forming a membrane upon contact with water. That a series of patents was filed at the time around the priority date independently of each other with descriptions of using HPMC capsules for inhalation, corroborates that the skilled person would not have seen regulatory factors as a decisive impediment. Even if a person with special knowledge of regulatory factors had been on the team or by other means been consulted, this would not have led to any decisive outcome in the assessment of whether the use of HPMC capsules would have been considered more closely.

This in turn leads to the question of whether it was obvious that the skilled person would seek to determine whether tiotropium is moisture-sensitive.

As the Court has explained above under the review of prior art, the person of skill in the formulation of dry inhalation medication will generally be concerned with examining moisture sensitivity since the presence of moisture can affect both the physical and the chemical stability of the medication. The skilled person would have been especially concerned with moisture sensitivity in testing tiotropium's chemical stability, since tiotropium contains an ester group. It is well known that ester compounds can be exposed to hydrolysis and are thereby potentially moisture sensitive.

In addition, it was well known on the priority date that tiotropium would be formulated as a salt in the form of tiotropium bromide, and active ingredients formulated as salts are usually known to be moisture-sensitive. As previously reviewed, it was also known that electrostatic interactions between particles of the excipient and particles of active ingredient would be affected by moisture, which would affect the physical stability of the medication. The skilled person would also expect that the active ingredient formulated as a salt such as tiotropium bromide, could also exist in various hydrate forms, including anhydrates, monohydrates and higher hydrates. Such hydrate forms imply no change in the active ingredient's chemical structure. The person skilled in the art would, however, find it necessary to make more detailed examinations of these conditions, because the transition between various hydrate forms will lead to changes in the amount of water physically bonded to the active ingredient, which can affect the medicinal product's physical stability and thus its medicinal efficacy.

Against this background, it is the Court's opinion that it would have been obvious for the skilled person to examine whether or not tiotropium was moisture-sensitive, and then to question what the investigations might lead to.

Boehringer has referred to experiments conducted by the company that indicate that tiotropium is not moisture-sensitive.

In the Court's opinion, there are significant methodical objections to the experiments that were carried out, as Teva has also pointed out. For the Court, it is sufficient to refer to the fact that the compatibility experiments were not performed repeatedly to verify the validity of the results, and that the time frame for the experiments was much too short for the person skilled in the art to conclude that tiotropium was not moisture-sensitive. Moreover, even if the skilled person had performed the same experiments and obtained comparable results to those produced by Boehringer, these would not have meant that the skilled person would have refrained from further investigations of tiotropium's moisture sensitivity and simply accepted that this was not a problem.

Boehringer has also pointed out that tiotropium was formulated in a nebuliser in an aqueous solution or suspension, corroborating that the substance is not moisture-sensitive. In the Court's opinion, these are not grounds for concluding that the use of tiotropium in a nebulizer in an aqueous solution or suspension implies that the substance is not moisture-sensitive. The skilled person would *inter alia* be aware that the chemical stability of a compound could have other effects in a dry powder composition than in an aqueous solution or suspension.

In the Court's opinion, quite to the contrary, it is likely that the skilled person's more detailed examinations would have concluded that tiotropium is moisture-sensitive.

First of all, the Court refers to US patent number US 6,645,466, where it is stated in one of the examples that the substance is moisture-sensitive. Boehringer has objected that this patent is not

related to tiotropium and the moisture sensitivity of this substance, but to the use of magnesium stearate in certain formulations. However, the Court cannot see that the patent applies to anything of particular relevance, as long as the patent assumes that tiotropium is moisture-sensitive.

Second, the "Center for Drug Evaluation and Research", a division of the US Federal Drug Administration (FDA), drew up a report dated 20 November 2002 in response to the application for a marketing authorisation for Boehringer's product Spiriva, which is a dry powder inhaler containing tiotropium. Points 10 and 11 state:

> "10. The formulation undergoes significant loss of emitted fine particles and emitted dose when exposed to the atmosphere for 24 hours. The applicant has disclosed that the losses are …. (redacted) To further investigate this situation, the applicant has been requested to provide data from any investigation of the use of alternative capsule materials.
>
> 11. As a result of the above problem, as well as degradation of the drug substance to … (redacted) The applicant has been requested to provide the results of a study that demonstrate the maximum length of time that the drug product may be held outside of its protective packaging without resulting in a significant change in either emitted dose or particle size distribution. The above …. (redacted) a degradant from (redacted) …."

The redacted report is clearly indicative that data produced by Boehringer as the basis for the report documents that tiotropium is moisture-sensitive. The Court finds reason to point out that Teva requested that Boehringer produce an unredacted version of the report, but Boehringer did not comply. In the Court's view, Boehringer has received a clear request to produce an unredacted version of the document, provided the company maintains there is reason to contend anything other than that the report and the documentation on which it is based, indicate that tiotropium is moisture-sensitive.

Third, the Court refers to a "Public Assessment Report" from the Dutch medicinal product authorities dated 21 May 2002, which also applies to said product Spiriva belonging to Boehringer. The following is excerpted from the report:

> "The active substance can be hydrolysed due to the presence of an ester bond. In addition, gelatin is susceptible to water loss, leading to brittleness of the capsules. The composition of the gelatin capsule has been optimised in order to lower the water content without causing brittleness. Before packaging, the water content of the filled capsules is conditioned. …."

Thus, the report shows challenges with tiotropium and moisture sensitivity because the compound contains an ester group. Moreover, the report shows that the composition of

the gelatin capsule has been optimised to reduce water content – this corroborates the moisture sensitivity of tiotropium.

Fourth, it appears from Boehringer's European patent EP 1 991 202 with priority from 3 December 2003, that:

> "Tiotropium is much more sensitive to moisture than most dry powder medicaments including other anticholinergic agents. It is therefore very important to protect the powder in the dose from water in all forms all the way from the point of manufacture up to the moment of inhalation."

Finally, the Court refers to Boehringer's patent US 2009/0192185, which states that:

> "Tiotropium is a new important anticholinergic substance for treatment of asthma and COPD but tiotropium is known in the industry to have problems maintaining in-use stability due to sensitivity to moisture.
>
> …
>
> "Surprisingly we have found and concluded in our tests that tiotropium is extremely sensitive to moisture and that a conventional packaging into gelatin capsules used for a majority of respiratory products will seriously affect the FPD."

The conclusion that tiotropium is moisture-sensitive would therefore have entailed that Ogura would lead the skilled person directly to using HPMC capsules instead of capsules made of gelatin, since HPMC capsules made it possible to use capsules with less moisture.

As indicated by the review of the patent in suit above, the differences between patent claims 6, 7 and 8 are the moisture levels in the capsules. The moisture level in the capsules in claim 6 should be equal to or lower than 5%, in claim 7, the figure is set at lower than 4%, while claim 8 sets it at lower than 2%.

The patent description gives a more detailed description of how to ensure that moisture levels are obtained and measured. Among other things, the parties disagree on whether the moisture levels in the patent claims are within what HPMC capsules normally have, and Teva asserts that it is not a novelty with inventive merit when Boehringer uses capsules with the moisture levels that the capsules will usually have. Further, the parties have different ideas about what are ordinary levels of relative humidity and temperature in connection with formulation work and during production, and when they make the transition to being controlled.

As the Court sees it, it is not necessarily to determine what constitutes normal, and what constitutes controlled conditions. In the Court's opinion, it is obvious

that the skilled person would test the HPMC capsules to determine their moisture levels from the manufacturer, and to stabilise them with a view to further experiments with tiotropium. In the light of the review of tiotropium above and the sensitivity to moisture, it is obvious that this would then have induced the skilled person to experiment with capsules with different moisture levels, and to conclude that capsules with low moisture levels are preferable. Claims 6 to 8 in the patent in suit do not satisfy the criterion for inventive step in §2 of the Patents Act.

After this, it is not necessary to go into the other question the case raises about claims 6 to 8. In the light of the parties' arguments, the Court nonetheless finds reason to go into what would happen if one were to have assumed that it was not obvious for the skilled person to experiment with capsules with different moisture levels, and to conclude that capsules with low moisture levels are preferable.

Under said circumstances, in the Court's opinion, using HPMC capsules with a moisture level like the level usually used could not in any event be considered to have inventive step.

As regards which moisture level HPMC capsules usually have, the Court refers first to the fact that Ogura contains a table that shows that the capsules have a moisture content from 2 to 5%. In an article by Shunji Nagata from August 2001, the water content was measured at between 4 and 6% when the capsules were stored at between 20 and 25 degrees Celsius and between 40 and 60% relative humidity.

In the Drug Master File submitted by the manufacturer Shionogi Qualicaps, Inc., the appended documentation shows that the humidity was between less than 4% and up to less than 7% during storage in different periods of time up to 42 months. The storage of six batches for up to 24 months took place at 60% relative humidity and a temperature of 25 degrees Celsius, the results here were between 4.4 and 6.8%.

The book "Hard Capsules, Development and Technology" from 1987 states that capsules achieve their optimal function when handled in an atmosphere with a relative humidity of between 30 and 50%.

J.C. Birchall et al. state in an article from 2008 that the moisture in the HPMC capsules was "as received", and was 4%. Further, an article by Irene Chiwele et al. from July 2000 describes that capsules were stored "under ambient room conditions" at between 18 and 20 degrees Celsius and 35 to 40% relative humidity. The witness testimony corroborated that down to about 30% relative humidity cannot be considered to be 'controlled conditions'.

Boehringer has referred to some other documentation, and if we understood correctly, contends that HPMC capsules under normal conditions have a moisture content of between 5 and 7%.

In the Court's opinion, said documentation substantiates that a normal moisture level for HPMC capsules must be assumed to go down to at least less than 4%. It cannot be considered to have inventive step to fill tiotropium into HPMC capsules that have the moisture level with which such capsules are usually delivered. This will then affect both claims 6 and 7 in the patent in suit. Boehringer has pointed out that although it is assumed that HPMC capsules have a moisture level of between 3 and 6%, this will mean that some capsules will fall outside both claims 6 and 7, since these pose requirements for moisture level set at lower than or equal to 5%, and lower than 4%, respectively. In the Court's opinion, this is not decisive, as long as some of the capsules would fall within the scope of the patent in suit without being tested for any kind of drying after delivery, it cannot be considered to have inventive merit to ensure that the capsules have a more specific moisture level.

As regards claim 8, it is more unclear whether HPMC capsules will have such a low moisture level as less than 2% from the manufacturer. Teva has argued that claims 7 and 8 must in any case be found invalid because they are arbitrary.

Case Law of the Boards of Appeal of the European Patent Office, Seventh Edition 2013, reports on the practice of choosing between several obvious solutions. From pages 222-223, the following is reproduced:

> "A merely arbitrary choice from a host of possible solutions cannot be considered inventive (T 939/92, OJ 1996, 309; T 739/08). In T 400/98 the board stated that applying one of the possible solutions which were available to the skilled person requires no particular skills and hence does not involve an inventive step (T 107/02)
>
> ..
>
> In T 190/03 of 29 March 2006 the board stated that in connection with the obviousness of a solution chosen from various possibilities, it is sufficient that the one chosen is obvious and it is not necessarily relevant that there are several other possible solutions. The board referred to T 939/92 (OJ 1996, 309) where it was stated that (albeit in the field of chemistry) an arbitrary selection of a solution from a number of possibilities in the absence of a hint to do so is not inventive if not justified by a hitherto unknown technical effect that distinguishes the claimed solution from the other solutions. In the case before it, the board could not see any unknown or surprising effects, but only immediately predictable ones".

In the opinion of the Court, there is nothing in the patent *per se* to corroborate that anything would be achieved by using HPMC capsules with a moisture level of less than 2%, as opposed to using capsules with a moisture level between less than 4% and 6%, which the Court has concluded is the normal humidity level. Boehringer has not offered evidence to

support what is achieved by reducing the moisture content to less than 2%, or why the limit is set precisely there, rather than, for example, at 3% or 1%. Given this situation, the conclusion must be that the limit was set arbitrarily. In addition, if the patent only indicates that a lower moisture level in capsules was preferable, this was a conclusion based on tiotropium's moisture sensitivity that was obvious to draw, so it lacks inventive step, cf. also the Court's comments above.

The conclusion is therefore that claims 6 to 8 must be found invalid.

The Court must then take a position on whether the dependent claims from 9 to 13 must also be found invalid as a result of the Court's assessment of claims 6, 7 and 8.

Boehringer has not made any submissions relating to the dependent claims, but has maintained that the Court is required to take position on them on its own initiative, since the question of patents' validity is not under the control of the parties.

The starting point for the assessment is that patents and patent claims are something a rightsholder can voluntarily relinquish, and it is up to the rightsholder whether or not the party in question would like to enforce them. This pulls heavily in the direction of a party in a civil case regarding the validity of a patent also being able in procedural terms to manage dependent claims by not making independent submissions, thus allowing the claims to stand or fall with the validity of the independent, but disputed patent claims.

In both Tore Schei et al., *The Dispute Act*, Annotated edition, 2nd edition, page 403, and Jens Edvin A. Skoghøy: *Resolution of Disputes,* 2nd edition, pages 519-520, the authors have taken the view that declaring the patent invalid is outside the control of the parties. These opinions are not explained in more detail, and there are significant, general objections against the Court taking a position on dependent claims that are unrelated to submissions. In this connection, the Court points out that there has been no presentation of evidence regarding the dependent claims in our case. On that account, there may be good reasons for a party to maintain control of dependent claims in procedural terms by not making submissions.

However, it is not necessary to take position on this, since the Court finds under any circumstances that the dependent claims do not meet the requirements for inventive step in §2.

As regards claim 9, it was prior art that an active ingredient would have been a lesser constituent of a dry powder composition. Relatively large particles of the excipient therefore act as carriers for smaller particles of active ingredient. The requirement specifies between 0.0001-2% tiotropium, which is both a wide range, and within what the skilled person would expect of an active ingredient. The claim does not fulfil the criterion for inventive step in §2.

As regards claim 10, it was prior art on the priority date to combine particles of the excipient of different sizes, so this does not fulfil the criterion in §2 regarding inventive step either.

Claim 11 is simply a list of different forms of tiotropium salts while claims 12 and 13 discuss the use of tiotropium-containing capsules for asthma or COPD. These claims do not satisfy the criteria in §2 either.

Even though the Court shows restraint in reviewing the Norwegian Industrial Property Office's decisions as a result of the Biomar judgment, the Court has arrived at the conclusion that both the independent and dependent claims 6 to 13 must be found invalid because Boehringer has been granted the patent without satisfying the conditions in §2 of the Patents Act, cf. §52, no. 1.

Against this background, it is not necessary to take a position on Teva's contention that the amendment to the dependent claims does not have the requisite support in the description, nor whether the patent in suit has failed to establish the probability of the technical effect.

Thus, the Court renders the judgment that Boehringer's patent NO 332 857 B3, claims 6 up to and including 13, are invalid.

Teva has won the case, and shall, pursuant to the general rule in §20-2 of the Dispute Act, receive full compensation for its costs, cf. §20-2, first cf. second subsection, of the Dispute Act. The Court has considered the exception provisions, without finding that any of them are applicable.

Teva has filed a statement of costs for NOK 6 801 707, of which NOK 4 626 025 in fees, and the rest in expenses, mainly for expert witnesses. In addition, there is the court fee, which amounts to NOK 24 940. Boehringer has filed objections to the claim.

The case took eight court days. The Court has considered the scope and complexity of the case, and assumes that it of great importance to the parties. In the light of these circumstances, among others, the Court finds that costs have been necessary, and that it has been reasonable for Teva to incur them, cf. §20-5, first subsection of the Dispute Act.

The parties are each liable for half the expenses for the expert lay judges in respect of the District Court, cf. §2 of the Court Fee Act. The expenses will be stipulated in a separate decision. Teva's share of these costs shall be covered by Boehringer in addition to the expenses above.

The judgment is unanimous.

The judgment was not handed down within the deadline laid down in the Act primarily due to the scope of the case, the presiding judge's other duties, and the fact that between the main hearing and the delivery of judgment, the judge was on parental leave.

CONCLUSION OF JUDGMENT

1. Norwegian patent NO 332 857 B3, claims 6 to 13, are found invalid.
2. Boehringer Ingelheim Pharma GmbH & Co KG is ordered to pay compensation for costs to Teva Norway AS in the amount of NOK 6 826 647 – six million, eight hundred and twenty-six thousand, six hundred and forty-seven Norwegian kroner within 2 – two – weeks after service of the judgment.
3. Boehringer Ingelheim Pharma GmbH & Co KG is also ordered to pay Teva Norway AS' expenses for the expert lay judges. The expenses are stipulated in a separate decision, and will fall due 2 – two – weeks after service of the decision.

Court is adjourned

Knut Hvidsten

Sigrid Lise Fossheim Jukka Rantanen

The guidelines for access to appeal in civil suits are attached.

Document in compliance with the signed original
Oslo District Court, 17 June 2016
Administrative Officer Ellen Strøm