[Norwegian Coat of Arms]

OSLO DISTRICT COURT

JUDGMENT AND COURT ORDER

Date rendered:	10 February 2011, by the Oslo District Court	
Case number:	10-062600TVI-OTIR/04	
Judges:		
	District Court Judge	Hilde Foyn Bruun
Lay judges:		
	Professor	Anne Fiksdahl
	Professor	Tore Sigvard Lejon
Subject matter of the case:	Patent law. Infringement. Damages. Preliminary injunction.	

Novartis AG	Advocate Gunnar Sørlie
Novartis Norway AS	Advocate Gunnar Sørlie
vs.	
Actavis Norway AS	Advocate Ingvild Hanssen-Bauer
Actavis Group PTC hf	Advocate Ingvild Hanssen-Bauer

JUDGMENT

The case concerns a request for a prohibition against the marketing and sale of a pharmaceutical product, a claim for damages and a request for a preliminary injunction, in an action relating to the alleged infringement of an analogous process patent for a pharmaceutical product. The question is whether there is infringement through equivalence.

Part I: Background to the case

1. Introduction.

The plaintiffs, Novartis AG and Novartis Norway AS (hereinafter jointly referred to as "Novartis"), develop, manufacture and market pharmaceutical products on a global basis. Novartis was established in 1996 following the merger of the companies Sandoz and Ciba-Geigy. Novartis AG holds a number of patents, including patents on the production of acyl compounds. One such compound is valsartan, with which the present case is concerned. Valsartan belongs to a group of compounds called sartans.

Novartis AG is the holder of patent NO 304 023, which concerns production of the active ingredient valsartan, which is used in Diovan®, which is a pharmaceutical product used in the treatment of hypertension (high blood pressure), myocardial infarction and heart failure. Diovan® acts by binding the so-called angiotensin II receptors and blocking for angiotensin II. Novartis also has developed, and manufactures and markets, a combination product, Co-Diovan® (Valsartan and HCTZ). Millions of people all over the world are treated with Diovan, which had a global turnover of approximately USD 6 billion in 2009.

The defendants, Actavis Group PTC hf and Actavis Norway AS (hereinafter jointly referred to as "Actavis"), are the parent company and the Norwegian subsidiary, respectively, of the pharmaceutical group Actavis, which was established in 1956. The Actavis group is currently one of the world's leading companies within the development, manufacturing and sale of so-called generic pharmaceutical products. The company was previously headquartered in Iceland, but has subsequently moved its headquarters to Zug in Switzerland. Actavis has development and production units in Europe, the United States and Asia. The product portfolio includes 650 products, and more than 350 products are under development. The group has products registered in more than 60 countries. The Actavis group has about 10,000 employees in more than 40 countries.

The wholly-owned subsidiary Actavis Norway AS is a distribution company, established in 2005.

The parent company of the Actavis group, Actavis Group PTC hf, is the holder of a marketing authorisation from the Norwegian Medicines Agency ("NoMA") in respect of valsartan tablets with strengths of 40, 80 and 160 mg. The authorisation was announced by NoMA in August 2008. Actavis' product is called "Valsartan Actavis". Actavis' products were launched in March 2010, shortly

after Novartis had revoked its petition for a preliminary injunction against Actavis, see Item 5 below. ”Valsartan Actavis” is included on the pharmacy substitution list, cf. Section 6-6 of the Pharmacy Act, which entered into force on 1 March 2001.

The active ingredient, valsartan, is manufactured for Actavis by Quimica Sintetica S.A. (“QSSA”) in Spain. The active ingredient is dispatched from QSSA to Actavis’ factory in Malta, where the active ingredient is combined with accessory ingredients (”formulated”) to make finished valsartan tablets.

QSSA has developed three processes for the manufacturing of valsartan. The parties have agreed to operate on the assumption that the active ingredient for the Norwegian market is manufactured through the so-called QSSA "Route C", which consequently constitutes the alleged infringing object.

2. Patent NO 304 023 – the relevant patent claims

Patent NO 304 023 is an analogous process patent, cf. Section 3, Sub-section 1, No. 3, of the Patents Act. Until 1992 it was not possible to obtain product patents on pharmaceutical products in Norway.

An analogous process patent is a patent on a process known from the production of other substances, and where the novel aspect of the invention lies in the product and its therapeutic effect. However, the actual process as such does not have to be novel or exhibit inventive step.

The Norwegian patent application was filed on 18 February 1991. The patent expires on 18 February 2011, cf. Section 40 of the Patents Act. The priority date of the patent is 19 February 1990.

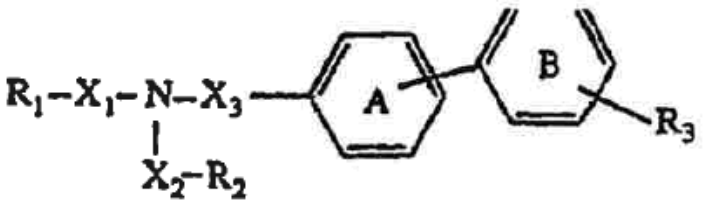
Translations of the patent claims and the description were submitted in June 1991. In November 1994, the Norwegian Industrial Property Office requested that the application be amended to concern an analogous process. The Norwegian Industrial Property Office furthermore requested the findings from trials showing the effect of the product as a pharmaceutical. In September 1995, Bryns Patentkontor AS filed new and limited claims, in which, inter alia, X3 in the formulas was limited to methylene. The Norwegian Industrial Property Office issued new comments in March 1996, requesting additional amendments to the patent claims. In June 1996, Bryns Patentkontor AS filed a new and limited set of claims. A Norwegian patent was granted on 12 October 1998.

The period of protection has been extended through the issuance of a supplementary protection certificate, SPC/NO 1998 024, which expires on 13 May 2011, cf. Sections 62 a and 62 b of the Patents Act. A separate protection certificate has been issued in respect of the basic patent for Co-Diovan®, until 25 September 2012, pursuant to SPC/NO 19991 001. There also exists an SPC that expires in 2016. Novartis’ request for a prohibition has a cut-off date of 13 May 2011. Novartis has stated that enforcement of the patent protection after 13 May 2011 will, if applicable, be pursued through new proceedings.

Novartis' patent NO 304 023 concerns an analogous process for the production of therapeutically active acyl compounds, hereunder valsartan, with a number of alternative processes. The patent claims include five claims, one of which is an independent claim, which is comprised of nine alternatives; Claim Alternatives 1 a) to 1 i). Novartis has argued that QSSA Route C represents an infringement of Claim 1 e) and Claim 1 h) or, alternatively, only one of these.

Claim 1 e) is worded as follows:

> "Patent claims
>
> 1.
> Analogous process for the production of a therapeutically active compound with formula:



(I)

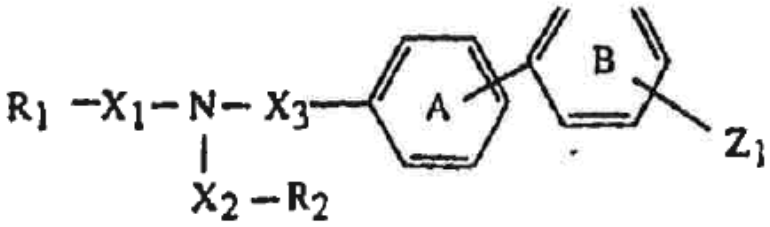
> where R1 means C1-C7-alkyl or C3-C7-alkenyl; X1 signifies CO; X2 signifies C1-C10 - alkylene or C1-C7-alkylidene, may potentially be substituted with: hydroxy, carboxy, amino, guanidino, 3- to 7-position cycloalkyl, phenyl or with imidazolyl, where a C-atom of C_1-C_{10}-alkylene or C_1-C_7-alkylidene, respectively, may be bridged via C_2-C_6 alkylene; R2 means carboxy, lower alkoxy, phenyl lower alkoxycarbonyl, carbamoyl, which may potentially be mono- or disubstituted with lower alkyl, phenyl lower alkyl independently of each other, or with lower alkylene, which may potentially be condensed into the two neighbouring carbon atoms with a benzol ring, or is disubstituted with lower alkyleneoxy lower alkylene, lower alkanoylamino, hydroxy, lower alkoxy, phenyl lower alkoxy or phenoxy; X3 is methylene; R3 means carboxy or 5-tetrazolyl; aromatic residues that include the rings A and B which may, independently of each other, potentially be substituted with halogen or hydroxy, in free form or in salt form

c h a r a c t e r i s e d in that one

> - - - [Claim 1 a) to Claim 1 d)]
>
> e) one starts out from a compound with formula (II) or a salt thereof, where Z_1 means protected tetrazolyl, and separates the tetrazolyl protecting group; or [- - - moves on to Claim 1 f)]

The compound with formula (Il) is specified in Claim 1 a) as follows:

a) in a compound with formula:



(II)

converts Z_1 to R_3, or a salt thereof, where Z_1 means a residual that can be converted to R_3, or - - - ”

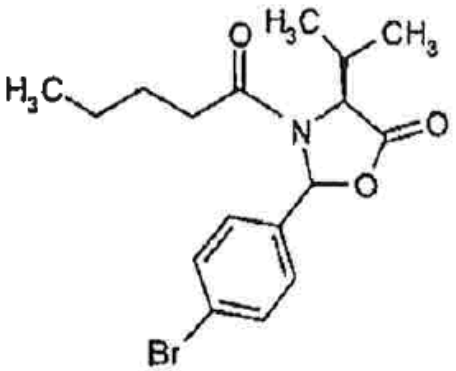
Claim 1 h) is worded as follows:

”

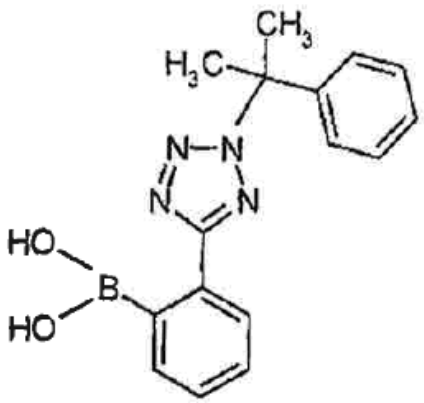
h) For the production of a compound with formula (I) or a salt thereof, where R_2 means carboxy, derived from an achieved compound with formula(I) or a salt thereof, in which R_1 means lower alkoxy, phenyl lower alkoxy-, lower alkoxy lower alkoxycarbonyl or carbamoyl, which may potentially be mono- or, independently of each other, disubstituted with lower alkyl, phenyl lower alkyl or lower alkylene, which may potentially be condensed into the two neighbouring carbon atoms with a benzol ring, or is disubstituted with lower alkyleneoxy lower alkylene, converted to a compound with formula (I), where R_2 is carboxy, or - - -
[moves on to Claim i)] ”.

3. QSSA Route C

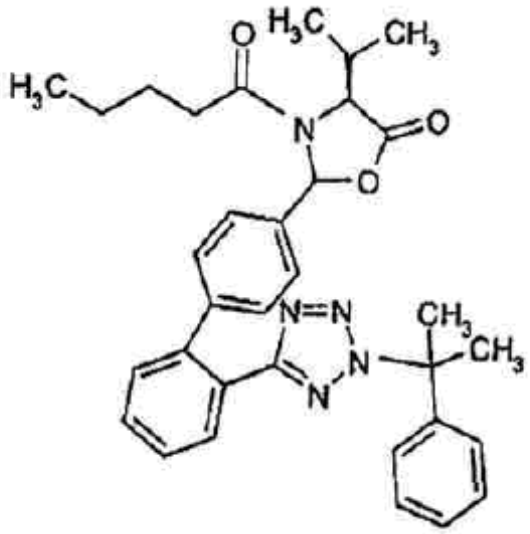
QSSA Route C is a synthesis route through which two intermediates referred to as Intermediate 1 and Intermediate 2 are coupled together and one achieves Intermediate 3; a compound that contains an oxazolidinone ring, and that features a protecting group on the tetrazole group. The intermediates are described by the following formulas:



[Intermediate 1]

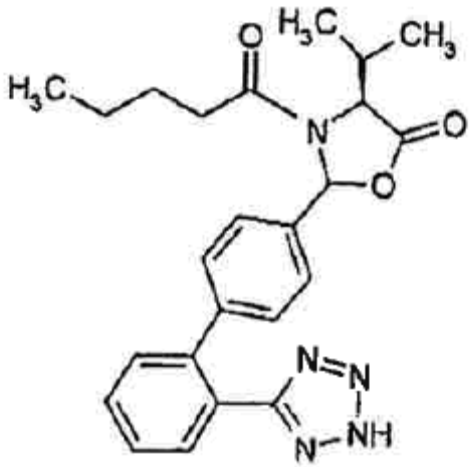


[Intermediate 2]



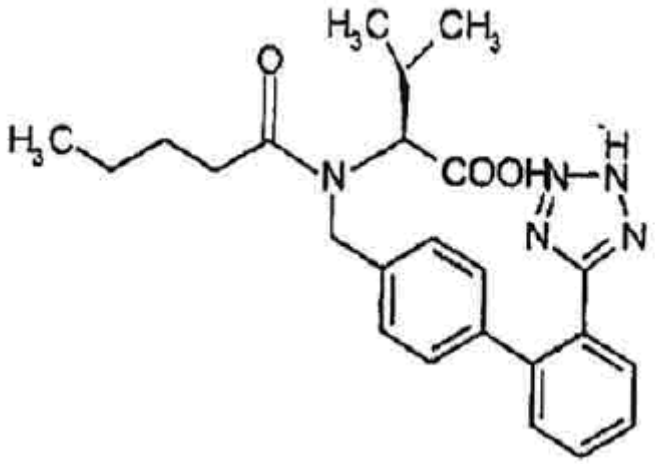
[Intermediate 3]

In the next step, the protecting group is separated from the tetrazole group, and one achieves the following compound:



[Intermediate 4]

In the final step, the oxazolidinone ring is opened, and one achieves valsartan.



[Valsartan]

4. The QSSA process – descriptions in other patents and applications.

Several of the synthesis steps and the intermediates in QSSA Route C are described in other European patents. Actavis has, in particular, emphasised European patent EP 1 533 305 B1, which was granted on 13 February 2008. The holder of the patent is Dipharma S.p.A. EP 1 533 305 B1 concerns a process for the production of valsartan. The priority date is 21 November 2003. Novartis' patent US-A-5399 578 was held to be the closest prior art in the application process pertaining to EP 1533 305. The said US patent is the American parallel to NO 304 023, the disputed patent in the present case. Novartis objected to EP 1 533 305. An oral hearing was conducted on 23 March 2010, and the Opposition Division found that EP 1 533 305 met the patentability requirements under the European Patent Convention (the "EPC"). Novartis has appealed the decision of the Opposition Division to the Board of Appeal of the EPO. It has been stated that the appeal has been referred for deliberation on its merits.

A US application paralleling EP 1 533 305 was granted on 21 October 2008; US 7,439,261 B2. U.S. PAT 5,399,578 (Buhlmayer et.al) was held to be the closest prior art for purposes of that application process.

Moreover, QSSA submitted a PCT application on 8 May 2008; WO 2008/138871 A1. A positive statement is made in a preliminary report of 17 November 2009 from the PCT Examination Authority.

5. The proceedings prior to the Writ of Summons

On 29 September 2009, Novartis filed a petition for a preliminary injunction, requesting that Actavis be prohibited from marketing generic pharmaceutical products with valsartan as an active ingredient. The petition was occasioned by Actavis having informed Novartis that Actavis would, by October 2009, be marketing generic pharmaceutical products with valsartan as an active ingredient in Norway. An oral hearing before the Oslo Court of Execution was scheduled for 8 – 12 March 2010.

Novartis argued, in the petition for a preliminary injunction, that Actavis' application for marketing authorisation in Belgium might suggest that the active ingredient, valsartan, was manufactured by the Chinese company Zhenjiang [sic] Huahai Pharmaceutical Co., Ltd. This argument was withdrawn in the opening statement of counsel during the oral hearing before the Court of Execution. Following such withdrawal, the only issue that remained for deliberation was whether QSSA Route C represented an infringement through equivalence.

The Oslo Court of Execution appointed two experts, who were given the following mandate:

i. Compare the processes described in NO 304 023, Claim 1e and Claim 1h, with the corresponding steps of the QSSA process designated as Route C.
ii. Assess whether the QSSA process is an obvious modification of the process described in Claim 1e and/or Claim 1h of the patent.

The oral hearing before the Oslo Court of Execution was conducted on 8 – 10 March 2010. The two court-appointed experts, Rolf Olaf Larsen and John S. Mjøen Svendsen, submitted their report on 10 March 2010. They concluded that QSSA Route C is not an obvious modification of the process stipulated in Claim 1 e) or Claim 1 h) of the patent. The following is quoted from their declaration:

> ”
>
> - - -
>
> We are of the view that Claim 1e is intended to encompass deprotection of a protected tetrazole group for all potential protecting groups by all potential processes, on a comprehensive range of compounds defined by the general Formula (II). However, the patent holder has introduced two limitations as far as the variables in Formula (II) are concerned; X_1 shall be carbonyl, whilst X_3 shall be methylene. We assume that the introduction of these limitations was a conscious decision on the part of the patent holder, and X_3 is, as mentioned above, of particular relevance to the present case. The definition of X_3 that restricts it to methylene only is in line with the structure of all the sartans of which the court-appointed experts are aware, which all have a methylene group in the position that corresponds to X_3 in the disputed patent.
>
> The court-appointed experts are of the view that the scope of protection offered by Claim 1e is very broad, although it also contains very clear limitations. These limitations have been introduced into the claim by the patent holder itself. The process defined by Claim 1e must therefore be interpreted in the context thereof. The QSSA process designated as Route C includes a step where a protecting group is separated from the tetrazole ring, which feature the QSSA process has in common with many synthesis processes, whilst QSSA’s intermediate product falls outside the scope of the definition of the variable X_3.
>
> However, the separation of the protecting group in the QSSA process designated as Route C must be performed in a manner that is completely different from what is common as far as such transformations are concerned (see Examples 55 and 76c of the 023 Patent). This is because the QSSA process designated as Route C features an oxazolidinone ring in the molecule. Oxazolidinone rings do not fall within the scope of Claim 1e, nor does the theory expounded by Claim 1e provide any guidance to such effect.
>
> The court-appointed experts are of the view that the deprotection process involved in the QSSA process designated as Route C is inventive in relation to the chosen starting material, and not an obvious modification of the process described in Claim 1e of the disputed patent.
>
> - - - .”

As far as Claim 1 h) is concerned, the court-appointed experts stated the following:

> ” - - -
>
> Claim 1 h does, like Claim 1e, encompass a large number of compounds. All of these compounds are esters or amides of the carboxylic acid defined by Formula (I). The ester derivatives are the most relevant as far as the present matter is concerned. A large number of esters fall within the scope of the claim; lower alkoxy, phenyl lower alkoxy and lower alkoxy lower alkoxy. The claim defines no limitations as to what processes are used to convert the ester into the carboxylic acid. The limitation is relation to the variable X_3, as discussed in the context of Claim 1e, also applies under this claim.
>
> The experts find no reactions in the QSSA process that directly encompass reactions that fall directly within the scope of Claim 1h. The QSSA process features no step that involves the release of carboxylic acid from lower alkoxy-, phenyl lower alkoxy-, or lower alkoxy lower alkoxy

-carbonyl derivatives or carbamoyl derivatives. Nevertheless, the QSSA process also includes a reaction that releases the carboxylic acid to be featured in valsartan. The QSSA process generates this carboxylic acid from an oxazolidinone derivate by way of hydrogenolysis.

- - -

This step of the QSSA process designated as Route C deviates from Claim 1h in the following manner: X_3 is not methylene (CH_2), but methine (CH); R_2 is not a single ester derivative, but instead forms part of an oxazolidinone ring.

The court-appointed experts are of the view that such an oxazolidinone ring is not an obvious modification of an ester group. The reactivity characteristics are too different to merit an obviousness conclusion, and the oxazolidinones exhibit a reactivity that is not typical of ester groups.

It is our assessment, against this background, that it would not be obvious to the person skilled in the art to replace the simple esters in Claim 1h with oxazolidinones when reading Claim 1h or the description in the patent.

Summary
The court-appointed experts therefore conclude that the QSSA process designated as Route C is not an obvious modification of the process defined by Claim 1e or Claim 1h of the patent.

(date) (sign) ”

Novartis revoked the petition for a preliminary injunction in a supplementary submission of 11 March 2010, after the experts had submitted their report. The following is quoted from the supplementary submission to the Oslo Court of Execution:

”Actavis has stated, during the presentation of evidence in the ongoing oral hearing, that no other process than QSSA’s Route C will be used in the production of the active ingredient of Actavis’ generic valsartan product for the Norwegian market for as long as Novartis’ patent, including the SPC, remains in effect.

Novartis has received the court-appointed experts’ report of 10 March 2010. Novartis disagrees strongly with the conclusions drawn in the report, and will bring a regular infringement action as soon as practicable.

The request for a preliminary injunction is hereby, against this background, revoked.”

6. The proceedings before the District Court.

The Writ of Summons from Novartis was received by the District Court on 16 April 2010. The main hearing was conducted from 6 December to 12 December 2010. The Court included expert lay judges with special knowhow within organic chemistry. Testimony was rendered by three witnesses and five expert witnesses. Reference is made to the court record.

Novartis amended its statement of claim during the main hearing, cf. the supplementary submission of 10 December 2010. The prohibition claim was made subject to a cut-off date; 13 May 2011, which is the expiry of SPC/NO 1998 024. Furthermore, Novartis amended the claim from concerning ”the pharmaceutical products addressed by the present action, which contain valsartan as an active ingredient” to ”the pharmaceutical products which contain valsartan produced by the process QSSA Route C as an active ingredient”. Novartis also submitted a new claim; a petition for a preliminary injunction (”anticipatory enforcement”).

The judgment has not been delivered within the statutory time limit. This is due to the complexity of the case.

Part II – The claims of the parties and the grounds invoked in support thereof

7. Novartis – claims and grounds invoked in support thereof

7.1 Introduction

Novartis has argued that QSSA Route C represents infringement by equivalence. There is infringement of both Claim 1 e) and Claim 1 h). It is sufficient to conclude that there is infringement of only one of the claims. The prerequisites for granting a preliminary injunction have been met. The underlying claim is proven on a balance of probabilities, and there are grounds for securing the claim. Likewise, Novartis is entitled to damages in respect of the loss the company has incurred during the period that has elapsed since Actavis started selling its valsartan products.

7.2 The infringement assessment

Novartis agrees with Actavis that QSSA Route C does not represent a direct infringement of the wording of the patent claims, but there is infringement by equivalence. The doctrine of equivalents is clearly integrated into Norwegian law, cf. the Supreme Court order of 2 September 2009 published in the 2009 volume of the Retstidende court reporter, p. 1055 (donepezil).

QSSA Route C is an obvious modification of the patent. From the perspective of principle, it is one and the same process.

The court-appointed experts before the Court of Execution were incorrect inasmuch as they have assumed that the deviation from X3 prevents equivalence.

If Actavis' arguments with regard to the requirements that need to be met in order to conclude that there is infringement are accepted, there would in practice be no room for concluding that there is infringement unless it follows from an interpretation of the patent claims. The judgment published in the 1997 volume of the Retstidende court reporter, p. 1949 (Lift-Up), does not pertain to equivalence, but to interpretation of patent claims.

The relevant skilled person in the present case is a chemist with expertise within organic chemistry and the development of processes for the production of active ingredients for pharmaceutical products or, alternatively, a team of such persons who cover this technical field.

As far as concerns the assessment as to whether identification of QSSA Route C meets the obviousness criterion, there is every indication that such assessment should be based on technical developments as per the infringement date. The question is whether the infringer or the patent holder shall benefit from developments during the period between the application date and the infringement date. However, it is not necessary to rule on

this on a general basis since QSSA Route C was obvious to the skilled person already as per the application date.

Whether the infringing object can be said to represent (only) a modification, or is instead a different method, depends, generally speaking, on the chosen level of abstraction. There will, as a main rule, be infringement if the difference lies solely in different reaction conditions, different protecting groups or a change in the reaction sequence. Reference is made to the Borgarting Court of Appeal's judgment of 2 June 2010 ("Losartan Mylan"/"Losartan II") as an example of an obvious modification.

There will, as a main rule, not be equivalence if there is a difference in terms of the main strategy for the composition of the basic structure of the molecule. Reference is made to the Borgarting Court of Appeal's judgment of 14 September 2009, LB-2008-142381 ("Losartan Krka"/"Losartan I"), as an example in such regard.

Weight must be attached, for purposes of the infringement assessment, to the fact that valsartan is a valuable invention that is entitled to enjoy fair protection. It is the product that justifies the patent. There exist no legitimate considerations that underpin the lack of product protection with regard to active ingredients that prevailed prior to the statutory amendment in 1992, when patents on pharmaceutical products were introduced in Norway. Norway is one of the last civilised [sic] countries to have introduced product patents on pharmaceutical products. The reason for this was protectionist considerations. This fact, together with the need of the pharmaceuticals industry to fund the development of new products, suggests that patent protection should be broadened. Novartis disagrees with the assessments and conclusions in the letter of 30 June 2006 from the Ministry of Health and Care Services, in which the Ministry deliberates the request from the Norwegian Association of Pharmaceutical Manufacturers for the rules to be amended such as not to enable an original pharmaceutical product based on a process patent to be replaced by a copy product for as long as the process patent remains in effect.

QSSA Route C would appear to serve no other purpose than to circumvent the patent. No technical advantages from QSSA Route C have been invoked or proven on a balance of probabilities.

The fact that Dipharma has been granted a European patent on the production of valsartan is not of decisive importance to the infringement assessment. The Opposition Division of the EPO has not examined the issue of infringement. Moreover, it is noted that the ruling of the Opposition Division is not final.

QSSA Route C represents infringement of Claim 1 e). It is a joint feature of QSSA Route C and Claim 1 e) that both include a step involving deprotection of the tetrazole group before one reaches valsartan. The deprotection methods are similar. There is nothing to suggest that the chemistry of the deprotection is influenced by what is at the other end of the molecule, where X3 is replaced by CH. The difference between QSSA's method and Claim 1 e) is that QSSA performs an additional step before one reaches valsartan. This is not sufficient to circumvent

the patent protection. This only amounts to a change in the reaction sequence. The wording of the claim does not state that the target molecule has to be achieved directly.

There is equivalence irrespective of the fact that QSSA Route C deviates from X3, which is unequivocally specified as methylene, CH2, in the last but one step of Claims 1e) and 1 h). X3 is specified in several alternatives in the original application. The patent was applied for at a stage when one had several candidates for the solution one had envisaged. The background to the narrowing down of X3 in 1996, during the application process, was that one had then reached an effective pharmaceutical product. One could therefore omit some of the target molecules that the patent claims of the original application from 1991 allowed for. Claim 1 of the approved patent (still) specifies many different target molecules. Valsartan is only one of the target molecules of NO 304 023. The patent protection is the same irrespective of whether the substituent is referred to as CH2, as in the molecule, or whether it is stated that X3=CH2. Neither can it be decisive whether the substituent from which there is a deviation has been specified in one or more alternatives. X3 forms part of the description of the target molecule and has nothing to do with the process.

There is, moreover, infringement of Claim 1 h). The equivalence assessment must be based on the premise that the skilled person is charged with identifying a synthesis of valsartan from valine that does not fall within the scope of the wording of NO 304 023. The problem is protecting the acid group in valine. The question is how this should be done.

The wording of NO 304 023 prescribes an external protecting group on the valine part. The use of an oxazolidinone ring to protect against unwanted reactions in the valine part is an obvious modification when compared to an external protecting group. Although QSSA Route C uses a different method for protecting the acid group, it is nevertheless the same process from the perspective of principle. Both processes involve a deprotection of the ester group through hydrogenolysis. QSSA Route C effects a reductive hydrogenolysis upon the oxazolidinone ring being opened. In NO 304 023, the benzyl group (Bn) is transformed on the ester group, to CO2H, carboxyl group, through hydrogenolysis.

Internal protection by way of an oxazolidinone ring and deprotection through hydrogenolysis, formed part of the prior art as per the application date. The article of Kinkel/Seebach (from 1991) is relevant in terms of determining what shall be deemed to be obvious, but not of decisive importance. The skilled person would consult Theodora W. Greene's book "Protective Groups in Organic Synthesis" (1985) (hereinafter referred to as "Greene"), and read what it says about protection of acid groups in amino acids. One will there find that oxazolidinone can offer selective protection of amino acids.

In NO 304 023, Example 54, one finds a structure that is similar to QSSA Route C. The methods in QSSA Route C and NO 304 023, in the description in Example 54, are similar in function and approach.

7.2 The prohibition claim – cut-off date and combination products

Novartis argues that the reference to QSSA Route C in the amended claim represents a limitation rather than an expansion. This process has constituted the matter in dispute ever since the proceedings before the Court of Execution. Actavis cannot circumvent the patent protection through supplementing the products by including another active ingredient in addition to valsartan.

There are no grounds for dismissing the claim with regard to combination products. Novartis has a current and acute legal interest in getting clarification in respect thereof. Reference is made to the witness Ole Bækken, General Manager, Actavis Norway AS, who gave testimony to the effect that Actavis is in the process of launching a combination product with valsartan and hydrochlorothiazide as active ingredients, and that valsartan in the combination product is manufactured through QSSA Route C. Neither are there any grounds for dismissal of this part of the claim as having been submitted too late. Novartis was not aware of Actavis' plans for the launch of combination products until 9 December 2010, during Ole Bækken's rendering of witness testimony.

7.3 The request for a preliminary injunction

The underlying claim is proven on a balance of probabilities. Reference is made to the arguments invoked by Novartis in relation to infringement assessment.

Principally, it is argued that there are grounds for securing the claim pursuant to Section 34-1, Sub-section 1, litra a, of the Civil Procedure Act. The exclusive right conferred by the patent protection is not compatible with Actavis offering a generic copy preparation in the market. The prerequisites for a preliminary injunction are in place even if the damage is of a financial nature only, cf. the ruling published in the 1967 volume of the Retstidende court reporter, p. 124.

Alternatively, if the Court finds that there are no grounds for securing the claim pursuant to Section 34-1, Sub-section 1, litra a, of the Civil Procedure Act, it is argued that there are, under any circumstance grounds for securing the claim pursuant to Section 34-1, Sub-section 1, litra b. Reference is made to the witness testimony from Petter Foss, Novartis Norway AS.

The balancing of interests pursuant to Section 34-1, Sub-section 2, of the Civil Procedure Act does not prevent the granting of a preliminary injunction. Actavis has not proven, on a balance of probabilities, that a preliminary injunction will inflict major damage of the company.

Besides, reference is made to Norway's international obligations pursuant to Article 50 (1) of the TRIPS Agreement.

7.4 The claim for damages

All prerequisites for awarding damages are met. There is a basis of liability pursuant to Section 58, Sub-section 1, of the Patents Act. Actavis has acted negligently. There is no basis for

a discretionary reduction in the amount of damages. The negligence assessment in the present case must correspond to that of the Borgarting Court of Appeal's judgment of 30 January 2008, LB-2006-186315 (Pfizer-Sandoz-Setraline).

Novartis has suffered an economic loss as a result of Actavis having launched its generic valsartan products. Loss of earnings from sales that Novartis would have made are estimated roughly on the basis of the total number of packets of generic valsartan that Actavis has sold since its launch in the Norwegian market, multiplied by the prices from Novartis to pharmacies, but with a discretionary deduction in respect of factors of uncertainty, cost savings and wholesaler margins. The total turnover of Novartis' valsartan products without Actavis' launch would have been NOK 18 million. Reference is made to the table showing the sales of Actavis. The deduction, inclusive of the commission to wholesalers, is put at NOK 3 million.

Novartis has entered the following statement of claim:

1. Actavis Group PTC hf and Actavis Norway AS are prohibited, until 13 May 2011, from offering for sale, bringing to the market or using the pharmaceutical products which contain valsartan produced by the process QSSA Route C as an active ingredient, and from importing or possessing said products with such intent, and are ordered to withdraw, to the extent possible, such products from the Norwegian market.

2. This prohibition/order shall take effect immediately in the form of a preliminary injunction, on such conditions, if any, as may be stipulated by the Court.

3. Actavis Group PTC hf and Actavis Norway AS are ordered to indemnify Novartis AG and Novartis Norway AS in respect of the loss incurred by them, in an amount determined at the discretion of the Court, as the result of the launch of generic valsartan in Norway by Actavis Norway AS and Actavis Group PTC hf.

4. Actavis Group PTC hf and Actavis Norway AS are ordered to indemnify Novartis AG and Novartis Norway AS in respect of the legal costs incurred by them.

8. Actavis – claims and grounds invoked in support thereof

8.1 The infringement assessment

Actavis has argued that the active ingredient valsartan in Actavis' product is produced though a process that does not represent infringement of patent NO 304 023. The parties agree that QSSA Route C does not fall within the scope of the wording of the patent claims of NO 304 023. Neither does QSSA's process represent infringement by equivalence.

The facts of the case are the same as when Novartis revoked the [petition for a] preliminary injunction pending before the Court of Execution. Actavis' legal arguments with regard to non-infringement have been strengthened. It is noted that Novartis has lost opposition proceedings before the EPO concerning one of the patents associated with QSSA's

process. A preliminary injunction against Actavis in Finland with regard to valsartan has been lifted. The position of Actavis has been strengthened although none of the said cases have been resolved with final effect.

Equivalence is a matter of interpretation of the patent claims, and a strict norm must be applied. A patent right is a prohibitive right, cf. Sections 57 to 59 of the Patents Act, which contain rules on criminal sanctions. This implies that clear authorisation is a prerequisite for imposing a prohibition. Reference is made to the Borgarting Court of Appeal's judgment of 30 May 2007 (atorvastatin).

The Protocol to Article 69 of the EPC stipulates that weight shall be attached to the following main considerations in determining the scope of protection under the patent: The patent holder shall be offered reasonable protection and third parties shall be offered a reasonable degree of certainty. Reference is made to the legislative history, in the form of the NU 1963:6 Green Paper, p. 186, and to page 1756 of the judgment published in the 1997 volume of the Retstidende court reporter, p. 1749 (Lift-Up). The Lift-Up Judgment concerns equivalence – not only principles of interpretation.

The statements of the Supreme Court in Paragraph 33 of the ruling published in the 2009 volume of the Retstidende court reporter, p. 1055 (donepezil), implies that the assessment of equivalence must be based on an interpretation of the patent claims. There is no doubt that the alternative method exhibits inventive step. The court order delivered by the Supreme Court represents a clarification and narrowing of patent protection.

Considerable weight must be attached to case law from other European countries. Two benchmark countries are England and Germany. Reference is made to the 21 October 2004 ruling of the House of Lords ("Kirin Amgen") and to the 12 March 2002 ruling of the Federal Court of Justice of Germany ("Custodiol II"). Patent protection has in both rulings been determined on the basis of an interpretation of the claims.

As far as analogous process patents in particular are concerned, one must for purposes of the interpretation take into consideration that the general rule with regard to such patents is that anyone may freely produce the same product by using other processes than the patented one. An analogous process patent is not intended to offer a level of protection that corresponds to that offered by a product patent, since that would represent a circumvention of the previously applicable prohibition against granting such patents in respect of pharmaceutical products. This was also reflected in the practice of the Norwegian Industrial Property Office in its processing of applications pertaining to pharmaceutical products prior to 1 January 1992. The Norwegian Industrial Property Office ensured that the claims were not made excessively comprehensive. Reference is made to a proposal presented by the Norwegian Association of Pharmaceutical Manufacturers in 2005 for reinforcing the protection offered under analogous process patents, which was rejected by the Government and the Storting. Reference is made to the letter of 30 June 2006 from the Ministry of Health and Care Services.

Case law does not provide any basis for grouping infringements into different types for purposes of determining the detailed meaning of the doctrine of equivalents, as suggested by Novartis. The infringement assessment must be made on the basis of the patent claims, which will differ from case to case. Any abstractions not merited by the patent claims cannot be applied for purposes of the comparison between the patent claims and the infringing object.

Methods of a different chemical nature from those stipulated in the patent claims will under any circumstance fall outside the scope of the protection conferred by the patent.

The question of which process is the best one is irrelevant as far as the infringement assessment is concerned. There is no requirement that the infringing object shall represent a real advantage or technical innovation in order to fall outside the scope of patent protection. Reference is made to the Borgarting Court of Appeal's judgment of 14 September 2009 ("Losartan I"). It would not be an argument in favour of infringement that a process is inferior. Actavis is of the view that QSSA Route C is a process that is superior to NO 304 023, but will not invoke this as an argument in favour of concluding that there is not infringement.

The question presented by the present case is whether there is an obvious modification. The two other criteria for equivalence will not be of relevance in relation to the infringement of an analogous process patent.

The question is what the skilled person would perceive that the patent claims stipulate as being encompassed thereby. It may also be the case that the skilled person finds that there is no room for any modification of the patent claims. The skilled person for purposes of the present case is an organic chemist. The skilled person will read the patent claims in view of common general knowledge within the art. It cannot be assumed that the skilled person is in possession of the same amount of knowledge as Dr Adlington. Patent journals and articles do not form part of common general knowledge within the art.

The date of reference for the skilled person's evaluation is the priority date. Reference is made to the Eidsivating Court of Appeal's judgment of 25 July 1988 (timolol). Reference is also made to policy considerations; it would be unreasonable for the scope of patent protection to be broadened over time as the result of discoveries made by others. QSSA Route C did not constitute prior art as per the priority date. Williams/Greene do not teach separation of only a bond on the oxazolidinone ring. The thesis of Kinkel/Seebach was published after the priority date, and even if the skilled person had located Kinkel/Seebach he would himself have had to identify the correct substituents.

There is no reason to grant protection beyond that clearly and unequivocally merited by the wording in the event of a low inventive step. Reference is made to the ruling published in the 1964 volume of the Retstidende court reporter, p. 1165 (Plastic Window). Valsartan is not a pioneering invention. It is a so-called "me-too product" when compared to other sartans, which had been invented before valsartan.

QSSA Route C is not an obvious modification of NO 304 023 and does, on the contrary, differ therefrom in material respects.

The infringement assessment must be based on the premise that it was up to Novartis to protect the synthesis routes it wanted to protect. Novartis has made a choice. There is no room for an extensive interpretation where conscious limitations have been introduced.

As far as concerns the positions R1, R2, R3, X2 and A and B in Formulas I and II of Claim 1, the definitions include a considerable number of alternatives. Two of the substituents are unequivocally defined: X1 = CO and X3 = CH2 (methylene). The patent claim does not allow for any of these positions to be replaced by ring structures. The skilled person would perceive the definition of X1 and X3 as a conscious limitation. The description of the various substituents is very comprehensive, but also in the description it is always the case that X1 is CO, and always the case that X3 is CH2, methylene.

If Novartis' arguments to the effect that patent protection should be expanded such as to allow X1 and X3 to be replaced by other compounds [are accepted], Novartis would in actual fact be granted a product patent. The holders of the analogous process patent have no legitimate interest in being alone in the market until the expiry of the patent term.

Furthermore, Claims 1 e) and 1 h) must be interpreted as defining how one gets from the precursor molecule and to the target molecule specified in Formula I. Both claims have in common the fact that they only cover the last step of the synthesis leading up to valsartan. The claims do not include deprotection in preceding steps of the process. The preceding steps described in the examples are not protected.

Both claims encompass deprotection steps. There is no limitation with regard to what protecting group may be used. Neither is there any limitation with regard to what reaction conditions are used.

There is nothing, whether in the wording of the patent claims or in the description, to indicate that R2 may form part of an oxazolidinone ring, as used in QSSA Route C.

Claim 1 e) encompasses a step in which a protecting group is separated from the tetrazole group and valsartan is generated directly. Consequently, the starting material used is a compound that corresponds to valsartan, apart from the protecting group on the tetrazole group. The QSSA process differs from Claim 1 e) in that a protecting group on the tetrazole group in separated in the last step but one, whilst the oxazolidinone ring still remains unopened. The QSSA process therefore diverges from Claim 1 e) of the disputed patent both in relation to the starting material and in relation to the outcome. It is in direct contradiction of the wording of the claim to replace X3 by anything other than methylene. The skilled person will interpret the claims as being limited in such a way that X3 can only be methylene. Reference is made to the report from the court-appointed experts before the Court of Execution.

Claim 1 h) encompasses a final step of the patent's synthesis, in which R2 is a substituted group that is converted to an R2 that is carboxy. This is in actual fact a step in which a protecting group is separated from carboxy in position R2, and one achieves valsartan. The protecting group may, inter alia, be an ester. The starting material used corresponds to valsartan, apart from the protecting group on carboxy. QSSA Route C involves no deseparation of an ester protecting group on carboxy, whilst there is instead an opening of the oxazolidinone ring. The QSSA process therefore diverges from Claim 1 h) of the patent.

It is noted that both the court-appointed experts before the Court of Execution and the Opposition Division of the EPO have found that the QSSA Route C process is novel and inventive. Reference is also made to the expert witness Professor Barrett.

8.2 The prohibition claim – combination products

Alternatively, in the event that the Court concludes that there is infringement, Novartis cannot under any circumstance be granted a prohibition in respect of any other product than mono valsartan. The original statement of claim entered by Novartis, prior to the amendment of 10 December 2010, only concerned mono valsartan, which Actavis has already launched in the market. SPC/NO 1998 024 pertains to mono valsartan only. The amendment to the statement of claim entered by Novartis represents an expansion that it is too late to enter during the main hearing. Protection of other products that those falling within the scope of SPC 1998 024 raises a number of unresolved issues. Novartis having included combination products in the prohibition claim has resulted in Actavis being taken by surprise.

8.3 Petition for a preliminary injunction.

Actavis has no procedural objections against the submission of the petition.

Actavis denies that there are grounds for securing the claim within the meaning of Section 34-1, Sub-section 1, of the Civil Procedure Act. The only damage, if any, sustained by Novartis would be in the form of economic loss. Moreover, the damage sustained by Actavis as the result of a preliminary injunction would be clearly disproportionate to the interests of Novartis in the injunction being granted, cf. Section 34-1, Sub-section 2, of the Civil Procedure Act. Actavis is already on the market.

8.4 Damages

Alternatively, it is argued, in the event that there is infringement, that there is no basis of liability pursuant to Section 58, Sub-section 1, of the Patents Act. Actavis has not acted intentionally or negligently. It is noted that Actavis postponed its launch in the market until after the proceedings before the Court of Execution had been called off, and after one have received the report of the court-appointed experts. In addition, Actavis had received the decision of 23 March 2010 from the Opposition Division of the EPO to the effect that EP 1 533 305 was being upheld.

Alternatively, the liability for damages must be reduced on a discretionary basis, even if the Court concludes that Actavis has acted negligently, cf. Section 58, Sub-section 1, second sentence, of the Patents Act.

It is argued, in the event that the Court finds that Actavis has not acted negligently, that it would not be reasonable to award damages.

The amount of damages, if any, shall under no circumstance exceed the earnings realised by Actavis from the sale of valsartan products.
Actavis has entered the following statement of claim:

1. The Court finds in favour of Actavis Norway AS and Actavis Group PTC hf.

2. The petition for a preliminary injunction is not upheld.

3. Novartis AG and Novartis Norway AS are ordered to indemnify Actavis Norway AS and Actavis Group PTC hf in respect of their legal costs.

Part III – The observations of the Court.

9. Legal underpinnings.

9.1 The doctrine of equivalents – key sources of law

The parties agree that QSSA Route C does not represent a direct infringement of the patent claims. The question is whether QSSA Route C represents an infringement of Novartis' patent NO 304 023 by equivalence.

The scope of patent protection is governed by Section 39 of the Patents Act, which is worded as follows:

> "The extent of the protection conferred by a patent shall be determined by the patent claims. The description may serve as a guide to the understanding of the patent claims."

Section 39 of the Patents Act corresponds to Article 69, No. 1, of the European Patent Convention (the "EPC"), which is also binding on national Norwegian patents, cf. Article 3, No. 4, of Protocol 28 to the EEA Agreement on copyright [sic]. Norway has subsequently acceded directly to the EPC, with effect from 1 January 2008. Article 69, No. 1, of the EPC is worded as follows:

> "Article 69
> Extent of protection
> (1) The extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims.
> - - - ."

There is a presumption that Section 39 of the Patents Act should have the same meaning as Article 69, No. 1, of the EPC, cf. Paragraph 27 of the judgment published in the 2009 volume of the *Retstidende* court reporter, p. 1055 (donepezil).

The patent claims form the basis for determining the scope of patent protection. The meaning of the patent claims shall be determined on the basis of an interpretation thereof. Relevant factors of interpretation are objective interpretations of the wording, the description and any drawings. The present case does not raise any special issues with regard to interpretation. The Court will therefore not address the rules of interpretation in any further detail.

It is an acknowledged fact that Section 39 of the Patents Act must be supplemented by a doctrine of equivalent protection, cf. Paragraph 28 of the judgment published in the 2009 volume of the *Retstidende* court reporter, p. 1055 (donepezil), in which the Supreme Court refers to Article 2 of the Protocol on the Interpretation of Article 69 EPC. Article 2 of the Protocol was added in 2000 and entered into force on 13 December 2007. The Protocol is an integral part of the Convention. The Protocol is worded as follows:

> ”Article 1
> General principles
> Article 69 should not be interpreted as meaning that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. Nor should it be taken to mean that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patent proprietor has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patent proprietor with a reasonable degree of legal certainty for third parties.
>
> Article 2
> For the purpose of determining the extent of protection conferred by a European patent, due account shall be taken of any element which is equivalent to an element specified in the claims.”

There is no statutory definition of equivalence. This term denotes the outcome if it is concluded that there is infringement, provided that the infringing object falls outside the direct scope of the patent claims. Guidance on the doctrine of equivalents must be sought from case law and legal theory. What degree of similarity is required to conclude that there is infringement of patent will depend on a specific and discretionary assessment. In the judgment published in the 2009 volume of the *Retstidende* court reporter, p. 1055 (doenpezil [sic]), the first justice to cast a vote stated the following:

> ”
> - - -
> (28)
> Article 2 [of the Protocol to Article 69 EPC] on equivalent protection must be said to express a more or less unified European practice, in which Norway has also participated. I perceive the so-called doctrine of equivalents as an attempt at a theoretical description as to when there is, based on said practice, such a degree of similarity - equivalence – between the infringing object and the subject matter of the patent that it falls within the scope of patent protection. I therefore conclude that one must, also in the interpretation of Section 39 of the Patents Act, allow for what the Court of Appeal has in the present case referred to as a more discretionary identity assessment, or equivalency assessment. This has been assumed in several Court of Appeal rulings, although the Supreme Court has not ruled on the issue thus far.
>
> (29)
> In the present case, the Court of Appeal quotes the judgment rendered by the Borgarting Court of Appeal on 28 April 2008 (LB-2007-9840), which concerned the generic production of the pharmaceutical product lansoprazole. The Court of Appeal is of the view that the said judgment adequately reflects applicable law within the field. Reference is made to the following excerpt from that judgment:
>
> «As far as the more detailed scope of equivalence protection is concerned, Norwegian case law offers little guidance. The Court of Appeal is of the view that, in particular, Norway's obligations under international law and concern for European legal unity within the area of patent law suggest that considerable weight should be attached to the EPC and convention-related case law. Although there is no clearly

defined content to equivalence protection internationally either, there would appear to be broad-based support for three criteria for equivalence: (1) The infringing object (here: the alternative method for producing lansoprazole) has to solve the *same problem* as does the patented invention, (2) the modifications made must have been *obvious to a skilled person*, and (3) the infringing object must not form part of *the state of the art* (known and freely available technical knowledge), cf. Are Stenvik: "*Patentrett*" ("Patent Law"), 2006, page 392. The criteria are to be found in, *inter alia*, key English and German rulings, see for example Improver Corp. vs. Remington Consumer Products Ltd. [1990] FSR 181 and the 12 March 2002 ruling of the Federal Court of Justice of Germany in Case No. X ZR 73/01 "Custodiol II".»

(30)
The parties to the present proceedings agree that [the assessment] shall be based on the three criteria, as expressed by Are Stenvik in "*Patentrett*" ("Patent Law"), 2006, page 392. I also consider this to be an appropriate basis [for the assessment]. As furthermore noted by the Court of Appeal in the quoted judgment, the criteria relating to obvious modifications and the state of the art are the most relevant ones as far as analogous process patents are concerned. The disagreement in the present case is exclusively concerned with the criterion that the modifications made must have been obvious to a skilled person.
(31)
Specifically, the disagreement concerns the issue of whether the patent protection extends to other processes for the production of the product, or only to modifications to the processes patented by the patent holder. The question is, in other words, whether the term "modifications" in the criterion is of independent relevance. This is, as noted by the Court of Appeal in the present case, a purely legal question. The Court of Appeal answers this question in the affirmative, and provides the following reasons in support of such conclusion:

«The Court of Appeal is of the considered opinion that the use of the term modification in the second equivalence criterion - that the modification must have been obvious to a skilled person - is of independent relevance in the sense that other methods fall outside the scope of the protection afforded, even if it was *obvious to a skilled person* to identify and use such method. A different interpretation would be too far from the basic premise and main rule under the Patents Act. The Court of Appeal disagrees with the Court of Execution in this regard.

It cannot be a requirement, as suggested by Eisai and Pfizer, that the alternative method/process must, in order to fall outside the scope of patent protection, be an innovation within the relevant field or, more generally, a better method than the protected one. The Court of Appeal disagrees with the Court of Execution in this regard as well. It may be reiterated that the law previously did not permit the patenting of the product, only of the process (the method), and that it is perfectly legal to attempt to find other processes that fall outside the scope of patent protection. »

(32)
I am satisfied that the interpretation of Section 39 of the Patents Act expressed by the Court of Appeal is not incorrect. The point of reference is constituted by the patent claims and the method or methods described therein. It is the process that is protected, and the patent applicant is, as emphasised by Krka, at liberty to claim protection in respect of any conceivable method that he is able to define as per the application date. The doctrine of equivalents, as described by myself, is a tool for extending the protection to methods that are just about identical, and which therefore can be described as modifications to the patent.

(33)
Patent protection would otherwise represent an obstacle to further research and development, and to legitimate competition in the market. This is especially so when the patented method does not in itself represent something novel that can be patented, as is the situation with the analogous process patents. The decisive factor must therefore be a specific assessment as to whether the method is sufficiently similar to the process in the patent claim to allow it to be characterised as just about identical. Anything else would be to deviate too far from the basic premise that the patent claim determines the scope of protection.
- - - ."

European case law is of relevance to cases that are to be resolved pursuant to Norwegian law, like the present case. It is noted that Section 39 of the Patents Act corresponds to Article 69, No. 1, of the EPC, which is

the same for all countries that have acceded to the Convention, cf. above. However, case law has evolved somewhat differently in different countries, as far as the enforcement of patent rights is concerned. The same does not apply to the rules on patentability. Reference is made to Are Stenvik, "*Ekvivalenslæren i utvikling*" ("Developments in the Doctrine of Equivalents") in Aase Gundersen and Are Stenvik (Eds.), "*Aktuell immaterialrett*" ("Contemporary Intellectual Property Law") (2008), hereunder Item 2.2 on p. 365.

Reference is also made to Gyldendal Rettsdata, Note 185 to Section 39 of the Patents Act, by Are Stenvik, last main revision 18 August 2010, where is stated the following:

> " - - -
> Generally speaking, one may say that virtually all countries with a well-developed patent system practise one form or other of equivalence protection (the most important exception being England, cf. the ruling of the House of Lords in Kirin-Amgen v. Hoechst [2005] RPC 169), although the prerequisites for such protection vary somewhat from country to country. - - - "

Reference is also made to Stenvik (2006), p. 394, second full paragraph, where is stated the following:

> " - - -
> It is difficult to reach any other conclusion than that *Kirin Amgen* expresses a distinctive legal understanding that differs from both the predominant tendencies in Europe and the legal understanding in the United States. Given this background, one probably should not accord much weight to the said ruling."

The Court will, under reference to the above, base its specific infringement assessment on Norwegian case law, cf. Item 10 below. The Court refers, in particular, to the Borgarting Court of Appeal's judgments of 30 January 2008, LB-2006-186315 (sertraline), 28 April 2008, LB-2007-9840 (lansoprazole), 14 September 2009, LB-2008-142381 (losartan Krka/losartan I) and 2 June 2010, LB-2009-134493 (losartan Mylan/losartan II), cf. Gyldendal Rettsdata, Note 185 to Section 39 of the Patents Act, by Are Stenvik.

9.2 Interpretation and infringement assessment: A two-stage model.

The Court will take the approach that the scope of patent protection shall be determined on the basis of a two-stage model. This means that the patent claims first need to interpreted. Once the meaning of the patent claims has been determined, a comparison is made with the object alleged to infringe the patent (stage 2). Reference is made to Are Stenvik, "*Ekvivalenslæren i utvikling*" ("Developments in the Doctrine of Equivalents") in Aase Gundersen and Are Stenvik (Eds.), "*Aktuell immaterialrett*" ("Contemporary Intellectual Property Law") (2008), pp. 367-368. The following is quoted from the said article:

> " - - - . If the infringing object falls directly within the literal meaning of the patent claims, there is patent infringement, in the form often referred to as *identical utilisation*. If, however, the comparison uncovers differences, one needs to move on to the equivalence assessment. If the equivalence requirements are met, it must be concluded that there is infringement – despite the object falling outside the literal meaning of the patent claims. This is often referred to as *equivalent utilisation*. The doctrine of equivalents consequently implies that the *extent of the protection conferred by the patent* ("Schutzumfang") may extend beyond the scope defined by the patent claims; what is often termed the *subject matter* of the patent. - - - . "

The Court is of the understanding that the parties differ in their interpretations of the doctrine of equivalents. Actavis has argued that equivalence is a matter of interpreting the patent claims. Novartis has argued that the scope of patent protection extends beyond direct infringement of the patent claims, since it also encompasses obvious modifications. Both parties have invoked the judgment published in the 2009 volume of the *Retstidende* court reporter, p. 1055 (donezepil [sic]), in support of their views.

The Court takes the view that it may be difficult to make a clear distinction between the two approaches to the doctrine of equivalents on the basis of case law. The approach does not necessarily have to be of decisive importance to the outcome of each individual case. The outcome depends on a specific discretionary assessment of both a technical and a legal nature.

However, in the present case the difference in approach appears to be of practical relevance. It is noted that the parties differ in their views with regard to the importance of one of the substituents of the base substance, X3, being unequivocally defined, cf. Item [sic] above under Items 7 and 8. The Court will revert to this below.

9.3 The state of the art as per the priority date or as per the infringement date?

The Court takes the view that applicable law provides no definite answer to the question as to the date of reference for purposes of determining whether the modification was obvious. Reference is made to Stenvik (2006), p. 403, and to Gyldendal Rettsdata, Note 185 to Section 39 of the Patents Act, by Are Stenvik, last main revision 18 August 2010, with reference to the Borgarting Court of Appeal's judgments of 30 January 2008, LB-2006-186315 (sertraline) and 2 June 2010, LB-2009-134493 (losartan Mylan).

Actavis has argued that the application date (the priority date) must be the date of reference. Actavis has invoked policy considerations, and the Eidsivating Court of Appeal's judgment of 25 July 1988 (LE-1987-458). The latter judgment concerned the issue of infringement of an analogous process patent relating to the end product timolol. The alleged infringer had used an intermediate, azetidinol, that was not mentioned in the patent claim. The Court of Appeal concluded that the said intermediate fell outside the scope of the wording of the patent claims. The Court of Appeal thereafter examined whether there was infringement by equivalence. It follows from the reasons presented by the Court of Appeal in support of its ruling that this assessment was based on whether the Merck patent, under the doctrine of equivalents " - - - can be interpreted to mean that the Star process, involving the intermediate azetidinol, nevertheless encompasses the patent." The Court of Appeal concluded that "such an extensive interpretation" was not justified. The Court of Appeal operated on the assumption that the "patent interpretation" should be based on the situation as per the application date. The Court is of the understanding that the Court of Appeal examined, in its judgment of 25 July 1988, the issue of equivalence on the basis of other criteria than those defined by subsequent case law, cf. the judgment published in the 2009 volume of the *Retstidende* court reporter, p. 1055 (donepezil), cf. Item 9.1 above. The issues of principle involved in using the application date as the date of reference for purposes of determining the state of the art are not addressed in the judgment of the Eidsivating Court of Appeal. The alternative date discussed is the date on which it was discovered that timolol could be used in new treatments (treatment of glaucoma – in addition to heart disorders). The judgment of the Eidsivating

Court of Appeal therefore cannot, in the opinion of the Court, be invoked in support of a general rule to the effect that the application date shall be the date of reference for purposes of determining the state of the art.

If the judgment of the Eidsivating Court of Appeal could be interpreted as expressing a general rule to the effect that the application date shall be the date of reference, such rule would nevertheless be in conflict with pronouncements in subsequent Court of Appeal judgments and in legal theory. The subsequent sources of law take precedence over the judgment of the Eidsivating Court of Appeal, which is more than 20 years old.

Since the state of the law is unclear, the District Court has to identify the appropriate date of reference on the basis of policy considerations. In Stenvik (2006), p. 403, it is stated that good arguments can be invoked in favour of both solutions, possibly with the balance tilting slightly in favour of the infringement date. It is further stated, on p. 404, that:

> ”
> - - -
> The principal advantage of using the application date as the date of reference is that it is simpler, from the perspective of legal practicality – one does not have to decide what should be adopted as the relevant infringement date, and one does not have to decide when the infringement took place – and it simplifies matters because the scope of patent protection remains unchanged throughout the patent term. On the other hand, these problems do not appear to have given rise to major difficulties under US case law, which may suggest that the practical difficulties are of somewhat limited importance.
>
> The disadvantage of using the application date as the date of reference is that it may in certain cases reduce the value of the patent protection to an unreasonable degree, because subsequent developments make it easier to circumvent the patent. Such a solution would seem particularly unreasonable where the invention takes the form of a general theory. Moreover, it may be noted that the patent holder will, if the infringement date is used as the date of reference, have an incentive to publish new information on how to best utilise the invention on an ongoing basis, because such information may expand the scope of equivalent protection. - - - . ”

The Court has concluded that the state of the art as per the infringement date is the appropriate basis on which to assess whether the modification was obvious. This means that the patent holder will benefit from subsequent technical developments. This would seem reasonable, given the time and costs devoted to developing the patent. The costs continue to be incurred after the date of the patent application. This must be contrasted with the observation that the infringer himself has not contributed to the development of the prior art used to circumvent the patent.

10. The infringement assessment

10.1 Introduction

The question is whether QSSA Route C constitutes an obvious modification of NO 304 023.

There is no need to examine the two other equivalence criteria here. It is evident that both methods solve the same problem, and the parties agree that the infringing object does not form part of the state of the art.

10.2 The relevant patent claims – interpretation

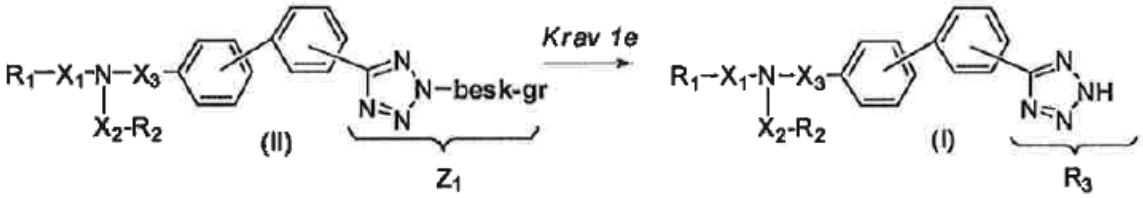
The comparison shall be based, on the one hand, on the patent claims and, on the other hand, on the process actually used in the production of valsartan in the products of Actavis; QSSA Route C. When the Court uses the terms the "Novartis Process" or the "Novartis 023 Patent" in the following it refers to the contents of patent NO 304 023.

The Court is of the view that the patent claims do not give rise to any issues of interpretation. The Court will, for ease of reference, summarise its understanding of the contents of the patent claims as follows:

Patent claim 1e protects an:

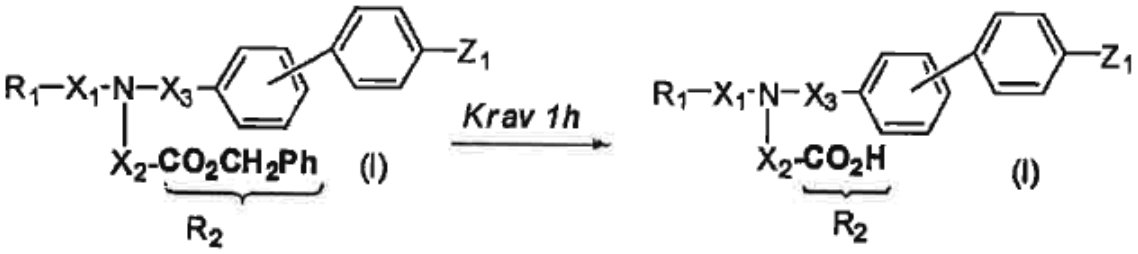
"Analogous process for the production of a therapeutically active compound with formula (I)
--- characterised in that one
e) in a compound with formula (II) converts Z1 to R3 -- Z1 means a residual that can be converted to R3"

Since it has been specified in the introductory part that R3 may be 5-tetrazolyl, Claim 1e may in general be illustrated by way of the reaction below, in which the tetrazole ring is deprotected. Claim 1e does not designate any specific protecting groups or under what reaction conditions these shall be separated/removed.



Patent claim 1h
protects an:
"Analogous process for the production of a therapeutically active compound with formula (I)
--- characterised in that one
h) for the production of a compound with formula (I) ---, where R_2 means carboxy, derived from an achieved compound with formula(I) --- where R2 means --- phenyl lower alkoxy-carbonyl, -----, converted to a compound with formula (I), where R_2 is carboxy."

Since it specified that R2 may be an ester (phenyl lower alkoxy-carbonyl), Claim 1h may in general be illustrated by way of the reaction below, in which a benzyl ester derivative is separated to generate a carboxylic acid. Claim 1h does not specify under what reaction conditions the ester group shall be separated.



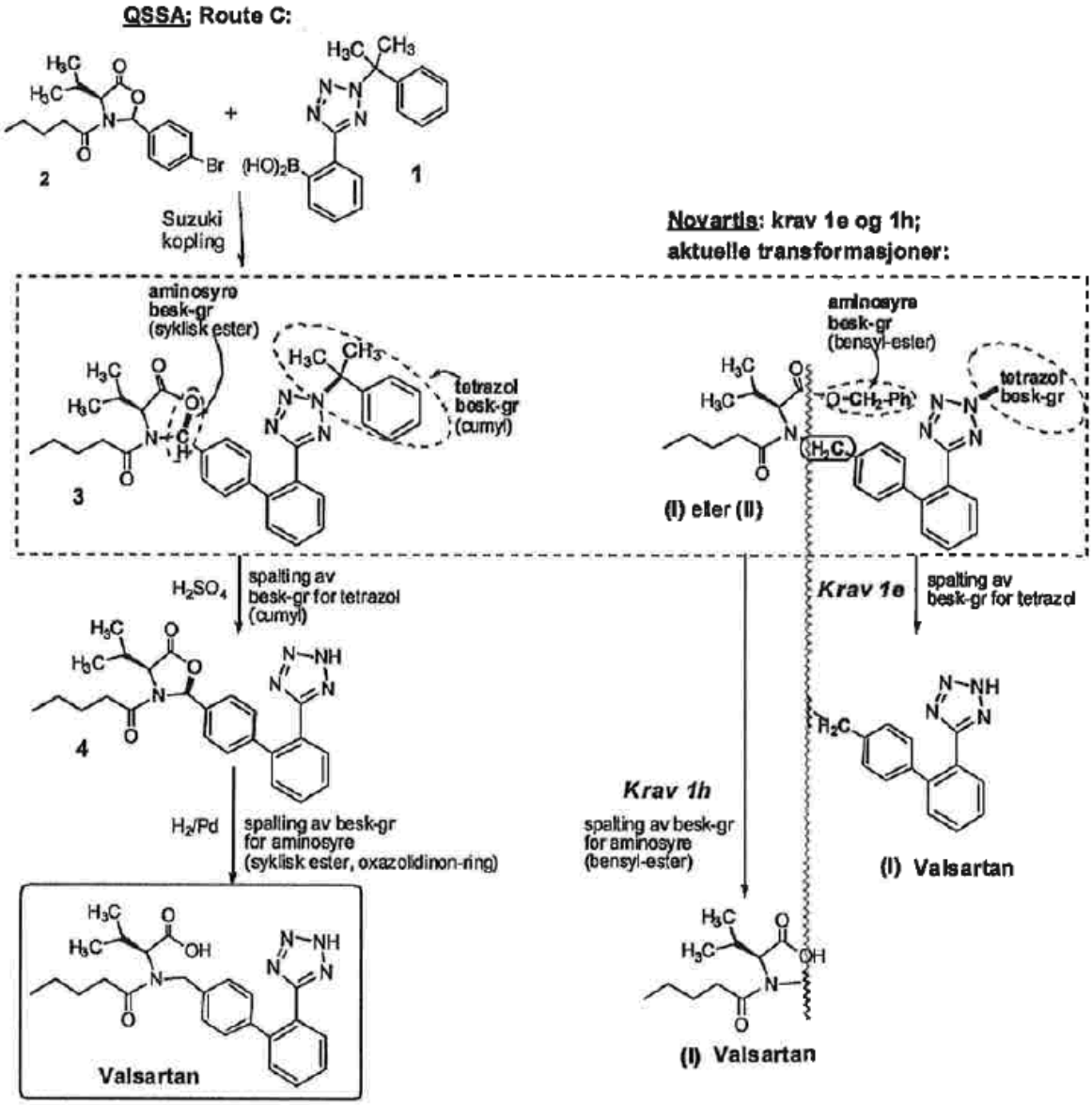
10.3 Comparison between QSSA Route C and NO 304 023.
- A different method or (only) a modification of the patent?

The Court will in the following make a comparison between QSSA Route C and NO 304 023.

The question is whether QSSA Route C is a different method than NO 304 023 or only a modification, cf. the judgment published in the 2009 volume of the *Retstidende* court reporter, p. 1055, paragraphs 31-33.

The Court is of the understanding that QSSA Route C, as utilised by Actavis, can be illustrated as shown in the diagram below. The corresponding reaction steps encompassed by Novartis' Patent Claims 1 e) and 1 h) for the production of valsartan are shown in parallel.

Since Claims 1 e) and 1 h), which are illustrated with general formulas in the diagrams above, cover a large number of compounds through interpretation of R1-2, X1-3 and Z1, the relevant transformations from the Novartis 023 Patent are illustrated below by the most obvious and relevant molecule functions under NO 304 023, in order to highlight the issues. The protecting groups are indicated, and the bonds broken in subsequent reactions are marked by thick lines.



i) The synthesis steps

QSSA produces intermediate **3** from the building blocks **1** and **2** by way of a so-called Suzuki coupling. The chiral part of valsartan has its origin in base substance **2**, which is a valine (amino acid) oxazolidinone derivative. The oxazolidinone is formed earlier in the QSSA process by way of cyclocondensation of valine, bromobenzaldehyde and valeroyl chloride, which are also used in the Novartis Process. The condensation operates via an imine intermediate, which is, incidentally, comparable to the imine also described by Novartis as used in earlier steps (e.g. 16, 22). This illustrates the similarity between the two processes, but is otherwise of minor relevance as far as infringement of patent is concerned, as these earlier steps do not fall within the scope of the patent claims.

The two key deprotection reaction steps are shown for the QSSA process; **3** → **4**, separation of tetrazole protecting group (cumyl) and **4** → valsartan, release of carboxyl from cyclic ester (oxazolidinone). It follows from the diagram that both reaction steps are in large part described in Claims 1e and 1h of the disputed patent. Claim 1e entails no restrictions with regard

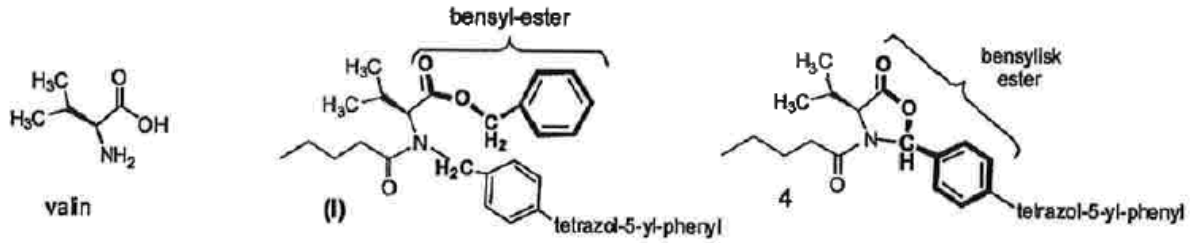
to what protecting groups are removed from the tetrazole ring, and does not specify reaction conditions for separation. QSSA's separation of cumyl is therefore encompassed by Claim 1e if the other conditions in the molecule are in place. Claim 1h shows a classic ester separation, whilst QSSA effects an oxazolidinone/cyclic ester separation to release the valsartan product.

ii) Intermediates

In both steps, QSSA uses compounds that contain an oxazolidinone ring, a cyclic, ring-enclosed ester, which results in the structure of compounds **3** and **4** deviating somewhat from that of Novartis' corresponding intermediate (I)/(II). In order to determine whether the two processes are "just about identical", cf. the judgment published in the 2009 volume of the *Retstidende* court reporter, p. 1055, it is necessary to make a comparison on the basis of potential definitions of the groups R1-2, X1-3 and Z1, which from part of the molecule structures (I) and (II) under NO 304 023, and QSSA's intermediates **3** or **4**.

Selection of the most obvious molecule functions for R1-2, X1-2 and Z1 from NO 304 023 shows that structures (I)/(II) are very similar to QSSA's intermediates **3** or **4**. The parties agree that the 023 Patent defines X3 exclusively as a CH2 group (methylene). In the corresponding position, QSSA uses a CH group (methine), due to their selection of a cyclic ester, oxazolidinone, as carboxy-protecting group. Consequently, the QSSA process is not directly encompassed by the wording of the 023 Patent. It must therefore be examined whether QSSA's process is an obvious modification of NO 304 023, cf. the judgment published in the 2009 volume of the *Retstidende* court reporter, p. 1055.

The pharmaceutical product valsartan is built on the basis of the amino acid valine (see below), which is an essential chiral part of the molecule. Consequently, valsartan is a valine derivative. The last and final step of both processes in the diagram above involves separation of a valine (amino acid) ester function to release the amino acid derivative valsartan. A large number of classic protecting groups, including esters, are used within amino acid and peptide chemistry. NO 304 023 makes no reference to specific "phenyl lower alkoxy-carbonyl" groups to define the ester R2, but it follows from Example 54 of the patent that a benzyl ester is a natural choice; see structure (I) below. One of the most important characteristics of benzyl esters is that they can, unlike other alkyl esters, be separated through reductive separation by way of hydrogenolysis (H2/Pd, room temp, 1-24 h).



QSSA has chosen to protect valine in the form of a cyclic internal ester called oxazolidine-5-one. Oxazolidinones are alternatively called *azlactones*, which can be "translated" as *azotic ring-enclosed ester* (az = nitrogen, lactone = cyclic ester). A 2-substituted 4-alkyloxazolidine-5-one, corresponding to QSSA's intermediate **4** above, is a well-known derivative of amino acids and has for 25 years been referred to in organic chemistry research literature as a "protected amino acid" which prevents, *inter alia*, racemisation of the stereogenic amino acid centre. Such compounds are described in chemistry hand books and produced by cyclocondensation of an amino acid, an aldehyde and an acyl chloride. This is the same method as is used by QSSA at the outset for oxazolidinone derivatisation of valine for production of the base substance **2**. However, it effects a classic complete deprotection of oxazolidinone-protected amino acids with the result that only the "naked" amino acid, in this case valine, is regenerated. It is therefore not relevant to use the classic separation method for production of the valine-derivative valsartan. However, QSSA's oxazolidinone intermediate **4** contains a cyclic internal benzylic ester (indicated by thick lines above), and QSSA has therefore chosen hydrogenolysis (H2/Pd); the same method of separation as Novartis, to selectively separate the benzyl ester function. Such a combination of using a benzylic oxazolidine-5-one and a subsequent selective reductive separation of the benzyl ester function is known previously for similar compounds.

Although oxazolidine-5-one is a natural choice of protecting group for an amino acid, the other characteristics of the oxazolidinone intermediate beyond the benzyl ester function are irrelevant in the present context, since Patent Claim 1 h) only covers the ester separation for the release of the carboxy function. The cyclic benzyl ester used by QSSA (**4**) must be held to be an obvious choice of protection function for carboxyl in an amino acid. Incidentally, Claim 1 h) does not use the term "protecting group" for the transformation from ester to carboxy. The fact that both QSSA and Novartis perform the separation of the two similar benzyl groups by the same method, hydrogenolysis, also shows how these two processes are related to each other.

QSSA's choice of oxazolidinone for masking carboxy in compounds **3** and **4** results in QSSA using the structure element O-substituted benzylic ester: CO-O-CH(N)-phenyl
as opposed to Novartis' simple benzyl esters (I)/(II): CO-O-CHH-phenyl.

This has the consequence that X3 = CH2 group (methylene) in the 023 Patent is in the QSSA process substituted by an oxygen function (from internal carboxylic acid) and forms a CH group (methine), prior to release to CH2 in the valsartan product.

The Court will now examine, based on the chemistry of the two processes as described above, whether these are "just about identical" methods, or whether QSSA Route C must be said to constitute a different method, cf. the judgment published in the 2009 volume of the *Retstidende* court reporter, p. 1055, paragraphs 31-33. The Court is on this issue spilt into a majority opinion and a minority opinion.

The majority, expert lay judge Anne Fiksdahl and the presiding judge, has concluded that it is a modification only. As far as the relationship to Claim 1 h) specifically is concerned, the majority notes:

- the similarity between QSSA's and Novartis' structure elements (benzylic esters);
- an identical purpose of the oxazolidinone function (internal ester formation prior to release of carboxy);
- identical separation methods (hydrogenolysis); and
- comparable characteristics for the relevant intermediates in their entirety.

Reference is also made to the observations noted by the majority under Item 10.5 below in relation to the issue of whether this is an *obvious* modification.

The minority, expert lay judge, Tore Lejon, has concluded that QSSA Route C constitutes, from the perspective of principle, a different method since neither the patent claims, nor the examples, refer to other compounds than those where X3 is methylene. Neither is any teaching provided on the use of oxazolidinone instead of benzyl ester, whether in the claims or in the examples.

10.4 Was QSSA Route C prior art as per the infringement date?

The entire Court has concluded that the prior art as per the infringement date shall form the basis for the assessment, cf. Item 9.3 above.

The parties agree that the skilled person could, by studying Greene, establish that amino acids could be protected as oxazolidinones, and that such knowledge existed as per the priority date (1990). A 2-substituted 4-alkyloxazolidin-5-one, corresponding to QSSA's intermediate **4** above, is a well-known derivative of amino acids.

The question is whether there existed any indications of hydrogenolysis of oxazolidinones as per the infringement date.

The entire Court is of the understanding that QSSA Route C is based on knowledge that constituted prior art no later than in 1991. In other words, QSSA Route C was prior art as per the infringement date.

There are diverging opinions within the Court when it comes to the precise time when this knowledge became part of the prior art. It is not necessary for the Court to rule on whether it formed part of the prior art before 1991, but the members of the Court will nevertheless explain their positions in view of the arguments invoked by the parties.

Expert lay judge Anne Fiksdahl notes that both deprotection steps in Claims 1 e) and 1 h) were well-known before 1991; benzyl ester separation has been known since 1950. Lay judge Fiksdahl therefore concludes that we are dealing with prior art even if the priority date (1990) is used as the date of reference. Lay judge Fiksdahl is of the view that the use of

an oxazolidinone ring as protection has been taught for 25 years in organic chemistry research literature as a ”protected amino acid” that prevents, *inter alia*, racemisation of the stereogenic amino acid centre. Such compounds are described in chemistry hand books and are produced by cyclocondensation of an amino acid, an aldehyde and an acyl chloride. Lay judge Fiksdahl is of the view that the relevant embodiment is in this case selective separation by hydrogenolysis of a benzyl ester, and not an oxazolidinone ring. Lay judge Fiksdahl is of the view that the other characteristics of the oxazolidinone intermediate, beyond the benzyl ester function, are irrelevant in this context, as it is only the ester separation for release of the carboxy function that is encompassed by patent claim 1 h. Separation of benzyl esters has been well known since before the application date.

Expert lay judge Tore Lejon and the presiding judge are of the view that hydrogenolysis of benzylic esters was known as per the application date, but that the literature offered no teaching on hydrogenolysis of oxazolidinones. Lay judge Lejon and the presiding judge are of the view that the next citation after Greene (1985) was published by Williams, prior to the application date. Williams proposed that it ought to be possible to hydrogenate oxazolidinones to selectively cleave the C-O bond in the ester, but there does not appear to be any citations showing that this has been done in the laboratory. Lay judge Lejon and the presiding judge are of the view that the first article to address hydrogenolysis of oxazolidinones is by Kinkel and Seebach, which article was published in 1991, after the priority date.

As far as the contents of Kinkel/Seebach are concerned, reference is made to the testimony of expert witness Dr Robert Adlington, University of Oxford, and his written statement dated 11 November 2010. The following is quoted from the summary on pp. 3-4:

> ” - - -
> Secondly, I also consider that the opening of the oxazolidinone ring in the conversion of compound (4) into valsartan, in the final step of QSSA’s Route C process, is equivalent to the type of processes covered by claim 1 (h). In this conversion, the oxazolidinone ring is opened to reveal the free carboxyl of valsartan which is exactly the same type of reaction as the ester deprotection (to reveal the free carboxyl of valsartan) which fall within the literal scope of claim 1 (h). Both of these reactions could be described as deprotections, reductive cleavages of hydrogenolysis reactions. In addition, the use of the oxazolidinone ring to protect the carboxyl group during the synthesis of valsartan would have been obvious to the skilled chemist in 1990/1991. The use of oxazolidinone ring structures to mask (protect) the carboxylic acid function of □-amino acids has been known for many years and formed part of the common general knowledge of any reasonably skilled organic chemist at the time of filing and grant of NO ’023. *There was also at that time a precedent, the Kinkel/Seebach paper as is described below, for the selective cleavage of the C-O bond in the oxazolidinone ring, as is used in QSSA’s Route C process.*
>
> - - - . ” [Emphasis added by the Court.]

The Court is of the understanding that the thesis of Kinkel/Seebach, to which Dr Adlington refers, was published in 1991 – after the application date. The thesis is published in ”Helvetica Chimica Acta”, Vol. 74 (1991), Appendix 14 to the written statement of 11 November 2010 from Dr Adlington.

10.5 Is QSSA Route C an obvious alternative for the skilled person?

The next question is whether we are faced with an *obvious* modification. A modified embodiment is held to be obvious if a skilled person would, based on the patent claims, have attempted the relevant embodiment with a reasonable expectation of success, cf. for example the Borgarting Court of Appeal's judgments of 30 January 2008, LB-2006-186315 (sertraline) and 28 April 2008, LB-2007-9840 (lansoprazole), cf. Gyldendal Rettsdata, Note 185 to Section 39 of the Patents Act, by Are Stenvik, with further references.

The skilled person for purposes of the present case is a chemist within organic chemistry with a few years' experience from the development of processes for the production of active ingredients in pharmaceutical products.

The majority of the members of the Court, lay judge Anne Fiksdahl and the presiding judge, have concluded that QSSA Route C represents an obvious modification of NO 304 023. The majority finds that the modification (benzyl ester) was an obvious alternative for the skilled person within the relevant technical field, and that the skilled person could, based on the claims, have attempted the relevant embodiment with a reasonable expectation of success. The relevant embodiment is in this case selective separation by hydrogenolysis of a benzyl ester and not an oxazolidinone ring. Lay judge Fiksdahl is of the view that the other characteristics of the oxazolidinone intermediate, beyond the benzyl ester function, are irrelevant in this context, as it is only the ester separation for release of the carboxy function that is encompassed by patent claim 1 h).

The majority *summarises* its views as follows:

The synthesis steps: Both processes perform deprotections of the tetrazole ring in accordance with *Claim 1e*, as well as separation of a benzylic ester, encompassed by *Claim 1 h*). The two key transformations in Novartis' and QSSA's processes are therefore, from the perspective of principles, identical or closely related. Both deprotection/separation reactions used by QSSA are described in Claims 1 e) and 1 h), [or] are obvious modifications of corresponding reactions that are described in Claims 1 e) and 1 h) of the disputed patent.

Intermediates: Although Claims 1e and 1h of the 023 Patent stipulate that X3 = CH2 in structures (I)/(II), whilst QSSA uses a CH group that forms part of cyclic benzylic ester as carboxyl protecting group in compounds **3** and **4**, the intermediates included in the production of valsartan are very similar in the two processes. QSSA's intermediates, the benzylic ester compounds **3** or **4**, are obvious modifications of Novartis' benzyl esters (I)/(II).

Selective separation of the benzyl ester function was well known before the priority date.

From an organic chemistry perspective, the principles behind the two processes are identical and undoubtedly represent the same synthesis strategy. It must be concluded that the two relevant **i) synthesis steps** and corresponding **ii) intermediates** involved in the two processes are, from the perspective of principle, identical or obvious variants. The minor divergences summarised in i) and ii) above are natural adaptations and obvious modifications of what is, from the perspective of principle, one production method, and are not held to be sufficient to fall outside the scope of Novartis' patent NO 304 023. Neither has it been documented that the QSSA process will offer any advantages. This shows that the QSSA process represents an obvious modification of Patent Claims 1e and 1h of the Novartis 023 Patent.

The majority is unable to see that the unequivocal definition of X3 in Formula II in NO 304 023 excludes infringement. The Court is unable to see that one would be justified in ruling out equivalence, as a matter of principle, if one modifies a substituent that is unequivocally specified. What is patented is the process as such. The question is whether the method is just about identical, cf. the judgment published in the 2009 volume of the *Retstidende* court reporter, p. 1055 (donepezil), paragraph 32. Reference is made, by way of illustration, to the Borgarting Court of Appeal's judgment of 2 June 2010 ("Losartan Mylan"), which concerned the issue of infringement of an analogous process patent by equivalence. In the infringing object, the component R11 was replaced by a compound that fell outside a literal interpretation of the patent claims. The Court of Appeal concluded that there was infringement. There were also other differences between the patent claims and the infringing object.

As follows from the majority's comments above, the majority finds that the method is just about identical even if X3 is not methylene in the final step before valsartan. The majority is of the understanding that the limitation of X3 to methylene primarily had to do with the fact that one had at that point of time identified the active ingredient valsartan. Reference is made to the letter of 25 September 1995 from Bryns Patentkontor AS to the Norwegian Industrial Property Office. Consequently, this is not a matter of conscious limitation of X3 in the process leading up to valsartan.

The majority is not of the view that the fact that Dipharma has been granted a patent, EP 1 533 305, on QSSA Route C, prevents infringement. The question of patentability and the question of infringement depend on two different assessments. Moreover, it is noted that the validity of EP 1 533 305 has not been upheld with final and binding effect, cf. Item 4 above.

Expert lay judge Anne Fiksdahl is of the view that there is infringement of both Claim 1 e) and Claim 1 h). Lay judge Fiksdahl notes that it is not unequivocally described in NO 304 023, Claims 1 e) and 1 h), that the reaction steps necessarily have to be the *final* steps in the production of valsartan. She takes the view that the claims may be interpreted as potential reaction steps that *form part of a process* for the production of valsartan.

The presiding judge is of the view that Claim 1 e) and Claim 1 h) must be interpreted as encompassing the final step towards valsartan. The presiding judge concludes that the reaction step from QSSA Route C's

intermediate **4** to valsartan represents an infringement of Claim 1 h). The presiding judge finds that it is therefore not necessary to take a view on whether there is also infringement of Claim 1 e).

The conclusion of the majority:
As its conclusion with regard to the overarching matter in dispute, as to whether Novartis' patent protection encompasses the process used by QSSA, *the majority* finds that:

The QSSA process represents an obvious modification of NO 304 023 on the production of valsartan, and

QSSA's production of valsartan represents an infringement of NO 304 023.

The minority, expert lay judge Tore Lejon, has no comments with regard to the description of the chemical processes above, but lay judge Lejon has concluded that these are, from the perspective of principle, two different methods, cf. Item 10.3 above. Furthermore, lay judge Lejon has concluded that QSSA Route C does not represent an obvious alternative to NO 304 023 based on the patent claims.

The minority is of the view that the skilled person will interpret the patent claims as being limited to processes in which X3 is methylene. There is nothing, whether in the wording or in the examples, to suggest anything else. The patent claims are clearly based on X3 being CH2 (methylene) without referring to any examples in which any other base material has been used. Not only has Novartis deliberately protected routes that use methylene; it has also refrained from showing, through examples, that there are other synthesis routes that it would like to protect.

The minority notes that X3 is not methylene. QSSA Route C uses a structure that differs from that of the patent claims. QSSA uses an oxazolidinone ring in its synthesis, and the patent claims do not allow for the protection of such a process. The minority finds that the scope of protection under NO 304 023 would be too broad if the patent claims are stretched to encompass the use of an oxazolidinone ring. The minority does not exclude the possibility of the scope of protection extending beyond a literal interpretation of the patent claims, but QSSA Route C is too far from NO 304 023 for it to represent, in the opinion of the minority, an obvious alternative for the skilled person in view of the fact that X3 is unequivocally specified. Reference is made to the comments of the minority under Item 10.3, where the minority has concluded that QSSA Route C is a different method. This is in itself sufficient to conclude that QSSA Route C does not represent an infringement of NO 304 023. The minority finds that the unequivocal definition of X3 as methylene strengthens the basis for concluding that this is not an obvious modification.

The conclusion of the minority is therefore that there is not infringement of Claim 1 h).

Since the minority does not find that the final step of the QSSA process represents an infringement of Novartis' Patent Claim 1 h), it concludes that a different synthesis strategy is being used, and it is thus not only a matter of changing the sequence of synthesis steps, and

hence it cannot represent an infringement of Claim 1 e) either, since this synthesis step does not result in a therapeutically active compound and therefore does not fall within the scope of the wording of the patent claim.

Under reference to the above conclusion of the majority, judgment is rendered in accordance with Item 1 of the claim made by Novartis, cf. Section 3, No. 3, of the Patents Act. The detailed content of such claim is commented on in Item 11 below.

11. The scope of the prohibition – in time and space.

11.1 Request for partial dismissal – has Novartis' claim been broadened?

Actavis has argued that the amendment made by Novartis to its statement of claim in the supplementary submission of 10 December 2010 represents a broadening of the claim. Alternatively, in the eventuality that the Court agrees with Novartis that there is infringement, Actavis has argued that any claim for a prohibition on Actavis' combination products that also contain the active ingredient valsartan must be dismissed.

In the Writ of Summons, Novartis entered the following prohibition claim:

> "
>
> 1. Actavis Group PTC hf and Actavis Norway AS are prohibited from offering for sale, bringing to the market or using the pharmaceutical products addressed by the present action, which contain valsartan as an active ingredient, and from importing or possessing said products with such intent, and are ordered to withdraw, to the extent possible, such products from the Norwegian market."

In the supplementary submission of 10 December 2010, the statement of claim was amended as follows:

> "
>
> 1. Actavis Group PTC hf and Actavis Norway AS are prohibited, *until 13 May 2011*, from offering for sale, bringing to the market or using the pharmaceutical products [*deleted "addressed by the present action,"*] which contain valsartan *produced by the process QSSA Route C* as an active ingredient, and from importing or possessing said products with such intent, and are ordered to withdraw, to the extent possible, such products from the Norwegian market."
> [Amendments indicated in italics by the Court.]

The amendment that represents a limitation of the duration was requested by Actavis, and it does not have any procedural objections to such amendment.

The Court is of the understanding that the insertion to the effect that the prohibition pertains to valsartan produced by QSSA Route C represents a curtailment, or a clarification, when compared to the statement of claim in the Writ of Summons.

The question is whether the claim has been broadened when it comes to what pharmaceutical products are to be subject to the prohibition, cf. the insertion concerning pharmaceutical products "addressed by the present action". This is a matter of interpreting the statement of claim on the Writ of Summons. It is stated under Item 6 of the Writ of Summons that Novartis' claim is for Actavis to be prohibited from bringing generic valsartan to the market in Norway. The Court is unable to see that there is anything in the Writ of Summons

to suggest that Novartis limited its claim for a prohibition such as to make it apply only to the use of valsartan as an active ingredient in mono products. The insertion concerning pharmaceutical products ”addressed by the present action” in the original statement of claim refers to Actavis' generic valsartan products as discussed under Item 3.7 of the Writ of Summons. Novartis was not aware, at the time of filing the Writ of Summons, that Actavis was planning the launch of a combination product containing valsartan and hydrochlorothiazide. The Court is of the understanding that Novartis did not become aware of Actavis' [plans] until Ole Brækken's witness testimony on 9 December 2010.

Consequently, there has emerged a new fact that was not known at the time of filing the Writ of Summons. The information about Actavis' plans to launch a combination product implies that the statement of claim needs to be amended. The Court takes the view that if Novartis had been aware of Actavis' plans for the marketing of a combination product, this would have been reflected in the Writ of Summons.

NO 304 023 has, as mentioned under Item 1 above, been granted for a term of 20 years from the application date, until 18 February 2011. Until that date, the prohibition against the marketing and sale of generic valsartan follows directly from Section 3, No. 3, of the Patents Act, which stipulates the following:

> **Section 3.** [1] The exclusive right [2] conferred by a patent shall, with the exceptions referred to in the third paragraph, imply that no one but the patent holder may, without his consent, exploit the invention by
>
> - - -
>
> 3. offering for sale, putting on the market or using a product made by a process protected by the patent [3], or importing or possessing the product for such purposes.

The Court is of the view that both the mono products and the combination products of Actavis fall within the scope of the term ”product” in Section 3, No. 3, of the Patents Act.

The question is whether SPC/NO 1998 024, after 18 February 2011, only protects against the marketing of generic mono products or also against generic combination products. The basic patent is NO 304 023. The specification next to ”product” is ”Valsartan”. The name of the pharmaceutical product marketed by Novartis is Diovan®, cf. Item 1 above.

Actavis has argued that the scope of protection pursuant to the SPC raises a number of issues, on which light has not been shed during the main hearing, and that the part of the statement of claim that encompasses combination products therefore must be dismissed.

The Court is not of the view that such part of the claim should be dismissed. It can hardly have been a surprise to Actavis that Novartis wanted to prohibit all pharmaceutical products that contained generic

valsartan. Besides, the scope of protection under the SPC is a matter of the application of law. The Court therefore concludes that there is no reason to dismiss this element of the statement of claim.

Protection pursuant to the SPC is governed by Section 62 a of the Patents Act, which is worded as follows:

> **Section 62a.** Annex XVII, item 6, to the Agreement establishing the European Economic Area (Council Regulation (EEC) No. 1768/92 concerning the creation of a supplementary protection certificate for medicinal products with adaptations to the EEA Agreement) including the amendments and additions provided in Protocol 1 to the Agreement and elsewhere in the Agreement shall apply as statutory provisions. [1]
> Applications for a supplementary protection certificate shall be filed with the Norwegian Industrial Property Office. [2] The applicant shall pay the prescribed fee.
> In the case of protection certificates, the prescribed fees shall be paid for every fee year [3] starting after the end of the patent term. In other respects the same rules apply to these annual fees as to the annual fees for patents. [4]
> Further provisions concerning applications for protection certificates and the processing and examination thereof, concerning the registration of protection certificates, concerning appeals against decisions and concerning the obligation of the applicant or the holder to have a representative in this country, etc., shall be laid down by the King.
> The penal provisions of Sections 57 and 62 shall apply correspondingly to protection certificates.

The protection period may be extended by up to 5 years, cf. Article 13 of the Council Regulation.

A supplementary protection certificate offers, as a general rule, the same protection as the basic patent, cf. Stenvik (2006), p. 358. The subject matter of protection is defined in more detail in Article 4 of the Council Regulation, which is worded as follows:

> Article 4. Subject-matter of protection
> Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorization to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorized before the expiry of the certificate.

The term “medicinal product” is defined in Article 1 a), which is worded as follows:

> a) ‘medicinal product’ means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;

The term “product” is defined in Article 1 b), which is worded as follows:

> b) ‘product’ means the active ingredient or combination of active ingredients of a medicinal product;

The wording of SPC/NO 1998 024 is not restricted to mono products. The target molecule is drawn under the product designation ”Valsartan”. This is an argument in favour of concluding that SPC/NO 1998 024 protects against infringement through the marketing of any form of valsartan.

The Court is of the view that valsartan is a ”product” for purposes of Article 1 b). Reference is also made to Stenvik (2006), p. 359, where it is assumed that a certificate will also protect against use of the active ingredient in combination products.

The Court therefore concludes that SPC/NO 1998 024 also protects against valsartan in combination products.

Novartis has, moreover, submitted an SPC granted on 23 April 2007, with expiry date 25 September 2012, with regard to Novartis' combination product, Co-Diovan. The basic patent is the same in respect of both protection certificates; NO 304 023.

The Court has concluded, under reference to the above, that Item 1 of Novartis' statement of claim shall be upheld without any amendment.

12. The claim for damages.

Prerequisites for awarding damages in respect of the infringement of patent are governed by Section 58 of the Patents Act, which is worded as follows:

> **Section 58.** Anyone who intentionally or by negligence has committed a patent infringement shall be liable to pay compensation for the exploitation of the invention, as well as compensation for the further damage caused by the infringement. The compensation may be reduced where the infringer is guilty of minor blame only.
> If the infringer has acted with care and in good faith, the court may, to the extent found reasonable, order the infringer to pay compensation for the damage caused by the exploitation.

The majority, lay judge Anne Fiksdahl and the presiding judge, has concluded that there is infringement, cf. Item 10 above. The majority shall therefore determine whether the prerequisites for awarding damages are met, as well as the amount of any claim.

The Court is of the view that Actavis has not acted intentionally as far as the scope of protection offered by the patent is concerned. It is noted, *inter alia*, that the state of the law is unclear with regard to the date of reference for purposes of determining what shall be deemed to constitute the prior art, cf. Item 9.3 as compared to Item 10.4 above. Reference is also made to the reports from the court-appointed experts before the Court of Execution.

The question is whether Actavis has acted negligently. The Court operates on the assumption that Actavis is fully aware of all factual circumstances with regard to the infringing object, and aware of NO 304 023 and the relevant factors of interpretation. Furthermore, Actavis was aware that Novartis intended to pursue the matter, even if the request for a preliminary injunction before the Court of Execution was revoked. The Court furthermore assumes that Actavis was aware, at the time of the launch of ”Valsartan Actavis”, that QSSA Route C [sic] arrived at its method by studying NO 304 023 in order to circumvent it. However, the present case differs from LB-2006-186315 (sertraline) due to the uncertainty with regard to the state of the law concerning what shall be the date of reference for purposes of determining what shall be deemed to constitute the prior art. Moreover, Actavis did not launch in the market until after the report from the experts before the Court of Execution had become available. The report concluded that QSSA Route C did not represent infringement, cf. Item 5 above.

The Court has concluded, based on an overall assessment, that Actavis has acted negligently, although the damages have to be reduced pursuant to Section 58, Sub-section 1, second sentence, of the Patents Act.

The Court has concluded that the [amount of] damages shall be determined on the basis of the profit realised by Actavis on the sale that has taken place from March 2010 to 31 December 2010, inclusive. Consequently, the judgment will not address damages for infringement in 2011.

Actavis has not submitted any specification of its earnings. It has been stated that Actavis has made sales to wholesalers at step price as from 1 May 2010, cf. Sections 12-13 and 12-14 of the Medicinal Products Regulations.

The Court will have to base its assessment of damages on the calculation submitted by Novartis as to its loss of earnings. Novartis has requested indemnification of lost sales, less 5% commission to the pharmacy chains and 10% in cost savings, in the amount of NOK 15 million as per yearend, based on a gross loss in the amount of NOK 18 million. Novartis' loss is documented in the form of an overview of total sales of four different packages of "Valsartan Actavis" from March 2010 to October 2010, inclusive. Furthermore, Novartis has submitted a list of pharmacy purchase prices ("AIP"), cf. Section 12-1 of the Medicinal Products Regulations. Novartis has calculated the loss of turnover on the basis hereof.

It follows from the list of step prices from the Norwegian Medicines Agency ("NoMA") that the discount rate was 55%. This means that the applicable step price (pharmacy retail price, "AUP") as from 1 April 2010 for the valsartan products was 45% of the "base price", which is the pharmacy purchase price ("AIP"). The Court therefore assumes that the total turnover of Actavis from March until yearend 2010 was in the region of NOK 18 million x 45%, i.e. approximately NOK 8 million gross. Actavis has not disclosed what amount of costs is incurred before being left with the net earnings. The Court therefore has to estimate this on a discretionary basis. The discretionary assessment of the Court also takes into consideration the scope for reducing the amount of damages. Damages are awarded in the discretionary amount of NOK 7 million.

13. Request for a preliminary injunction

The majority of the members of the Court have concluded that the prohibition claim of Novartis shall be upheld, and the question is whether a court order granting a preliminary injunction should be rendered.

The prerequisite for granting a preliminary injunction is that the underlying claim, as well as the grounds for securing such claim, is proven on a balance of probabilities, cf. Sections 34-1 and 34-2 of the Civil Procedure Act.

The underlying claim has been proven on a balance of probabilities, cf. Item 10 above. The question is whether any grounds for securing such claim have been proven on a balance of probabilities. Reference is made to Section 34-1 of the Civil Procedure Act, which is worded as follows:

Section 34-1. Grounds for securing the claim
(1) The court can grant a preliminary injunction when:

a) the defendant's conduct makes it necessary [1] to provisionally secure the claim because the action or execution of the claim would otherwise be considerably impeded; or

b) the court finds it necessary to make a temporary arrangement in a disputed legal issue in order to avert considerable loss or inconvenience, or to avert violence which the conduct of the defendant gives reason to fear.

(2) A preliminary injunction cannot be granted if the loss or inconvenience to the defendant is clearly disproportionate to the interests of the petitioner in the preliminary injunction being granted. [2]

The question is whether "execution of the claim would - - - be considerably impeded" if Actavis is allowed to continue its marketing of generic valsartan, cf. Section 34-1, Sub-section 1 a), of the Civil Procedure Act. It is not sufficient to avert a preliminary injunction that Novartis will have the possibility of claiming indemnification of its economic loss from Actavis, which is assumed to be solvent. Reference is made to the ruling published in the 1967 volume of the *Retstidende* court reporter, p. 124.

The Court also refers to Article 50, No. 1, of the TRIPS Agreement, which is worded as follows:

«The judicial authorities shall have the authority to order prompt and effective provisional measures:
1. to prevent an infringement of any intellectual property right from occurring, and in particular to prevent the entry into the channels of commerce in their jurisdiction of goods, including imported goods immediately after customs clearance; - - - "

It is concluded that Section 34-1 of the Civil Procedure Act must be interpreted such as to be in conformity with Norway's obligations under the TRIPS Agreement. This means that a preliminary injunction may be granted for purposes of protecting patent rights.

The Court takes the view that there are also grounds for securing the claim pursuant to Section 34-1, Sub-section 1 b), of the Civil Procedure Act. The Court is of the understanding that Novartis has thus far lost 75% of its market to Diovan®. Reference is made to witness testimony from Petter Foss, the Chief Executive Officer of Novartis Norway. Loss of market shares and turnover will continue until 2016, when the 5-year term under the SPC expires. The overall loss from the market lost for Diovan® is estimated at approximately NOK 150 million from March 2010 until the expiry of the period of protection. In addition, there is the risk of loss as the result of Actavis' planned launch of a combination product in competition with Co-Diovan. Research and development form a key part of Novartis' activities, and are funded by pharmaceutical products already on the market. If Actavis is permitted to continue the marketing of generic valsartan, Novartis will have to scale back the part of its activities comprised by research and development. The Chief Executive Officer, Mr Foss, has stated that Actavis' launch of generic valsartan has resulted in a recruitment freeze, but no redundancies.

The Court does not find that a balancing of interests pursuant to Section 34-1, Sub-section 2, of the Civil Procedure Act represents an obstacle to the granting of a preliminary injunction. It is noted that the Court is charged with enforcing the intellectual property right represented by this patent right, cf. above. Besides, the economic loss incurred by Novartis

will exceed the loss incurred by Actavis as the result of the implementation of the prohibition. The Court concludes, on this basis, that the loss or inconvenience to Actavis is not disproportionate to the interests of Novartis in the immediate implementation of the prohibition.

The petition for a preliminary injunction is therefore upheld.

The parties have not entered any specific claims in respect of legal costs relating to the petition for a preliminary injunction. Besides, this was not addressed during the preparation of the case, and it was only the issue of grounds for securing the claim that required separate treatment. Only a small amount of time was devoted to said issue during the main hearing, which concentrated on the underlying claim. It is also noted that the Court has concluded that costs should not be awarded in respect of the underlying claim, cf. Item 14 below. The reasons underpinning the said conclusion also apply with regard to proving the underlying claim on a balance of probabilities in relation to the petition for a preliminary injunction.

14. Legal costs.

Novartis' claim for a prohibition and its request for a preliminary injunction have been upheld. Novartis' claim for damages has not been upheld in full, cf. Item 12 above. The Court is nevertheless of the view that Novartis' claims have for the main part been upheld, and it has therefore succeeded with its action, cf. Section 20-2, Sub-section 2, of the Civil Procedure Act. The successful party will as a main rule be entitled to full indemnification of its legal costs, cf. Section 20-2, Sub-section 1, of the Civil Procedure Act. However, the Court finds that the excepting provision in Section 20-2, Sub-section 3, of the Civil Procedure Act shall apply, cf. in particular a) thereof. There was doubt as to the outcome of the case. It is noted that the state of the law is unclear with regard to what shall be the date of reference for purposes of determining what shall be deemed to constitute the prior art as far as the infringement assessment is concerned.

The Court therefore concludes that no costs should be awarded.

Both parties have requested the appointment of expert lay judges. Each of the plaintiffs and the defendants shall therefore pay one half of the costs associated with the expert lay judges, cf. Section 2, Sub-section 2, of the Court Fees Act. The costs associated with the expert lay judges will be determined separately.

A dissenting opinion has been rendered in respect of the judgment. *The majority, expert lay judge Anne Fiksdahl and the presiding judge*, has voted in favour of Item 1 and Item 2 of the below conclusion of the judgment. *The minority, expert lay judge Tore Lejon*, has voted in favour of Actavis. The entire Court has voted in favour of Items 3 and 4 of the conclusion of the judgment.

A dissenting opinion has been rendered in respect of the court order. *The majority, expert lay judge Anne Fiksdahl and the presiding judge*, has voted in favour of upholding the petition for a preliminary injunction. *The minority, expert lay judge Tore Lejon*, has voted against upholding the petition.

CONCLUSION OF THE JUDGMENT

1. Actavis Group PTC hf and Actavis Norway AS are prohibited, until 13 May 2011, from offering for sale, bringing to the market or using the pharmaceutical products which contain valsartan produced by the process QSSA Route C as an active ingredient, and from importing or possessing said products with such intent, and are ordered to withdraw, to the extent possible, such products from the Norwegian market.

2. Actavis Group PTC hf and Actavis Norway AS are ordered to pay damages to Novartis AG and Novartis Norway AS in the amount of NOK 7,000,000 – seven million – within 2 – two – weeks of service of the judgment.

3. No costs are awarded.

4. Expenses associated with the expert lay judges shall be determined by the Court. The plaintiffs and the defendants, respectively, shall each pay one half of such expenses.

CONCLUSION OF THE COURT ORDER

The prohibition/order under Item 1 of the above conclusion of the judgment, that Actavis Group PTC hf and Actavis Norway AS are prohibited, until 13 May 2011, from offering for sale, bringing to the market or using the pharmaceutical products which contain valsartan produced by the process QSSA Route C as an active ingredient, and from importing or possessing said products with such intent, and are ordered to withdraw, to the extent possible, such products from the Norwegian market, shall be implemented immediately by way of a preliminary injunction.

Court adjourned

Hilde Foyn Bruun

Anne Fiksdahl Tore Sigvard Lejon

Guidance notes on the right of appeal in civil actions are enclosed.