OSLO DISTRICT COURT

JUDGMENT

Rendered:	11 July 2017 by the Oslo District Court,
Case No.:	15-177113TVI-OTIR/07
Judge:	District Court Judge Dagfinn Grønvik
Lay judges:	Jørn Sonnergaard Hans Lennernäs
Subject matter of the case:	Invalidation of patent

Actelion Pharmaceuticals Ltd	Attorney Ingvild Hanssen-Bauer Associate Åse Røynestad Konsmo
v.	
Icos Corporation	Attorney Camilla Sophie Vislie Attorney Andreas Nordby

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JUDGMENT

The case concerns invalidation of patent and, in particular, the issue of whether micronisation of a known active ingredient, tadalafil, exhibits a sufficient inventive step.

Presentation of the case

The parties

The claimant, Actelion Pharmaceuticals Ltd (hereinafter referred to as Actelion), is an international pharmaceuticals company. The company was incorporated in 1997 and is headquartered in Allschwil in Switzerland. Actelion wishes to enter the market in Norway with a product containing the active ingredient tadalafil unless the patent prevents it from doing so.

The defendant, Icos Corporation (hereinafter referred to as Icos), was incorporated in 1989. Icos was in 2007 acquired by Eli Lilly Company, which is an international pharmaceuticals group that develops, manufactures and markets prescription drugs. Icos is the holder of patents that protect products containing the active ingredient tadalafil.

The background to the case

Tadalafil is the generic name (International Non-proprietary Name, INN) of the active ingredient of the prescription drug Cialis for the treatment of erectile dysfunction (impotence) and Adcirca, for the treatment of pulmonary arterial hypertension (high blood pressure in the pulmonary vasculature).

The basic patent for the active substance tadalafil, NO306 465, expired on 19 January 2015. A supplementary protection certificate (SPC) NO2003002 extends the protection for medicinal products containing the active ingredient tadalafil until 12 November 2017.

Tadalafil was a known active substance in August 1999, and it was known that tadalafil can be used in the treatment of erectile dysfunction. Sildenafil, which is a corresponding substance, had been approved by the Food and Drug Administration (FDA) for the same indication under the trademark Viagra.

Tadalafil is a compound that belongs to the class β-carbolines. These are compounds which inhibit an enzyme called "cGMP (cyclic guanosine 5'-monophosphate)-specific phosphodiesterase type 5" ("PDE5"). The enzyme PDE5 is present in smooth muscle, including, *inter alia*, in the sponge-like regions (corpus cavernosum) of the penis, as well as in the walls of blood vessels and in cavernous tissue. cGMP is a compound that, through a chain of reactions, results in relaxation of smooth muscle. Relaxation results in the opening up of blood vessels (arteries) that are otherwise squeezed when the smooth muscle is tight, thereby achieving a greater inflow of blood. This again causes veins that will normally lead the blood out to be squeezed

together, which results in swelling. PDE5 is an enzyme that breaks down cGMP. Under normal conditions, the PDE5 enzyme is active and will break down cGMP continuously. This again results in the smooth muscle not relaxing. By inhibiting the PDE5 enzyme, one achieves that cGMP is not broken down, smooth muscle relaxes, blood flows in, and erection occurs.

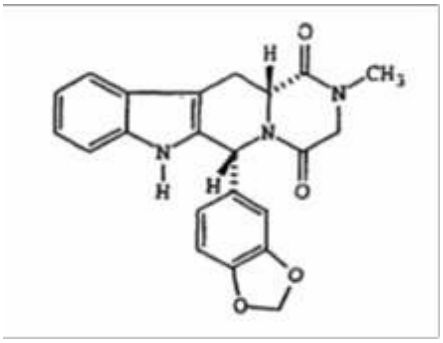
A key limiting factor in the use of medicinal products is how quickly these are absorbed in the body (i.e. absorption) and bioavailability. Bioavailability is an expression of the rate at which, and extent to which, an active substance; a medicinal product, is absorbed, avoids the first pass effect and becomes available at the site of action. For medicinal products in tablet form, the question is whether and to what extent the substance is dissolved (solubility) in the fluids of the gastrointestinal tract, and thereafter permeate the intestinal wall (permeability) such as to enter the bloodstream and be distributed around the tissue and cells of the body. Bioavailability is affected by factors such as the nutrient's chemical form and physical-chemical properties, the various pharmaceutical excipients in the formulation, as well as their quantities and properties, the nutritional state of the person, the physiology of the gastrointestinal tract and interaction with other nutritional factors.

Micronisation denotes the grinding of substances to reach a median particle size of about 5-10 µm. One µm, or one micrometre, is 0.001 mm.

The key subject matter in dispute in the case is whether such micronisation of the active ingredient Tadalafil exhibited a sufficient inventive step as at the priority date.

Icos is the holder of Norwegian patent NO 321 602 B1 (hereinafter referred to as the "'602 Patent" or the "Disputed Patent"), which pertains to tadalafil of a specified particle size. 12 patent claims have been granted, of which Claim 1 is an independent claim.

Claim 1 is words as follows:

> "Solid particles of a compound not intimately embedded in a polymeric co-precipitate, characterised by the formula
>
> 
>
> and pharmaceutically acceptable salts and solvates thereof, comprising particles of the compound wherein at least 90% of the particles have a particle size of less than about 40 microns."

Claims 2-9 are dependent claims, of which Claims 2, 3 and 4 concern tadalafil with a particle size of 25, 15 and 10 microns, respectively.
Claim 5 concerns tadalafil pursuant to Claim 1 and one or more pharmaceutically acceptable carriers, diluents and excipients.
Claim 6 is a use claim teaching the treatment of sexual dysfunction in a patient in need thereof. Claims 7 and 8 are use claims addressing sexual dysfunction in males and females, respectively. Claim 9 teaches a method of manufacturing the solid particles according to Claim 1.

The application for the 602 Patent was filed in Norway on 1 February 2002. The application was a continuation of international application WO 01/08 688 ("WO '688") and claims priority from a US application, US 60/147,048, filed on 3 August 1999.

The Norwegian Industrial Property Office issued its first statement on the merits of the application on 2 March 2005 in a letter to Bryn Aarflot AS. The outcome of the novelty examination was that no relevant documents had been identified. The Norwegian Industrial Property Office stated that the compound according to Claim 1 in the form defined in the claim has not previously been disclosed. Noting that this particle form exhibited surprisingly improved bioavailability compared to earlier pharmaceutical formulations of the same compound, the Norwegian Industrial Property Office held that Claims 1-5 exhibited novelty and inventive step. However, the Norwegian Industrial Property Office had objections as far as the use claims were concerned, and identified certain formal deficiencies. These deficiencies were remedied.

The Norwegian Industrial Property Office thereafter approved the application, and the patent was granted on 12 June 2006.

The parallel European patent to NO '602; EP 1 200 092 ("EP '092"), was granted on 21 April 2004. Like NO '602, the application that resulted in EP '092 is based on WO '688.

Parallel invalidation proceedings against EP '092 are pending in other European countries. In addition, Actelion has filed a request for a so-called inter partes review (IPR) with the United States Patent and Trademark Office (USPTO) of the parallel US patent (US 6,821,975).

The Writ of Summons was received on 9 November 2015.

The main hearing was conducted over six court days over the period 24 to 31 October 2016.

The grounds invoked by the claimant in support of its claims

The patent is invalid because of a lack of inventive step, alternatively a lack of novelty, cf. Sections 2, 6 and 52 of the Patents Act, Section 14 of the Patent Regulations, Art. 4 of the Paris Convention and EPC Art. 87.

A patent may be declared invalid by judgment, and the courts have full jurisdiction over such matters. The patent decision of the Norwegian Industrial Property Office cannot be accorded weight in the assessment to be performed by the Court; no contradictory proceedings were involved. The facts of the case have now been comprehensively examined, with the presentation of new citations and new evidence concerning common general knowledge in the art. Expert witnesses have been called and the Court has included expert lay judges. There is no reason for the Court to exercise restraint in its assessment.

The skilled person is a team comprising, at a minimum, a person with skills and experience in pharmaceutical formulation (galenic pharmacy), provided, however, that other expertise, e.g. in pharmacology, will be consulted if necessary.

The claims in NO '602 lack inventive step when compared to WO 97/03675 (WO '675), alternatively WO 95/19978 (WO '978).

The technical problem solved by NO '602 must be defined as bringing about tadalafil in a form with an improved dissolution rate, and thereby improved absorption and bioavailability.

The skilled person wishing to improve the dissolution rate of tadalafil and improve absorption and bioavailability knows that the conventional way of increasing the dissolution rate is to reduce the particle size, in order to thereby increase the surface area available for the solvent. This forms part of the common general knowledge of the skilled person. Starting out from WO '675, and in view of common general knowledge in the art, this is thus one of the standard solutions that the skilled person will attempt. The same applies if one starts out from WO '978 as the closest prior art. Consequently, the technical solution taught by NO '602 was obvious to a skilled person in view of common general knowledge in the art as at the priority date.

The skilled person would have conducted pre-formulation studies to examine the properties of tadalafil, such as solubility and permeability, two key factors determining absorption and bioavailability. Such checks would be a matter of routine for the skilled person.

Tadalafil was a known active ingredient in August 1999 and it was known that tadalafil can be used in the treatment of erectile dysfunction. WO 97/03 675, with 14 July 1995 as priority date, disclosed its use against sexual dysfunction. Sildenafil had already been approved by the Food and Drug Administration (FDA) for the same indication with the medicinal product Viagra.

Tadalafil has low solubility in water, but it has higher solubility when measured in simulated intestinal fluid at 37 degrees Celsius, and the skilled person would have expected that.

Tadalafil has high permeability (in biological membranes); the intestine. The skilled person would have found this by conducting a Caco-2 assay; reference is made to the testimony of Blakey and Bauer-Brandl. There was, in any event, no reason to expect permeability problems based on logP and Lipinski's Rule of Five. Tadalafil is a Class 2 substance according to the Biopharmaceutical Classification System (BCS), with low solubility and high permeability.

It was part of common general knowledge in the art as at the priority date of the patent that reduced particle size improves the dissolution rate, absorption and bioavailability.

The same conclusion has been reached by the EPO Board of Appeal and the UK Patents Court.

In the event that the Court holds WO 96/38131 (WO '131) to be the closest prior art, as argued by Icos, the technical problem must be defined as bringing about an alternative formulation with tadalafil, since NO '602 has not demonstrated any beneficial effects of the invention relative to WO '131, such as improved absorption and bioavailability and more rapid attainment of maximum plasma concentration (Tmax). Reduction of the particle size of the active pharmaceutical substance was a more obvious alternative for the skilled person, compared to the co-precipitate solution disclosed in WO '131.

Reduction of the particle size of the active pharmaceutical substance would also have been obvious to the skilled person if the Court were to take the view that the technical problem solved by the invention, when compared to WO '131, is bringing about a formulation of tadalafil with improved absorption and bioavailability, as argued by Icos.

It is denied that this would primarily have been attempted with theoretical models. None of the models formed part of common general knowledge in the art or the state of the art as at the priority date of the patent. There was research in relation to theoretical models, but no consensus as to the relevance of the various models. The models had originally been developed for use during the Drug Discovery phase.

None of the models are suited for reflecting in vivo conditions, and all of the models will generate different results. All of the models will entail a significant margin of error.

"Very often we may find that a theoretical model inappropriately explains experimental results." (Yu, B3, p. 1336)

The skilled person would under any circumstance have attached less weight to such results than to empirical studies. The skilled person would choose parameters that reflect, to the greatest possible extent, in vivo conditions. Byrn's calculations are consistently based on parameters that would generate the weakest results.

Butler provides no guidance on how to produce a suitable co-precipitate. It describes

formulations with both immediate and sustained release, a wide range for the active ingredient/carrier ratio and no teaching as to which carrier to use for immediate release.

Moreover, Actelion argues that NO '602 cannot claim priority from 3 August 1999 based on US 60/147,048 (US '048). The correct priority date is the date of filing of WO '688, i.e. 1 August 2000. This implies that WO 01/08686 (WO '686) becomes a relevant citation. The rights have not been properly assigned from the inventor to Icos.

It is argued that all features of NO '602 are anticipated by WO '686, thus implying that the novelty requirement has not been met.

The other claims contribute nothing novel or inventive.

The claimant's statement of claim

1. NO 321 602 to be declared invalid.

2. Icos Corporation to be ordered to pay the legal costs of Actelion Pharmaceuticals Ltd.

The grounds invoked by the defendant in support of its claims

The patent is valid, and it exhibits a sufficient inventive step.

The Norwegian Industrial Property Office has validly granted the disputed patent following thorough examination. There are no grounds for the District Court to deviate from the patentability assessment of the Norwegian Industrial Property Office, cf. the rulings published on p. 603 onwards of the 1975 volume (Swingball) and p. 1555 onwards of the 2008 volume (Biomar) of the *Norsk Retstidende* court reporter for the Supreme Court. The reason given by the Supreme Court for its stance is that the Norwegian Industrial Property Office is in possession of special expertise and a broad empirical basis with regard to the thresholds applicable to the various patent conditions.

Parallel patents have been granted in more than twenty countries, plus a number of validations of the EP patent. Another patent held by ICOS, which pertains to a formulation of tadalafil and uses the same method as NO '602, and for which the parties to the opposition proceedings invoked the same citations and arguments as have been invoked in the present case, has been upheld by the EPO Opposition Division. There is no final and binding ruling from other countries on the validity of the parallel patent.

The invention meets the inventive step requirement, cf. Section 2 of the Patents Act, i.e. it was not obvious to the skilled person in view of the state of the art as at the priority date.

The purpose of the invention is to bring about an improved pharmaceutical formulation of the practically insoluble active ingredient tadalafil in order to achieve improved absorption and bioavailability, including a more rapid effect as the result of a higher maximum tadalafil plasma concentration a short time after dosage.

The objective problem faced by the inventors, and also the actual solution and the benefits resulting from the solution taught by the disputed patent, need to be considered from the perspective of the "person of average skill in the art", which is the patentability benchmark. The person of average skill in the art is, in the present case, a team of skilled persons with knowledge of pre-formulation of medicinal products and how the solubility and absorption of various candidate substances are determined (biopharmaceutical knowledge), pharmacological knowledge, as well as knowledge of dosage methods and dosage forms.

The closest prior art is not WO 675 (which pertains to a specific use of tadalafil), or alternatively WO '978 (the basic tadalafil patent), as argued by Actelion. Unlike Butler, none of these patents address the same technical problem or serve the same purpose as the disputed patent.

The closest prior art is Butler; WO '131. Butler identifies the same problems as NO '602, i.e. the very poor solubility of tadalafil in water, and how to improve the absorption and bioavailability of tadalafil. Consequently, Butler is realistically the closest prior art.

Butler teaches a different solution to the problem than the solution disclosed in the disputed patent. The solution in Butler is a solid dispersion of tadalafil in the form of a co-precipitate. It was known that solid dispersions, such as co-precipitates of poorly soluble active substances, resulted in higher solubility, absorption and bioavailability, because, *inter alia*, these represented the "ultimate in size reduction" and active substances dispersed (finely distributed) in a solid solution represented the ultimate form of subdivision. This is representative of how the skilled person was thinking as at the priority date.

The invention in the disputed patent differs from WO ’131 in that i) tadalafil is used as a free drug, ii) is not in a solid dispersion/co-precipitate, and iii) has a specified distribution of particle size.

It is not, if starting out from Butler, obvious to arrive at the invention. Starting out from Butler as the closest prior art, it would be appropriate for the skilled person to examine alternative techniques such as solid dispersions or solvent deposition. It was surprising that it was possible to achieve improved bioavailability with micronised tadalafil in free particulate form since Butler is teaching co-precipitation. The drug is not in free particulate form in case of co-precipitation, and for co-precipitation the skilled person would expect that dispersed (finely distributed) tadalafil would be significantly smaller than the particle size

attained by micronised tadalafil. Consequently, the skilled person could not expect that improved absorption and bioavailability could be attained by micronised tadalafil. Consequently, it is evident that the invention is not obvious if starting out from Butler.

Actelion's arguments are not based on a realistic and objective assessment as to whether the invention was obvious from the perspective of the closest prior art. Instead, Actelion bases its arguments on generalisations from something that was known, and uses the knowledge in the invention to theorise about how one might have arrived at such knowledge. This is precisely the type of hindsight assessment one seeks to avoid by applying the problem-and-solution approach. Hence, Actelion's arguments are incorrect, both legally and factually.

The other issue raised by the case is whether ICOS is entitled to claim priority from US '048. NO ' 602 is a continuation of international application WO 01/08 688 – which claims priority from US '048. ICOS maintains that the company is entitled to claim priority, as the legal successor and assign of the applicant as at the application date of the disputed patent; 3 August 1999.

In order to claim priority from an earlier patent application, the subsequent patent application must be filed by the applicant under the earlier patent application or the legal successor and assign of such applicant, cf. Section 6 of the Patents Acts and Article 4 A.1 of the Paris Convention.

The issue of whether ICOS is entitled to claim priority from US '048 must, as a general premise, be resolved pursuant to the national legislation of relevance to the assignment in question. The District Court is required to rule on whether the legal position that had been established under national legislation as at the priority date was sufficient to meet the conditions for priority under Article 4 A.1 of the Paris Convention.

The inventors specified in US '048 were all employees in the research department of Eli Lilly & Co in Indiana and were all working on the project for the development of tadalafil, which fell within the scope of the collaboration between ICOS and Eli Lilly. Eli Lilly acquired the rights to the invention disclosed in US '048 in its capacity of employer, and such rights were subsequently assigned from Eli Lilly to Lilly ICOS. ICOS is arguing that the legal position held by Lilly ICOS as at the application date is sufficient to claim priority under Article 4 A.1 of the Paris Convention.

The defendant's statement of claim

1. The Court to find in favour of ICOS Corporation.

2. Actelion Pharmaceuticals Ltd. to be ordered to pay the legal costs of ICOS Corporations.

The observations of the Court

The Court has concluded that the patent must be declared invalid because the person skilled in the art would have arrived at the method of micronising tadalafil. This is prior art which the skilled person would have used to improve the absorption and bioavailability. Hence, the patent does not exhibit a sufficient inventive step relative to the prior art.

The requirements for obtaining a patent are set out in the Patents Act and the legislative history.

The legal premises are quoted from the ruling published on p. 1555 onwards of the 2008 volume of the *Norsk Retstidende* court reporter for the Supreme Court (Biomar).

> *(28) The prerequisites for achieving a patent are set out in Section 2, Sub-section 1, of the Patents Act of 15 December 1967 No. 9, which is worded as follows:*
>
> *«Patents shall be granted only for inventions which are new in relation to what was known before the filing date of the patent application, and which also differ essentially therefrom.»*
>
> *(29) The term «invention» is made somewhat more specific in Section 1 of the Patents Act. It is there stipulated that the invention must be susceptible of industrial application, and that the term does not include «discoveries, scientific theories and mathematical methods». An invention is, briefly summarised, a practical solution to a technical problem, cf. Stenvik:* Patentrett *["Patent Law"], 2nd edition, page 13.*
>
> *(30) The invention must be new in relation to what was known before the filing date of the patent application. What prevents the invention from exhibiting novelty is specified in Section 2, Sub-section 2: «everything made available to the public.» This is referred to as the prior art or the state of the art. During the examination of the patent application, the state of the art will be documented by technical articles, etc. These are referred to as «citations».*
>
> *(31) The final prerequisite under Section 2, Sub-section 1, is that the invention must «differ essentially» from the state of the art. This is the reference to inventive step, which is a key issue in the present case.*
>
> *(32) It can be difficult to specify the detailed meaning of the requirement that [the invention] shall differ essentially from the state of the art. The following is stated in relation thereto on page 127 of the joint Nordic patent report from 1964, which formed the basis for largely identical patent acts in the Nordic countries:*
>
> > *«Whether the required inventive step is exhibited in a specific case must to some extent be a matter of discretionary assessment on the part of the patent authorities and the courts of law. One has considered whether it would be feasible to specify objective criteria for assessing this issue. Numerous attempts have been made at defining such objective criteria, but the committees have not found that it will be feasible to stipulate such criteria in legislative wording.»*

(33) The following is stated in the comments on Section 2 on page 102 of Norwegian Official Report NOU 1976:49:

> *«The inventive step requirements implies that the invention shall not only be new, but also needs to entail such development of the art as to not be considered obvious from the perspective of the prior art.»*

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

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

(35) The person skilled in the art referred to therein is discussed in more detail on page 127 of the Nordic patent report from 1964:

> *«Consequently, an invention needs to differ essentially from what must be considered obvious to a person skilled in the relevant art. This is a reference to what can be held to be the person of average skill in the art, meaning a skilled person who is not in possession of special inventive skills, but who is, on the other hand, fully informed of the state of the art at the relevant point in time – the application date – and who has the ability to exploit all the known materials in a good professional manner, also including the taking of obvious new steps.»*

(36) The guidelines of the Norwegian Industrial Property Office, which are largely harmonised with the European regulatory framework on patent examination, describes the «person skilled in the art» as follows in Chapter 4, Paragraph 5.6:

«5.6 The «person skilled in the art»

> *The 'person skilled in the art' shall be assumed to be an average practitioner who is familiar with common general knowledge in the art as at the relevant date. He or she shall also be assumed to have had access to all prior art, especially the documents cited in the examination report, to have had the customary means at his or her disposal, and to have had the ability to perform routine work and experimentation. If the problem impels the person skilled in the art to seek its solution within a different art, it is the person skilled in such latter art who is qualified to solve the problem.»*

(37) The prerequisites for obtaining a patent reflect a trade-off between the fundamental considerations underpinning the patent arrangement – the desire to promote technical development by protecting

the efforts of the inventor, whilst at the same time protecting the general technical developments that are continually taking place in a society. This is, for example, reflected on page 121 and page 127 of the Nordic report from 1964:

> *«The considerations underpinning the patent right – both the perspective that the patent is a form of remuneration owing from society to the person who contributes something new to technical development, and the perspective that society has an interest in promoting intellectual property innovations by protecting the originator in his or her possession of his or her invention, thus enabling him or her to enjoy the fruits of his or her activities without fear of infringement by other parties – suggest that the novelty requirement should be strict, since there can be no societal interest in bestowing benefits on those who have simply brought about something which is already known to experts, or about which they could have accessed knowledge.*
> ...
> *Since there is a seamless, gradual transition from an insignificant technical (craftsmanlike) change or improvement of a constructive nature to a significant pioneering invention, the issue arises of where, along this scale, the threshold for a patentable invention should be placed. This will involve a trade-off between consideration for the applicant, who wants protection for his or her ideas, and consideration for the general public, whose ability to make use of the technical aids should only be restricted through exclusive rights by way of patenting in those cases where there is an interest worthy of protection.»*

(38) It follows from this that the viability of a patent claim must be determined on the basis of a discretionary professional assessment. It is evident from the legislation that the inventor is only entitled to be granted a patent when the prerequisites for obtaining a patent have been met. Hence, this is a matter of a statutory discretionary assessment, over which the courts of law have full jurisdiction. However, the technical nature of such professional assessment suggests that the courts should exercise restraint in their judicial assessment. This has been given clear expression in case law, cf. the ruling published on p. 603 onwards of the 1975 volume of the Norsk Retstidende *court reporter for the Supreme Court (Swingball):*

> *«I also mention that the discretionary assessment performed by the patent authorities pursuant to Section 2 of the Act must be characterised as a matter of assessing, although on a discretionary basis, whether the facts meet the statutory conditions. The Act does not allow any latitude for taking expediency into consideration in individual cases: If the conditions of novelty and inventive step are met, the applicant has the "right" to be granted the patent, cf. Section 1. I find, as already stated, that this discretionary assessment can be reviewed by the courts of law. I emphasise, however, that there is every reason for the courts to exercise restraint in departing from the decisions of the Norwegian Industrial Property Office, in view of the special expertise and the broad empirical basis possessed by the Office.»*

(39) The appellee has noted that some criticism has been expressed against the idea that the courts shall exercise special restraint in their judicial review of patent cases. It has been noted that the Oslo District Court is mandatory venue for the judicial review of rejected patent applications, cf. Section 63 of the Patents Act, and that the District Court and the Court of Appeal will include expert lay judges. The argument runs, moreover, that these will often be in possession of expertise that is even better tailored to the specific needs of the case, compared to the personnel of the Norwegian Industrial Property Office.

(40) Irrespective of whether this is correct, in and of itself, I note that the reason for the restraint exercised by the courts lies, not least, in the fact that the Norwegian Industrial Property Office is in possession of a broad empirical basis with regard to the thresholds applicable to the various prerequisites for obtaining a patent condition, cf. my above quote from Swingball. I see no grounds for deviating from the presumption of restraint on the part of the courts in their judicial review of the decisions of the Norwegian Industrial Property Office, as reflected in the Swingball Judgment.

The Court does not find that there is much need for exercising restraint in the judicial assessment of the decision of the Norwegian Industrial Property Office in the present case. The decision of the Norwegian Industrial Property Office was a first instance decision without opposition. It is not evident from the decision of the Norwegian Industrial Property Office that it was aware of the state of the art. The facts of the case have now been comprehensively examined and the Court includes expert lay judges. Nor is the decision of the EPO Opposition Division a final ruling. Besides, it is noted that a number of rulings have been handed down in other countries.

In their arguments, the parties have given prominence to the issue of whether there is a sufficient inventive step. Consequently, the Court will first address the said issue.

The "problem-and-solution approach" is applied for purposes of assessing whether there is a sufficient inventive step, as long advocated by the EPO. This has also been advocated in Norway. This requires the Court to i) identify the closest prior art, ii) establish the problem objectively solved by the invention, and examine which technical results are achieved through the invention that were not achieved through the solution in the closest prior art, and iii) consider whether it would have been obvious to the skilled person, starting from the closest prior art, to solve the problem by the means defined in the patent claim.

I The closest prior art

In order to determine what is the closest prior art, the claim needs to be read in an objective manner.

The main aspect of the claim is micronisation of tadalafil, where *at least 90% of the particles have a particle size of less than about 40 microns.* The description refers to the need for improved absorption and bioavailability such as to bring about more rapid attainment (shorter Tmax) of maximum blood concentration (Cmax).

Cmax is the maximum concentration achieved by a drug after dosage. Tmax is the time it takes to attain the maximum plasma concentration (Cmax).

The defendant has argued that the closest prior art is not WO 675 (which pertains to a specific use of tadalafil), or alternatively WO '978 (the basic tadalafil patent), as argued by the defendant. The Court agrees with the defendant that these patents do not identify or address the same technical problem or serve the same purpose as the disputed patent, i.e. to expressly improve the absorption and bioavailability.

Consequently, the Court agrees with the defendant that the closest prior art is Butler; WO '131. The Court attaches weight to the patent identifying the same problem types as NO '602, i.e. the very poor solubility of tadalafil in water and how to improve the absorption and bioavailability of tadalafil. Hence, the Court agrees that this is realistically the closest prior art.

Butler discloses a solution to this problem in the form of a co-precipitate formulation. Butler teaches that co-precipitation and solid dispersions are recognised techniques for improving the absorption and bioavailability of poorly soluble active substances. The purpose of Butler is to solve the problem of low solubility – which itself leads to poor absorption and bioavailability. "Co-precipitation is a recognised technique for increasing the dissolution of poorly water soluble drugs (…) so as to consequently improve bioavailability thereof."

The Court notes, moreover, that the said citation was mentioned in the patent application. The Court notes that the EPO Opposition Division has also concluded that this is the closest prior art. The following is quoted form Paragraph 5.2 of its ruling:

> *The closest prior art for assessing inventive step is a prior art document disclosing subject-matter conceived for the same purpose or aiming at the same objective as the claimed invention and requiring the minimum of structural and functional modifications to arrive at the claimed invention.*
>
> *The opponents stated that 02 could not be considered as closest prior art since the co-precipitates of tadalafil and a carrier rather led to a sustained release and not to an improvement of the bioavailability.*
>
> *D2 is considered the closest prior art, since it is the only document that relates specifically to tadalafil (compound A in D2) and aims to increase its dissolution in an aqueous environment, thereby overcoming the problem of poor water solubility and resultant low bioavailability (see page 1, lines 15-16 and lines 20-21 of 02). There is no proof in 02 that the compositions rather show a sustained release as argued by the opponents.*

D1 can not be considered as closest prior art document since its aim is the use of tetracyclic derivatives which are potent and selective inhibitors of cyclic guanosine 3',5'-monophosphate specific phosphodiesterase for the treatment of impotence (page 1, lines 3-5). The problem of bioavailability is not mentioned in D1.

The court-appointed experts in Denmark have also reached this conclusion.

II The problem objectively solved by the invention, and examine which technical results are achieved through the invention that were not achieved through the solution in the closest prior art.

The Court holds that the objective problem to be solved is how to bring about a more rapid effect and improved absorption and bioavailability, relative to the closest prior art, which is Butler, WO '131.

This is also the view taken by the Norwegian Industrial Property Office in its examination, as well as by the EPO Opposition Division.

The Court notes that the problem is obvious and of major importance. If one is to have a medicinal product to treat erectile dysfunction or impotence, it is important that such medicinal product works within a reasonable period of time. It will not always be the case that its use is planned a long time in advance, and the need for such medicinal product will not seldomly be triggered by situational lust and spontaneity, and such situations may wither away if it takes too long time for said medicinal product to work. The Court thus concludes that the purpose is to establish a therapeutic window; a sufficient concentration is needed to achieve a therapeutic effect, but not so high as to have a toxic effect.

The Court deems it evident that micronisation reduces particle size, in order to thereby increase the surface area ("A") in the Noyes-Whitney equation from 1897:

$$\frac{dm}{dt} = A\frac{D}{d}(C_s - C_b)$$

wherein dm/dt is the dissolution rate of a particle; A is the surface area of such particle; C is the concentration of such substance in the solution; Cs is the saturation concentration of such substance in the solution; D is the diffusion coefficient of such substance in the solution and d is the thickness of the diffusion layer surrounding the solid particle.

The Court concludes that it has been demonstrated, on the balance of probabilities, that such micronisation had technical effects in the form of improved solubility, absorption and bioavailability, as argued by the defendant and as concluded by the EPO. Reference is made to the improvement of Tmax and the higher plasma level disclosed in the patent application. It has been demonstrated, on the balance of probabilities, that Tmax for KIT is an average of 1.5 time less than for the co-precipitate, and that Cmax is 27% higher on average. This is described as a "surprising technical advantage" over Butler in the EPO ruling relating to EP1200090.

III Consider whether it would have been obvious to the skilled person, starting from the closest prior art, to solve the problem by the means defined in the patent claim.

The Court now moves on to discuss whether it would have been obvious to the skilled person to solve the problem by micronisation of the active substance tadalafil.

Both parties have taken the view that the skilled person is a team comprising, at a minimum, one person with skills and experience in pharmaceutical formulation (galenic pharmacy), provided, however, that other expertise, e.g. in pharmacology, will be consulted if necessary. There is technical knowledge of pharmaceutical formulation, biopharmacy, chemistry and pharmacology. The Court finds that this defines an appropriate point of departure.

This assessment must be based on the state of the art as at the priority date, 3 August 1999. Hence, the questions are what knowledge of the problems was in the possession of such a team of skilled persons, with skills and experience in pharmaceutical formulation and pharmacology, at the said date and, thereafter, whether it would have been obvious to the skilled person to use the method of micronising the active substance tadalafil in order to attain improved absorption and bioavailability.

Each citation shall, as a general rule, be assessed separately, but shall be combined with information from other documents explicitly referred to in the citation, and shall be combined with common general knowledge in the art. Common general knowledge in the art will typically include textbooks, handbooks and knowledge that would have been acquired by the person skilled in the relevant art. Reference is made to EPO case law and to Are Stenvik, *Patentrett* ["Patent Law"] (2013), page 200 onwards; the following is quoted from page 201:

> *One may instead take the view that common general knowledge in the art is something which will always be in the possession of the person skilled in the art, and which he or she will draw on as a matter of course when he or she studies a citation.*

The Court finds that this approach is correct.

The Court takes the view that the skilled person would have started out from the premise that the medicinal product had to be administered orally in the form of a tablet. The medicinal product needs to be administered by ordinary users without the assistance of medical personnel, thus implying that intravenous administration by syringe is not desirable. Oral administration is the ordinary route of administration for this type of medicinal products. Reference is also made to the testimony of Bauer Brandel in this regard.

Under oral administration, absorption will primarily take place in the intestine (absorbed). The issue of whether and how the medicinal product dissolves (solubility) and thereafter permeates the intestinal wall and enters the bloodstream (permeability). The issue of absorption and

bioavailability is thus an issue of solubility and permeability, which are key factors in the biopharmaceutical classification system.

The Court agrees with both parties that the skilled person in 1999 would, in order to solve the problem of improved bioavailability for Tadalafil, have started with a pre-formulation study. Its purpose is to establish fundamental physical and chemical properties of a pharmaceutical molecule and other derived properties of the pharmaceutical powder. However, there is disagreement between the parties with regard to how far one would go with such a pre-formulation study.

The Court notes, in this regard, that the skilled person is a team with knowledge of pharmaceutical formulation and pharmacology. The Court deems it evident that one would have tried out common general knowledge in the art as at 1999 in that respect, to establish a basis for determining what to do thereafter in attempting to solve the problem. This would seem appropriate to the skilled person in order to know as much as possible, in order to save time and money in the subsequent work, and in order to establish the best possible basis for identifying a solution. The skilled person will always attempt to find a simple solution. Consequently, the Court finds that the skilled person would have used customary and known pharmaceutical, biopharmaceutical and chemical methods to find out as much as possible about the properties of tadalafil in such a pre-formulation study.

The BCS (Biopharmaceutics Classification System) is a system for classifying drugs on the basis of their solubility and permeability:
Class I - high solubility and high permeability;
Class II - high permeability and low solubility;
Class III - low permeability and high solubility;
Class IV - low permeability and low solubility.

Tadalafil is in BCS Class 2 with low solubility and high permeability

A simple initial approach is Lipinski's Rule of Five, which is a rule of thumb developed to assist in the selection of early phase candidate drugs, used to predict the likelihood of a pharmaceutical compound exhibiting poor absorption and bioavailability or permeability. It is comprised of four rules, and poor absorption is likely if all four are satisfied. If any two (or more) are satisfied, poor absorption and bioavailability is held to be possible. The four rules are:

1. There are more than 5 hydrogen bond donors in the compound;
2. The molecular weight (i.e. molecular mass) of the compound is more than 500 Daltons;
3. logP of the compound is greater than 5; and
4. There are more than 10 hydrogen bond acceptors in the compound.

According to the rule, it is likely that tadalafil will exhibit good permeability over the intestinal barrier. This would be known to the skilled person in 1999. It would be found, through the said study, that tadalafil is likely to exhibit low solubility; "practically insoluble", but offer good permeability.

A different approach is logP or the partition coefficient, which is the logarithm of the ratio of the concentration of such compound in two immiscible liquids, i.e. the ratio between an organic solvent and a water-based solvent. LogP is, for example, typically used to characterise whether a compound has a greater likelihood of dissolving in an organic solvent or in water, and if the former is the case it will be considered a lipophilic/hydrophobic compound, and if the latter is the case it will be considered a lipophilic/hydrophilic compound. The higher the logP value, the more lipophilic is the compound.

None of the models are suited for reflecting entirely specific in vivo conditions, and are better characterised as rules of thumb than as genuine quantitative models. All of the models will entail a significant margin of error. Yu stated the following in 1996 in "Transport approaches to the biopharmaceutical design of oral drug delivery systems: prediction of intestinal absorption":

"Very often we may find that a theoretical model inappropriately explains experimental results."

The Court finds that the skilled person would have carried out practical experiments to find out whether the theoretical models were in conformity with simple experiments. In such practical experiments, the skilled person would choose parameters that reflect, to the greatest possible extent, in vivo conditions.

The skilled person knew that it makes a major difference, when measuring solubility, whether it is measured in water or in a liquid similar to intestinal fluid. It is more relevant to carry out solubility experiments in an artificial and biorelevant liquid that is similar to intestinal fluid (Simulated Intestinal Fluid, SIF) than in water. Reference is made to Lin from 1968, "Interdependence of Physiological Surfactant and Drug Particle Size on the Dissolution Behavior of Water-Insoluble Drugs" and Yu (op. cit.) 1996. Moreover, the skilled person would expect higher solubility when measured under conditions that are closer to the conditions in the gastrointestinal system, i.e. when measured in simulated intestinal fluid at 37 grader Celsius. Solubility will depend on surface area and saturation concentration in the solution, i.e. it is rapid at the beginning and slows down thereafter. Besides, there is a constant, K, which does not change.

The skilled person would have conducted a Caco-2 assay in 1999; reference is made to the testimony of Blakey and Bauer-Brandl that this was in common use in companies in 1999. Reference is also made to Yee, 1997, in "In Vitro Permeability Across Caco-2 Cells (Colonic) Can Predict In Vivo (Small Intestinal) Absorption in Man – Fact or Myth". Cultures of Caco-2 cell monolayers are used in the pharmaceuticals industry as an in vitro model of the mucous membrane of the humane small intestine in order to anticipate the absorption of orally administered medicinal products. Caco-2 cells are human epithelial cells that, when cultivated under specific conditions, resemble the enterocytes that coat the small intestine.

Such a Caco test would have confirmed the theoretical assumption that tadalafil had a high degree of permeability. It is evident from Blakey's report that Tadalafil has high permeability, since its absorption ratio after oral administration is 97% of a given dose. A pharmaceutical substance is classified as having high permeability when its absorption ratio exceeds 85% of a given dose.

Hence, a provisional summary would suggest that the skilled person in 1999 would have known that tadalafil has low solubility and high permeability. This would have been established in the pre-formulation studies.

Moreover, the skilled person would know that absorption in the intestine will be better than what is calculated theoretically on the basis of static experiments in a container. Michael Edward Aulton testified that some liquid will always leave the stomach; there is a 2 mm opening, thus implying that there will be gradual emptying of the stomach through the lower stomach opening. Half the tablet will leave the stomach within 8 to 15 minutes. The theoretical concentration in a closed system, kA (Cs – C), will be nil when Cs-C is nil. This will not happen in the intestine, where absorption is taking place continuously, thus implying that the dissolved concentration is kept low in the intestine (so-called sink conditions). Consequently, solubility will be better in vivo in a human (or other mammal) than in an in vitro laboratory experiment. The same will apply to permeability through the intestinal wall because new liquid will be added on the other side of the intestinal wall (i.e. the bloodstream), thus implying that the concentration difference is to some extent maintained.

The Court deems it evident that it was part of common general knowledge in the art as at the priority date of the patent that reduced particle size improves the dissolution rate, absorption and bioavailability.

Reference is made to Amidon 1981, "Drug Derivatization as a Means of Solubilization: Physicochemical and Biochemical Strategies", wherein is stated: "Quite often the first approach to increase the dissolution rate of drugs in this class [BCS class 2] is micronisation."

Aulton, 1988, "Pharmaceutics: The Science of Dosage Form Design", pages 163 and 164: "It is now generally recognized that poorly soluble drugs showing a dissolution rate-limiting step in the absorption process will be more readily bioavailable when administered in a finely subdivided form with a larger surface than as a coarse material. […] The fine material often in micronized form with larger specific surface dissolves at faster rates which can lead to improved drug absorption by passive diffusion."

Lieberman, Lachman & Schwarz, Wadke, 1989, "Pharmaceutical Dosage Forms: Tablets", "It is now generally recognized that poorly soluble drugs showing a dissolution rate-limited step in the absorption process will be more readily bioavailable when administered in a finely subdivided state than as a coarse material. (…) Because of these significant roles, it is important to decide on a desired size range, and thence to maintain and control

it. It is probably safest to grind most new drugs having particles that are above approximately 100 μm in diameter. If the material consists of particles primarily 30 μm or less in diameter, then grinding is unnecessary, except if the material exists as needles - where grinding may improve flow and handling properties, or if the material is poorly water-soluble where grinding increases dissolution rate. Grinding should reduce coarse material."

Gibaldi, 1991, "Biopharmaceutics and Clinical Pharmacokinetics", page 51: "A drug dissolves more rapidly when its surface area is increased. This is usually accomplished by reducing the particle size of the drug. Many poorly soluble, slowly dissolving drugs are marketed in micronized or microcrystalline form. Particle size reduction usually results in more rapid and complete absorption."

Remington, 1995, "The Science and Practice of Pharmacy". "Gastrointestinal absorption of a poorly soluble drug may be affected by the particle size distribution. If the dissolution rate of the drug is less than the diffusion rate to the site of absorption and the absorption rate itself, then the particle size of the drug is of great importance. Smaller particles should increase dissolution rate and thus, bring about more rapid gastrointestinal absorption."

Lieberman, Lachman, Schwartz, 1990, Pharmaceutical Dosage form (Stavchansky, McGinity), Bioavailability in Tablet Technology, page 108.
"Since dissolution rate is directly proportional to surface area […], a decrease in size of the primary particles of the drug will create a greater surface area in contact with the dissolution medium, resulting in a faster rate of solution. This becomes important when the absorption is rate-limited by the dissolution process. Particle size is generally important for poorly or slowly soluble drugs."

Seth, U.S. Patent Number: 721,709, 26 January 1988, "As has been mentioned above a conventional method for increasing the rate of dissolution of solids is by reduction of their particle size by micronisation or similar dry grinding methods, […]"

The question is thereby whether the skilled person would have attempted micronisation with a reasonable expectation of success through increased absorption and bioavailability.

The Court deems it evident that reduction of the particle size would also be obvious to the skilled person in order to solve the technical problem in relation to WO '131 of bringing about a formulation of tadalafil with improved absorption and bioavailability.

This would be the most obvious solution. Smaller particles are also more likely to dissolve in liquid. This is quite simply because their surface area is relatively larger. There is an overwhelming amount of technical literature suggesting that this is a method that would be attempted in order to improve absorption and bioavailability.

The defendant has forcefully argued that the guidance provided by the closest prior art, Butler WO 131, would not have caused micronisation to be attempted, but instead a solution with co-precipitate to a solid solution or a solid dispersion. Aulton (1988) describes it as follows: "Co-precipitate. If active substances, preferably with the addition of highly polymeric carriers, are dispersed or dissolved and thereafter separated from the solvate, one brings about solid dispersions or solid solutions, so-called co-precipitates. Such medications contain the active substance very finely dispersed. (...) The solubility and dissolution rate of the active ingredients will be significantly increased by the colloidal dispersion (…)

The Court does not agree with this. The Court finds that the most obvious approach would have been for the skilled person to attempt the art's standard solution to the problem, i.e. micronisation of the active pharmaceutical substance, before attempting more sophisticated and complex solutions. Even if the closest prior art points in one direction, it will not prevent the skilled person from exercising common general knowledge in the art, especially not when it is so well known in the art.

The Court finds that one would not primarily have attempted theoretical models as argued by the defendant. None of the models formed part of common general knowledge in the art or the prior art as at the priority date of the patent; reference is made to Lipinsky, "Drug-like Properties and the Causes of Poor Solubility and Poor Permeability," J. Pharmacol. & Toxicol. Methods 44: 235-249, and Yu "An Integrated Model for Determining Causes of Poor Oral Drug Absorption," Pharm. Research 16(12): 1883-1887 (September 1999). There was research in relation to theoretical models, but no consensus as to the relevance of the various models.

These models had originally been developed for use during the Drug Discovery phase. None of the models are suited for reflecting in vivo conditions, and the models will often generate different results; they entail a significant margin of error. Yu op. cit.: "Very often we may find that a theoretical model inappropriately explains experimental results."

The skilled person would under any circumstance have attached less weight to such results than to empirical and established experiments and studies.

The defendant has, furthermore, noted the potential disadvantages of micronisation. There is a risk of aggregation. These problems are known to the skilled person, and will, if occurring, be sought resolved by changing surface tension or mixing in other substances. The Court deems it evident that this would not have prevented micronisation attempts. Reference is made to the extensive literature and knowledge on how to solve such problems.

The UK Patents Court states the following in this regard:
"However, micronisation is not just an item in a list of common general knowledge techniques to be tried to improve the situation when one has a BCS class II drug, it is at the top of the list to be considered." (paragraph 419)

Wadke teaches that the skilled person should in any case micronise when the particle size is in excess of 100 µm. "Raw" tadalafil has a particle size of 75- 200 µm, encompassing a broad range of particle sizes. Micronisation is a simple method; this was confirmed by Aulton and Bauer-Brandl.

The Court refers to the UK Patents Court and quotes:
"Prof. Buckton's view was that the skilled person would always try to apply the "KISS" approach ("Keep It Simple Stupid"). Prof. Frijlink agreed that the formulator would always consider simple methods before complex ones."

The UK Patents Court, op. cit., paragraph 420
"A point on micronisation is that it can lead to aggregation. The formulator knows that. It would not deter them and would not diminish whatever expectation they had in achieving a good result."

Moreover, the Court notes the clear need for keeping the use of very well known prior art, such as micronisation of medicinal products, free for common use. By recognising this one would pave the way for others to patent such micronisation, thus creating problems for those holdings rights to the original patent. This would be undesirable, especially when the micronisation does not contribute unexpected results. Indeed, the results are in conformity with established and common general knowledge in the art with regard to expected and disclosed effects of micronisation.

Micronisation entails certain disadvantages. There is a risk of aggregation. This can be resolved by an intensive mixing process, by changing surface tension with granulation liquid or by mixing in other substances. This was known in the art in 1999.

All in all, the Court concludes that the skilled person not only could have performed micronisation of tadalafil in 1999 in order to improve absorption and bioavailability. It is clear to the Court that a team of skilled persons without inventive abilities would have attempted micronisation with a *reasonable expectation of success*. This would be in conformity with common general knowledge in the art, and the first thing a skilled person would attempt to solve this problem. Micronisation is, and was in 1999, the most obvious solution to the technical problem.

The Court concludes, based on the above, that the patent does not exhibit a sufficient inventive step, thus implying that it must be declared invalid.

Legal costs

Actelion Pharmaceuticals Ltd has prevailed in the case and is entitled to compensation for its legal costs, cf. Section 20-2 of the Dispute Act. Attorney Hanssen-Bauer has submitted a legal cost specification with legal fees of NOK 3,691,450, additional expenses of NOK 238,291.80 and expenses relating to fees, travel and subsistence for expert witnesses of NOK 1,954,271; totalling NOK 5,884,012.80. No objections have been filed in respect of such specification, and the Court accepts it. Court fees for the main hearing over 6 days, in the amount of NOK 21,525, and fees, travel and subsistence for expert lay judges, in the amount of NOK 303,149.65 are additional thereto. Total legal costs are NOK 6,208,687.45.

The judgment is unanimous.

The judgment has not been rendered within the statutory time limit. The reasons are death in the family, illness, extensive case, and a large workload.

CONCLUSION OF THE JUDGMENT

1. NO 321 602 is declared invalid.

2. Icos Corporation shall pay the legal costs of Actelion Pharmaceuticals Ltd in the amount of 6,208,687.45 – six million two hundred and eight thousand six hundred and eighty seven point forty five – Norwegian kroner, within 2 – two – weeks of service of the judgment.

Court adjourned

Dagfinn Grønvik

Jørn Sonnergaard Hans Lennernäs

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

Guidance notes on the right of appeal in civil actions

The provisions of Chapters 29 and 30 of the Civil Procedure Act on appeal to the Court of Appeal and the Supreme Court govern the right of the parties to have judicial rulings reviewed by the courts above. There are certain differences between the provisions of the Civil Procedure Act in relation to appeals over judgments, appeals over court orders and appeals over decisions, respectively.

The time limit for filing an appeal is one month from the date on which the ruling was served or communicated, unless otherwise explicitly specified by the court. The time limit for filing an appeal is extended for the duration of the court vacations. The court vacations are as follows: The court vacations run from the last Saturday before Palm Sunday until Easter Monday, inclusive, from 1 July until 15 August, inclusive, and from 24 December until 3 January, inclusive, cf. Section 140 of the Courts of Justice Act.

The appellant must pay a processing fee. The court that gave the ruling can provide more detailed information about the amount of the fee and how to pay it.

Appeal to the Court of Appeal over a judgment rendered by the District Court
The Court of Appeal is the appellate court for the rulings of the District Court. A judgment from the District Court may be appealed on the grounds of errors in the assessment of the facts of the case, in the application of law, or in the procedural handling of the case.

The Civil Procedure Act stipulates certain limitations to the right of appeal. An appeal over a judgment in a case concerning economic interests will not be heard without the consent of the Court of Appeal if the value of the subject-matter of the appeal is less than NOK 125,000. In determining whether to grant consent, the court shall take into consideration, *inter alia*, the nature of the case, the parties' need for judicial review, and whether there would appear to be weaknesses associated with the ruling that has been appealed or in the handling of the case.

In addition, the Court of Appeal may refuse to hear an appeal – irrespective of the value of the subject-matter of the appeal – when it finds it evident that the appeal will not be upheld. Such refusal may be limited to individual claims or individual grounds for appeal.

An appeal shall be filed in the form of a written notice of appeal to the District Court that rendered the ruling. Parties representing themselves may file an appeal orally by appearing personally before the District Court. The Court may also permit a counsel who is not an advocate to file an oral appeal.

The notice of appeal shall specify, in particular, what one objects to in the appealed ruling and what, if any, are the new factual or legal grounds or new evidence invoked.
The notice of appeal shall specify:

- the appellate court;
- the names and addresses of parties, representatives and counsel;
- what ruling is appealed;
- whether the appeal concerns the ruling in its entirety, or only parts thereof;
- the claim with which the appeal is concerned, and a pleading specifying the findings requested by the appellant;
- the errors that are alleged to exist in the appealed ruling;
- the factual and legal grounds on which it is argued that errors exist;
- the evidence that will be presented;
- the basis on which the court may hear the appeal, if there has been any doubt in relation thereto;
- the views of the appellant as to the further handling of the appeal.

An appeal over a judgment will normally be resolved by judgement following an oral hearing before the Court of Appeal. The deliberation of the appeal shall be concentrated on those parts of the ruling of the District Courts that are disputed and open to doubt when the case is brought before the Court of Appeal.

Appeal to the Court of Appeal over court orders and decisions rendered by the District Court

A *court order* may, as a main rule, be appealed on the grounds of errors in the assessment of the evidence, in the application of law, or in the procedural handling of the case. However, if the court order concerns a procedural ruling that shall, according to statute, be rendered on the basis of a discretionary assessment as to what is the appropriate and sensible approach, the ruling may only be contested, as far as the discretionary assessment is concerned, on the grounds that the ruling is unsound or clearly unreasonable.

A *decision* may only be appealed on the grounds that the court has applied an incorrect general interpretation of the law as to what rulings the court may render under the applied provision, or on the grounds that the ruling is obviously unsound or unreasonable.

The requirements as to the contents of the notice of appeal are, as a main rule, the same as for an appeal over a judgment.

After the District Court has resolved the case through a judgment, the rulings of the District Court as to the procedural handling of the case cannot be appealed separately. In such case the judgment may instead be appealed on the grounds of errors in the procedural handling of the case.

An appeal over a court order or a decision shall be filed with the District Court that rendered the ruling. An appeal over a court order or a decision will normally be resolved by court order following only a written deliberation before the Court of Appeal.

Appeal to the Supreme Court

The Supreme Court is the appellate court for the rulings of the Court of Appeal.

An appeal to the Supreme Court over a *judgement* will always require the consent of the Appeals Selection Committee of the Supreme Court. Such consent shall only be granted when the appeal concerns matters that are of relevance outside the present case, or when it is, for other reasons, of particular importance that the case be heard before the Supreme Court. – An appeal over a judgment will normally be resolved following an oral hearing.

The Appeals Selection Committee of the Supreme Court may refuse to accept appeals over *court orders and decisions* for deliberation if these do not raise matters that are of relevance outside the present case, and no other considerations suggest that the appeal should be heard, or if these primarily raise complex evidential matters.

When an appeal over a court order or a decision of the District Court has been resolved by a court order rendered by the Court of Appeal, the ruling cannot, as a main rule, be appealed on to the Supreme Court.

An appeal over a court order or a decision of the Court of Appeal will normally be resolved following a written deliberation before the Appeals Selection Committee of the Supreme Court.