16/02891

24 November 2017

G.R.B. van Peursem, LL.M.

Opinion

in the matter of:

Resolution Chemicals Limited,
(hereinafter: Resolution),
claimant in the appeal in cassation,
attorney: A.M. van Aerde, LL.M.,

versus

1. **AstraZeneca B.V.**,
2. **Shionogi Seiyaka Kabushiki Kasiha**,
   (hereinafter: Shionogi)

(hereinafter collectively: AstraZeneca et al.),
defendants in the appeal in cassation,
attorney: W.A. Hoyng, LL.M.

In this patent case dealing with the extent of the protection that is conferred by EP 471 (for a new cholesterol inhibitor), the question to be answered is whether a limiting definition ("own lexicon") in the description of the claim feature "pharmaceutically acceptable salt" is involved. In contrast to the District Court, following an extensive substantiation, the Court of Appeal ruled that the average skilled person would not take the definition given in paragraph 7 of the description to be a limiting definition. I feel that the complaints in cassation directed against this, in summary entailing that this interpretation is incomprehensible and in breach of Article 69 EPC, do not hold.
I also feel that the complaints directed against the Court of Appeal's interpretation of the grounds for appeal and the finding that no added subject matter is involved are unsuccessful. Thus, I conclude that the appeal in cassation is dismissed.
The Supreme Court could use this case to clarify whether the waiver doctrine from *Van Bentum/Kool*[1] is still valid law. This is a difficult disputed point in the patent practice (and in the case at issue, as well), which would benefit from clarity regarding this point.
I believe that the waiver doctrine stems from the era of the abandoned protective scope doctrine of the essence and does not fit (or no longer fits) within the correct application of Article 69 EPC according to the Protocol on the interpretation of this article, as this has also been almost fully worked out in the Netherlands. Because according to prevailing Dutch patent law, the inventive idea is no longer the *starting point* in determining the protective scope, but is a *point of view* that may play a role in this, I believe that in practical terms, it is

[1] HR 22 March 2002, ECLI:NL:HR:2002:AD8184, *NJ* 2002/530, annotated by Ch. Gielen (*Van Bentum/Kool*).

possible to arrive at a system that comes close to the waiver doctrine: in my opinion, in the scope of the *point of view* of the *inventive idea*, in conformance with Article 69 EPC, it is possible to include this when considering whether according to the average skilled person, the intention was to limit the extent of the protection. On balance, this is the method that the Court of Appeal used in the ruling that is challenged in the case at issue. This differs slightly (not radically) from the waiver doctrine as we know it, but in practice, this will rather frequently produce similar results in terms of outcome.

1. Facts[2] and course of the proceedings

1.1 Resolutions' business is the development and production of active pharmaceutical ingredients.

1.2 Shionogi is a Japanese pharmaceutical company that is the holder of the supplementary protection certificate 300125 (hereinafter also: the SPC) for the Netherlands that has been granted for the product '*Rosuvastatinum, if required in the form of a non-toxic pharmaceutically acceptable salt, in particular calcium salt*'. The SPC, which is based on European patent 0 521 471 (hereinafter: EP 471 or the (basic) patent), has been exclusively licensed to Astrazeneca B.V. In the Netherlands, Astrazeneca B.V. markets rosuvastatin calcium under the brand name Crestor®. Astrazeneca B.V. is also the holder of the marketing authorization for Crestor® in the Netherlands. The SPC expires on 29 June 2017, unless the application for paediatric extension of the SPC is granted. In that case, the duration of the SPC will be extended to 29 December 2017.

1.3 Shionogi was the holder of EP 471, which pertains to '*Pyrimidine derivatives as HMG-CoA reductase inhibitors*' (in the unchallenged Dutch translation: '*Pyrimidinederivaten als HMG-CoA-reductase-inhibitoren*'). The patent was granted on 25 October 2000 by virtue of a patent application dated 30 June 1992, invoking priority of 1 July 1991 based on JP 18801591. The patent, which expired on 29 June 2012, was designated for the Netherlands, amongst other countries. No opposition was brought against the grant of the patent.

1.3 The patent has 16 claims. Claim 1 pertains to the compound rosuvastatin acid or a non-toxic pharmaceutical salt thereof.

1.4 The (authentic) English text of claim 1 reads as follows:

> 1. The compound (+)-7-[4-(4-fluorophenyl)-6-isopropyl-2-(N-methyl-N-methylsulfonylamino)pyrimidin-5-yl]-(3R,5S)-dihydroxy-(E)-6-heptenoic acid or a non-toxic pharmaceutically acceptable salt thereof.

[2] Derived from par. 2.1-2.12 and 3.1-3.7 of the challenged ruling: Court of Appeal of The Hague 6 February 2016, ECLI:NL:GHDHA:2016:339, BIE 2016/23, annotated by P.L. Reeskamp (*Astrazeneca et al./Resolution*).

1.5 The undisputed Dutch translation of claim 1 of EP 471 reads as follows:

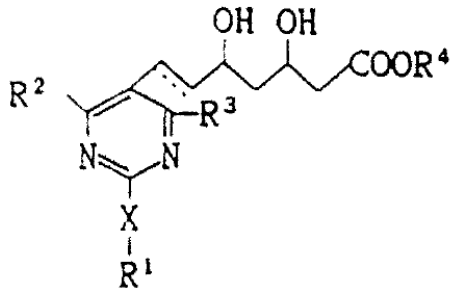
1. Verbinding (+)-7-[4-(4-fluorfenyl)-6-isopropyl-2-(N-methyl-N-methylsulfonylamino)pyrimidin-5-yl]-(3R,5S)-dihydroxi-(E)-6-hepteenzuur of een niet-toxisch farmaceutisch aanvaardbaar zout daarvan.

1.6 The description of EP 471 *inter alia* contains the following passages:

[0001] The present invention relates to 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase inhibitors.
[0002] The first generation of drags [bedoeld zal zijn: drugs, A-G] for the treatment of atherosclerosis by inhibiting the activity of HMG-CoA reductase, are mevinolin (...), pravastatin sodium (...), and simvastatin (...), which are fungal metabolites or chemical derivatives thereof. Recently, synthetic inhibitors of HMG-CoA reductase such as fluvastatin (...) were developed as the second generation drags [idem, A-G].
[0003] The compounds of the present invention inhibit the HMG-CoA reductase, which plays a major role in the synthesis of cholesterol, and thus they suppress the biosynthesis of cholesterol. Therefore, they are useful in the treatment of hypercholesterolemia, hyperlipoproteinemia and atherosclerosis.
(...)
[0006] In the specification, the term "lower alkyl" refers to a straight, branched, or cyclic C1 to C6 alkyl, including methyl, ethyl, n-propyl, isopropyl, cyclopropyl, n-butyl, isobutyl, sec-butyl, tert-butyl, cyclobutyl, n-pentyl, isopentyl, neopentyl, tert-pentyl, cyclopentyl, n-hexyl, and isohexyl and the like. Further, the lower alkyl may be substituted by 1 to 3 substituents independently selected from the group consisting of halogen, amino, and cyano. Halogen means fluorine, chlorine, bromine and iodine.
[0007] The term "a non-toxic pharmaceutically acceptable salt" refers to a salt in which the cation is an alkali metal ion, an alkaline earth metal ion, or an ammonium ion. Examples of alkali metals are lithium, sodium, potassium, and cesium, and examples of alkaline earth metals are beryllium, magnesium, and calcium. Sodium and calcium are preferred.
(...)
[0029] The present invention is illustrated by the following examples and reference examples, which are not to be considered as limiting.
(...)

1.7 Claim 1 as set forth in the original application of EP 471 reads as follows:

1. A compound represented by the formula (I):



(I)

wherein R1 is lower alkyl, aryl of aralkyl, each of which may have one or more substituents; R2 and R3 each is independently hydrogen, lower alkyl or aryl, and each of said lower alkyl and aryl may have one or more substituents; R4 is hydrogen, lower alkyl, or a cation capable of forming a non-toxic pharmaceutically acceptable salt; X is sulfur, oxygen, or sulfonyl, or imino which may have a substituent; the dotted line represents the presence or absence of a double bond, or the corresponding ring-closed lactone.

1.8 The description of the original application includes the following passages:

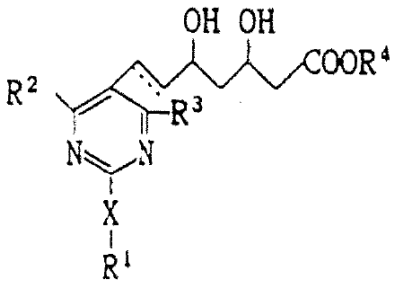
(page 2, lines 1 and 2)

The present invention relates to 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase inhibitors.

(page 2, lines 9-29)

The compounds of the present invention inhibit the HMG-CoA reductase, which plays a major role in the synthesis of cholesterol, and thus they suppress the biosynthesis of cholesterol. Therefore, they are useful in the treatment of hypercholesterolemia, hyperlipoproteinemia and atherosclerosis.

The present invention relates to compounds of the formula (I):



(I)

wherein R1 is lower alkyl, aryl of aralkyl, each of which may have one or more substituents; R2 and R3 each is independently hydrogen, lower alkyl or aryl, and each of said lower alkyl and aryl may have one or more substituents; R4 is hydrogen, lower alkyl, or a cation capable of forming a non-toxic pharmaceutically acceptable salt; X is sulfur, oxygen, or sulfonyl, or imino which may have a substituent; the dotted line represents the presence or absence of a double bond, or the corresponding ring-closed lactone. This invention also provides a pharmaceutical composition comprising the same.

(page 2, lines 42-45)

The term "a cation capable of forming a non-toxic pharmaceutically acceptable salt" refers to an alkali metal ion, an alkaline earth metal ion, or an ammonium ion. Examples of alkali metals are lithium, sodium, potassium, and cesium, and examples of alkaline earth metals are beryllium, magnesium, and calcium. Sodium and calcium are preferred.

(page 4, lines 29 and 30)

The present invention is illustrated by the following examples and reference examples, which are not to be considered as limiting.

(page 8, lines 43-47)

Example 1

Sodium (+)-7-[4-(4-fluorophenyl)-6-isopropyl-2(N-methyl-N-methylsulfonylaminopyrimidin)-5-yl]-(3R,5S)-dihydroxy-(E)-6-heptenate (Ia-1)
[...]

(page 13, lines 16-58 and page 14, lines 1-22)

Example 7

Calcium salt of the compound (Ia-1)

The compound (Ia-1) (sodium salt) 1.50 g (3.00 mmol) is dissolved in 15 ml of water and stirred at room temperature under a nitrogen atmosphere. Successively 3.00 ml (3.00 mmol) of 1 mol/L calcium chloride 3.00 ml (3.00 mmol) is added dropwise thereto over 3 minutes. The reaction mixture is stirred at the same temperature for 2 hours, and the resulting precipitate is collected, washed with water and dried to give 1.32 g of calcium salt as powder. This compound started to melt at a temperature of 155 ° C, but the definitive melting point is ambiguous. [α]D = +6.3±0.2° (C = 2.011, 25.0 ° C, MeOH)

Anal Calcd. (%) for $C_{22}H_{27}N_3O_6SF \cdot 0.5Ca \cdot 0.5H_2O$					
:	C,51.85;	H,5.53;	N,8.25;	F,3.73;	Ca,3.93
Found :	C,51.65;	H,5.51;	N,8.47;	F,3.74;	Ca,4.07

Biological Activity

Experiment

The HMG-CoA reductase inhibitory effect

(1) Preparation of rat liver microsomes

Sprague-Dawley rats, which were in free access to ordinary dietes containing 2% cholestyramine and water for 2 weeks, were used for the preparation of rat liver microsomes. The thus obtained microsomes were then purified according to the manner described by Kuroda et al., Biochem. Biophys. Act, 486, 70 (1977). The microsomal fraction obtained by centrifugation at 105000 x g was washed once with a buffered solution containing 15 mM nicotinamide and 2 mM magnesium chloride (in a 100 mM potassium phosphate buffer, pH 7.4). It was homogenized with a buffer containing nicotinamide and magnesium chloride at the same weight as the liver employed. The thus obtained homogenate was cooled down and kept at -80 ° C.

(2) Measurement of the HMG-CoA reductase inhibitory activities

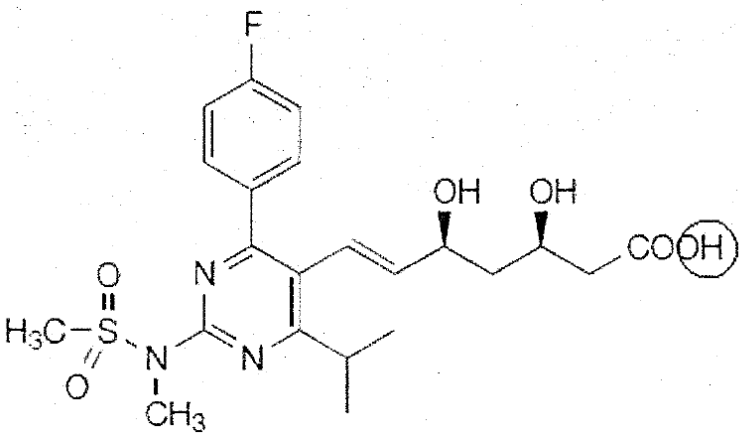
The rat liver microsome sample (100 μ l), which was preserved at -80 ° C, was fused at 0 ° C and diluted with 0.7 ml of a cold potassium phosphate buffer (100 mM pH7.4). This was mixed with 0.8 ml of 50 mM EDTA (buffered with the aforementioned potassium phosphate buffer) and 0.4 ml of 100 mM dithiothreitol solution (buffered with the aforementioned potassium phosphate buffer), and the mixture was kept at 0 ° C. The microsome solution (1.675 ml) was mixed with 670 μ l of 25 mM NADPH (buffered with the aforementioned potassium phosphate buffer), and the solution was added to the solution of 0.5mM [3-14C]HMG-CoA (3mCi/mmol). A solution (5 μ l) of sodium salt of the test compound dissolved in potassium phosphate buffer was added to 45 μ l of the mixture. The resulting mixture was incubated at 37 ° C for 30 minutes and cooled. After termination of the reaction by addition of 10 μ l of 2N-HCL, the mixture was incubated again at 37 ° C for 15 minutes and then 30 μ l of this mixture was applied to thin-layer chromatography on silica gel of 0.5 mm in thickness (Merck AG, Art 5744). The chromatograms were developed in toluene/acetone (1/1) and the spot, whose Rf value was between 0.45 to 0.60, were scraped. The obtained products were put into a vial containing 10 ml of scintillator to measure specific radio-activity with a scintillation counter. The activities of the present compounds are shown in Table 4 as comparative data, based on the assumption that the activity of mevinolin (sodium salt) as the reference drug is 100.

Table 4

Test Compound	HMG-CoA reductase inhibitory activities
I a-1	442
I a-3	385
I a-5	279
I a-7	260
Mevinolin Na	100

The test data demonstrates that the compounds of the present invention exhibit HMG-CoA reductase inhibition activities superior to mevinolin.

1.9 In contrast to the original application, which claimed a class of compounds by means of a Markush formula, EP 471 only pertains to rosuvastatin. EP 471 claims the acid of rosuvastatin; see the structural formula below (which has been derived from the statement by Professor Dr J.W. Jukema that Astrazeneca submitted as Exhibit GP3). In that case, the R4 group represented in claim 1 of the original application (see 1.8) is H, circled in red below. Choices are also made for the R1, R2, R3 and X groups.



1.10 Resolution obtained a marketing authorization for the marketing of rosuvastatin zinc and intends to put that product on the market in the Netherlands. Resolution notified AstraZeneca et al. of this in a letter dated 26 March 2014. On 4 April 2014, attorney Hoyng informed Resolution on AstraZeneca et al.'s behalf that AstraZeneca et al. is not prepared to confirm that it will not invoke SPC 300125 against Resolution, its buyers and their buyers if they start selling rosuvastatin zinc on the Dutch market.

The technical background[3]

1.11 Cholesterol is a fatty substance that the human body primarily uses as a building

[3] The Court of Appeal derived the explanation of the patent's technical background from the undisputed explanation in the judgment, as follows from chapter 3 of the challenged ruling. For a better understanding, I follow this here, as well.

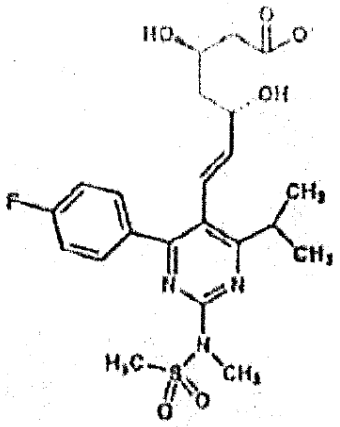
block for cell membranes and to produce bile acid. Given that cholesterol is insoluble, the blood transports it as a complex in specific, various types of proteins. Two main types of cholesterol are distinguished: LDL cholesterol (LDL means ‘low density lipoprotein’) and HDL cholesterol (HDL means ‘high density lipoprotein). However, these are the same cholesterol, but ‘packaged’ in different proteins.

1.12 LDL and HDL perform different functions. LDL transports cholesterol from the liver through the body, while HDL returns (an excess of) cholesterol to the liver, where it can be broken down and further eliminated. If the LDL cholesterol content in the blood is relatively high, it will stick to the inside of the arteries. This is especially true if the cholesterol is oxidized. As a result, the arteries get clogged, which increases the risk of cardiovascular disorders, such as heart attacks and strokes. HDL does not have such effects.

1.13 Approximately 1/3 of the cholesterol that is present in the human body has been consumed. The other 2/3 is primarily produced in the liver. The cholesterol that is produced in the liver is transported primarily in LDL ‘packets’. The biological process of the production of cholesterol is very complex; this involves a large number of steps, including several enzymatic conversions.

1.14 The rate-limiting step in the production of cholesterol is the conversion of HMG-CoA to mevalonate by the HMG-CoA reductase enzyme. Statins (also called HMG-CoA reductase inhibitors) are a class of medicinal products that are used to reduce the cholesterol levels (as LDL complex) by inhibiting the HMG-CoA reductase enzyme, which plays a central role in the production of cholesterol in the liver. Reducing the production of cholesterol in the liver also inhibits the amount of LDL cholesterol that is transported through the body in the blood.

1.15 One of the statins referred to above is rosuvastatin. The pharmaceutically active form is the rosuvastatin anion, a negatively-charged ion. This anion binds to the HMG-CoA reductase enzyme. If HMG-CoA reductase binds to the rosuvastatin anion rather than to HMG-CoA, the reductase is blocked (inhibited), as a result of which the production of cholesterol in the liver is inhibited. The structural formula of the rosuvastatin anion is depicted below:



Rosuvastatin
(IC_{50} = 5nM)

1.16 Only the anion is responsible for the biological activity of rosuvastatin, namely the HGM-CoA reductase inhibiting effect. It is not possible to make a tablet in which the active ingredient is the anion; only neutral substances can be used. This implies the presence of a cation (a positively-charged particle with which rosuvastatin salt is formed) or hydrogen (with which rosuvastatin acid is formed).

1.17 The salt form of rosuvastatin influences the practical suitability of the medicinal product, because the salt form is relevant, for example, for the solubility and the chemical and storage capacity. The suitability of the salt form is determined by salt screening.

Course of the proceedings

1.18 On 17 April 2014, Resolution initiated proceedings against AstraZeneca et al. in accordance with the rules regarding accelerated proceedings on the merits in patent cases, in which Resolution *inter alia* moved that the District Court nullifies claims 1 and 2 of the Dutch part of EP 471 and the dependent claims, and further nullifies SPC 300125 to the extent that the subject matter of this SPC pertains to a compound other than rosuvastatin calcium and/or rosuvastatin sodium. To this end, Resolution contended that claims 1 and 2 of the Dutch part of EP 471 as well as the dependent claims should not have been granted on account of added subject matter to the extent that these comprise more than rosuvastatin calcium and/or rosuvastatin sodium; this means that by virtue of Article 15(1) c of Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, SPC 300125 is partially invalid, given that after the basic patent expired, there are invalidity grounds that would have justified a limitation. In addition, Resolution claimed a declaratory judgment to the effect that

Resolution does not and/or its customers do not infringe Shionogi's rights under SPC 300125, either directly or indirectly, by marketing rosuvastatin zinc in the Netherlands. AstraZeneca et al. have conducted a substantiated defence.

1.19 By virtue of a judgment dated 15 July 2015[4], the District Court of The Hague nullified the SPC to the extent that the protection it confers extends to products other than the non-toxic pharmaceutically acceptable salts of rosuvastatin in which the cation comprises an alkali metal ion, an alkaline earth metal ion or an ammonium anion. The District Court held that the average skilled person would read the feature "*a non-toxic pharmaceutically acceptable salt thereof*" mentioned in EP 471 in conjunction with the definition that the invention previously discloses in paragraph [0007] of the description (which was also in the original application), i.e. "*the term "a non-toxic pharmaceutically acceptable salt" refers to a salt in which the cation is an alkali metal ion, an alkaline earth metal ion, or an ammonium ion*" and would take this to be a limiting definition and understand that the proprietor only wanted to confer protection for those salts for use with rosuvastatin (par. 4.16 and 4.17). The District Court did not follow AstraZeneca et al.'s argument that paragraph [0007] of the description does not contain a definition, but should be regarded as a non-exhaustive list (par. 4.17-4.19). The District Court further held that rosuvastatin salts - other than the calcium or sodium salt - do not constitute added subject matter, while the rosuvastatin acid does (par. 4.21-4.29). The declaratory judgment of non-infringement claimed by Resolution was awarded.

1.20 AstraZeneca et al. initiated an appeal against the District Court's judgment. By virtue of a ruling dated 16 February 2016[5], the Court of Appeal of The Hague set aside the District Court's judgment and still dismissed Resolution's claims. The Court of Appeal of The Hague found as follows to this end:

> "4.5 AstraZeneca directed grounds for appeal against the District Court's finding that the average skilled person would take paragraph 7 of the patent's description to be a limiting definition and understand that the patent proprietor only wanted to confer protection for the salts mentioned in this paragraph for use with rosuvastatin (judgment, par. 4.16) and the rejection of AstraZeneca's point of view that this paragraph 7 would only be regarded as a non-exhaustive list (judgment, par. 4.17 – 4.19). AstraZeneca further (*inter alia*) directed a ground for appeal against the District Court's finding (judgment, par. 4.28) that the claimed acid of rosuvastatin constitutes added subject matter.
>
> 4.6 In its cross appeal, Resolution *inter alia* challenges par. 4.10 of the judgment, in which the facts regarding salt screening are allegedly established in a too limited manner and further

[4] District Court of The Hague 15 July 2015, ECLI:NL:RBDHA:2015:8197, BIE 2015/46, annotated by R.M. Kleemans (*Resolution/AstraZeneca et al.*).
[5] Court of Appeal of The Hague 16 February 2016, ECLI:NL:GHDHA:2016:339, BIE 2016/23, annotated by P.L. Reeskamp (*AstraZeneca et al./Resolution*).

against the District Court's finding (judgment, par. 4.21 – 4.27) that claiming salts of rosuvastatin other than the calcium or sodium salt does not constitute added subject matter.

5. Assessment

In the appeal on the main issue

5.1 The question to be answered is how the claim feature '*or a non-toxic pharmaceutically acceptable salt thereof*' in claim 1 of EP 471 must be interpreted. Resolution's point of view that AstraZeneca did not direct any ground for appeal against par. 4.17 of the judgment and that it is an established fact between the parties that paragraph 7 of the description offers a definition in the form of an exhaustive list is rejected. Ground for Appeal II of AstraZeneca, read in conjunction with paragraphs 35-39 of the notice of appeal, comprises that AstraZeneca also complained about the District Court's rejection of its argument that the average skilled person will take paragraph 7 of the description to be a non-exhaustive list.

5.2 With regard to the interpretation of a patent claim, the Supreme Court *inter alia* found as follows in the *Medinol / Abbott* ruling (HR 4 April 2014, ECLI:NL:HR:2014:816) (in par. 3.4.2):

> *Article 69 (1) of the European Patent Convention (EPC) comprises that the extent of the protection that is conferred by a patent is determined by the claims of the patent specification, in which the description and drawings serve to interpret those claims. Article 1 of the protocol on the interpretation of Article 69 EPC (hereinafter: the Protocol) reads:* "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, in which the description and drawings are only employed 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." *In accordance with this interpretation rule of the Protocol, the Supreme Court labelled the formulations used in its preceding rulings,* "which is essential for the invention whose protection is invoked", and "the inventive idea underlying the words of those claims" *as a point of view, as opposed to the literal text of the claims (the "extremes" in the words of the Protocol) (cf. HR 7 September 2007, ECLI:NL:HR:2007:BA3522, NJ 2007/466 and HR 25 May 2012, ECLI:NL:HR:2012:BV3680, NJ 2013/68). In this context, establishing the inventive idea underlying the words of the claims serves to avoid an interpretation that is based exclusively on the literal meaning of the wording and therefore may possibly be too limited or unnecessarily broad for a reasonable protection of the patent proprietor (cf. HR 13 January 1995, ECLI:NL:HR:1995:ZC1609, NJ 1995/391). In this framework, the description and drawings constitute an important source. The description includes an overview of the prior art that the applicant considers useful for understanding the invention (Rule 42 of the Implementing Regulations to the EPC). Prior art that is not mentioned in the description may also be relevant. After all, the*

guiding principle in interpreting a patent is the perspective of the average skilled person with his knowledge of the prior art.

The inventive idea underlying the words of the claims

5.3 The issue in identifying the inventive idea is establishing what the patent adds to the prior art; the perspective of the average skilled person and his knowledge of the prior art on the priority date is the guiding principle in this (cf. HR in *Medinol / Abbott*, par. 3.5.2). In addition, the description and drawings constitute an important source in establishing the inventive idea (cf. HR in *Medinol / Abbott*, par. 3.4.2 cited above). It is not in dispute that in the case at issue, the average skilled person is an organic chemist who is active in the development of new medicinal products, who in any event has basic knowledge of the activity of the medicinal products on the market, such as rosuvastatin.

5.4 Resolution's point of view (on the occasion of the pleadings on appeal) that the inventive idea lies in finding specific precursors (i.e. a number of specific salts of rosuvastatin) that after ingestion release the active ingredient that has an HMG-CoA reductase inhibitory effect is dismissed. Resolution bases its point of view on paragraph 7 of the patent. In so doing, Resolution fails to recognize that even though the description is an important source for identifying the inventive idea, the perspective of the average skilled person and his general professional knowledge on the priority date must also be taken into account (as a guiding principle).

5.5 The average skilled person reads in the description (paragraphs 1-3) that first-generation (fungal metabolites) and second-generation (synthetic) inhibitors of HMG-CoA reductase (also referred to as statins) had already been developed and that the patent discovered a new group of statins, namely 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase inhibitors. Paragraph 4 of the description specifically mentions the acid or salt form of rosuvastatin that falls into this group, while it is further explained (in paragraph 5) that the invention also pertains to pharmaceutical compositions comprising the same and the process for preparing the same. Paragraphs 6 and 7 address the terms "lower alkyl group" and "a non-toxic pharmaceutically acceptable salt". The subsequent paragraphs (8-26) describe the process for preparing the new statins. Paragraphs 26-28 mention possible pharmaceutical compositions, along with how these can be prepared in the usual way as well as possible dosages. This is followed by reference examples in which processes for preparing a few compounds are set out, examples in which sodium and calcium salts of rosuvastatin are prepared and finally an experiment measuring the biological activity (the HMG-CoA reductase inhibitory effect). In the final paragraph 51 it is noted that the test data demonstrate that the compounds according to the invention – according to the table, this specifically refers to rosuvastatin – exhibit HMG-CoA inhibitory activity superior to mevinolin (a first-generation statin mentioned in paragraph 2 of the description).

5.6 In view of the description considered as a whole, taking into account his general professional knowledge on the priority date, the average skilled person will understand that the invention pertains to a new group of statins – in particular the specifically claimed rosuvastatin – whose biological activity is superior to a known first generation of statins. The novelty and inventive step of rosuvastatin has not been challenged. Thus, starting from the

perspective of the average skilled person on the priority date, the patent adds a new group of statins to the known prior art, including – more specifically – rosuvastatin. The discovery of this qualifies as the inventive idea underlying the words of the claim(s).

5.7 The average skilled person does not find any indication in the description that (the most) suitable salts of this new group of statins and/or of rosuvastatin were searched for in particular. He does not infer this from paragraph 7 of the description or the examples. On the priority date – at which time first-generation and second-generation statins were already on the market – it was part of the average skilled person's general professional knowledge that the anion is the active ingredient of the statins (as Resolution acknowledged in point 36 of its written pleadings on appeal), but that this had to be administered in the acid or salt form, because it is not possible to produce a tablet with an anion (see par. 3.6 above). The salts mentioned in paragraph 7 of the description involve salts that – on the priority date – were used to prepare the tablet form of already known statins (which did not include zinc) for administration. For that reason, the average skilled person understands from that paragraph that these are salts that may be expected to be suitable for preparing a tablet form containing a new statin according to the invention, whereby after intake into the body and dissolution of the salt, the pharmaceutically active anions are formed. The two examples included in the description only describe the process for preparing two salt forms of rosuvastatin, without comparing these forms or subjecting them to further tests. Subsequently, the experiment was only performed with the sodium salt; the biological activity was not compared with the calcium (or other) salt, but with another statin known from the prior art.

5.8 The above means that the notion that finding a suitable precursor (salt form) is the inventive idea underlying the wording of the claim(s) cannot be accepted as correct.

5.9 The fact that claim 1 of EP 471 only mentions rosuvastatin acid or a non-toxic pharmaceutically acceptable salt does not lead to any other opinion, either. As found before, in determining the inventive idea, the guiding principle is formed by what is added to the prior art viewed from the perspective of the average skilled person and not by the (literal) wording of the claim(s). After all, the inventive idea serves as the point of view in interpreting the claim(s).

Interpretation of 'or a non-toxic pharmaceutically acceptable salt thereof'

5.10 Claim 1 of EP 471 does not claim the active ingredient of rosuvastatin, the rosuvastatin anion, but rosuvastatin acid or a non-toxic pharmaceutically acceptable salt thereof. The parties disagree in particular regarding the interpretation of the feature 'or a non-toxic pharmaceutically acceptable salt thereof'. Resolution takes the position that in light of paragraph 7 of the description, this feature must be interpreted such that 'salt' only comprises one of the salts mentioned in paragraph 7. This means that according to Resolution, claim 1 must be interpreted more strictly than the literal wording of this claim give rise to. AstraZeneca takes the position that the average skilled person, taking into account his general professional knowledge on the priority date, would take paragraph 7 of the description to mean a non-exhaustive list and that there is no reason to interpret claim 1 more strictly than its literal meaning.

5.11 The Court of Appeal does not accept as correct that if and as soon as a patent contains a further description of a term used in a patent claim, this must always be taken to be

restrictive, as Resolution appears to assume. Although this further description must be taken into account as part of the description in interpreting the patent claim, this is without prejudice to the fact that the question regarding whether such description must be taken to be restrictive depends on the question of how the average skilled person would understand this further description, taking into account the description and his general professional knowledge on the priority date. Just as the literal meaning of the words of the claim may not simply be started from in interpreting this claim, the literal text of a passage from that description may not simply be started from in interpreting this claim in light of the description. A passage from the description that is relevant for the interpretation of a claim must likewise be interpreted in the context of the entire description and from the perspective of the average skilled person with his general professional knowledge on the priority date. Only if the average skilled person takes a further description (or 'definition') to be an exhaustive list, is this a decisive factor for the meaning of the feature of the claim to which this further description or definition pertains.

5.12 The Court of Appeal believes that in par. 4.18 of the judgment, with reference to the *AGA / Occlutech* ruling (HR 25 May 2012, ECLI:NL:HR:2012:BV3680), the District Court rightly held first and foremost that the average skilled person may only assume that part of the protection to which the patent confers entitlement has been waived in the event that there are valid reasons to do so in view of the content of the patent specification in light of possible other information, including the public information from the prosecution file. It follows from the preceding paragraph (par. 5.11) that the mere fact that the description contains a further description of a claim feature is insufficient to assume such valid grounds on this basis alone. Whether or not this is the case will depend on the answer to the question regarding how the average skilled person would construe this further description, in particular whether or not he would take this to be an exhaustive list.

5.13 Based on the findings below, in contrast to the District Court, the Court of Appeal finds that on the priority date, the average skilled person did not have valid reasons to assume that the patent proprietor only wanted protection for the salts of rosuvastatin mentioned in paragraph 7 and waived the broader protection that claim 1 offered according to its literal wording.

5.14 In interpreting a claim in light of the description, the inventive idea underlying the words of the claim must be taken into account as a point of view. As found before, this inventive idea can be formulated as finding a new group of statins, specifically including rosuvastatin, with an HMG-CoA reductase inhibitory effect. The average skilled person will realize that claim 1 is formulated in a more limited manner than the inventive idea gives rise to, namely the claim only confers protection for the rosuvastatin acid and the pharmaceutically acceptable non-toxic rosuvastatin salts thereof. He will explain this by the fact that it is not possible to administer the active ingredient (the rosuvastatin anion), so that rosuvastatin in the possible administration forms is claimed for this reason. The – broader – inventive idea does not give the average skilled person any reason to assume that the patent proprietor only wanted the patent to confer protection for specific salt forms and to waive all other salt forms. After all, as the average skilled person knows on the priority date, the salt form in which statins are administered is irrelevant for their biological activity, because the anion of the statin is the active ingredient and the salt only serves to administer the rosuvastatin anion in tablet form.

5.15 To the extent that Resolution intended to contend that according to the Protocol, the claims must be interpreted in light of the description, so that there is no room for taking the inventive idea underlying the words of the claim into account, or at least that the wording of the description must prevail, this point of view is dismissed. After all, an interpretation of the patent claims in light of the description must always start from the perspective of the average skilled person on the priority date, taking into account his general professional knowledge. This perspective is in part determined by the inventive idea.

5.16 Where Resolution pointed out that the inventive idea is just one of the points of view that must be taken into account in interpreting a patent claim, this is correct; however, this cannot help Resolution. After all, the other points of view mentioned by the Supreme Court do not point in another direction.

5.17 One of the other points of view pertains to the extent to which the invention brought innovation (see also par. 3.3.1 of HR 13 January 1995 in *Ciba Geigy / Oté Optics*, ECLI:NL:HR:1995:ZC1609). As AstraZeneca advanced and as not contested based on a sufficient substantiation, rosuvastatin is a very potent statin that is still the market leader, despite the presence of various (cheaper) generic statins.

5.18 Another point of view to be taken into account pertains to the nature of the patent; this also points in the direction of a broader extent of protection here than Resolution suggests. The patent is not a formulation patent disclosing a new administration form of a known substance, in which the extent of the protection is limited to this administration form alone. EP 471 discloses a new group of pharmaceutically active substances, of which claim 1 more specifically claims the new and inventive substance rosuvastatin; thus, this is a ‘substance patent’ for which absolute substance protection can be obtained and is generally also envisaged by the patent proprietor.

5.19 Nor does the description lead the average skilled person to realize that claim 1 must be interpreted more strictly than the literal words of this claim give rise to. As already found before (see par. 5.7), on the priority date, the average skilled person would realize that paragraph 7 of the description mentions salts that have been used to prepare the tablet form for administration of known statins; for that reason, he would understand that these are salts that may be expected to be suitable for preparing a tablet form containing a new statin according to the invention, in which the biologically active anions are formed after ingestion in the body. The patent specification does not offer the average skilled person any reason to assume that the list of salts provided in paragraph 7 was based on a salt screening. Only two salts are prepared in the examples, while the experiment does not compare different salt forms, but only compares the efficacy of a statin according to the invention against a statin according to the prior art. For the rest, the description does not offer any indication for the idea that the patent proprietor found that specific salts (let alone all salts except those mentioned in paragraph 7) are unsuitable for use with rosuvastatin, either.

5.20 Nor does the general professional knowledge of the average skilled person lead the average skilled person to assume that the list of salts in paragraph 7 is meant to be exhaustive. The average skilled person knew that it was common practice on the priority date to conduct a salt screening for pharmaceutical preparations that are (or must be) administered in the salt form, such as statins. After all, the selected salt may, for example, influence the

chemical stability, storage stability and solubility of the pharmaceutical preparation. However, as AstraZeneca contended with reference to various statements by experts testifying on its behalf (Dr [S], 3rd statement, par. 13-16; Professor Dr [F], par. 14-18 with reference to J.I. Wells, Pharmaceutical preformulation, 1988; [T], par. 10, 32-34; Dr [B], par. 13-20; Dr [H], par. 16-21 and Dr [X], par. 15-17), the average skilled person also knows that – especially at the stage in which a patent application must be drawn up and filed under time pressure and only a limited amount of the discovered substance is usually available – it was not customary to conduct an exhaustive salt screening. This was limited to a number of salts (generally including sodium as the salt that was by far the most commonly used, followed by calcium and potassium) and was only expanded to include other salts if there was a reason to do so. Resolution did not advance a sufficiently substantiated challenge to this. The publication by Morris et al. that Resolution cited (*An integrated approach to the selection of optimal salt form for a new drug candidate*, 1994 (dating from after the priority date)) does not present any other picture. This publication describes a salt screening – albeit at a later stage of the development process and in a more structured way than the more pragmatic approach commonly used – also with (just) 7 different salts, including the salts mentioned above. The description does not include any indication that in the case at issue, in contrast to common practice, an exhaustive salt screening was nevertheless performed, based on which the patent proprietor was able to make a deliberate choice for these specific salts alone. For this reason, the average skilled person will not assume that paragraph 7 is based on such an exhaustive salt screening or that, with this paragraph, the patent proprietor only envisaged conferring protection for these salts for use with rosuvastatin, notwithstanding the wording of claim 1 in which no restriction regarding the type of salt is included (other than the usual restriction that the salt must be non-toxic and pharmaceutically acceptable).

5.21 Nor does the description or the prosecution file offer any indication for the existence of an underlying (legal) problem that may have been a reason for the patent proprietor to waive part of the protection offered by claim 1 of the patent. Nor did Resolution advance a sufficiently substantiated argument for this. Resolution merely speculated that by not also claiming (according to Resolution) salts other than those mentioned in paragraph 7, the patent proprietor wanted to avoid possible sufficiency of disclosure problems across the whole gamut of the claims. However, Resolution failed to substantiate in any way why the average skilled person would assume this, nor did Resolution conduct any ‘Gillette defence’ in the sense that if the patent would not be interpreted strictly in the sense advocated by Resolution, the patent would be invalid on account of insufficiency of disclosure.

5.22 All of the above leads to the conclusion that on the priority date, the average skilled person did not have valid reasons to assume that the patent proprietor wanted to limit his patent to the salts for use with rosuvastatin mentioned in paragraph 7 and in so doing wanted to waive part of the protection to which he was entitled by virtue of the literal wording of claim 1. Or, in other words, the average skilled person would not assume that the patent proprietor deliberately opted to exclusively confer protection for the salts of rosuvastatin mentioned in paragraph 7. Therefore, he would not consider the list provided in paragraph 7 to be exhaustive. This means that claim 1 must be interpreted such that the extent of the protection it confers extends to (in addition to the rosuvastatin acid) all non-toxic pharmaceutically acceptable salts of rosuvastatin, including those that are not mentioned in paragraph 7 of the description. Moreover, even independent of the ‘valid reasons for the waiver doctrine’, based on the findings in par. 5.14-5.24, the same conclusion would be arrived at.

5.23 Reasonable legal certainty does not object to this interpretation of the claim. Because the average skilled person would not understand paragraph 7 to be exhaustive, in a restrictive sense, and thus, in contrast to what Resolution contends, does not rely on this paragraph to interpret the claim, he is not misled if the claim is interpreted in accordance with the clear, literal wording of the claim. On the contrary, the reasonable protection for the patent proprietor would be at issue if despite the (much) broader inventive idea, the claim would be interpreted in the more limited sense advocated by Resolution.

5.24 Nor does this interpretation constitute any 'interpreting away' a feature from the claim, as Resolution alleges. After all, the interpretation pertains to the claim feature '*or a non-toxic pharmaceutically acceptable salt thereof*'. As follows from the findings in par. 5.11 above, the starting point is not that paragraph 7 must first be read into the claim to subsequently interpret the claim that has been limited in this way, something that Resolution apparently and wrongfully starts from.

5.25 Nor is this interpretation based on the abandoned essence doctrine, which already follows from the fact that the extent of the protection conferred by the claim as interpreted is more limited than the extent of the protection if only the broader inventive idea had been started from. The inventive idea is just one of the points of view taken into account in interpreting the claim feature in light of the description viewed as a whole, from the perspective of the average skilled person, taking into account his general professional knowledge on the priority date.

Added subject matter

5.26 Resolution takes the position that claim 1 of EP 471 is invalid due to breach of Section 75 (1) c ROW (added subject matter) to the extent that the claim pertains to anything other than rosuvastatin sodium or calcium salt, because the original application allegedly does not directly and unambiguously disclose rosuvastatin acid or other salt forms to the average skilled person. The District Court held that only rosuvastatin acid constitutes added subject matter.

5.27 The original application discloses a new group of statins and claims this group by means of a Markush formula, in which the R1-R4 and X groups can be varied. By way of example of this group of statins, rosuvastatin is disclosed, in example 1 as sodium salt and in example 7 as calcium salt (and further also as alkyl ether). In these examples, the same choices have been made for the R1-R3 and X groups; for the R4 position, sodium, calcium and methyl have been selected from the possibilities mentioned. The original application states that '*hydrogen, lower alkyl, or a cation capable of forming a non-toxic pharmaceutically acceptable salt*' could be selected for the R4 position.

5.28 As found before, on the priority date, it was part of the average skilled person's general professional knowledge that the biological activity of a statin lies in the anion and that the statin acid or salt form exclusively serves to administer the active ingredient in tablet form. After intake, the acid or salt will dissolve in the body, releasing the active anion. In accordance with this, the potency of different statins (including rosuvastatin) is studied in the 'Experiment' in the original application and not different acid or salt forms of one statin. After all, the acid or salt form chosen is irrelevant for the efficacy (in the sense of biological activity, namely the HMG-CoA reductase inhibitory effect).

5.29 The foregoing means that with the rosuvastatin disclosed in the application, the average skilled person would also read – or, in other words, be reminded of – the possible choices for R4 other than sodium or calcium, i.e. the acid form and other salt forms, as well. Because this choice is not relevant for the biological activity of rosuvastatin, this does not provide any (technical) information that cannot be directly and unambiguously inferred from the original application. Nor is any inadmissible generalization involved. Rosuvastatin is a newly discovered statin, with specific fixed choices on R1-R3 and X; the biological activity is independent of the acid or salt form chosen. Position R4 determines the acid or salt form. Hydrogen (meaning the hydrogen ion that the acid form produces) and cations that can form non-toxic pharmaceutically acceptable salts with a statin are already explicitly mentioned in the original application as belonging to the group from which the parameter for the R4 position can be selected. The explicitly disclosed sodium and calcium salts from this group are examples of this – which the skilled person takes to be non-exhaustive (on p. 4, lines 29-30 of the original application, these examples are also referred to as '*not to be considered as limiting*'). Sodium and calcium belong to the most frequently used salts for pharmaceutical preparations in salt form, but the application does not offer the average skilled person any reason to assume that there is any specific reason to opt for these salts. For this reason, the average skilled person understands that he can vary the R4 position with one of the other ions mentioned, without this having any impact on the biological activity of the explicitly disclosed rosuvastatin. It follows from the preceding findings regarding the interpretation of claim 1 that in contrast to the District Court, the Court of Appeal believes that the average skilled person is reminded of the hydrogen ion and all cations that produce a non-toxic pharmaceutically acceptable salt and not only those mentioned on page 2, lines 42-45 of the application (which corresponds to paragraph 7 of the patent specification).

5.30 It is not clear why all this would be different, because in addition to rosuvastatin, other statins are also disclosed (thus with other choices for R1-R-3 and X), as Resolution alleges (paragraph 36 of the written pleadings in the first instance). After all, the application demonstrates to the average skilled person what the invention is about, namely that a new group of statins has been found, of which in any event the statins mentioned in the Experiment are more potent than any known statin from the prior art. On the same basis as explained before regarding rosuvastatin, each of the statins explicitly disclosed in the examples are directly and unambiguously disclosed in every acid or salt form from the R4 group. The issue is the biological activity of the statin, not the acid or salt form in which the statin can be administered as a tablet, as the average skilled person knew on the priority date.

5.31 The fact that the average skilled person was unable to predict in advance whether and to what extent in practice the acid form and salt forms of rosuvastatin would actually be suitable for use in a pharmaceutical preparation with rosuvastatin, as Resolution contends, does not stand in the way of the direct and unambiguous disclosure in the application of the acid form and salt forms claimed in claim 1 of EP 471. Non-effective salt forms do not fall under claim 1, because this claim only claims pharmaceutically acceptable salts. It is pointed out that Resolution – on whom the duty to contend facts and circumstances and, if necessary, the burden of proof falls in this regard – has not advanced a sufficiently substantiated argument based on which it must be assumed that the average skilled person would nevertheless not also read hydrogen (with which the acid is formed) or any cation with which a salt of rosuvastatin can be formed as a real possibility on the R4 position, despite the fact that this is explicitly mentioned in the application. With regard to the acid form, Resolution referred

to the publication by Berghe from 1977 (*Pharmaceutical Salts, Journal of Pharmaceutical Sciences*, Vol. 66, 1), which notes – not specifically regarding statins – that '*most organic acids and bases are only poorly soluble in H2O*'. However, this is insufficient, in part in light of AstraZeneca's argument, with reference to statements by the experts testifying on its behalf: [S] (3rd statement, par. 3-8 and the publication of T.M. Serajuddin regarding different statins mentioned here (*Journal of Pharmaceutical Sciences*, Vol. 80, 9), which discloses that polar statins such as rosuvastatin have fair solubility as a free acid) and [F] (1st statement, par. 6-11) that the average skilled person will consider the free acid and a salt to be virtually identical. Nor has Resolution challenged that claim 1 is sufficiently disclosed.

5.32 Based on the above, the Court of Appeal believes that no added subject matter is involved, because claim 1 of EP 471 also extends to rosuvastatin acid as well as non-toxic pharmaceutically acceptable salts other than the sodium and calcium salt."

1.21 Resolution has brought an appeal in cassation against this ruling in time. AstraZeneca et al. has conducted a defence. On 16 December 2016, oral pleadings were held before the Supreme Court, where the parties explained parts 1 to 4 of the appeal in cassation. The parties explained part 5 in writing, after which AstraZeneca et al. filed a rejoinder regarding this latter part.

2. Assessment of the appeal in cassation

2.1 The appeal in cassation comprises five parts and various sub-parts.
Part 1 regards the Court of Appeal's interpretation of AstraZeneca et al.'s grounds for appeal in par. 4.5 and 5.1.
Parts 2-4 regard the extent of the protection that is conferred by EP 471 and are directed against par. 5.10-5.25, where the claim feature "*or a non-toxic pharmaceutically acceptable salt thereof*" (in the undisputed Dutch translation: "*of een niet-toxisch farmaceutisch aanvaardbaar zout daarvan*") is interpreted such that the extent of the protection it confers (in addition to the rosuvastatin acid) extends to all non-toxic pharmaceutically acceptable salts of rosuvastatin, including those that are not mentioned in paragraph 7 of the description.
Part 2 complains about the finding that the average skilled person would not take paragraph 7 of the description to be a definition in the form of an exhaustive list of this claim feature (the "own lexicon" problem) and how the inventive idea should be used in light of Article 69 EPC and the Protocol.
According to part 3, the Court of Appeal used an incorrect interpretation method in breach of Article 69(1) EPC by taking the literal text of the claims as the starting point to examine – based on the description – whether the proprietor waived protection. There is no longer any room for the waiver doctrine and the part continues with substantiation complaints against

the Court of Appeal's finding regarding the non-exhaustive effect of paragraph 7 of the description assumed based on grounds other than the waiver doctrine.
Part 4 complains that the considerations regarding the inventive idea (par. 5.5 and 5.6) and the extent to which the invention brought innovation (par. 5.17) are also incorrect and/or incomprehensible.
Part 5 is directed against the finding that no added subject matter is involved, because claim 1 of EP 471 also extends to rosuvastatin acid as well as non-toxic pharmaceutically acceptable salts other than the sodium and calcium salt (par. 5.26-5.32).

Part 1: interpretation of grounds for appeal

2.2 Part 1 contains complaints regarding points of law and the reasons given directed against the finding in par. 4.5 and 5.1 that Ground for Appeal II of AstraZeneca et al., read in conjunction with paragraphs 35-39 of the notice of appeal entails that AstraZeneca et al. complained about the District Court's rejection of its argument that the average skilled person will take paragraph 7 of the description to be a non-exhaustive list.
Following an introduction in par. 1.1 and 1.2, par. 1.3 complains that the arguments between the parties and the notice of appeal do not allow any conclusion other than that AstraZeneca et al. did not direct any ground for appeal against the District Court's finding in par. 4.16 and 4.17. According to this part, AstraZeneca et al. did complain about the District Court's finding in par. 4.19 (the rejection of the defence that there is no valid ground that the proprietor relinquished any salts other than those disclosed in paragraph 7 of the description), but they did not conduct the defence rejected in par. 4.17 (that the list of salts in paragraph 7 of the description is non-exhaustive) again, which Resolution explicitly observed in par. 9 of the Defence on Appeal, which was subsequently not refuted during the pleadings, which means that AstraZeneca et al. accepted that paragraph 7 contains a definition in the form of an exhaustive list.
The complaint in par. 1.4 is that to the extent that the Court of Appeal found that AstraZeneca et al.'s mere allegation that the District Court's findings in par. 4.13-4.20 are incorrect qualifies as a ground for appeal against par. 4.16-4.17, it started from an incorrect interpretation of the law and/or failed to give sufficient (or sufficiently clear) reasons for its decision. According to the complaint, in that case, the Court of Appeal failed to recognize that the grounds based on which the District Court's decision should be set aside must be properly advanced, so that they are sufficiently apparent for the appellate judge and the other party, which must know what it is to defend itself against.
At least, according to sub-part 1.5, the Court of Appeal rendered an unacceptable surprise decision, given that Resolution assumed that the legal battle on this point was no longer open and, in view of the arguments between the parties, was also entitled to assume this.
Sub-part 1.6 merely contains a complaint that expands upon the previous complaint and is directed against par. 5.10-5.25, 5.29, 5.35-5.36 and the operative part.

2.3 First and foremost, the interpretation of grounds for appeal is reserved for the judge deciding questions of fact[6]. In cassation, this interpretation can only be reviewed – for its comprehensibility – to a limited extent. The *complaints of part 1 regarding points of law* already fail on this basis.
For the rest, s*ub-part 1.3* starts from too limited a reading of what was submitted on appeal to the Court of Appeal. The defences that are disentangled in the complaint are directly in line, of course; from the argument in par. 35-39 of the notice of appeal (that there is no reason for a more limited interpretation of the claim that literally covers the zinc salt), the Court of Appeal could understandably infer that AstraZeneca et al. did complain about the finding that paragraph 0007 of the description contained a limiting definition of the technical feature a pharmaceutically acceptable salt.
After all, in par. 35 of the notice of appeal, AstraZeneca et al. advanced the following:

> "the only question that can still be asked with all this is whether […] there is nevertheless a reason to stipulate a more limited protective scope due to the fact that in par. [0007], the inventor included a definition of "*non-toxic pharmaceutically acceptable salts*"."

Subsequently, in par. 39 of the notice of appeal, AstraZeneca et al. answered this question in the negative:

> "With regard to the text of the description, the skilled person knows that the average skilled person will not screen all possible salts (if this had been done, zinc would have been included). In short, he realizes that the issue in the description is to provide a useful specification of salts that are active, but – especially in view of the inventive idea and the wording of claim 1 – he cannot possibly derive from the description that other suitable salts are not claimed, but that these have been relinquished. No "valid ground" whatsoever can be found for this."

I feel that the fact that the Court of Appeal interpreted these arguments – in combination with the general comment in par. 24 of the notice of appeal that what the District Court found in par. 4.13-4.20 is incorrect – such that AstraZeneca et al. complained about the District Court's finding in par. 4.16 and 4.17 that – in brief – the average skilled person would take paragraph 7 of the description to be a limiting (exhaustive) definition of claim 1 is not incomprehensible[7]. The substantiation complaints in *par. 1.3 and 1.5* already fail on this basis.
I even leave aside the fact that – in contrast to what Resolution contends in sub-part 1.3.7 – in AstraZeneca et al.'s pleading notes on appeal, I do read a challenge that paragraph 7 of the description contains a definition in the form of an exhaustive list of salts that are claimed

[6] Asser Procesrecht/Korthals Altes & Groen 7 2015/157.
[7] Resolution also argued that AstraZeneca et al. acknowledged that paragraph 7 of the description contains "a definition" (notice of appeal in cassation, par. 1.3.6 and pleading notes in cassation, par. 23 and 24). However, this does not mean that AstraZeneca et al. allegedly acknowledged that (according to the average skilled person) this is a *limiting (exhaustive)* definition (see AstraZeneca et al.'s pleading notes in cassation, par. 4). It is also possible to understand "a definition" as meant in the (limiting) sense of "own lexicon", but this is not necessarily the case – at least, not so clear here that this can only be interpreted in this sense.

in claim 1. In par. 16 and following of those pleading notes, AstraZeneca et al. contends that how the skilled person interprets paragraph 7 is relevant and explains that the skilled person will understand that in view of the broad formulation in the claim and the inventive idea, the patent proprietor also wanted protection for salts that are not mentioned in paragraph 7. It can be inferred from the case documents that Resolution also understood this to be the case (see, for example, Resolution's pleading notes on appeal, par. 4)[8].
I believe that the substantiation complaint in *par. 1.4* fails for lack of a factual basis, because the Court of Appeal not only designated AstraZeneca et al.'s mere argument that the District Court's findings in par. 4.13-4.20 are incorrect (notice of appeal, par. 24) as a ground for appeal directed against par. 4.16-4.17, but also felt that nos. 35-39 of the notice of appeal are relevant in this regard, as follows from par. 5.1.
This puts an end to *part 1*.

Parts 2-4: extent of the protection that is conferred by the patent

2.4 Before discussing the complaints of these parts, it seems useful to once again address the protective scope of patents in general.

2.5 Determining the extent of the protection that a European patent confers takes place based on Article 69 EPC and the related interpretation protocol (hereinafter: the Protocol). As I explained in my opinion[9] in the *Bayer/Sandoz* case[10], this interpretation rule is somewhere between the too limited literal text of the claim approach and the too broad purely inventive idea approach. This interpretation is based on the construction that the skilled person (the fictitious person under patent law) reads the text of the claims with his general professional knowledge, in light of the description and drawings[11] (in the corridors also referred to as

[8] Cf. Asser Procesrecht/Bakels, Hammerstein & Wesseling-van Gent 4 2012/117: "The fact that the Court of Appeal interpreted the grounds for appeal in the same way the respondent did is a strong argument for considering this interpretation to be not incomprehensible."
[9] ECLI:NL:PHR:2015:2200, par. 2.1-2.8 (2.3 in particular) and 2.33-2.34.
[10] HR 5 February 2016, ECLI:NL:HR:2016:196, *NJ* 2016/496, annotated by Ch. Gielen; Ars Aequi AA20160650, annotated by Th.C.J.A. van Engelen; BIE 2016/15, annotated by J.H.J. den Hartog and T.M. Blomme (*Bayer/Sandoz*). Before that, in a similar sense, also HR 4 April 2014, ECLI:NL:HR:2014:816, *NJ* 2015/11, annotated by Ch. Gielen; IER 2014/65, annotated by T.H.B. Iserief and A.M.E. Verschuur; Ars Aequi AA 20140743, annotated by Th.C.J.A. van Engelen (*Medinol/Abbott*), par. 3.4.2.
[11] In AstraZeneca et al.'s pleading notes in cassation, par. 54 and 77, attorney Hoyng wrongfully suggests – as his colleagues J.H.J. den Hartog and T.M. Blomme did previously in their annotation of the *Bayer/Sandoz* ruling, BIE 2016/15, p. 110-111 – that I allegedly pleaded for the (meanwhile old) English interpretation (*purposive construction*) and not for the Dutch points of view doctrine. A similar misconception is in par. 29-33 of the defence and in par. 29 of AstraZeneca et al.'s pleading notes on appeal: "He [which refers to me, A-G] supports the context-bound interpretation, by which he essentially seems to endorse the "purposive construction" of the House of Lords in Kirin-Amgen." I would like to rectify this, because this is totally incorrect, as I already noted during the pleadings in cassation. It is based on an incorrect interpretation of my opinion in *Bayer/Sandoz*. In that opinion, in par. 2.34, I endorsed and embraced the Supreme Court's points of view doctrine: "I believe that the practice can work very well with this criterion [i.e.: the inventive idea as *point of view*]; moreover, this is in accordance with Article 69 EPC and the Protocol. In this regard, I disagree with the Brinkhof camp and (in this sense) concur with Hoyng as well as A-G Huydecoper in his opinion for *AGA/Occlutech*." See also my use of the points of view doctrine in par. 2.39 of that opinion. All I said in par. 2.37 of the opinion was that our approach "essentially *strongly resembles* the English "purposive construction""

context-bound or contextual interpretation in the specialist patent case law of the lower Hague courts[12]). In par. 3.3.5 of that ruling, the Supreme Court gave an overview of Supreme Court case law dealing with Article 69 EPC and the Protocol; more recently, the Supreme Court referred to this overview in the case *MSD/Teva*[13].
In the *Bayer/Sandoz* case, the Supreme Court held first and foremost (in par. 3.3.3) that according to settled case law (with reference to *Lely/Delaval*[14]), the interpretation of patents is so closely interwoven with factual valuations, that this means that it can only be reviewed in cassation to a limited extent. Subsequently, the interpretation rule is formulated and specified as follows:

> "3.3.4 Article 69(1) of the European Patent Convention (EPC) entails that the extent of the protection conferred by a patent is determined by the claims of the patent specification, in which the description and drawings are used to interpret those claims. Articles 1 and 2 of the protocol on the interpretation of Article 69 EPC (hereinafter: the Protocol) read 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 the 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.

(with further explanation/details); this is not the same as "endorsing" this English approach rather than the points of view doctrine, or that I allegedly "support" this English doctrine.
[12] For a very recent example of interpreting the term "context-bound" in the Hague patent case law, see the Summary Trial Judge in the District Court of The Hague 14 November 2017, ECLI:NL:RBDHA:2017:13109 (*Basic Holdings/Ruby Decor*), par. 4.11 end: "This interpretation [*sc.* according to Article 69 EPC and the Protocol, as previously explained in par. 4.11; A-G] must be 'context-bound' in the sense that it is examined how the average skilled person would understand the claims on the priority date, in which the description and drawings are an important source." This ruling – which dates from long after the English pemetrexed case still to be discussed – does not refer in any way to "purposive construction", of course, because that doctrine was abandoned in the English case mentioned. Moreover, in contrast to what was apparently felt in some circles of the patent platform, I believe that this has never been the case. In the opinion for *Bayer/Sandoz*, all that I meant by "context" was (nothing other than): viewed through the eyes of the skilled person, with his general professional knowledge and in light of the description and figures, *as the Protocol prescribes*, i.e.: *according to the Protocol (Protocolair)* (in that opinion, I used the latter word as a synonym for "context-bound"). In *Kort Begrip*, Hermans and De Lange also refer to context-bound interpretation, but they mean something entirely different, as I will explain later. Context-bound/according to the Protocol is not the same as purpose-bound. Footnote 9 of my opinion in *Bayer/Sandoz* explains exactly what I mean by context-bound and that it is incorrect that this allegedly is not in conformance with the Supreme Court's patent case law and that it is also incorrect that this is legally incorrect, as Bayer advanced in that case in cassation. Finally, see also my use of this term in par. 2.34 of that opinion. Perhaps the term "context-bound" should be avoided from now on (in that case), given that it apparently (but not very understandably) leads to unintended misunderstandings. Sometimes, wisdom comes after the fact. From now on, I will use the term "according to the Protocol".
[13] HR 3 November 2017, ECLI:NL:HR:2017:2807 (*MSD/Teva*), par. 3.4.3.
[14] HR 7 September 2007, ECLI:NL:HR:2007:BA3522, *NJ* 2007/466 (*Lely/Delaval*).

> Article 2 – Equivalents
> 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.
>
> 3.3.5 In accordance with this interpretation rule of the Protocol, the Supreme Court labelled the formulations used in its earlier rulings, "which is essential for the invention whose protection is invoked", and "the inventive idea underlying the words of those claims", as a point of view, as opposed to the literal text of the claims (the "extremes" in the words of the Protocol) (cf. HR 7 September 2007, ECLI:NL:HR:2007:BA3522, *NJ* 2007/466 and HR 25 May 2012, ECLI:NL:HR:2012:BV3680, *NJ* 2013/68). Identifying the inventive idea underlying the words of the claims serves to avoid an interpretation that is based exclusively on the literal meaning of the wording and therefore may possibly be too limited or unnecessarily broad for a reasonable protection of the patent proprietor (cf. HR 13 January 1995, ECLI:NL:HR:1995:ZC1609, *NJ* 1995/391). In this scope, the description and drawings are an important source. Part of the description is a representation of the prior art that the applicant considers to be useful for understanding the invention (rule 42 of the Implementing Regulations to the EPC). Prior art that is not mentioned in the description may also be relevant. After all, the perspective of the average skilled person with his knowledge of the prior art is the guiding principle in interpreting a patent (HR 4 April 2014, ECLI:HR:2014:816, *NJ* 2015/11 (*Medinol/Abbott*)).
> (…)
>
> 3.3.8 (…) To determine the extent of the protection that is conferred by a patent, the issue is establishing what the patent adds to the prior art. Only in the scope of the infringement question can relevance also be ascribed to the knowledge of the average skilled person at the time of the alleged infringement, in particular when the issue is whether equivalent elements are involved (HR 4 April 2014, ECLI:HR:2014:816, *NJ* 2015/11 (*Medinol/Abbott*), par. 3.5.2)."

Relinquishing the waiver doctrine

2.6 The issue in this case is whether part of the protection has been "waived" in paragraph 7 of the description and in this scope, whether the waiver doctrine as formulated in the *Van Benum/Kool* ruling[15] (and before that in the *Meyn/Stork* ruling[16]) is still applicable law[17].

2.7 In *Van Bentum/Kool* (building on *Meyn/Stork*), the Supreme Court described the waiver doctrine as follows:

> "3.4 In its ruling dated 13 January 1995, no. 15 564, *NJ* 1995, 391, the Supreme Court devoted a further consideration – in relation to the ruling dated 27 January 1989, no. 13394,

[15] HR 22 March 2002, ECLI:NL:HR:2002:AD8184, *NJ* 2002/530, annotated by Gielen (*Van Bentum/Kool*).
[16] HR 27 January 1989, ECLI:NL:HR:1989:AD0607, *NJ* 1989/506, annotated by L. Wichers Hoeth (*Meyn/Stork*), par. 3.5.
[17] See Resolution's pleading notes in cassation, par. 65: "The parties wholeheartedly disagree about the question regarding whether the waiver doctrine is indeed no longer applicable law."

NJ 1989, 506 – to the criteria that the judge is to use in interpreting the claims of a patent specification. In addition to the findings, in particular in par. 3.3.1 and 3.4.1, what is also relevant for this interpretation is the rule accepted in the ruling last mentioned that the average skilled person may only assume that part of the protection to which the patent confers entitlement according to the essence of the invention has been waived if there are valid reasons for this, in view of the contents of the patent specification in light of any other information known, such as the information from the patent prosecution file also apparent to them." (Emphasis added by A-G)

As also demonstrated by the above finding, this waiver doctrine was developed in the scope of interpreting patents and determining the extent of the protection under the *old* essence doctrine (initiated by the Supreme Court in 1930[18]), which has meanwhile (rightfully) been abandoned in view of Article 69 EPC and the Protocol[19]. The fact that the essence as a primary focus in determining the extent of the protection was actually in decline, only became apparent, in fact, for the first time in *PCT/Dieseko*[20], which was continued in *Lely/Delaval*. Thus, this case law from 2004 and 2007 dates from after *Van Bentum/Kool* (2002).

2.8 As I already briefly touched upon in my opinion in *Bayer/Sandoz*[21], I believe that in determining the extent of the protection in conformance with the interpretation rule of Article 69 EPC there is no longer any room for a waiver doctrine like *Van Bentum/Kool*[22]. The question regarding whether this has a lot of practical relevance is legitimate, because I feel that in an interpretation in line with Article 69 EPC and the Protocol, whether the average skilled person believes that it was *deliberately* chosen to limit the extent of the protection may

[18] HR 20 June 1930, *NJ* 1930, p. 1217 and following, annotated by PS (*Philips/Tasseron*). The extent of the protection that a patent confers is determined by the inventive idea underlying the wording of the claims, as this was interpreted later.

[19] See regarding the old Dutch doctrine of the essence of the patented invention: Huydecoper/Van der Kooij/Van Nispen/Cohen Jehoram, Industriële eigendom 1 (2016), par. 3.5.2.1 and following and my opinion in *Bayer/Sandoz*, ECLI:NL:PHR:2015:2200, 2.3 and 2.33-2.34.

[20] HR 12 March 2004, ECLI:NL:HR:2004:AO0969, JOL 2004/134, JWB 2004/98 (*PCT/Dieseko*), par. 3.3 (in which the inventive idea is presented as a point of view); see also three years later in HR 7 September 2007, ECLI:NL:HR:2007:BA3522, *NJ* 2007/466, BIE 2008/1, annotated by J. Brinkhof (*Lely/ Delaval*), par. 3.3 (indicating that due to Article 69 EPC and the Protocol, the inventive idea is no longer a starting point but a point of view). In his contribution to the Hoyng bundle, Huydecoper also places the caesura with *PCT/Dieseko*, cf. T. Huydecoper, Fair protection, in: Willem Hoyng Litigator, (Hoyng bundle), 2013, p. 56.
Many insiders completely failed to notice the fact that this farewell to the essence as a criterion/*starting point* for determining the extent of the protection (with the note that this can still be taken into account in this as a *point of view*) according to *Lely/Delaval* is allegedly already demonstrated by HR 13 January 1995, ECLI:NL:HR:1995:ZC1609, *NJ* 1995/391, annotated by D.W.F. Verkade (*Ciba Geigy/Oté Optics*): cf. Huydecoper/Van der Kooij/Van Nispen/Cohen Jehoram, Industriële eigendom 1 (2016), par. 3.5.2.4: (According to the same paragraph [reference is made to par. 3.3 from *Lely/Delaval*, A-G], this viewpoint [no longer a starting point but a point of view, A-G] was allegedly already expressed in HR 13 January 1995 – a statement that we respect, of course, with the comment that quite a number of practitioners of patent law failed to recognize this meaning of the ruling from 1995)." [Followed by a footnote with reference to nos. III.5.2.14 and III.5.2.15 from the authors' own previous edition from 2002, 7 years after *Ciba/Geigy*! According to those passages from the 2002 edition, they saw a clear confirmation in *Van Bentum/Kool* that the doctrine of the essence as a primary focus for determining the extent of the protection was still applicable law.]

[21] See ECLI:NL:PHR:2015:2200, par. 3.9.

[22] The question regarding whether a waiver of any protection is involved can still be dealt with at a later time, cf. Section 63 ROW 1995 and Articles 105a-105c EPC.

play a role, namely in the scope of the *point of view* of the inventive idea, as I will further detail below[23]. This clearly is a different framework systematically, because by its nature, a waiver of a right is less readily assumed.

2.9 To this end, it should first of all be recalled that by and large, there are two trends in the Netherlands regarding the extent of protection that is conferred by patents, which are diametrically opposed.

2.10 The line with Huydecoper[24] and Hoyng[25] as exponents, with which Gielen concurs[26], emphasizes how difficult it is for (fallible) people to express as precisely as possible in words what is being claimed as the invention. They are advocates of a more or less prominent role of the inventive idea – of what the invention essentially entails – to ultimately determine what was meant to be claimed in view of the text of the claim, read by the skilled person with his general professional knowledge, in light of the description and drawings from the patent specification.
They feel that this is possible within the system of Article 69 EPC and the Protocol and the Supreme Court's points of view doctrine[27]. In searching for a balance between the opposite poles of reasonable protection for the patent proprietor and sufficient legal certainty for third parties, they (Hoyng more than Huydecoper) believe that the emphasis is on the first aspect – at least, in the other line to be discussed below (of Brinkhof et al.), Hoyng sees this interest wrongfully becoming secondary to the aspect of legal certainty for third parties.
As a method for finding a correct balance, the prosecution history can also be consulted.

[23] Attorney Hoyng blames me for (I quote) putting the waiver doctrine "out with the trash without offering any conclusive reasoning that justifies this" in my opinion in *Bayer/Sandoz*, cf. AstraZeneca et al.'s pleading notes on appeal, par. 30, and AstraZeneca et al.'s pleading notes in cassation, par. 77 – where "trash" had been changed to "rubbish". In this opinion, I propose an alternative for the waiver doctrine, which I believe can be reconciled with Article 69 EPC; in *Bayer/Sandoz*, there was no need to go into this any deeper. The unsubstantiated reproach in the paragraphs mentioned in both pleading notes that I allegedly fail to recognize the relevance of innovation which flourishes in a well-functioning patent system lacks a factual basis in view of many years of professional efforts for IP law in general and patent law in particular.
[24] His opinion for HR 25 May 2012, ECLI:NL:HR:2012:BV3860, *NJ* 2013/68, annotated by Van Engelen (*AGA/Occlutech*), nos. 9-24 and T. Huydecoper, Fair protection, in: Willem Hoyng Litigator (Hoyng bundle), 2013, p. 46 and following.
[25] W. Hoyng, The Dutch Supreme Court and art. 69 EPC, an inspiration for the UPC, in: Verschuur/Geerts/Van Oerle (ed.), gIElen, *een bekend begrip* (Gielen bundle), 2015, p. 151 and following.
[26] At least, in as far as he counters the criticism of R. Hermans in *Kort Begrip* (cf. the next footnote) that the points of view doctrine of the Supreme Court is allegedly in breach of Article 69 EPC and the Protocol, cf. his *NJ* 2015/11 annotation under *Medinol/Abbott* in 2 and 3; see the end of footnote 12 of my opinion in *Bayer/Sandoz* regarding this. This annotation pertained to the previous edition of *Kort Begrip*, but this passage remained unchanged in the last (12th) edition from 2017.
[27] In his BIE note under the Court of Appeal's ruling that is being challenged in our case, P.L. Reeskamp refers to this as a "toned-down essence doctrine" (BIE 2016/23, p. 151, 12).

2.11 The (what I will refer to as the) Brinkhof line[28] refuses to accept this route, which they claim is in breach of Article 69 EPC and the Protocol and is basically a reminiscence of the former doctrine that was used in the Netherlands of the essence of the invention to determine the extent of the protection that is conferred by the patent. This is determined exclusively by the text of the claim, read by the average skilled person in the context of the description and the drawings from the patent specification. The prosecution history may not play any role in this.
This is a fairly "literal" interpretation of Article 69 EPC and *inter alia* relies heavily[29] on the doctrine of the *purposive construction* that has meanwhile been abandoned in England.

2.12 I believe that the first line – specifically in the form propagated by Huydecoper – strikes the best balance and is most compatible with the system that the Supreme Court devised, which I feel – as stated before – is "Article 69 EPC proof"[30]. The tendency (in the interim) in England and Germany can be regarded to be in line with this, or at least to point in the same direction, as I will argue below.

2.13 Secondly, it should be borne in mind that equivalent protection and waiving protection (or not) are aspects of the same protective scope doctrine. In *Bayer/Sandoz*, as the finishing touch to a series of rulings, this doctrine has been pretty much fully worked out by now for the Netherlands. It is a flexible and pragmatic system that uses the inventive idea as the point of view (not the starting point); I believe that this will serve very well in practice and in my view, this does not differ fundamentally from the opinions (in the interim) in England and Germany. I also believe that this is an appropriate system for resolving the problem of the waiver doctrine. This will be addressed now.

2.14 The following finding in *Bayer/Sandoz* has occasionally been interpreted in the literature as the Supreme Court coming back to the waiver doctrine from the *Van Bentum/Kool* ruling[31]:

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[28] See the locations mentioned in footnote 12 of my opinion in *Bayer/Sandoz*; the following can be added to this: R. Hermans and D. de Lange in: Ch. Gielen (ed.), *Kort Begrip van het intellectuele eigendomsrecht*, 12th edition, 2017, Chapter II, § 6 (Extent of protection), specifically nos. 75-78.
[29] I quote from Hermans' contribution to the Gielen bundle: Verschuur/Geerts/Van Oerle (ed.), gIElen, *een bekend begrip*, 2015, Art. 69.1 European Patent Convention, p. 147-148: "I can recommend that anyone who is involved in patent law reads the entire ruling [*i.e. Kirin-Amgen*; A-G]. It is a gem. (…) [This ruling convinces me], because Hoffmann stays the closest to the meaning of Article 69.1 EPC and shows with convincing arguments why this should be done. That is why you should read the entire ruling (…)". However, the *purposive construction* entailed in this has been superseded since the English pemetrexed case from the summer of 2017, as I will explain later.
[30] In par. 11 of his BIE note under the Court of Appeal's ruling that is challenged in our case, Reeskamp submits the following in this regard: "I indeed believe that a sensitive circumstances catalogue is more suitable for providing a tailor-made solution than the two extreme points of view of the Protocol alone, and may ultimately also lead to more legal certainty. However, this entails the risk that this Dutch circumstances catalogue will take on a life of its own and that for the rest, for the most part lip service is paid to the Protocol." (BIE 2016/23, p. 149 and following).
[31] See the annotation of Van Engelen in Ars Aequi September 2016, AA20160650, p. 653: "The Supreme Court sets this 'waiver requirement' aside as a criterion.", the NJ note by Gielen: "7. (…) What is interesting is that the Supreme Court's finding differs from the older rulings *Meyn/Stork* (NJ 1989/506, annotated by L. Wichers Hoeth and *Van Benthem/Kool*, NJ 2002/530 with my note). Thus, the Supreme Court seems to come back to those decisions, without saying so. AG van Peursem also

> "3.3.6 To the extent that part 1.1.1 reproaches the Court of Appeal for failing to recognize the rule that the criterion for not protecting equivalent measures must be that there must be valid grounds for the patent proprietor to waive this protection, even though he could have obtained it, starts from a notion that is not supported in the law. (…)"

However, like AstraZeneca et al.[32], I do not read this directly or explicitly/sufficiently unambiguously in this finding. The Supreme Court could take this case to (still) provide clarity in this regard[33].

2.15 In its pleading notes in cassation in the case at issue (par. 55-59), AstraZeneca et al. attempts to revive the waiver doctrine (with a slightly different interpretation). According to AstraZeneca et al., the waiver doctrine is in line with the interpretation rule of Article 69 EPC, in which it notes that this doctrine should be considered from the point of view of the skilled person (and not the subjective will of the patent proprietor to waive protection) and that a decisive factor is whether this skilled person has valid reasons to assume that the claim must be interpreted literally or in a more limited manner, or: "he believes and may reasonably believe that the patent proprietor deliberately made a limited claim". AstraZeneca et al.'s attorney also argued this previously in the Gielen bundle – although with less emphasis on the point of view of the skilled person[34].

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believes that the doctrine of those rulings no longer applies (see no. 3.9)." See also the *Terugblik Octrooirecht* 2016 in BIE March/April 2017, p. 58: "Bayer complained in cassation that the Court of Appeal should have examined whether there are valid grounds for assuming that protection for the use of TEMPO in the process had been waived. The Supreme Court finds that this opinion is not supported in the law and in so doing, as annotator Van Engelen notes, seems to come back to the criterion as formulated in *Van Bentum/Kool* (in his opinion, A-G Van Peursem says that this criterion is indeed no longer applicable law, par. 3.9). However, the Supreme Court does not specify this explicitly."

[32] Pleading notes in cassation, par. 61 and following.

[33] In the case at issue, the District Court ruled that it infers from *AGA/Occlutech* that the Supreme Court apparently did not come back to the waiver doctrine (see par. 4.18).The District Court probably refers here to par. 4.3.2 from this ruling (HR 25 May 2012, ECLI:NL:2012:BV3680, IER 2012/58, annotated by AFK: BIE 2013/12, annotated by A. Tsoutsanis, cf. also J. den Hartog, *Equivalentiedoctrine; een beetje levend?* BIE 2013/7); however, if I understand things correctly, this paragraph only confirms what the Court of Appeal held, without expressing any opinion regarding the waiver doctrine. Nor was this further relevant in *AGA/Occlutech* – in view of the complaints in cassation. It does underscore that clarity should be obtained regarding this issue.
Reeskamp (BIE 2016/23, p. 155) formulates this as follows in his note under the Court of Appeal's ruling in our case: "Let us hope that the Supreme Court nevertheless [i.e. notwithstanding the settled case law that the interpretation of patents is primarily a factual affair; A-G] deals with the question – to stay in the animal kingdom – regarding the extent to which the patent proprietor may be a chameleon or a zebra."

[34] W. Hoyng, The Dutch Supreme Court and art. 69 EPC, an inspiration for the UPC, in: Verschuur/Geerts/Van Oerle (ed.), gIElen, *een bekend begrip* (Gielen bundle), 2015, p. 151-169, p. 156: "In my opinion also this ruling [Van Bentum/Kool; added by A-G] is completely compatible with art. 69 and the Protocol. If it is clear from reading the claims and the description (including the prior art) for what (which inventive idea) the patent was granted and thus what the essence of the patented invention is then a fair protection of the patentee also requires protection of the variants which use the essence of the invention. However, the reasonable certainty of third parties requires that if it is obvious that the patentee, despite the fact that the variant uses his inventive idea, chose not to protect such variant then (of course) the reasonable degree of certainty for the third party should prevail. It is also understandable to require that such giving up of possible protection should be obvious as it is normal also for a ("willing") third party to assume that a patentee does not give up protection which he could

2.16 I believe that such “valid grounds/waiver doctrine” (rooted in the “essence” era, for example already found in *Meyn/Stork*[35]) is not very compatible with the system of Article 69 EPC and the Protocol. After all, (compared to the old Dutch doctrine of the essence of the invention), this system heavily relies on the fact that the extent of the protection must be *apparent* from the claims of the patent specification, the description and the drawings (Article 69(1) EPC). In determining the inventive idea, as well, this *being apparent* (for third parties) is relevant, which is demonstrated by Article 1 of the Protocol (“from a consideration of the description and drawings by a person skilled in the art”) and par. 3.5 of the *Bayer/Sandoz* ruling, which emphasizes that in determining the inventive idea, the description and drawings form an important source.

2.17 A rather formal argument is that in terms of structure, as well, the waiver doctrine does not seem to be very compatible with the interpretation system of Article 69 EPC. Where under the old essence doctrine – in which the essence of the invention came first when determining the extent of the protection – it was possible to “waive” protection that could be included under the broad essence of the invention, strictly speaking, “waiving” protection (implying that protection initially existed) under Article 69 EPC and the Protocol is not involved, because in that case the question is whether the extent of the protection has been (deliberately) *limited* from the start. Hermans and De Lange formulate this as follows in *Kort Begrip*: This is incompatible with the uniform character of European patent law and this waiver doctrine seems to have been superseded, given that in interpreting claims, the essence of the invention is merely a point of view rather than a starting point[36].

2.18 In addition, as far as I know, no (clear, separate) valid reasons/waiver doctrine are used in other European countries that are a contracting state to the EPC, but this is not entirely certain[37].

2.19 As I indicated before, I believe that in practice, we can do very well without this: a rule that I see is in line with the system of Article 69 EPC and which could replace the waiver

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have obtained.”. I believe that this is too decisive a role for the inventive idea, which was in line with the doctrine of the essence, but is no longer so under Article 69 EPC; after all, the inventive idea point of view has become the decisive factor for protection here. This goes too far. In a similar sense: A-G Huydecoper in his opinion for HR 25 May 2012, ECLI:NL:HR:2010:BV3680, IER 2012/58, annotated by AFK, BIE 2013/12, annotated by A. Tsoutsanis and J. den Hartog (*AGA/Occlutech*) under 23 and footnote 22.

[35] HR 27 January 1989, ECLI:NL:HR:1989:AD0607, *NJ* 1989/506, annotated by L. Wichers Hoeth (*Meyn/Stork*).

[36] Gielen (ed.), *Kort Begrip van het intellectuele eigendomsrecht*, 12th edition, 2017, p. 82, footnote 237 regarding the “valid reasons” required for waiver from *Stork/Meyn* and regarding the waiver doctrine having been superseded from *Van Bentum/Kool* being incompatible with Article 69 EPC, p. 85. Cf. also Resolution’s pleading notes in cassation, par. 62: “After all, such an assessment implies the incorrect (or at least the premature) assumption that the patent proprietor is entitled to protective scope according to the literal wording of the claim, even though this protective scope must be determined by interpreting the claim based on the description (and the drawings).”

[37] At best, traces of this can be found in Krasser, cf. below, par. 2.20. It may be doubted whether any waiver doctrine can be recognized in the pemetrexed case to be discussed in par. 2.21 below, in which England rejected the *purposive construction* doctrine.

doctrine, is – within the scope of the point of view of the inventive idea – to allocate weight to whether and, if so how, according to the average skilled person there was an intention to limit the extent of the protection. In other words: according to the skilled person, was a specific limited extent of the protection deliberately chosen[38]. In my analysis, the Court of Appeal also used this method in our case[39]. This is not a word game, but a difference in approach using a more flexible instrument as the outcome – after all, waiving a right is not quickly involved.

2.20 (Cautious) indications that a similar approach based on a *role for the inventive idea* can be seen in Germany can be found (but I realize that the main line in Germany really is that "Patentansprüche" prominently (sometimes more prominently than in the Netherlands) have "preference", as it is called there): in assessing the extent of the protection, *the objective intention of the invention* must be taken into account. In striking a balance between fair protection of the patent proprietor ("angemessener Schutz") and a reasonable degree of certainty for third parties ("ausreichende Rechtssicherheit für Dritte"), the following is found with Rinken in the last edition of Schulte of this year[40]:

> "(…) **Angemessener Schutz** (*fair protection*) für den Patentinhaber ist gewährleistet, wenn ihm der **gerechte Lohn für die Offenbarung** seiner Erfindung gewährt wird. Das ist der Fall, wenn die unter Schutz gestellte Erfindung gegen jede Nachahmung geschützt wird. Dabei kann die objektive Bedeutung der Erfindung nicht auβer Betracht bleiben; dh der Umfang des Schutzbereich wird sich nach dem *Ausmaβ der objektiven Bereicherung* der Technik richten, soweit diese im Patentanspruch unter Schutz gestellt ist. Dagegen is die Intensität der persönlichen Anstrengung, der Fleiβ der Erfinders belanglos, da das Patent nicht den <vergossenen Schweiβ>, sondern die erbrachte Leistung belohnt." [Emphasis added by A-G]

Osterrieth[41] also provides a pointer in the direction that the inventive idea plays a role as a point of view:

> "Technische Begriffe in den Patentansprüchen sind so zo deuten, wie sie der angesprochene Fachmann nach dem Gesamtinhalt der Patentschrift unter Berücksichtigung der in ihr objektiv offenbarten Lösung versteht. Dabei ist nicht am Wortlaut zu haften, sondern auf den technischen Gesamtzusammenhang abzustellen. Es kommt daher nicht auf eine philologische Betrachtung, sondern auf den technischen Sinn des Inhalts des Patentanspruchs an. Der

[38] Cf. also my opinion in *Bayer/Sandoz*, par. 3.11.
[39] See also par. 5.22 of the challenged ruling: "(…) Or, in other words, the average skilled person would not assume that the patent proprietor deliberately opted to exclusively confer protection for the salts of rosuvastatin mentioned in paragraph 7. (…)". Resolution also sees room for a form of waiver doctrine; cf. Resolution's pleading notes in cassation, par. 66: "N.B.: this does not mean that there is no room at all for a waiver doctrine. If the extent of the protection has been determined in the correct way, i.e. by interpreting the claims in conformance with the description and drawings, a waiver of part of the extent of the protection may still be involved, for example by positions taken in the patent prosecution file, which waiver may not be assumed too readily (not without valid grounds) in that case. The reference to *Meyn/Stork* in *AGA/Occlutech* pertains to that situation (par. 4.3.2)."
[40] Schuilte/Rinken, PatG, 10. Auflage (2017), § 14 Rdn 16.
[41] Osterrieth, Patentrecht, 5. Auflage 2015. 6. Teil. Patentverletzung, Rn. 919-920.

Erfindungsgedanke muss unter Ermittlung von Aufgabe und Lösung, wie sie sich aus dem Patent ergeben, bestimmt werden, wobei auf den technischen Sinn der in der Patentschrift benutzten Worte und Begriffe auszustellen ist und dabei inbesondere die **technische zweckgerichtete Bedeutung** eines Merkmals zu analysieren ist."
(...)
Der in der Patentschrift benutzten Worte und Begriffe sind stets im Lichte der in der Patentschrift offenbarten Lehre auszulegen. Dies bedeutet, dass dann, wenn die verwendeten technischen Begriffe vom allgemeinen (technischen) Sprachgebrauch abweichen, letztlich nur der aus der Patentschrift sich ergebende Begriffsinhalt massgeblich ist. Die Rechtsprechung spricht insoweit anschaulich davon, dass Patentschriften im Hinblick auf die dort gebrauchten Begriffe gleichsam **ihr eigenes Lexikon** darstellen. (...)" (Emphasis added by A-G)

I further refer to Ann in Krasser/Ann[42] (which comes closest to some sort of waiver doctrine):

"4. Aus der Beschreibung kann sich ergeben, dass die eine oder andere nach dem Worlaut der Ansprüche als möglich erscheinende Auslegung anzuschliessen ist. Das trifft zu, wenn klar zum Ausdruck kommt, dass in bestimmten Umfang kein Schutz beansprucht oder gewährt wird. In seine Entscheidung **Lagerregal** [Fn. 57: 9.12.2008 GRUR 2009, 390, 391] stellt der BGH ausdrücklich klar, dass das Fehlen einer sonst nirgends thematisierten Stütze in den Zeichnungen **für sich genommen nicht darauf schliessen lässt**, das Fehlen der Stütze sei ein negatives Merkmal des patentgemässen Gestells – und dessen Ausführung mit Stütze folglich nicht patentgemäss. Wollte man ein negatives Patentmerkmal annehmen, bedürfe es vilemehr weiterer Anhaltspunkte.

Als Teil der schutsgewährenden Entscheidung vom Verletzungsgericht zu beachten sind freilich **ausdrücklichen Schutzbegrenzungen**, gleichgültig ob nach dem SdT gebten oder nicht. Sie bestimmen den Schutzbereich des Patents und rubrizieren gewöhnlich als Verzichte oder Beschränkungen.
(...)
Auch derartige Verzichte und Beschränkungen sind jedoch nur zu breücksichtigen, wenn sie aus der Beschreibung selbst ersichtlich sind [Fn. 58: BGH 16.12.1958 Schaumgummi GRUR 1959, 317, 319l.; *Preu*, GRUR 1980, 693 und 1985, 731; *Benkard/Scharen* § 14 PatG Rn. 119; *Bossung*, FS Preu (1988), 219, 232 f.; grundsätzlich auch *Schmieder*, GRUR 1978, 564; *Busse/Keukenschrijver*, § 14 PatG Rn. 49; *v. Falck*, GRUR-FS, 543, 556 Rn. 13.] (...)"[43]

[42] Krasser/Ann, Patentrecht, 7. Auflage 2016, § 32 Der Schutzbereich des Patents und des Gebrauchsmusters, Rn. 56-58.
[43] AstraZeneca's pleading notes in cassation quotes in par. 50 from par. 22, 27 and 30 of BGH 02.03.1999 X ZR 85/96 *Spannschraube*: (I quote slightly broader): "22.II. (…) In den Tatsachenbereich gehört es, wenn im Rahmen der Ermittlung des in der Patentschrift offenbarten Erfindungsgegenstandes festgestellt wird, wie der Durchschnittsfachmann die in den Patentansprüchen verwendeten Begriffe unter Berücksichtigung der Beschreibung und der Zeichnungen versteht und welche konkreten Vorstellungen er mit ihnen und mit dem geschilderten Erfindungsgedanken verbindet (...)".
"27 a) (...) Nach Art. 69 Abs. 1 EPÜ wird der Schutzbereich des Patents durch den Inhalt der Patentansprüche bestimmt, wobei die Beschreibung und die Zeichnungen zur Auslegung der Patentansprüche heranzuziehen sind. Inhalt bedeutet nicht Wortlaut, sondern Sinngehalt. Maβgebend ist der Offenbarungsgehalt der Patentansprüche und ergänzend – im Sinne einder Auslegungshilfe – der Offenbarungsgehalt der Patentschrift, soweit dieser Niederschlag in den Ansprüchen gefunden hat. Dies ergibt sich aus dem Protokoll über die Auslegung des Art. 69 Abs. 1 EPÜ (BGBl. 1976 II, 1000). Danach dient die Auslegung nicht nur zur Behebung etwaiger Unklarheiten in den Patentansprüchen, sondern auch zur Klarstellung der in den Patentansprüchen verwendeten

2.21 It can be argued that in England, as well, such an approach (referred to in par. 2.19) has recently been accepted, even though this could also be regarded as a variant of the waiver doctrine as was once formulated in the Netherlands. Last summer (2017), in the pemetrexed case[44], the English Supreme Court made a U-turn and renounced the more restrictive "*purpose construction*" approach from *Kirin-Amgen* from 2004. This involved a case dealing with equivalence, in which a Swiss-type claim for the use of pemetrexed disodium salt was interpreted in the highest instance such that the extent of the protection also covered dipotassium salts and the free acid of pemetrexed. I refer to the following passages from the leading speech of Lord Neuberger[45]:

> "56. (…) In my opinion, issue (ii) involves not merely identifying what the words of a claim would mean in their context to the notional addressee, but also considering the extent if any to which the scope of protection afforded by the claim should extend beyond that meaning. As Sir Hugh Laddie wrote in his instructive article *Kirin-Amgen – The End of Equivalents in England?* (2009) 40 IIC 3, para 68, "[t]he Protocol is not concerned with the rules of construction of claims" but with "determining the scope of protection. (…)
>
> 74. Looking at matters more broadly, the addressee of the Patent would, as I see it, understand that the reason why the claims were limited to the disodium salt was because that was the only pemetrexed salt on which the experiments described in the specification had been carried out. However, it does not follow that the patentee did not intend any other pemetrexed salts to infringe: the suggestion confuses the disclosure of the specification of a patent with the scope of protection afforded by its claims. Particularly given the facts set out in para 25 above [i.e. factual determination in the first instance regarding the general professional knowledge of the average skilled person regarding salts in 2001/2002; added by A-G], it seems to me very unlikely that the notional addressee would have concluded that the patentee could have intended to exclude any pemetrexed salts other than pemetrexed disodium, or indeed pemetrexed free acid, from the scope of protection." (Emphasis added by A-G)

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technischen Begriffe sowie zur Klärung der Bedeutung und der Tragweite der Erfindung (st. Rspr. des Sen. BGHZ 105, 1 (BGH 14.06.1988 – X ZR 5/87) – Ionenanalyse; BGHZ 133, 1 [BGH 07.05.1996 – VI ZR 102/95] – Autowaschvorrichtung; vgl. auch zu § 14 PatG: BGHZ 98, 12 – Formstein). Für die Beurteilung entscheidend ist dabei die Sicht des in dem jeweiligen Fachgebiet tätigen Fachmanns. Begriffe in den Patentansprüchen und in der Patentbeschreibung sind deshalb so zu deuten, wie sie der angesprochene Durchschnittsfachmann nach dem Gesamtinhalt der Patentschrift unter Berücksichtigung von Aufgabe und Lösung der Erfindung versteht (Sen.Urt. v. 31.01.1984 – X ZR 7/82, GRUR 1984, 425, 426 – Bierklärmittel; Urt. v. 26.09.1996 – X ZR 72/94, GRUR 1997, 116, 117 f. (BGH 26.09.1996 – X ZR 72/94) – Prospekthalter; Urt. v. 29.04.1997 – X ZR 101/93, GRUR 1998, 133, 134 (BGH 29.04.1997 – X ZR 101/93) – Kunstoffaufbereitung)."
"30 c (…) Der Senat hat wiederholt zum früheren Recht ausgeführt, daß für die Auslegung eines Patents nicht am Wortlaut zu haften ist, sondern auf den techischen Gesamtzusammenhang abzustellen ist, den der Inhalt der Patentschrift dem Durchschnittsfachmann vermittelt. Der Patentanspruch ist nicht wörtlich in philologischer Betrachtung, sondern seinem technischen Sinn nach aufzufassen, das heißt der Erfindungsgedanke muß unter Ermittlung von Aufgabe und Lösung, wie sie sich aus dem Patent ergeben, bestimmt werden. (...) (Emphasis added by A-G)

[44] UKSC 12 July 2017 (2017) UKSC 48 (*Actavis/Eli Lilly*), which can also be found on the Bailii website (http://www//bailii.org), via this link: http://www.bailii.org/uk/cases/UKSC/2017/48.html.

[45] In this ruling it was also assumed that in certain cases, the patent prosecution file may carry weight in determining the extent of the protection (leading speech Lord Neuberger, par. 87-89); this also constitutes a landslide in England & Wales, where until then, this was invariably rejected.

This approach is very reminiscent of the points of view doctrine (and, moreover, the method that the Court of Appeal applied in our case): the average skilled person takes the limitation to the disodium salt here not as limiting for the extent of the protection, because he sees that experiments were only conducted with this salt. No limitation to this salt was envisaged, as becomes clear to him, in view of the problems inherent to salt screening. Other salts or even the free acid may also be included.
A waiver doctrine may possibly even be read into this, but as far as I can see, this was not mentioned as such in the ruling.

2.22 This brings me to conclude this. In cases in which the average skilled person believes that it is *clear* that a limitation included in (the claims of) the patent is not in line with the inventive idea, the point of view of the inventive idea may have a corrective effect, namely if it is clear to this skilled person that limited protection was not deliberately chosen. In that case, fair protection is offered to the patent proprietor as well as reasonable legal certainty for third parties in conformance with Article 1 of the Protocol. I believe that this comes down to a far less rigid consideration method than the waiver doctrine as we know it from *Van Bentum/Kool*.

2.23 Former (patent) attorney and A-G Huydecoper uses a similar line of reasoning in his contribution to the Hoyng bundle[46] (a beautiful analysis of the intrinsic problems in striking a balance between reasonable legal protection of the patent proprietor and sufficient legal certainty for third parties):

> "In line with the case law in the 'leading countries' elsewhere, I would therefore choose to adopt primacy of the claims as the starting point. We might then, I believe, have a basis for introducing the approach that a person skilled in the art who reads the claims in the light of the description and drawings and tries to understand them, will be inclined to do so – by which I mean: to understand the claims – taking due account of the inventive concept described in the patent. This does assume, of course, that the patent clearly discloses a particular inventive concept – if that is not the case, and the court is invited to perform a somewhat random search for an inventive concept that could support a broader construction, such reasoning should not be adopted.
>
> Reading the claims in the light of an inventive concept sufficiently disclosed by the patent, should usually lead the person skilled in the art to understand restrictions included in the claims that are not in line with the inventive concept to be non-binding – and thus as immaterial, or as examples of best modes that may be replaced by others. The notion that one may assume that the author envisaged broad protection, may be taken into account; mirroring this, one may not assume too readily that restrictions that are not in line with the inventive concept, should nevertheless be considered as 'intended to be binding'."

2.24 This is also how I – cautiously – value the Presiding judge of the "Patentsenat" of the Bundesgerichtshof P. Meier-Beck in the Brinkhof bundle[47], even though he writes about

[46] T. Huydecoper, Fair protection, in: Willem Hoyng Litigator (Hoyng bundle), 2013, p. 58-59.
[47] P. Meier-Beck, Scope of Patent Protection – Protection of Equivalents?, in: Van Engelen (ed.), On the Brink of European Patent Law (Brinkhof bundle), 2011, p. 32.

equivalence, where he refers to the role of the *protected inventive achievement* in the eyes of the average skilled person with his general professional knowledge in determining the extent of the protection:

> "Article 1 of the Protocol demands a position 'which combines a fair protection with a reasonable degree of legal certainty for third parties' [footnote 17: Protocol, *supra* note 2, Art. 1.]. Therefore, it is the task of the courts to find criteria for the determination of the scope of protection which reconcile both demands.
>
> The most pragmatic instrument of choice here is the cognitive faculties of a person skilled in the art, who is, on the basis of his knowledge and skill in the art, analyzing the patent claim and using the description and the drawings to interpret the claim [footnote 18: *id.* (mentioning explicitly the 'consideration of the description and drawings by a *person skilled in the art*' (emphasis added))]. The scope of the patent is determined by this person's conclusions. It extends to any variant that is made obvious by the claim to the person skilled in the art [footnote 19: BGH 14-06-88, Case No. X ZR5/87 – *Ionenanalyse*, 22 IIC 249.]. On the one hand, this has the effect that the scope of the patent is proportionate to all subject-matter that can be done or carried out by the person skilled in the art, on the basis of the protected inventive achievement, without being inventive himself (to meet demand for fair protection). On the other hand, this extent of protection is (almost) becoming predictable by focusing on subject-matter, which is recognizable by a person skilled in the art, as being part of the protection conferred by the patent (to meet demand for legal certainty)." (Emphasis added by A-G)

2.25 This clearly differed from what Pieron taught in his dissertation[48]:

> "This means that it must be checked whether the limitation was the consequence – deemed inevitable – of difficulties that occurred in formulating the invention in its full scope and depth and/or in choosing the correct formulation, or whether they could have been avoided in carefully considering the invention and the formulation of the patent application. In the first case, the limitation is non-binding, provided that the broadening is sufficiently predictable for the average skilled person; in the second case, the limitation should be considered to be binding."
>
> and
>
> "Neither of the two authors [Turner and Fergusson; added by A-G] clarifies why the applicant should not have recognized and corrected the "likelihood of error" that is "obvious" to third parties, or the "apparently foolish restriction" himself and why the risk that this was not done does not come at the patent proprietor's expense."

2.26 Hermans and De Lange are also dismissive in *Kort Begrip*[49]. These authors take Article 69 EPC literally (and see this confirmed in *inter alia* the meanwhile superseded – as we have seen – *purposive construction* model from England):

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[48] A.P. Pieroen, *Beschermingsomvang van octrooien in Nederland, Duitsland en Engeland*, diss. 1988, p. 278-279 and 685, respectively.
[49] Ch. Gielen (ed.), *Kort Begrip van het intellectuele eigendomsrecht*, 12th edition, 2017, ch. II, § 6, no. 75.

> "Thus, words included in the claim are never meaningless. However, the claims must be interpreted. This means that the meaning to be attached to the claims by the skilled person at the time of filing must be determined (not the later meaning, because this would mean that the extent of the protection could change in time and this would be in breach of patent law). This involves determining the meaning of the wording of the claims. This does not regard finding the inventive idea underlying the wording of the claims. The issue is to understand and interpret the wording of the claims in the context of the description and drawings. Nothing more, but certainly nothing less. The Convention is very clear regarding this."
>
> (…)
>
> "However, all that Article 69 EPC stipulates is that to determine the extent of the protection that is conferred by the European patent, we must read the claims. All elements are relevant here. In interpreting those claims, we must constantly keep the context in which they have been drawn up, which is apparent from the description and drawings, in mind [footnote 234: For an extensive substantiation, see: House of Lords 21 October 2004 [2004] *UKHL* 46 (*Kirin-Amgen Inc/Hoechst Marion Roussel Ltd*). (…)]. The issue here is how the skilled person understands the claims. In this regard, his general professional knowledge on the application date must be taken into account [footnote 235: For a recent example in which other elements were also taken into account in determining the extent of the protection: Court of Appeal of The Hague 16 February 2016 (*AstraZeneca and Shionogi/Resolution*). *BIE* 2016/2, p. 139 with a critical note by Reeskamp.]"

In a similar sense, see Hermans' contribution to the Gielen bundle[50], as well, where he also heavily relies on the superseded English *purposive construction* doctrine:

> "The claims determine the extent of the protection, not numerous points of view that are or are not at issue. Is this nevertheless still necessary? Is it convenient? The additional points of view that the Supreme Court formulated regarding Article 69.1 EPC lead to applications for cassation. The parties and attorneys will ascribe considerable relevance to those starting points in Dutch proceedings and, if the Court of Appeal fails to express its opinion, find a reason to file an application for cassation. Instead of clarifying the case, the Supreme Court rendered it more obscure. And do we really need additional legal formulations, given that this only involves the question of how the average skilled person interprets a technical text? (…) I think not (…)
> Is it necessary? No, again, I think not. Foreign countries (…) teach us that there is also another way."

This is followed by praise for *Kirin-Amgen* and BGH case law which allegedly demonstrates that the text of the claims is adhered to.

2.27 In contrast to what Pieron, Hermans and De Lange (and also repeatedly Brinkhof; see for locations footnote 12 of my opinion in *Bayer/Sandoz* and the other authors of the Brinkhof line mentioned there) advocate and Resolution also seems to argue, I believe that a patent that in retrospect has not been optimally edited should not always automatically come

[50] R. Hermans, Art. 69.1 European Patent Convention in: Verschuur/Geerts/Van Oerle (ed.), gIElen, *een bekend begrip* (Gielen bundle), 2015, p. 143 and following.

at the patent proprietor's expense and risk (even if "the error" was foreseeable[51]). After all, in the event that it is *clear* to the average skilled person that a limitation included in (the claims of) the patent is not in line with the inventive idea (while it is not possible to recognize any cause for this that can be designated in the development history, which would change this; cf. the following "divisional example" of A-G Huydecoper in par. 2.28) – and, according to the underlying idea, a reasonable legal certainty for third parties is thus present, especially because this is clear to the skilled person – I believe that adequate protection of the patent proprietor entails that he is not bound to the (clearly unintended) limitation. This is sometimes formulated such that in principle, the merit of the invention should be the guiding principle for the extent of the protection[52]. The fact that caution is in order here does not require any further argument.

2.28 But/because where is the boundary here?

I believe that this cannot be stipulated in absolute terms.

The problem plays a role (as stated before, cf. par. 2.13 above) both in the question regarding whether an equivalent measure is envisaged to be included in the protection and in the question regarding whether in the eyes of the skilled person, a limiting definition of a technical feature in the claim was envisaged; as it were, these are two sides of the same protective scope coin.

By way of example, I offer the rule *disclosed but not claimed is disclaimed* – assuming this would have been accepted by the Supreme Court as a *general rule* in par. 3.4.2 from *Bayer/Sandoz* regarding equivalence (I believe not, given that this was directed at the specific case[53]).

It can be argued that in that case, in general it is *clear* to the skilled person that despite a broader disclosure in the patent specification, the proprietor apparently deliberately chose to opt for a more limited protection. This will usually be the route.

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[51] Differently in this connection, the District Court of The Hague, 18 June 2014, BIE 2014/41 (*MBI/Shimano et al.*) – which did not lead to any ruling from the Court of Appeal – where the rule "foreseeable but not claimed is disclaimed" is used: "4.21. Within the assessment framework of the context-bound interpretation, the legal certainty to which third parties are entitled opposes the assumption in this case that an equivalent measure is involved. When asked at the hearing, MBI explained that on the first date, the skilled person possibly might have realized that gripping the sun wheel could also occur with one pawl, but that this was not 'entirely evident'. The District Court inferred from this and found that the use of one pawl as an equivalent measure was foreseeable in and of itself, but that – as Shimano rightfully advanced – it is likely that the skilled person would have realized that in that case, additional measures were required to make gripping possible. However, the latter is not what the patent adds to the prior art, so that it is not clear that the reasonable protection for the applicant would entail that the claim is still interpreted in this way to his advantage. In editing the subject-matter for which protection is requested, where the applicant opts to exclusively claim 'at least two collections of pawls', in principle, third parties may assume that the extent of the protection conferred by the patent is apparently limited to this and does not also comprise 'at least two collections of one or more pawls'."

[52] Huydecoper/Van der Kooij/Van Nispen/Cohen Jehoram, *Industriële eigendom* 1, 2016, 3.5.2.6.

[53] Likewise Den Hartog and Blomme in their BIE annotation of *Bayer/Sandoz*, BIE 2016/15, p. 113: The 'disclosed but not claimed is disclaimed' rule is not an ironclad rule, but is a strong indication that a disclosed variant has been relinquished (followed by an example of a nucleotide sequence discrepancy between the claim and the description in which honouring this rule indeed does not immediately seem to be the most appealing option).

But in an exceptional case of *disclosed but not claimed is not claimed*, can the point of view of the inventive idea not sometimes "win" in the eyes of the skilled person – for example if it becomes very *clear* to the skilled person from the description and drawings that what is "disclosed" there falls under the envisaged protection, but was erroneously not included in the claim? Or does this go too far in view of Article 69 EPC? If we change to an equivalence problem, things really become complicated in the example given by A-G Huydecoper in his opinion for *AGA/Occlutech*[54], par. 22, 3rd dash of a "clumsily" adapted description in a divisional application; the result was that in certain respects, the invention described in the introductory parts of the description invokes an essentially different picture than what is set forth in the (amended) claims. Identifying the inventive idea in such a patent and subsequently claiming more protection than follows from the text of the claim is not a beneficial route – but you could also say that the required *clarity* for the skilled person in the sense referred to above is not involved here.

In my view, exactly where the line should be drawn cannot be specified in general; thus, this must be assessed on a case-by-case basis by the judge deciding questions of fact based on the specific circumstances of the case. This seems to be a bit of a platitude[55], but in the area of determining the protective scope, the judge deciding questions of fact in the Netherlands has been given considerable room according to settled case law of the Supreme Court. One possible provisional lower boundary seems to be at "interpreting away" part of the claim – even if it becomes clear to the average skilled person from the description and drawings (and/or the inventive idea, used as a point of view) that the invention does not pertain to this. This is simply the consequence of the primacy of the claim in determining the extent of the protection under the current system of Article 69 EPC and the Protocol. Again, not everybody will agree with this.

One consequence of the advocated rule also seems to be that any observed *lack of clarity* for the skilled person must be interpreted to the detriment of the patent proprietor[56]. As a "countercheck", the judge deciding questions of fact must consistently keep an eye on the legal certainty for third parties in the exercises at issue here.

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[54] HR 25 May 2012, ECLI:NL:HR:2012:BV3680, IER 2012/58, annotated by AFK, BIE 2013/12, annotated by A. Tsoutsanis and J. den Hartog (*AGA/Occlutech*).

[55] A-G Huydecoper formulates this more positively in par. 23 of the opinion mentioned in the previous footnote: "With these examples, I (…) wanted to illustrate that there is no uniform route for the interpretation of patents. Each patent must be interpreted in the scope of the circumstances intrinsic to that patent, including particularities and peculiarities, like the ones suggested above by way of example. What AGA defended in cassation seems to be based on a different starting point: for each patent, the 'essence of the inventive idea' should be determined to assess whether the claims have not been formulated in too limited a fashion; if the latter is determined, the interpretation should also focus on the 'essence' found, in as far as necessary ignoring the limitations included in the claims [footnote 22: In the paraphrase of AGA's point of view that I gave, the reader will recognize a doctrine that closely ties in with the 'classic' Dutch doctrine regarding the interpretation of patents indicated above in paragraphs 14 and 15; thus, as I subsequently discussed, this is broader than an interpretation that is compatible with the rule set forth in Article 69 EPC, and the interpretation that has meanwhile been given to this rule in practice.]"

[56] Idem *Kort Begrip*, see the previous footnote, p. 80.

2.29 This analysis has possibly taken us one step further in the recalcitrant field of the extent of protection that is conferred by patents.

2.30 In light of the above, I will not discuss the complaints of parts 2-4.

Parts 2-4 (protective scope): discussion of the complaints

2.31 Following an introduction in par. 2.1, part 2 contains in sub-part 2.2 the complaint on an issue of law that in par. 5.10-5.25 (and par. 5.11 and 5.24, in particular), the Court of Appeal failed to recognize that if the description of a patent gives a further definition of a claim feature, this feature has this further defined meaning, even if in and of itself (according to the letter), the claim feature seems to have a different, broader or more limited meaning. According to the complaint, this is settled case law of the Technical Boards of Appeal of the European Patent Office (own lexicon doctrine). Ignoring or interpreting away such further definition in the description has the same effect as ignoring or interpreting away a limitation of the claim feature itself.

2.32 Following my introductory comments, it will be clear (that I believe) that this complaint does not hold in general. Whether a description of a technical feature in the claim reads as a (limiting) definition of this claim feature for the skilled person depends; this may be true, but this is by no means always the case – as in the case at issue.
First of all, the complaint on an issue of law fails to recognize that a decisive factor in determining the extent of the protection that is conferred by a patent is whether the average skilled person, with his general professional knowledge, will regard the definition in the description to be restrictive (which the Court of Appeal properly recognized, see par. 5.22-5.23) and not, as the part seems to suggest, whether in linguistic terms – by means of the words that the patent proprietor has chosen[57] – the definition is restrictive or not[58]. The fact that this entails a limitation as advocated by Resolution is immediately unappealing to this average skilled person, because based on his general professional knowledge, he knows that the active ingredient at issue in this invention (just as in the earlier generations of statins) is the anion, which as such cannot exist independently or included in a tablet, but needs a cation “as a carrier”. The essence of the invention does not lie in the precise salts (anion-cation combinations), but in the new active anion, as this skilled person will understand[59].

[57] See Resolution’s pleading notes in cassation, par. 33, where Resolution apparently seeks to tie in with the “*purpose-construction*” approach that has meanwhile been abandoned in England; cf. par. 2.21 above.
[58] In contrast to what AstraZeneca et al. contends in par. 11 of the pleading notes in cassation, I do not read in the complaint that a definition of a claim feature in the description must always be read “in the form of an exhaustive list”. After all, in par. 2.2, the complaint refers to a “further definition” and a “definition of a claim feature that gives the feature a different, broader or more limited meaning than the claim feature has according to the letter, without this further definition (…)”. See also Resolution’s pleading notes in cassation, par. 47.
[59] Cf. AstraZeneca et al.’s pleading notes in cassation, par. 20-23.

In addition, the proposed rule would reverse the meaning of claim and description from Article 69 EPC as it were, because in that case, more value should (always) be ascribed to a definition "by itself" in the description than to the relevant feature in the text of the claim, or, in other words, this claim feature always compellingly has the content that it is given in the description. This is incorrect; according to Article 69 EPC, the claim determines the extent of the protection, although this claim must be interpreted *in light of* inter alia the *entire* description. In that case, it may be clear to the skilled person that an "own lexicon" is involved, but this is not compellingly so in all cases[60].
I already briefly mentioned that the average skilled person must read the description *in its entirety*, as AstraZeneca et al. rightfully contended (see also par. 5.11 of the challenged ruling; "in the context of the entire description"), which means that (in our case) not only paragraph 7 of the description is (certainly) decisive for the extent of the protection. This complaint also fails to recognize this.
As substantiation, the part refers to the "own lexicon" case law of the Technical Boards of Appeal of the European Patent Office (hereinafter: TBA) (*inter alia* T 1321/04[61]) and a ruling by the Bundesgerichtshof (BGH) in the *Spannschraube* case[62], but this cannot help the part. Quite the contrary: this case law confirms that such a further definition in the description should not be viewed *alone*, but that the rest of the description and the average skilled person's general professional knowledge must also be taken into account in this (as the Court of Appeal did in our case; cf. par. 5.11)[63].

See, for example, TBA 28 February 2005, T 1321/04:

> "2.3 For understanding the meaning of the terms used in a patent document, the person skilled in the art does not consider the terms in isolation from the remainder of the document, ie with their literal meaning. On the contrary, the terms are considered in the context of the contents of the document as a whole (T 312/94, T 969/92, neither published in the OJ EPO).
>
> Therefore, terms must be construed as they would be by the person skilled in the art according to the whole content of the application, taking into account what is achieved by the invention.
>
> These findings are in line with the principle laid down by the boards of appeal that the description and the drawings are used to interpret a claim when an objective assessment of its content has to be made (see "Case Law of the Boards of Appeal of the European Patent Office", 4th edition, II.B.4.3, 2nd paragraph)."

[60] See also AstraZeneca et al.'s pleading notes in cassation, par. 8 and 9.
[61] "Thus, if a special meaning can be derived from the patent document, only this meaning is ultimately decisive.".
[62] BGH 2 March 1999, X ZR 85/96 (*Spannschraube*): "b. With respect to the terms used therein, patent specifications virtually represent their own lexicon. If these terms differ from general (technical) linguistic use, it is ultimately only the contents of the terms resulting from the patent specification that apply."
[63] In a similar sense: AstraZeneca et al.'s pleading notes in cassation, par. 12.

See also Case Law of the Boards of Appeal of the European Patent Office, 8th edition (July 2016), 4.1 General rules of interpretation, p. 101-102:

> "In **T 312/94**, the board held that for the interpretation of any document, in particular a patent application or patent, in order to determine its true meaning and thus its content and disclosure, no part of such a document should be construed in isolation from the remainder of the document: on the contrary, each part of such a document had to be construed in the **context of the contents of the document as a whole**. Thus, even though a part of a document appeared to have a particular meaning when interpreted literally and in isolation from the remainder of the document, the true meaning of that part of the document could be different having regard to the remainder of the document (see also **T 546/07, T 860/06, T 456/10**)."

BGH 2 March 1999, X ZR 85/96 (*Spannschraube*):

> "a. Bei der Auslegung eines europäischen Patents ist nicht am Wortlaut zu haften, sondern auf den technischen Gesamtzusammenhang abzustellen, den der Inhalt der Patentschrift dem Fachmann vermittelt. Nicht die sprachliche oder logisch-wissenschaftliche Bestimmung der in der Patentschrift verwendeten Begriffe ist entscheidend, sondern das Verständnis des unbefangenen Fachmanns."

2.33 The substantiation complaint of sub-part 2.3.1 contends that the text of paragraph 7 of the description was meant to be restrictive in view of other non-exhaustive lists elsewhere in the description, for example with the addition "*and the like*", or the description "*examples*" of term X are Y and Z, or that this must involve "*preferred substituents*", which the Court of Appeal allegedly disregarded without giving any reason.
According to sub-part 2.3.2., par. 5.11, 1st sentence, starts from an incomprehensible restricted reading of Resolution's arguments, because Resolution did not contend that *every* further description of a patent claim must always be taken to be restrictive (such as in case of the one with the addition "*and the like*"); Resolution merely contended that paragraph 7 is a restrictive definition.

2.34 What comes first and foremost with these substantiation complaints is that the interpretation of arguments in the discussion between the parties is reserved for the judge deciding questions of fact. That the Court of Appeal understands paragraph 7 as non-restrictive for the average skilled person has been amply substantiated and can be easily followed. The *a contrario* reasoning from *sub-part 2.3.1* fails on this basis.
It has also been sufficiently indicated that the Court of Appeal regards Resolution's argument in question as pertaining to the description from paragraph 7 and not in general, based on which *sub-part 2.3.2* fails; the complaint starts from a too limited reading of par. 5.11.

2.35 Sub-part 2.3.3 complains that in par. 5.15, the Court of Appeal failed to recognize that according to Article 69 EPC, the description must be used in interpreting the claims; at best, the inventive idea is a point of view in this. Thus, a (clear) wording of the description most certainly prevails over the inventive idea.

Sub-part 2.3.4 complains that it is legally incorrect that the perspective of the average skilled person is in part determined by the inventive idea. According to the complaint, this fails to recognize the description as an important source in identifying the inventive idea and not the other way round.
Even if the finding that is attacked here must be understood such that *here* the prior art mentioned in the description is not relevant for identifying the inventive idea, a lack of grounds is involved, because in that case which prior art is referred to has not been made apparent.
In fact, it has been wrongly held here that the inventive idea is a source of interpretation for the description, and that in the event of any discrepancy, the description does not prevail. This has elevated the inventive idea to a starting point instead of using it as a point of view, according to this complaint.

2.36 The complaints *in 2.3.3 and 2.3.4* also fail, given that they start from an incorrect interpretation of the ruling. The Court of Appeal did not find at all that the inventive idea prevails over the wording of the description. In par, 5.15, the Court of Appeal held that in as far as Resolution intended to contend that since the claims must be interpreted in light of the description, there is no longer any room for taking the inventive idea into account, or at least the wording of the description must prevail, that this point of view in that case is rejected. The reason that the Court of Appeal gave for this is that in interpreting in light of the description, the perspective of the average skilled person is always decisive, taking into account his general professional knowledge, which perspective is in part determined by the inventive idea. I do not share the idea that the latter is allegedly incorrect (sub-part 2.3.4, 1st section), nor does Resolution work this out any further. The point of view of the inventive idea (here, as we will see: finding a new group of statins, more in particular rosuvastatin) naturally determines in part how the average skilled person will regard the invention.
The Court of Appeal made its interpretation after careful deliberation and gives extensive and cumulative reasons here. The work method that the Court of Appeal used in determining the meaning of the term 'pharmaceutically acceptable salt' in the patent is as follows.
Firstly, the Court of Appeal determined finding a new group of statins, including more specifically rosuvastatin, as the inventive idea (cf. par. 5.6 and 5.14).
Following this, the Court of Appeal turns to the text of the claim; in interpreting this text in light of the description, the Court of Appeal ascribes meaning to the skilled person's general professional knowledge and *inter alia* (see the following paragraph for this) the point of view of this inventive idea (which is broader than claimed). According to current Dutch patent law, this is not incorrect.
Apart from the point of view of the inventive idea, in par. 5.17 and 5.18, the Court of Appeal subsequently takes the extent of innovation (very potent statin that continues to be the market leader, despite cheaper generic statins) and the nature of the patent (new substance patent with absolute protection, no formulation patent) into account as additional points of

view, which do not constitute any reason, either, for a more limited interpretation of the claim feature a 'pharmaceutically acceptable salt'.
In par. 5.19 this is followed by the finding that the description does not give the skilled person any reason for an interpretation that is more limited than the broadly formulated text of the claim, because he would realize that the salts mentioned in paragraph 7 are only the salts that are already used in preparing the tablet form of known statins on the priority date, thus, which may be expected to be suitable for the tablet synthesis of the new statins according to the invention, as well. According to the Court of Appeal, he will not infer from this that paragraph 7 was based on a salt screening.
According to par. 5.20, his general professional knowledge will not lead the average skilled person to assume that paragraph 7 is meant to be restrictive, since he knew that on the priority date, it was unusual to conduct an exhaustive salt screening and it does not follow from the description that in contrast to common practice, this was conducted here.
Nor do the description or the prosecution file offer the average skilled person any indication that an underlying (legal) problem was to be blamed for a limited "salt claim", as the Court of Appeal continues in par. 5.2.1.
With all these arguments, the Court of Appeal substantiates that the skilled person will not read any limitation of the salt claim to the salts mentioned in paragraph 7 in the claim. Elevating the inventive idea from a point of view to a starting point – as the last part of the complaint reads[64] – is certainly not involved.

2.37 As an aside: this does not mean that this exercise by the Court of Appeal (which is largely factual in cassation) cannot be called into question. Caution is in order, of course, but I would like to point out that annotator Reeskamp (BIE 2016/23, p. 152-154, par. 17-31), for example, is very critical about this. Is the inventive idea sufficiently *clearly* apparent here (par. 18-21)? Comments can certainly be made to the "non-waiver indications" that the Court of Appeal took into account (par. 22-24). Can general professional knowledge to determine the extent of the protection be used to the patent proprietor's advantage (par. 25-27)? Does this not force a third party to consult the patent prosecution file (par. 27-29)? He believes that the primacy of the claims in this ruling "does not amount to much"[65] and that the Court of

[64] Cf. also Resolution's pleading notes in cassation, par. 54: lip service is paid to the Supreme Court by designating the inventive idea as a point of view, but this inventive idea is, in fact, used as a starting point.
[65] In par. 30 he notes: "On balance, according to this ruling, a third party must do the following to determine the extent of the protection that is conferred by the patent:
a. he will have to reconstruct the general professional knowledge at the time;
b. he must read the claims in conjunction with the description and drawings;
c. because a and b do not per se provide a definitive answer, he must subsequently check what the inventive idea is underlying the claim;
d. then he will have to check whether this leads to a broader protective scope;
e. in which he must determine the degree of innovation;
f. in which he would do well to check the commercial success of the invention;
g. he should not take the description or the claims too literally, because these have been drawn up under pressure of time;
h. finally, he must consult the patent prosecution file to verify whether A+1 protection has indeed been claimed."

Appeal's ruling can "possibly be summarized somewhat exaggerated with the rule of thumb that the protective scope extends to the inventive idea, unless *disclaiming* is involved." Without wanting to create the impression that I endorse all of this (certainly not the last summary)[66], I note that with the current position of the Supreme Court's case law regarding the interpretation of patents, there is not much that can be successfully done about this in cassation (which would be possible at our eastern and western neighbours in the highest instance, because this type of issue is a question of law in those countries).

2.38 According to the complaint on an issue of law in par. 2.4, in par. 5.20 and 5.22, the Court of Appeal wrongly ascribed a supporting role to the ***applicant's*** will or intention to waive any protection or not[67].

2.39 This lacks a factual basis, because in the challenged passages, the Court of Appeal does not take the applicant's subjective will or intention into account in determining the extent of the protection, but assessed how the average skilled person would understand the description, in which it also took into account whether the average skilled person would assume that the patent proprietor had deliberately opted only to confer protection for the salts of rosuvastatin mentioned in paragraph 7. Thus, this does not pertain to the subjective will of the patent proprietor/applicant, as the complaint wrongfully contends, but to the question regarding what the average skilled person would understand on the priority date – and that is the correct approach.

2.40 With the complaints in 2.5, Resolution essentially tries to redo the discussion in the factual instances. There is no room for this in cassation.

[66] To complement the picture, I note that another route of the Court of Appeal could have been to read paragraph 7 as "own lexicon" and subsequently to assess whether the zinc salt would fall under the equivalent protective scope; cf. Resolution's pleading notes in cassation, par. 51: in the event of cassation and referral, Resolution believes that this should still be dealt with. This probably would have been less controversial than the approach that the Court of Appeal currently selected, which caused quite a stir (cf. Reeskamp's critical note, BIE 2016/23, p. 149 and following).
Moreover, I point out that the Court of Appeal's approach in our case goes *considerably less far* than what the highest English patent court did in the pemetrexed case: in this case, a "pharmaceutically acceptable salt" was not in the claim, but specifically the disodium salt; subsequently, the acid and dicalcium salt was placed under equivalent protection from the perspective of the skilled person who knows that essentially this salt or acid form is not involved with regard to the active ingredient. This should be borne in mind when monitoring boundaries is involved. Cf. meanwhile in a similar sense the Summary Trial Judge in the District Court of The Hague 24 October 2017, ECLI:NL:RBDHA:2017:12045 (*Lilly/Teva*) and the Summary Trial Judge in the District Court of The Hague 24 October 2017, ECLI:NL:RBDHA:2017:12046 (*Lilly/Fresenius*), the Dutch pemetrexed cases in interlocutory proceedings, with extensive reasons in par. 4.6.1-4.8.

[67] To this end, the complaint refers to par. 3.3.7 from *Bayer/Sandoz*: "The will or intention of the applicant to waive that protection does not play any decisive role in this."

2.41 The first complaint in 2.5.1a begins by submitting that the parties did not contend that the salts mentioned in paragraph 7 were used for statins on the priority date; according to this complaint, AstraZeneca et al. only stated that those salts are the most common salts.

2.42 This already fails based on the lack of a factual basis, because AstraZeneca et al. did contend that the salts mentioned in paragraph 7 were used for statins on the priority date[68]. This means that no supplementation of a factual basis by the Court of Appeal in breach of Section 24 DCCP is involved.

2.43 In addition, in contrast to what is advanced in 2.5.1a, I believe that the finding in par. 5.17 and 5.19 that on the priority date, the salts mentioned in paragraph 7 were used to prepare the tablet form for administration of known statins at that time is not incomprehensible in view of the discussion between the parties[69].

2.44 The last complaint from sub-part 2.5.1a about ignoring Resolution's arguments regarding a salt table in a manual (from which it follows that paragraph 7 includes both customary and unusual salts, while other relatively customary salts are allegedly absent) and that Resolution's argument that properties of salt forms cannot be predicted but must be examined was not taken into account, requires a degree of detailed reasons that is not supported in our law; these arguments apparently (factually) implicitly failed in light of, for example, the counter-arguments advanced by AstraZeneca et al. referred to in the penultimate footnote.

2.45 Something similar applies to the attack in sub-part 2.5.1b. The finding in par. 5.14 and 5.28 that the specific salt form is irrelevant for the biological activity of statins[70], is to be understood in light of the fact that the active ingredient here is the anion and the invention pertains to this, not to specific salt forms. The fact that the Court of Appeal noticed that specific salts are more suitable than others is demonstrated by par. 5.7. No incorrectness or incomprehensibility is involved here; again, the complaint starts from a degree of substantiation that is not demanded in our law.

[68] See the pleading notes on appeal, par. 64: "The passage covered all salt forms of statins known and actually prepared until that time." See also par. 52 of those pleading notes on appeal, in which the expert of the generics is quoted under cross-examination in the parallel U.S. proceedings as confirming that the salts from paragraph 7 "in fact covered virtually everything that everybody was actually using."

[69] See also AstraZeneca et al.'s pleading notes in cassation, par. 25-26: if in a dispute regarding statins, AstraZeneca contends that the salts from paragraph 7 are the most commonly used, the following should be read into this: for the preparation of statins.

[70] In the Introduction under G of the notice of appeal in cassation, Resolution itself writes the following: "Only the anion is responsible for the biological activity of rosuvastatin, namely the HGM-CoA reductase inhibiting effect." See further AstraZeneca et al.'s pleading notes in cassation, par. 29. Moreover, the Court of Appeal kept in mind that the salt form may influence the practical suitability of the medicinal product (see par. 3.7), but that is something different.

2.46 The complaints in 2.5.2, 2.6 and 2.7, which merely build on sub-parts 2.5.1a and b, respectively part 2 and sub-part 2.5.1 succeeding cannot hold, so that these do not have to be discussed.

2.47 In my view, no incomprehensible circular reasoning is involved in par. 5.19-5.20, as further argued in 2.5.2 (with arguments that entail a repetition of arguments from previous complaints); the complaint on an issue of law in 2.5.3 lacks a factual basis, given that the Court of Appeal did not assume that the skilled person would have doubts regarding the patent proprietor's intentions in question.

2.48 We now arrive at the more interesting issue of this case in terms of patent law, which I already addressed at length in the introductory comments to parts 2-4 (in 2.6-2.28).
In 3.1 and 3.2, part 3 complains that the Court of Appeal used an incorrect interpretation method that is in breach of Article 69 EPC by starting from the literal text of claim 1 and subsequently applying the waiver doctrine. According to the part, it is irreconcilable with Article 69 EPC and the Protocol to start from the protection that claims offer according to their literal wording, to subsequently examine based on the description whether the patent proprietor waived this protection, something that may only be assumed if there are valid reasons for this.
The part complains in 3.3 that to the extent that with the finding in par. 5.22 "*in other words, the average skilled person would not assume that the patent proprietor deliberately opted to exclusively confer protection for the salts of rosuvastatin mentioned in paragraph 7*", the Court of Appeal applied the same criterion as the "valid reason for the waiver doctrine", the Court of Appeal started from the same incorrect interpretation of the law that sub-part 3.2 complains about.
To the extent that a different criterion is applied here, the Court of Appeal gave insufficient reasons for its finding, according to the complaint. Sub-part 3.3 speculates in footnote 59 that this "post scriptum" appears to have been inspired by par. 3.3.6 from *Bayer/Sandoz*.
In 3.4, a substantiation complaint is directed against the finding that "*moreover, even independent of the 'valid reasons for the waiver doctrine', based on the findings in par. 5.14 to 5.24, the same conclusion would have been arrived at*". According to the complaint, the Court of Appeal failed to substantiate why or how, other than via the waiver doctrine, the same conclusion would have been arrived at.

2.49 I believe that the complaints *in 3.1 and 3.2* start from an incorrect interpretation of the ruling, so that they cannot lead to cassation. The Court of Appeal correctly applied Article 69 EPC by using the description to interpret the claim[71]. According to the Court of Appeal, based

[71] See, for example, par. 5.14, first sentence: "In interpreting a claim in light of the description, the inventive idea underlying the words of the claim must be taken into account as a point of view." In par. 5.2, the Court of Appeal starts from the correct criterion, after which it explores the point of view of the inventive idea of the patent in par. 5.3-5.9.

on the (entire) description and the inventive idea (demonstrated by the description) (in part used as a point of view in addition to other points of view), the average skilled person would not interpret the claim more restrictively than the generally formulated salt claim, because he will not take paragraph 7 as a limiting description of this, but would understand it differently, as explained in the discussion of parts 2 and 3 (see the overview in 2.36 in particular).

2.50 As follows from the introductory comments in 2.6-2.28, I believe that the part rightfully points out that the waiver doctrine is not in line with the system of Article 69 EPC, because this doctrine assumes that the patent proprietor already has a specific protective scope, even though this very protective scope must be determined based on Article 69 EPC.
Nevertheless, no interpretation in breach of Article 69 EPC is involved in this case. After all, in par. 5.22, the Court of Appeal finds that *even independent of the waiver doctrine*, it would have arrived at the same conclusion along the lines of its findings in par. 5.14-5.24. I believe that on balance, along the possible route from the point of view of the inventive idea, the Court of Appeal substantively did consider whether the average skilled person would assume that the salt claim from the claim was limited to the salts mentioned in paragraph 7 of the description (cf. above in the general introduction, penultimate sentence and in 2.8, 2.19 and 2.2 *in fine*). The passage from par. 5.22 that “in other words”, the average skilled person would not assume that the patent proprietor had deliberately opted to restrict the salt claim to the salts mentioned in paragraph 7 also indicates this.

2.51 This eliminates the interest in cassation in respect of the point of applying the waiver doctrine.
Nevertheless, it would be desirable for the development of law if the Supreme Court would express an opinion on the question regarding whether the waiver doctrine is still applicable law, as I advocated above in the general introduction and worked out in 2.7-2.8, 2.14 *in fine* and 2.16-2.28.

2.52 The first part of the complaint in *sub-part 3.3* is in line with the complaint in sub-part 3.2 and fails for the reasons indicated in dealing with sub-part 3.2.
The substantiation complaint in *sub-part 3.3* is directed against a non-supporting finding (“in other words”); on this basis alone, this cannot lead to cassation, if my analysis that the previous complaints of part 3 do not hold is followed. It is more important for the development of law that the substantiation complaint about this criterion, i.e. that the average skilled person would not assume that the patent proprietor deliberately opted only to confer protection for the salts mentioned in paragraph 7, appears to be legally correct and could take the place of the waiver doctrine, if used from the perspective of the average skilled person and with the inventive idea as point of view, as I argued in par. 2.6 and following and the Court of Appeal also essentially did (as indicated in the general introduction, penultimate

sentence and in par. 2.8, 2.19 and 2.21 *in fine*). A substantiation complaint directed against a correct legal ruling does not hold.

2.53 The substantiation complaint of *sub-part 3.4* cannot succeed, either. According to settled Supreme Court case law (cf. par. 2.5 above with locations), the interpretation of patents is so closely interwoven with factual valuations that this interpretation can only be reviewed to a limited extent in cassation. The interpretation that the Court of Appeal gives to the patent in par. 5.14-5.24 is certainly sufficiently understandable, even without these findings being placed in the context of the waiver doctrine, and I believe that the Court of Appeal was not required to substantiate this any further.
This can also be explained from a different angle. I believe that the substantiation complaint in *sub-part 3.4* directed against the last sentence of par. 5.22 (even independent of the waiver doctrine, based on the findings in par. 5.14-5.24, the Court of Appeal would have arrived at the same conclusion that paragraph 7 of the description is not meant to be limited to the salt claim in the claim) cannot succeed, because this passage lacks independent meaning next to the unsuccessfully attacked previous passage from par. 5.22 referred to in sub-part 3.3 (in other words: the average skilled person would not assume that the patent proprietor deliberately opted to exclusively confer protection for the salts from paragraph 7 of the description; thus, this paragraph was not meant to be exhaustive). With all this, the Court of Appeal apparently means the same; I already indicated that I believe that this is a correct rule of law that may replace the waiver doctrine, which dates from the time of the essence, which cannot be successfully challenged with a substantiation complaint.

2.54 According to the heading in the notice of appeal in cassation, part 4 is directed against "other findings underlying the decision regarding the extent of the protection" which are allegedly "also incorrect and/or at least incomprehensible".

2.55 Par. 4.1 complains that the inventive idea that the Court of Appeal determined in par. 5.3-5.9 – i.e. adding a new group of statins to the known prior art, more specifically rosuvastatin, whose biological activity is superior to that of known statins – is incomprehensible in light of the Court of Appeal's prior establishments of the facts, the description of the patent and the parties' arguments.

2.56 I do not believe that the substantiation complaints in 4.1.1-4.1.3 will hold. The finding regarding the inventive idea is factual and not incomprehensible or inconsistent. The Court of Appeal explains that the invention pertains to rosuvastatin which has an HMG-CoA reductase inhibitory activity that is superior to that of mevinolin (a first-generation statin), see par. 2.10 ("In contrast to the original application, which claimed a class of compounds by means of a Markush formula, EP 471 only pertains to rosuvastatin") and par. 5.5-5.7 (the patent discloses third-generation statins, more in particular rosuvastatin; in the description,

the skilled person does not find any indications that suitable salt forms were searched for in particular); in par. 5.8, the Court of Appeal rejects the inventive idea proposed by Resolution – this is the issue in the run-up in par. 5.5-5.7. The average skilled person will see that after limitation from the Markush formula in the original application to rosuvastatin acid and pharmaceutically acceptable salts alone, the description was not modified, something that frequently occurs in the patent practice. No arguments can be derived from this, as Resolution attempts to do here.

2.57 Given that the substantiation complaints from sub-part 4.1 fail, the complaint in 4.2 that merely builds on this cannot succeed, either, which means that this complaint does not have to be discussed.

2.58 In 4.3, several complaints are directed against the finding in par. 5.17 regarding the extent to which the invention brought innovation and more specifically regarding the finding that – as AstraZeneca et al. advanced and as not contested based on a sufficient substantiation – rosuvastatin is a very potent statin that is still the market leader, despite the presence of various (cheaper) generic statins. This is a factual finding that – being based on an interpretation of case documents – is reserved for the Court of Appeal as the court deciding questions of fact. The complaints on issues of law (from *sub-parts 4.3.3 and 4.3.5*) already fail on this basis. The complaint from *sub-part 4.3.1* that *AstraZeneca et al.* allegedly insufficiently substantiated this (sic) also fails on this basis.

2.59 The complaint in 4.3.1 first submits that AstraZeneca et al. only invoked that rosuvastatin is the market leader on the occasion of the pleadings on appeal, that Resolution was no longer able to respond to this (and continues by submitting that this argument by AstraZeneca et al. has not been sufficiently substantiated; cf. in this regard par. 2.58 *in fine*).

2.60 The first complaint lacks a factual basis, because this market leadership, or at least the degree of innovation for rosuvastatin and popularity/high degree of use of rosuvastatin was already addressed in par. 26 of the defence in the first instance[72]. Bearing this in mind,

[72] "26. Professor Jukema further describes in his statement (par. 31-40) [submitted as Exhibit G3; added by A-G] that rosuvastatin is by far the most potent statin, has the best LDL cholesterol lowering / HDL cholesterol elevating ratios and that fewer side effects are experienced that [read: than; added by A-G] other potent statins in high doses. That is why it is so popular. Thus, even though it is the only statin that still enjoys protection and as a result is more expensive than the statins whose patent / SPC has expired, it is still a very frequently used statin." [Emphasis added by A-G]
From this statement by Professor Jukema: "28. As mentioned, all of the statins, except for rosuvastatin, ran out of patent protection in the Netherlands. AstraZeneca markets rosuvastatin under the name of Crestor®. 29. One would therefore think that other statins, which could be used for the same indications, would be preferred over rosuvastatin, e.g. because of price considerations. 30. However: Rosuvastatin / Crestor® is, with atorvastatin, still one of the most widely used statin drugs. I do fully understand why this is the case: Rosuvastatin is by far the most potent of all statins with the best LDL lowering/HDL elevating ratios (I will further elaborate on this below). For this reason, it is also one of my favorites especially in high risk subgroups. 31. The table below shows in a very clear way that rosuvastatin is the most potent of the statins which are commercially available. It can reduce more LDL cholesterol than others and the dosages required of this drug are lower. (…) 40. From all of this it is very clear that rosuvastatin is certainly not a "me-too" drug. It is a statin that is distinctive from and more potent than all other statins." In par. 12 and footnote 2 of AstraZeneca et al.'s pleading notes on

Resolution fails to advance a sufficiently well-founded argument contending why it was unable to sufficiently respond to the "market leader argument" during the pleadings on appeal (after all, to this end, it exclusively referred to an expert opinion that had already been submitted with the defence in the first instance, while it was already indicated in par. 26 of the defence that rosuvastatin was "so popular" due to its superior properties and despite the fact that patent protection had not yet expired, "was still very frequently used", even though patent-free alternative statins were on the market. In my opinion, in view of the discussion between the parties, the conclusion of the Court of Appeal that market leadership is involved is in that case not incomprehensible. No breach of the principle of hearing both sides of the argument is involved. I do not even point out that par. 5.17 does not independently support the Court of Appeal's ruling, but the degree to which innovation was brought is a point of view that – in addition to other points of view – is included in the Court of Appeal's finding that the skilled person would not see any reason to assume that the salt claim in the claim must be taken to be limited to the salts from paragraph 7 of the description. Thus, the complaint discussed here cannot lead to cassation.
It is pointed out that public sources also indicate that market leadership is involved; the BIE annotators of the rulings in our case in the first and second instance point this out[73].

2.61 Sub-part 4.3.2 complains that if Resolution would have been able to adequately respond to this argument during the pleadings on appeal, it would have indicated that in the Netherlands, rosuvastatin may possibly be prescribed as a second-line statin, substantiated with a reference to the Dutch Pharmacotherapeutic Compass.

2.62 This is an impermissible new fact in cassation[74]. Moreover, the same argument was already advanced in the defence in the first instance, which means that there was sufficient opportunity to respond to this.

2.63 To the extent that the Court of Appeal weighed the degree of innovation based on commercial success, this is incorrect or incomprehensible, according to sub-part 4.3.3. This success depends on many more factors, for example marketing, and according to the complaint, this constitutes a breach of Section 24 DCCP.

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appeal, reference is again made to no. 30 of this expert statement by Jukema to substantiate the stated market leadership. For the alleged out of time market leadership claim, the complaint in cassation subsequently only refers to this passage from AstraZeneca et al.'s pleading notes on appeal.

[73] Kleemans' note under the judgment of the District Court teaches that in 2013, rosuvastatin was the third-most prescribed brand medicine (Crestor®) in the world, with reference to www.imshealth.com/deplyedfiles/imshealth/Global/Content/Corporate/Press%20Room/Global_2013/Top_20_Global_Products_2013.pdf (BIE 2015/46, p. 222, footnote 11) and – more indirectly – Reeskamp states in his note under the Court of Appeal's ruling that this pertains to "(…) the "block buster drug Crestor® of AstraZeneca. A cholesterol inhibitor that has generated over USD 5 billion in revenues per year worldwide since 2010." (BIE 2016/23, p. 149).

[74] Asser Procesrecht/Korthals Altes & Groen 7 2015/207.

2.64 This lacks a factual basis, because for the degree of innovation, the Court of Appeal apparently looked at the superior technical properties (it has been contended undisputed that a very potent statin is involved, which is still very popular, despite cheaper alternatives). No breach of Section 24 DCCP is involved.

2.65 Sub-part 4.3.4 complains that the Court of Appeal's implicit finding that the patent has brought a high degree of innovation is incomprehensible, or at any rate is an unacceptable supplementation of the factual basis, given that statins were already known and, according to AstraZeneca et al., this is merely a third-generation form, while it failed to sufficiently express this large degree of innovation on appeal.

2.66 This also lacks a factual basis: it follows from the passages quoted in par. 26 of the defence and par. 12 of the pleading notes on appeal that the Court of Appeal could understandably derive this from the arguments that were not challenged.

2.67 The complaints in 4.3.5 also lack a factual basis, given that these wrongfully start from the fact that the Court of Appeal allegedly found that a "pioneering invention" is involved.

Part 5: added subject matter

2.68 Part 5 is directed against the Court of Appeal's finding in par. 5.26-5.32 that no added subject matter is involved, because claim 1 of EP 471 also extends to rosuvastatin acid and non-toxic pharmaceutically acceptable salts other than the sodium or calcium salt (examples 1 and 7 from the original application). The District Court had assumed added subject matter regarding the acid.

2.69 In 5.1.1, the part contains the complaint on an issue of law that an incorrect criterion was used in par. 5.29 and par. 5.31, because according to Section 75 (1)c ROW 1995 and Article 123 (2) EPC, the Court of Appeal should have examined whether salts other than the sodium and calcium salt and the acid (at the R4 position in the Markush formula from the original application) are directly and unambiguously disclosed in the original application. This is a strict test, identical to the one for novelty.
Moreover, the Court of Appeal failed to recognize the trap of "intermediate generalization": if features of a specific embodiment of the invention are "extrapolated" or "generalized" in the original application, those generalized features cannot qualify as directly and unambiguously disclosed, unless it is clear to the skilled person that there is no structural or functional relationship between the feature that is generalized and the other features of the embodiment.

2.70 Based on Article 123 (2) EPC and Section 28 (3) ROW 1995, a patent application may not be amended such that the subject-matter is no longer covered by the contents of the

original application. If this does occur, impermissible “added subject-matter” is involved, as a result of which a patent may be (partially) nullified (Article 138 (1)c EPC and Section 75 (1)c ROW). The criterion to assess whether added subject-matter is involved is the *gold standard*, in brief: whether the subject matter is directly and unambiguously disclosed to the average skilled person in the original application[75]. This is indeed a strict test. In Case Law of the Boards of Appeal of the European Patent Office (8th ed. 2016, p. 401), this criterion is described as follows:

> “The “**gold standard**” (**G 2/10**, OJ 2012, 376) for assessing compliance with Art. 123(2) EPC is the following; any amendment to the parts of a European patent application or of a European patent relating to the disclosure (the description, claims and drawings) is subject to the mandatory prohibition on extension laid down in Art. 123(2) EPC and can therefore, irrespective of the context of the amendment made, only be made within the limits of what a skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of these documents as filed (**G 3/89**, OJ 1993, 117; **G 11/91**, OJ 1993, 125).”

2.71 The complaints on issues of law fail, given that the Court of Appeal applied a correct review, as demonstrated by the words “direct and unambiguous disclosure” from par. 5.26 and 5.31. According to the Court of Appeal, the average skilled person reads salts and acids in the disclosure/is reminded of these in the Markush formula at position R4 of the original application (without any change in the choices for R1-R3 and X, which determine the biologically active rosuvastatin anion), decisive for the acid or salt form, where an H* is already indicated as a possibility (for the acid) or a cation that produces a non-toxic pharmaceutically acceptable salt with the rosuvastatin anion. In view of par. 5.26-5.31, viewed in conjunction, it is clear that by this “reading in/being reminded of”, the Court of Appeal means that for the skilled person, this is a “direct and unambiguous disclosure”; there is no room for interpretation here, as the first complaint on an issue of law wrongfully argues. The fact that Na* and So* salts are disclosed as non-exhaustive examples from the salt group does not mean that other salts that are not mentioned in the examples have not been directly and unambiguously disclosed in this way. I agree with the Court of Appeal that the fact that this would be different, given that other choices can also be made for R1-R3 and X seems to be a wrong track, because it is clear to the average skilled person that the invention pertains to a new group of statins. The fact that without any salt screening, it is not clear which salts (this also applies to the acid) will prove to be practically suitable is without prejudice to their direct and unambiguous disclosure, as the Court of Appeal rightly finds in par. 5.31.

2.72 The sub-part further wrongfully starts from the fact that “generalization” is allegedly involved; this lacks a factual basis. Resolution wrongfully wishes to turn this into a situation in

[75] See regarding added subject-matter, *inter alia*, T. Blomme, *Uitbreiding van materie in het octrooirecht*, BIE 2016, p. 206-211; A. Kupecz, *Toegevoegde materie: artikel 123(1) EPC te streng toegepast?*, IER 2014/13 and Case Law of the Boards of Appeal of the European Patent Office, 8th ed. 2016, II.E.1. Article 123(2) EPC – added subject-matter.

which the original application contains a broad general disclosure on the one hand, while specific examples are involved, on the other, while the amended claim subsequently strikes a balance between these two, so that the stringent rules for *intermediate generalization* apply (cf. Case Law, 2016, II.E.1.7, p. 439 and following), but this is not at issue here at all. There are no isolated features from a set of features that was originally claimed in combination, such as a specific embodiment from the description, generalized in the form of a combination of those isolated features that is not disclosed to the skilled person. Resolution wants to link this to the Markush formula from the original application with three options for R4: hydrogen, a lower alkyl group or cation that can produce a pharmaceutically acceptable salt – the first and last pertain to categories that comprise several options. In addition, the original application contained seven examples, with rosuvastatin sodium in example 1 and rosuvastatin calcium in example 7. In that case, the line of reasoning is that with rosuvastatin acid and non-toxic pharmaceutically acceptable salts in amended claim 1, a limited group is, in fact, involved in which the same specific choice is made for R1-R3 and X as in examples 1 and 7 from the original application, but in which a different or broader choice is made for R4. Thus, the explicit disclosure from examples 1 and 7 is combined with the very broad disclosure from the Markush formula that also offers other possibilities for the R4 position, which is not permitted. However, together with AstraZeneca et al. (written explanation, 14), I feel that this is artificial. This does not involve any generalization of the calcium and sodium salt of rosuvastatin to the acid and the pharmaceutically acceptable salts: filling in rosuvastatin for R1-R3 and X is not a generalization, but rather one choice, without limitation of R4 (which has been left general, in contrast to what Resolution suggests; cf. the rejoinder, par. 3; leaving out the lower alkyl group item from the list for R4 is not a choice in this connection). This puts an end to the second complaint on an issue of law.

2.73 In 5.1.2-5.1.6, the part contains several substantiation complaints.

2.74 The complaint in 5.1.2 directed against par. 5.28 is in so many words a complaint that builds on sub-part 2.5.1.b (“insufficiently (clearly) substantiated on the grounds of sub-part 2.5.1.b”), which does not hold, as discussed in par. 2.45 above. In that case, the follow-up complaint merely building on this that this means that par. 5.29 cannot be upheld, either, does not hold.
Sub-part 5.1.4 is also a complaint that builds “on the grounds of sub-part 2.5.1.b” and therefore shares the same fate.

2.75 The complaints in 5.1.3 lack a factual basis, given that the Court of Appeal did not (in part) base the finding that the average skilled person would read the acid form and other salt forms into the original application on Serajuddin’s publication and/or Spargo’s statement, as the sub-part assumes.

2.76 The complaint in 5.1.5 fails now that the finding against which this complaint is directed[76] is factual and not incomprehensible (including not in light of the many locations that Resolution refers to in footnote 72 of the notice of appeal in cassation).[77]

2.77 Sub-part 5.1.6 complains that in rejecting the raised point of "intermediate generalization", in par. 5.29, the Court of Appeal failed to (clearly) take the invoked case law and relevant guidelines of the EPC into account. This complaint should already fail, given that it starts from the fact that impermissible generalization is involved, which does not hold, as we have seen in par. 2.72. "Filling in" a Markush formula does not constitute any impermissible generalization here. The Court of Appeal observed, in fact, that there is no structural or functional relationship between the rosuvastatin anion, on the one hand, and the sodium and calcium ions, on the other, given that rosuvastatin was a newly found statin with specific fixed choices on R1-R3 and X, whose biological activity is independent of the salt or acid form chosen and in which position R4 determines the acid or salt form. This means that no choice for R4 from two lists is involved, as Resolution suggests in par. 2.7 of the written explanation (challenged in par. 3 of AstraZeneca et al.'s rejoinder), which could lead to added subject-matter. The substantiation of Resolution's argument fails, because in contrast to that case, our case does have a general definition for R4 in the description (cf. par. 6 of AstraZeneca et al.'s rejoinder).

Costs of the proceedings

2.78 The parties have reached agreement regarding the costs of the proceedings in the cassation instance[78].

[76] This involves the following passage from par. 5.31: "(It is pointed out that Resolution) (…) has not advanced a sufficiently substantiated argument based on which it must be assumed that the average skilled person would nevertheless also read hydrogen (with which the acid is formed) or any cation with which a salt of rosuvastatin can be formed as a real possibility on the R4 position, despite the fact that this is explicitly mentioned in the application (…)".
[77] See AstraZeneca et al.'s written explanation, par. 32.
[78] See AstraZeneca et al.'s rejoinder under "Costs" and par. 5.1 of Resolutions' written explanation (in which I assume that – without any comments to the contrary in the *Borgersbrief* (letter containing further submissions following the opinion of the Advocate-General) – AstraZeneca et al. also agrees to the amount that Resolution mentioned should the Supreme Court set aside the challenged ruling).

3. Conclusion

I conclude that the appeal in cassation is dismissed.

The Procurator-General with the
Netherlands Supreme Court

Advocate-General