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**Datasheet for the decision
of 23 November 2016**

Case Number: T 2132/13 - 3.3.01

Application Number: 04812772.4

Publication Number: 1689723

IPC: C07D239/70

Language of the proceedings: EN

Title of invention:

REFERENCE STANDARD FOR CHARACTERIZATION OF ROSUVASTATIN

Patent Proprietor:

TEVA PHARMACEUTICAL INDUSTRIES, LTD.

Opponent:

STRAWMAN LIMITED

Headword:

Rosuvastatin photodegradation products/TEVA

Relevant legal provisions:

EPC R. 115(2)
RPBA Art. 15(3)
EPC Art. 56

Keyword:

Inventive step - obvious solution

Decisions cited:

T 0698/10

Catchword:



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Case Number: T 2132/13 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 23 November 2016

Appellant:

(Opponent)

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Decision under appeal:

**Interlocutory decision of the Opposition
Division of the European Patent Office posted on
1 August 2013 concerning maintenance of the
European Patent No. 1689723 in amended form.**

Composition of the Board:

Chairman A. Lindner
Members: G. Seufert
 L. Bühler

Summary of Facts and Submissions

- I. The opponent (appellant) lodged an appeal against the interlocutory decision of the opposition division on the amended form in which European patent No. 1 689 723 could be maintained.
- II. The present decision refers to the following documents:
- (4a) WO 01/54669 (parent application of EP 2 018 853 = document (4) of the decision under appeal)
 - (5) ICH Harmonised Tripartite Guideline, "Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients", Q7, Current *Step 4* version dated 10 November 2000, pages i to iv and 1 to 43
 - (6) ICH Harmonised Tripartite Guideline, "Stability Testing of New Drug Substances and Products", Q1A(R2), Current *Step 4* version dated 6 February 2003, Cover Note, pages i to ii and 1 to 18
 - (7) ICH Harmonised Tripartite Guideline, "Stability Testing: Photostability Testing of New Drug Substances and Products", Q1B, Current *Step 4* version dated 6 November 1996, pages i and 1 to 8
 - (9) C. K. Hull *et al.*, Journal of Chromatography B, Vol. 772, 2002, pages 219 to 228
 - (11) A. Astarita *et al.*, Journal of Photochemistry and Photobiology A: Chemistry, Vol. 187, 2007, pages 263 to 268
 - (12) WO 03/016317
 - (13) Declaration by Dr. Lincoln Tsang, dated 9 June 2013, pages 1 to 8
 - (14) "Rosuvastatin Ca - Impurity profile"
Experimental evidence provided by the patent

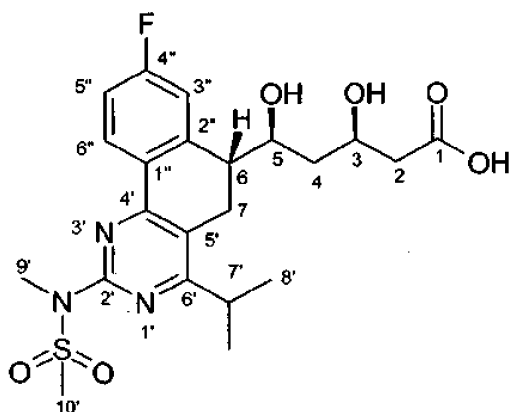
proprietor with letter of 4 June 2013, 2 pages
(17) M. Litvić *et al.*, Journal of Photochemistry and
Photobiology A: Chemistry, Vol. 252, 2013,
pages 84 to 92

- III. Notice of opposition was filed by the appellant,
requesting revocation of the patent in suit in its
entirety on the grounds of lack of novelty, lack of
inventive step, insufficiency of disclosure and added
matter (Article 100(a), (b) and (c) EPC).
- IV. The decision under appeal is based on a main request
(claims as granted) and a first auxiliary request filed
with letter dated 4 June 2013.

The opposition division decided that the main request
contravened Article 123(2) EPC. The first auxiliary
request was held to comply with the requirements of the
EPC. In its assessment of inventive step, the
opposition division considered document (9) to be the
closest state of the art and formulated the problem to
be solved as the provision of an alternative reference
standard for the analysis of rosuvastatin.

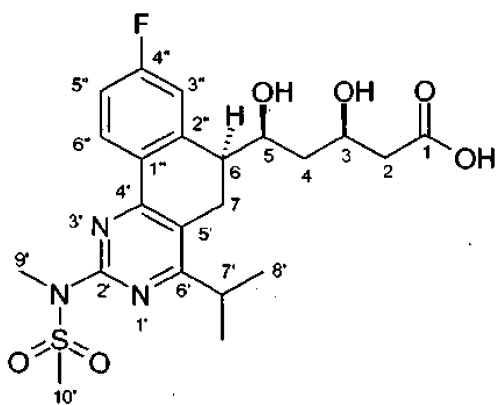
- V. The first auxiliary request underlying the decision
under appeal consists of 33 claims, claims 1 and 2
reading as follows:

"1. A rosuvastatin degradation product having the
following structure:



"

"2. A rosuvastatin degradation product having the following structure:



"

Further independent claims are directed to the corresponding alkali and alkaline earth salts (claims 3 and 4), 6-membered lactones formed between the hydroxy group in position 5 and the carboxy group in position 1 (claims 9 and 10), rosuvastatin degradation products with undefined stereochemistry in position 6, where the carboxy group may be esterified and/or the hydroxy-groups may be protected by hydrolysable protecting groups or wherein the carboxy group in position 1 and the hydroxy group in position 5 form a lactone (claim 31), various processes for the preparation of the acid, salt and lactone degradation products (claims 6, 7, 11, 14, 19, 20, 23, 29 and 30), a method

of chromatographically analysing a sample of rosuvastatin (claim 16) and a method for determining the retention time of a chromatographic column for rosuvastatin (claim 26).

- VI. With the statement of grounds of appeal, the appellant maintained its objections of added matter, insufficiency of disclosure, lack of novelty and lack of inventive step.
- VII. In the reply to the statement of grounds of appeal, the respondent (patent proprietor) defended the patent in suit on the basis of the first auxiliary request underlying the decision under appeal as its main request and filed first to third auxiliary requests. It also filed document (4a).

The first auxiliary request differs from the main request in that claims 26 and 31 have been amended to no longer include the degradation products in which the carboxy group is esterified and the hydroxy groups are protected by hydrolysable protecting groups.

The second auxiliary request differs from the main request in that claim 19 directed to the preparation of the acid, salt and lactone degradation products of rosuvastatin has been deleted, and the subsequent claims have been renumbered.

The third auxiliary request combines the amendments of first and second auxiliary requests.

- VIII. With letter dated 1 November 2016, the appellant provided further arguments in support of its previously raised objections and submitted document (17).

- IX. With letter dated 21 November 2016, the respondent informed the board that it was withdrawing its request for oral proceedings and would not be attending those scheduled for 23 November 2016. It also provided brief comments on the appellant's latest submissions.
- X. The arguments of the appellant, as far as they concern the decisive issues of the present decision, can be summarised as follows:

Document (4a) was the closest state of the art. It was directed to pharmaceutical compositions of rosuvastatin and addressed the issue of rosuvastatin purity. In particular, it disclosed the existence of photodegradation products of rosuvastatin and measures to prevent their formation (see page 6, lines 11 to 13 and 15 to 16). In contrast, document (9) disclosed an analytical procedure for the detection and quantification of very small concentrations of rosuvastatin in human plasma. That was an entirely different technical field compared to the patent in suit, which was concerned with analysing the purity of rosuvastatin.

The subject-matter of the main request differed from the disclosure of document (4a) in that it provided the identity/structure of rosuvastatin photodegradation products, the existence of which were explicitly taught in document (4a). These products could then be used to check the purity of rosuvastatin. In the light of document (4a), the problem to be solved could therefore be seen as the identification of photodegradation products of rosuvastatin.

Being aware that rosuvastatin formed photodegradation products, the skilled person in the field of providing

rosuvastatin for use as a pharmaceutical would not only be motivated but was duty-bound to examine the photostability of rosuvastatin and to identify the degradation products in order to ensure that rosuvastatin was suitable for the intended use. The manner in which to proceed was part of the skilled person's common general knowledge, which was illustrated in documents (5) to (7). These documents provided guidelines for good manufacturing practice which had to be followed and disclosed tests which would routinely be performed for each batch before a drug could be put on the market. As explained by the appellant's expert, such routine tests included stability tests to assess a drug's sensitivity to various factors such as temperature, humidity and light (see document (13), points 16 to 18). So-called stress testing helped identify likely degradation products and was useful in developing and validating suitable analytical procedures. An integral part of this stress testing was photostability testing (see document (13), point 19), the details of which were described in document (7).

Starting from document (4a), the skilled person only needed to take the normal and routine steps of carrying out stability tests including photostability tests, which would identify any degradation product formed. No inventive skills were required. Taking these steps would lead to the subject-matter of claim 1 of the main request. This was clearly shown by the experimental evidence provided with document (11), which proved that mere exposure to light inevitably resulted in the formation of degradation products of claim 1 of the main request (page 264, left column, penultimate paragraph and page 266, left column, first full paragraph, compound 2). Specific conditions were not

required. The length of time, power wattage and temperature mentioned in the patent in suit merely shortened the reaction time so that enough rosuvastatin degradation products could be isolated. The formation of additional photodegradation products was irrelevant and could not be used as evidence that specific conditions were required to obtain the claimed compounds.

XI. The arguments of the respondent, as far as they concern the decisive issues of the present decision, can be summarised as follows:

Document (9) was the closest prior art, because it related to the same or a similar technical problem as that addressed in the patent, namely analytical HPLC procedures for rosuvastatin involving reference standards. All other documents cited as a potential starting point for the assessment of inventive step, including document (4a), were completely silent on this aspect. Document (4a) was directed to formulations which could prevent the occurrence of degradation products in the final dosage form and as such was not concerned with the same technical problem as that addressed in the patent in suit. The classification of the compounds of the patent in suit as rosuvastatin degradation compounds could not be used for the identification of the closest prior art as it was hindsight knowledge conveyed by the patent in suit itself.

Furthermore, document (4a) mentioned the light protective coating only in passing in the description. Without hindsight knowledge, the skilled person would not have attributed particular importance to this passage. In addition, he would not have understood this

passage as a disclosure that rosuvastatin was in fact photolabile. Even if he had considered this to be the case, his conclusion would have been that the protective coating was aimed at preventing the formation of the 5-keto impurity, as other impurities created by photodegradation were not known for rosuvastatin at the priority date. Accordingly, document (4a) did not provide any hint or suggestion towards the claimed compounds. Nor did it prompt the skilled person to carry out further stability testing, let alone specific photodegradation studies. With regard to the alleged desire of the skilled person to carry out a full set of stability tests, there was no evidence that such tests were routinely performed. Moreover, the skilled person who was faced with the problem of providing alternative reference standards for HPLC methods had no motivation to carry out such tests which might possibly be required for obtaining market authorisation. The claimed subject-matter was therefore inventive over document (4a) taken alone or in combination with other prior art such as documents (5) to (7).

Furthermore, the claimed compounds were not the inevitable result of exposing rosuvastatin to light. Rather, their formation required specific conditions, as was apparent from the patent in suit (page 7, lines 30 to 31). This was actually confirmed by the experimental evidence provided by the appellant. In document (11) exposure to light resulted in a mixture of different compounds and continued exposure to light even led to complete elimination of the entire side-chain.

- XII. The appellant requested that the decision under appeal be set aside and that the European patent No. 1 689 723 be revoked.
- XIII. The respondent requested in writing that the appeal be dismissed (main request), or, alternatively, that the patent be maintained in amended form on the basis of one of the first to third auxiliary requests filed with the reply to the statement of grounds of appeal. It further had requested that the technical arguments relating to the NMR data and document (17) submitted with the appellant's letter dated 1 November 2016 not be admitted into the appeal proceedings.
- XIV. At the end of the oral proceedings, which took place as scheduled, the decision of the board was announced.

Reasons for the Decision

1. The appeal is admissible.
2. Non-appearance of a party at oral proceedings before the board
 - 2.1 The respondent did not attend the oral proceedings before the board to which it had been duly summoned (see point IX above).

According to Rule 115(2) EPC, oral proceedings may continue in the absence of a duly summoned party that does not appear. According to Article 15(3) of the Rules of Procedure of the Boards of Appeal (RPBA), the board is not obliged to delay any step in the proceedings, including its decision, by reasons only of the absence at the oral proceedings of any party duly

summoned, which may then be treated as relying only on its written case. In deciding not to attend oral proceedings, the respondent chose not to avail itself of the opportunity to present its observations and comments orally.

The present decision is based on grounds, facts and evidence put forward during the written proceedings, on which the respondent had an opportunity to present its observations and comments. The board was, therefore, despite the absence of the duly summoned respondent, in a position to take a final decision at the oral proceedings.

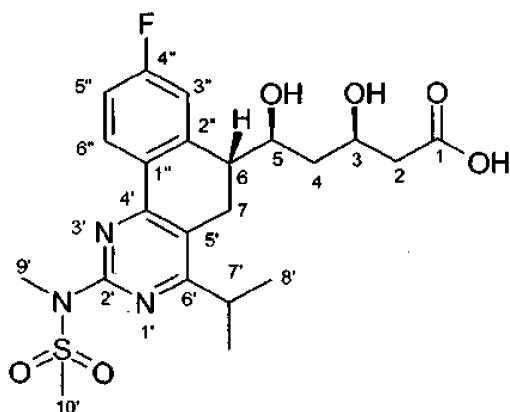
3. Amendments, sufficiency of disclosure, novelty

The appellant challenged the opposition division's decision on added matter, sufficiency of disclosure and novelty of the first auxiliary request (now the respondent's main request) over document (12). Since the main request and first to third auxiliary requests fail for other reasons (see point 4 below), the board did not need to decide on these issues.

Main request and first to third auxiliary requests

4. Inventive step (Article 56 EPC)

4.1 Claim 1 of the main request is directed to a rosuvastatin degradation product with the following structure



Claim 2 is directed to the corresponding diastereomer.

4.2 In accordance with the problem-solution approach consistently applied by the boards of appeal to assess inventive step, it is first necessary to identify the closest prior art, then to determine in the light thereof the technical problem which the claimed invention addresses and successfully solves, and finally to examine whether or not the proposed solution to this problem is obvious for the skilled person in view of the state of the art.

4.3 In the present case, the parties were divided as to which document was the closest prior art. According to the appellant, it was document (4a), or alternatively document (12), while the respondent, in accordance with the opposition division, considered document (9) as the only realistic starting point for the assessment of inventive step.

4.4 According to established jurisprudence of the boards of appeal, the closest prior art should disclose subject-matter conceived for the same purpose or aiming at the same objective, corresponding to a similar use, or relating to the same or a similar technical problem, or at least to the same or a closely related technical

field. As a further criterion, the closest prior art should disclose subject-matter having the greatest number of relevant technical features in common with the claimed invention (cf. Case Law of the Boards of Appeal, 8th edition 2016, I.D.3; see also T 698/10, point 3 of the Reasons, first three paragraphs).

- 4.5 The patent in suit relates to rosuvastatin degradation products and their use in determining the purity of rosuvastatin (see paragraphs [0001] and [0010]). Rosuvastatin and its salts are well-known, highly effective drugs for the treatment of hypercholesterolemia, hyperlipoproteinaemia and atherosclerosis (paragraphs [0002] to [0006]). It is therefore of the utmost importance for any manufacturer or provider of rosuvastatin or rosuvastatin products to examine the stability and purity of such products so that it can decide whether or not they are suitable for continued processing or safe for use in a pharmaceutical product (see paragraph [0010]). The rosuvastatin degradation products according to the invention can be used as a reference standard for both quantitative and qualitative analysis of rosuvastatin. This includes use as a reference marker in qualitative analysis to identify components present in a rosuvastatin product based upon their position, e.g. in a chromatogram or on a Thin Layer Chromatography plate (see paragraphs [0011], [0029] and [0030]). For this purpose the reference marker does not necessarily have to be added, if it is present in the mixture. In other words, if impurities or potential degradation products of rosuvastatin are identified, their presence or absence can be easily verified in any rosuvastatin product by simply comparing the chromatographic data of the rosuvastatin product with the chromatographic data

of the identified degradation product (see paragraph [0011], lines 20 to 25, claims 17 to 19).

From the above, the board concludes that the patent in suit relates to the field of drug manufacturing and safety and aims at ensuring that rosuvastatin is sufficiently pure to be used in a pharmaceutical product.

- 4.6 Document (9) relates to the development and validation of a bioanalytical assay to quantify rosuvastatin in human plasma by employing liquid chromatography with tandem mass spectrometry (see abstract and point 1 "Introduction" on pages 219 to 220). This document is not concerned with measuring and ensuring the purity and safety of rosuvastatin as a drug, but with the detection of very low concentrations of said drug in the blood of a patient, as required for example in clinical trials. For this specific purpose and due to its similar behaviour to the analyte (rosuvastatin) in mass spectrometry, deuterated rosuvastatin is used as an internal standard (see point 3.1).

It follows from the above that document (9) relates to an entirely different technical field and has a different objective from that of the patent in suit. It is not a realistic starting point for a skilled person looking at ways to establish the purity of rosuvastatin and ensure its safe use.

- 4.7 Document (4a) is directed to pharmaceutical compositions containing rosuvastatin or its salts, especially the calcium salt (page 1, lines 3 to 9). Furthermore, this document discloses that rosuvastatin is particularly sensitive to degradation, which jeopardises its use as a pharmaceutical product. The

major known degradation products are the corresponding lactone and an oxidation product, in which the hydroxy group in position 5 adjacent to the carbon-carbon double bond is oxidised to a keto group (see page 1, lines 16 to 22). Document (4a) aims at suppressing the formation of these degradation products and measures its success by detecting their presence, although no details are given (see last paragraph on the last page). Document (4a) also explicitly discloses that rosuvastatin forms photodegradation products (see page 6, lines 11 to 13). These products are not characterised in document (4a), but measures are suggested to reduce their formation.

Document (4a) therefore belongs to the same field (drug manufacturing) and has the same purpose, namely to ensure the purity and safe use of rosuvastatin.

- 4.8 In view of the above, the board concurs with the appellant that document (4a) rather than document (9) represents a suitable starting point for the assessment of inventive step. The respondent's contention that document (4a) is based on hindsight is not accepted, for the reasons set out above. The board notes that the selection of the closest prior art requires the skilled person's knowledge of the whole state of the art at the effective filing date of the original application. The selection of document (4a) can therefore not be based on hindsight. Hindsight, however, is not permissible in the later stage of the problem-solution approach, i.e. in the process of evaluating whether the solution to the problem as defined in the light of the closest prior art is obvious to the skilled person. Incidentally, the board also notes that the respondent considered that a document which was not concerned with the assessment of purity of rosuvastatin could not

represent the closest prior art (see point 65 of the reply to the statement of grounds of appeal), which clearly speaks against document (9).

- 4.9 Starting from the relevant disclosure in document (4a) reporting on photodegradation products of rosuvastatin, the subject-matter of claims 1 and 2 of the main request differs in that the structure of these products has been revealed. Accordingly, the problem to be solved by the present invention can be seen in the identification/characterisation of the photodegradation products of rosuvastatin.

The board is satisfied that this problem has been solved by the subject-matter of claim 1 of the main request.

- 4.10 It then remains to be decided whether the proposed solution was obvious in the light of the prior art and common general knowledge.

- 4.10.1 The board concurs with the appellant that the disclosure of the formation of photodegradation products of rosuvastatin in document (4a) provides the skilled person with a strong incentive to embark on the process for their identification/characterisation in order to facilitate their detection and to control their amounts during manufacture, formulation or storage, in the general interest of drug safety. The respondent's submission that the aspect of light protection mentioned in document (4a) would not prompt the skilled person to carry out further investigations is therefore not accepted. Moreover, the board notes that according to page 6, lines 15 to 16, light protection is clearly an embodiment of the invention of document (4a), irrespective of whether or not it is

present in the claims. Hence, the respondent's argument that this aspect was mentioned only in passing is not convincing.

Nor does the board agree with the respondent's submission that from the passage on page 6, lines 11 to 13, of document (4a) the skilled person would not actually deduce that rosuvastatin was photosensitive. On the contrary, said passage reads "Coatings containing ferric oxides are especially prepared as they reduce the rate of formation of photodegradation products of **the Agent**" (emphasis added by the board). The term "the Agent" in document (4a) clearly refers to rosuvastatin or its salts (see page 1, first paragraph). The board also does not accept the respondent's argument that a person skilled in the art would conclude that the protective coating mentioned on page 6 was aimed at preventing the formation of the 5-keto compound of rosuvastatin. Document (4a) clearly distinguishes between the degradation products of rosuvastatin obtained by internal esterification (i.e. a lactone) or oxidation (i.e. a 5-keto compound) and measures to prevent their formation, on the one hand, and photodegradation products and measures to prevent their formation, on the other hand. There is no reason why the skilled person would consider the oxidation product and the photodegradation products to be the same.

- 4.10.2 Since there is undoubtedly a strong incentive to identify the photodegradation products of rosuvastatin, what needs to be examined next is whether that identification is merely routine practice for the skilled person in the relevant technical field or whether inventive skills are required to arrive at the products according to claim 1.

4.10.3 In this context, the board notes that the skilled person in the field of drug manufacturing and safety would have been aware of the guidelines regarding good manufacturing practice, and the corresponding tests, which have been developed to ensure the quality and purity of a drug. This common general knowledge is illustrated in documents (5) to (7) and extensively referred to in the declaration by the appellant's expert (document (13)).

Document (5) sets out the general principles regarding good practice for manufacturing a drug, including production, packaging, labelling, quality control, release, storage, distribution, etc. (see page 1, point 1, first two paragraphs). It addresses such issues as quality management, production and in-process controls and laboratory controls, including appropriate tests of the drug's purity and stability (see page 23, point 11.2, page 24, point 11.5).

Document (6) is concerned with stability testing of new drugs and products for the purpose of providing evidence on how the quality of a drug varies with time under the influence of such factors as temperature, humidity or light (see page 1, point 1.3, document (13), points 17 and 18). Stress testing is mentioned as a suitable method for identifying likely degradation products, and photostability testing is considered to be an integral part thereof (see point 2.1.2 on pages 1 and 2, document (13), point 19).

Document (7) is concerned with photostability testing of drug substances and products. According to this document, such tests are carried out using any light source that produces an output similar to the D65/ID65

emission standard, such as an artificial daylight fluorescent lamp combining visible and ultraviolet outputs, or a xenon or metal halide lamp. D65 is the internationally recognised standard for outdoor daylight as defined in ISO 10977 (1993). ID65 is the equivalent indoor indirect daylight standard. A further option is exposure to both a cool white fluorescent lamp and a near-ultraviolet lamp (see page 2, point B entitled "Light sources"; document (13), points 23 to 25). Document (7) also refers to forced degradation testing under a variety of exposure conditions to evaluate the overall photosensitivity of a drug for the purpose of developing an analytical method that is capable of detecting degradation by-products and elucidating degradation pathways (see page 4, first three paragraphs, document (13), points 20 and 21).

4.10.4 Furthermore, the appellant provided evidence that exposure of rosuvastatin to visible light (sunlight) or irradiation with UV-light - conditions equivalent to those used in commonly known photostability testing - leads to the formation of compounds 2 to 4 (see document (11), page 264, left-hand column, penultimate paragraph to right-hand column, line 3 and page 265, right-hand column, third line from the bottom to page 266, left-hand column, line 14). Compound 2 is obtained as a mixture of two diastereomers, which were separated and which correspond to the compounds according to claims 1 and 2 of the present main request (see page 266, left-hand column, last paragraph to right-hand column, line 22 and Figure 2).

4.10.5 In the light of this evidence, the board has no doubt that the skilled person would have arrived at the subject-matter according to claims 1 and 2 of the main request by simply following well-known and routine

steps in the pharmaceutical industry for identifying possible degradation products as taught in documents (6) or (7). No inventive skills are required.

4.11 The respondent submitted that specific conditions were required to generate the claimed compounds, none of which was taught in any of documents (5) to (7). The provision of the claimed compounds was therefore not simply a matter of routine, but required inventive ingenuity. Furthermore, the formation of compounds 3 and 4 in document (11) was evidence of the "very specific conditions" that had to be adhered to in order to generate the claimed compounds.

4.12 The board does not agree.

According to the patent in suit, the claimed compounds are formed by exposing rosuvastatin or its salts to visible light irradiation (see paragraphs [0026], [0032]). The irradiation may be performed in solid state or solution at a temperature from room temperature to reflux temperature. Visible light irradiation of about 750W at 35°C was used for rosuvastatin calcium salt (see paragraph [0034], examples 1 and 2). It is also stated that "one skilled in the art may choose a narrow spectrum within these spectrums or a mixture of various spectrums" (see paragraph [0034]). The board sees nothing special in these conditions compared to those that are applied in routine photostability tests as disclosed in document (7). No specific wavelength or light intensity is defined. Nor is there any evidence on file that such routine tests would not lead to the claimed compounds. On the contrary, document (11) shows that no specific conditions, for example a particularly strong light

source in proximity to a solution of rosuvastatin, as asserted by the respondent, are required.

With regard to the formation of compounds 3 and 4 the board notes that they are additional degradation products derived from compound 2 (see page 267, left-hand column, last paragraph, lines 1 to 10). Their formation cannot alter the fact that compound 2 (i.e. the claimed compound) is formed if rosuvastatin is exposed to irradiation with visible or UV-light. Moreover, continuous monitoring and analysis of the generated degradation products is a matter of course in tests designed to examine the photostability of a compound. Hence, the formation of the claimed compounds in photostability testing would be noticed by the skilled person, and their structure identified in a routine manner.

4.13 For the sake of completeness, the board notes that the experimental evidence provided by the respondent (document (14)) is not relevant, as it is not concerned with conducting a photostability study of rosuvastatin. On the contrary, in three of the four experiments described therein rosuvastatin, in the form of its calcium salt, is kept in amber vials or in the refrigerator. Such conditions are generally applied to prevent photodegradation. At best, document (14) provides an indication that rosuvastatin calcium salt, in solid form, is sufficiently stable to be handled for a short period of time without any problems (see the table on the second page; third experiment). It cannot cast doubt on the experimental evidence provided in document (11).

4.14 For the aforementioned reasons, the board concludes that the subject-matter of claims 1 and 2 of the main

request does not involve an inventive step (Article 56 EPC). The same applies to claims 1 and 2 of the first, second and third auxiliary requests, which are identical to claims 1 and 2 of the main request.

5. Having decided that the main request and first to third auxiliary requests do not comply with Article 56 EPC, the board does not need to decide whether to admit document (17) and the appellant's allegedly new technical arguments in support of its objection under Article 123(2) EPC, submitted on 1 November 2016 (see point XIII above).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:



M. Schalow

A. Lindner

Decision electronically authenticated