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**Datasheet for the decision  
of 3 June 2014**

**Case Number:** T 0571/10 - 3.3.07  
**Application Number:** 08165575.5  
**Publication Number:** 2018853  
**IPC:** A61K9/20, A61K31/505, A61K9/16,  
A61K9/26, A61K9/32  
**Language of the proceedings:** EN

**Title of invention:**

Pharmaceutical compositions comprising a HMG COA reductase inhibitor

**Applicant:**

AstraZeneca AB

**Relevant legal provisions:**

EPC Art. 54(3), 56, 76(1), 84, 88(2), 88(3), 123(2)  
EPC R. 43(1)  
RPBA Art. 13  
Travaux préparatoires M/48/I, Section C

**Keyword:**

Late-filed request - justification for late filing (yes)  
Divisional application - added subject-matter (no)  
Claims - essential features  
Amendments - added subject-matter (no)  
Priority - "OR"-claims using a generic term or formula -  
partial priority (yes)  
Novelty - (yes)  
Inventive step - (yes)

**Decisions cited:**

G 0002/98, T 1127/00, T 1443/05, T 1877/08, T 0476/09,  
T 1222/11

**Catchword:**

In a case in which a single priority is claimed for a given application and a number of features of a claim of said application are generalisations of specific features disclosed in the priority document, a partial priority is to be acknowledged, as long as it is possible to conceptually identify, by a comparison of the claimed subject-matter with the disclosure of the priority document, a limited number of clearly defined alternative subject-matters, including among the alternatives the specific embodiments which are directly and unambiguously derivable from the priority document. In order for this condition to be met, it is not necessary that the clearly defined alternative subject-matters are spelt out as such in the application, nor that the word "or" actually occurs (see point 4.5.12).

This condition extends to the case of multiple priorities. In that case, a comparison with the disclosure of each of the priority documents is necessary and for each of the clearly defined alternative subject-matters the earliest priority from which the alternative subject-matter is directly and unambiguously derivable is acknowledged (see point 4.5.13).



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Case Number: T 0571/10 - 3.3.07

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.07**  
**of 3 June 2014**

**Appellant:** AstraZeneca AB  
(Applicant) AstraZeneca Intellectual Property  
151 85 Södertälje (SE)

**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted on 26 October 2009  
refusing European patent application No.  
08165575.5 pursuant to Article 97(2) EPC.

**Composition of the Board:**

**Chairman** D. Boulois  
**Members:** D. Semino  
P. Schmitz

## Summary of Facts and Submissions

- I. The appeal lies from the decision of the examining division announced at oral proceedings on 25 September 2009 to refuse European patent application n° 08 165 575.5. The application was filed as a divisional application of European patent application n° 00 951 701.2, which was filed on 4 August 2000, claiming priority from GB 0001621.1 filed on 26 January 2000.
- II. The decision was based on claims 1 to 15 of the main request and claims 1 to 14 of the first auxiliary request, both filed during oral proceedings held on 25 September 2009.

Claim 1 of the main request read as follows:

"A pharmaceutical composition comprising (E)-7-[4-(4-fluorophenyl)-6-isopropyl-2-[methyl(methylsulfonyl)amino]pyrimidin-5-yl]-(3R,5S)-3,5-dihydroxyhept-6-enoic acid or a pharmaceutically acceptable salt thereof as the active ingredient, the composition having a ferric oxide light protective coating; provided that the composition does not comprise the calcium salt of the active ingredient and a tribasic phosphate salt in which the cation is multivalent."

Claim 1 of the auxiliary request corresponded to claim 1 of the main request with the additional feature that the pharmaceutical composition comprised "an inorganic salt in which the cation is multivalent".

- III. In the decision under appeal, the following documents were cited *inter alia*:

D1: EP-A-0 521 471

D2: Graul et al., "Hypolipidemic HMG-CoA Reductase Inhibitor", Drugs of the Future 1999, 24(5), 511-513

D3: GB-A-2 262 229

D4: WO-A-94/16693

D9: WO-A-01/54668 (published on 2 August 2001, filed on 4 August 2000 and claiming priority from GB 0001621.1 filed on 26 January 2000)

IV. The decision of the examining division can be summarised as follows:

- a) Claim 1 of the main request did not meet the requirements of Articles 76(1) EPC, since in the earlier application as filed the provision of a composition having a ferric oxide light protective coating could not be read in isolation from the feature defining the presence of an inorganic salt in which the cation is multivalent, which feature was absent from claim 1 of the main request. The latter feature being essential to the definition of the invention, the requirements of Article 84 EPC in combination with Rule 43(1) EPC were also not met.
  
- b) Claim 1 of the first auxiliary request lacked inventive step in view of D1 or D2 as closest prior art, in combination with D3. D1 and D2 disclosed the active ingredient, rosuvastatin, and differed from claim 1 in that they did not disclose the combination of the active ingredient with an inorganic salt in which the cation is multivalent, nor a light protective coating comprising ferric oxide. The problem was identified as the provision of a composition wherein degradation of the active agent under

storage conditions was minimised or avoided. The solution was obvious in view of D3 which taught the use of a pharmaceutical composition comprising the active agent in admixture with a water-soluble alkaline substance such as calcium carbonate and further comprising a film coating of "Opadry Yellow" which was a light protective coating comprising ferric oxide.

In addition, the minutes of the oral proceedings at which the decision was taken indicated that it was announced by the chairperson that the disclaimer in claim 1 according to the first auxiliary request was "allowable and established novelty over D9 (Article 54(3) EPC)" (see paragraph bridging pages 1 and 2 in the minutes).

- V. The appellant (applicant) filed an appeal against that decision. With the statement setting out the grounds of appeal, the appellant filed four sets of claims as main request and first to third auxiliary requests. A disclaimer was present in claim 1 of all requests.

In that statement of grounds the appellant additionally cited *inter alia* the following documents:

D13: Extract from a report labelled "Appendix A" (originally filed with the letter dated 24 July 2009)  
D15: Declaration of Joseph Richard Creekmore dated 3 July 2006 (originally filed with the letter dated 13 February 2009)  
D15a: "Appendix A" of D15 (originally filed with the letter dated 13 February 2009)

- VI. With the letter dated 8 December 2010 the appellant filed eight sets of claims to replace those on file,

whereby claim 1 in all requests still contained a disclaimer, and the following document in response to the third party observations which had been filed anonymously with letter dated 30 September 2010:

D17: Supplementary declaration of Richard Creekmore dated 19 November 2010

- VII. In a communication sent in preparation for oral proceedings the Board reviewed the submissions of the appellant. In particular, with regard to the disclaimers included in all requests on file, it expressed the preliminary opinion that said disclaimers appeared unnecessary to establish novelty over document D9. With respect to inventive step, the Board pointed out that the available tests did not convincingly demonstrate an effect across the entire scope of the claim.
- VIII. In reaction to that communication the appellant filed with letter of 13 May 2014 eight further sets of claims to replace those on file, in which the disclaimer had been deleted and further amendments had been introduced.
- IX. Oral proceedings were held on 3 June 2014, during which a set of claims 1 to 12 was submitted as the main request and all previous requests were withdrawn.

Claim 1 of said request read as follows:

"1. The use of a light protective coating containing lactose, hydroxypropyl methyl cellulose, triacetin, titanium dioxide and ferric oxide to reduce the rate of formation of photodegradation products of (E)-7-[4-(4-fluorophenyl)-6-isopropyl-2-[methyl(methylsulfonyl)amino]pyrimidin-5-yl]-(3R,5S)-3,5-dihydroxyhept-6-enoic acid or a pharmaceutically

acceptable salt thereof in a pharmaceutical composition comprising the said compound or salt as the active ingredient, wherein the pharmaceutical composition further comprises an inorganic salt in which the cation is multivalent, and wherein the coating comprises 1 to 3% by weight of the composition."

- X. The arguments of the appellant, as far as relevant to the present decision, can be summarised as follows:

*Admittance of the main request*

Objections raised by the Board for the first time in oral proceedings arose from the requests filed by the appellant after the communication of the Board in preparation of oral proceedings had been issued. The newly filed request represented a reasonable attempt to address and overcome all raised objections and consequently should be admitted into the proceedings.

*Inventive step*

Claim 1 involved an inventive step, since the skilled person starting from D2, which was the closest prior art, and wishing to provide stable pharmaceutical compositions, would look to the disclosure of D4 in which the issue of photodegradation was addressed. Nothing in D4 pointed to a coating as a method of reducing photodegradation. Rather, D4 taught that the problem of photodegradation could be solved by using calcium carbonate. On that basis the presence of an inventive step was to be acknowledged.

- XI. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis



of the main request filed at oral proceedings before the Board on 3 June 2014.

## **Reasons for the Decision**

### *Admittance of the main request*

1. The main request was submitted during oral proceedings before the Board on 3 June 2014.
  - 1.1 This new request was filed as a direct response to objections raised by the Board with respect to requests previously on file. Since some of said objections arose from requests which had been filed after the communication of the Board in preparation for oral proceedings had been issued, the appellant was only made aware of them during said oral proceedings. The request represents a direct, clear and fair attempt to address the issues raised by the Board without giving rise to new ones and does not add complexity to the case under consideration.
  - 1.2 Consequently, the Board exercises its discretion by admitting the main request into the proceedings in accordance with Article 13(1)(3) RPBA.

### *Article 76, Article 84 and Rule 43(1) EPC*

2. According to the appealed decision, claim 1 of the main request before the examining division did not meet the requirements of Articles 76(1) EPC, since the feature defining the presence of an inorganic salt in which the cation is multivalent was absent in the claim. Since said feature was seen as an essential feature, the requirements of Article 84 EPC in combination with Rule 43(1) EPC were equally not met.

- 2.1 Since the disputed feature has been included in claim 1 of the new main request, the corresponding objections have been overcome.
- 2.2 The Board has no other concern with regard to the requirements of Article 76(1) EPC, Article 84 EPC and Rule 43(1) EPC.

*Basis in the application as filed*

3. Claim 1 results from a combination of independent claim 2 of the application as filed with dependent claims 13 and 14, which refer to the weight percentage of the coating, and dependent claim 15, which specifies the composition of the coating, together with a change of category from a product claim (a pharmaceutical composition) to a use claim (the use of a light protective coating to reduce the rate of formation of photodegradation products). The specific purpose indicated in the use claim is disclosed in the original description for coatings containing ferric oxides in close association with the coating composition specified in the claim and the weight percentage range thereof (page 6, lines 5 to 12, see in particular the last sentence).
- 3.1 On that basis, claim 1 of the main request fulfills the requirements of Article 123(2) EPC. The Board has no concerns regarding Article 123(2) EPC for the dependent claims.

*Novelty over D9*

4. Claim 1 according to both requests on which the decision was based contained the disclaimer: "provided that the

composition does not comprise the calcium salt of the active ingredient and a tribasic phosphate salt in which the cation is multivalent". While no analysis related to the presence of the disclaimer and compliance with the requirements of Article 123(2) EPC was made in the decision under appeal, the minutes of the oral proceedings at which the decision was taken indicated that the disclaimer was allowable and established novelty over D9 (see point IV, above). As no disclaimer is present in claim 1 of the main request, the issue of novelty over document D9 needs to be analysed.

- 4.1 Since the requirements of Article 76(1) EPC, second sentence, have been found to be complied with, the present divisional application shall be deemed to have been filed on the date of filing of the earlier application and shall enjoy any right of priority of the earlier application.
- 4.2 By virtue of this, document D9, which was published well after the filing date of the present application, does not belong to the state of the art according to Article 54(2) EPC.
- 4.3 As to Article 54(3) EPC, the present application and document D9 share not only the same filing date, but also the same priority claim, since they claim priority from the same document (see points I and III, above). On that basis, document D9 could belong to the state of the art under Article 54(3) EPC, only insofar as the priority of the present application is not validly claimed, while the priority of D9 is effective.
- 4.4 The crucial point in order to analyse novelty over D9 resides therefore in the validity of the priority for the present application and for document D9.

4.5 *Priority of the present application*

4.5.1 The priority document discloses in a paragraph exactly corresponding to a paragraph of the present application (cf. page 4, lines 6 to 13 of the priority document and page 6, lines 5 to 12 of the present application) the use of coatings containing ferric oxides to reduce the rate of formation of photodegradation products of the active agent of a coated pharmaceutical composition in close association with the coating composition specified in claim 1 of the main request and the weight percentage range thereof.

4.5.2 As to the active agent and the salt included in the coated pharmaceutical composition, the priority document discloses a pharmaceutical composition comprising (E)-7-[4-(4-fluorophenyl)-6-isopropyl-2-[methyl(methylsulfonyl)amino]pyrimidin-5-yl]-(3R, 5S)-3,5-dihydroxyhept-6-enoic calcium salt as the active agent and a tribasic phosphate salt in which the cation is multivalent (page 1, lines 3 to 6 and 24 to 25).

4.5.3 Both the active agent and the accompanying salt disclosed in the priority document are specific embodiments with respect to the generic disclosures in claim 1 of the main request, in which the active agent is the substituted dihydroxyhept-6-enoic acid or a pharmaceutically acceptable salt thereof (a generic class including the calcium salt) and the accompanying salt is an inorganic salt in which the cation is multivalent (a generic class including a tribasic phosphate salt in which the cation is multivalent).

4.5.4 While it is clear that priority cannot be acknowledged for the whole scope of the claim in view of the

generalisations, the question to be answered is whether and to what extent a partial priority can be acknowledged with respect to the subject-matter disclosed in the priority document. This is to be decided on the basis of the articles of the EPC relevant for priority (Articles 87 to 89, in particular Article 88(2) and (3) EPC, as far as multiple priorities and partial priority are concerned) and of the case law relating to those articles.

- 4.5.5 With reference to Article 88 EPC and in particular of the situation as the present one in which several alternatives (in the present case the acid, the calcium salt or a different salt for the active agent and a tribasic phosphate salt or a different inorganic salt for the salt) are covered by a claim (the so-called "OR"-claim), decision G 2/98 (OJ EPO 2001, 413) includes a full paragraph related to this subject. In detail, it refers to a memorandum which is part of the historical documentation related to the EPC (Memorandum C drawn by FICPI, M 48/I, Section C, simply referred to as the memorandum in what follows) and is said to express the legislative intent underlying Article 88(2) EPC, second sentence (point 6.4 of the decision) and states the following:

"As regards the "OR"-claim ..., it is held in the memorandum that where a first priority document discloses a feature A, and a second priority document discloses a feature B for use as an alternative to feature A, then a claim directed to A or B can enjoy the first priority for part A of the claim and the second priority for part B of the claim. It is further suggested that these two priorities may also be claimed for a claim directed to C, if the feature C, either in the form of a generic term or formula, or otherwise,

encompasses feature A as well as feature B. The use of a generic term or formula in a claim for which multiple priorities are claimed in accordance with Article 88(2) EPC, second sentence, is perfectly acceptable under Articles 87(1) and 88(3) EPC, provided that it gives rise to the claiming of a limited number of clearly defined alternative subject-matters." (point 6.7 in G 2/98)

- 4.5.6 A detailed analysis of G 2/98, of the memorandum and of previous case law was accomplished in T 1222/11 of 4 December 2012 in order to fully understand the conditions for acknowledging the validity of priority when the "OR"-claim is drafted using a generic term or formula (see points 11.1 to 11.8 of the reasons for the decision).
- 4.5.7 In T 1222/11 it was found that the assessment as to which elements of the "OR"-claim are covered by any of the multiple priority documents can be achieved only by a comparison of the claimed subject-matter of the "OR"-claim with the multiple priority documents, so that the words "gives rise to the claiming of a limited number of clearly defined alternative subject-matters" used in the cited passage of G 2/98 refer to the ability to conceptually identify by said comparison a limited number of clearly defined alternative subject-matters to which the multiple rights of priority claimed can be attributed or not (point 11.5.2 of the decision). That this comparison should give rise to a limited number of clearly defined alternative subject-matters is obviously necessary in order to identify which parts of the claims benefit from the effect of the priority right defined in Article 89 EPC (point 11.5.3 of the decision).

- 4.5.8 This approach was found to be supported by the memorandum, which according to G 2/98 proved the intent of the legislator concerning the question of multiple priorities. In particular reference was made in T 1222/11 to a statement on page 2 of the memorandum, which reads "It is of course immaterial whether the word "or" actually occurs in the claim, or is implied through the use of a generic term, or otherwise" (point 11.5.4 of the decision) and to three examples provided in the memorandum and referring to the "Broadening of a chemical formula", the "Broadening of range (temperature, pressure, concentration, etc.)" and a method of coating the inner wall of a pipe vs a method of coating the inner wall of bottles or any other hollow bodies (points 11.5.5 to 11.5.7 of the decision).
- 4.5.9 In particular with reference to the first example in the memorandum, which is the one which comes closer to the present situation, a passage of the memorandum was cited in T 1222/11, which reads: "A first priority document discloses a relatively narrow chemical formula supported by representative examples. A second priority document discloses a broader chemical formula which within its scope includes the narrower chemical formula, and which is supported by additional examples justifying the broader formula. If multiple priorities for one and the same claim are allowed [*as it is indeed the case according to Article 88(2) EPC, second sentence*], it will suffice to draw up a single claim directed to the broad formula. This claim will then enjoy priority from the first priority date to the extent that the compound in question comes within the scope of the narrow formula, and the second priority for the rest of its scope." This example was found to confirm that the attribution of the partial priorities to the different parts of the claim has to be made by a comparison of the

subject-matter of the claim with the disclosure of the priority documents, the clearly defined alternative subject-matters being in this example the narrow formula and the rest of the scope of the claim (point 11.5.5 of the decision).

4.5.10 Moreover, while said analysis referred to the case of multiple priorities, in T 1222/11 it was concluded that there is no reason why the assessment of partial priority for an "OR"-claim should be different depending on whether a single priority or multiple priorities are claimed, nor is there any provision in the EPC which would support a different view (point 11.6 of the decision).

4.5.11 In addition, while the Board in T 1222/11 was well aware of a number of previous decisions of other Boards (T 1877/08 of 23 February 2010, T 476/09 of 21 September 2012, T 1443/05 of 4 July 2008 and T1127/00 of 16 December 2003) which followed a strict and literal interpretation of the condition "provided that it gives rise to the claiming of a limited number of clearly defined alternative subject-matters" mentioned in G 2/98, which was seen as characterising the manner in which the subject-matter of the "OR"-claim must be defined, it found that said condition, when read in its proper context, should be given a different meaning than that attributed to it in those decisions (points 11.4 and 11.5 of the decision of T1222/11).

4.5.12 The present Board fully shares the analysis and the approach of T 1222/11 and, on that basis, comes to the conclusion that in a case such as the present one, in which a single priority is claimed for a given application and a number of features of a claim of said application are generalisations of specific features



disclosed in the priority document, a partial priority is to be acknowledged, as long as it is possible to conceptually identify, by a comparison of the claimed subject-matter with the disclosure of the priority document, a limited number of clearly defined alternative subject-matters, including among the alternatives the specific embodiments which are directly and unambiguously derivable from the priority document. In order for this condition to be met, it is not necessary that the clearly defined alternative subject-matters are spelt out as such in the application, nor that the word "or" actually occurs.

4.5.13 This condition clearly extends to the case of multiple priorities. In that case, a comparison with the disclosure of each of the priority documents is necessary and for each of the clearly defined alternative subject-matters the earliest priority from which the alternative subject-matter is directly and unambiguously derivable is acknowledged.

4.5.14 Applying this condition to the present case, one can identify, by comparing the claimed subject-matter with the disclosure of the priority document, two clearly defined alternative subject-matters covered by claim 1 of the main request, namely:

- (a) the use of claim 1 of the main request in a pharmaceutical composition comprising the **calcium salt** of the substituted dihydroxyhept-6-enoic acid as the active ingredient and a **tribasic phosphate salt** in which the cation is multivalent,
- (b) the use of claim 1 of the main request in a pharmaceutical composition comprising the substituted dihydroxyhept-6-enoic **acid or a**

**pharmaceutically acceptable salt thereof** as the active ingredient and an **inorganic salt** in which the cation is multivalent, wherein the active ingredient and the inorganic salt are **other than the calcium salt of the acid and a tribasic phosphate salt in combination.**

4.5.15 The subject-matter of alternative (a) is fully disclosed in the priority document (see points 4.5.1 and 4.5.2, above) and enjoys the claimed priority, while the subject-matter of alternative (b) is not directly and unambiguously derivable from the priority document and does not enjoy a priority right.

#### 4.6 *Priority of document D9*

4.6.1 Document D9 discloses, in a paragraph exactly corresponding to a paragraph of the priority document (cf. page 4, line 20 - page 5, line 5 of D9 and page 4, lines 6 to 13 of the priority document), the use of coatings containing ferric oxides to reduce the rate of formation of photodegradation products of the active agent of a coated pharmaceutical composition in close association with the coating composition specified in claim 1 of the main request and the weight percentage range thereof.

4.6.2 As to the active agent and the salt included in the coated pharmaceutical composition, D9 discloses a pharmaceutical composition comprising the substituted dihydroxyhept-6-enoic acid or a pharmaceutically acceptable salt thereof as the active agent and a tribasic phosphate salt in which the cation is multivalent (claim 1).

4.6.3 An analysis of the priority of D9 (which is the same as the priority of the application under analysis, see its content in points 4.5.1 and 4.5.2, above) and an application of the same condition as above lead also in this case to the identification of two clearly defined alternative subject-matters, namely:

- (a) the use of claim 1 of the main request in a pharmaceutical composition comprising the **calcium salt** of the substituted dihydroxyhept-6-enoic acid as the active ingredient and a **tribasic phosphate salt** in which the cation is multivalent,
  
- (b) the use of claim 1 of the main request in a pharmaceutical composition comprising the substituted dihydroxyhept-6-enoic **acid or a pharmaceutically acceptable salt thereof other than a calcium salt** as the active ingredient and a **tribasic phosphate salt** in which the cation is multivalent.

4.6.4 Also in this case the subject-matter of alternative (a) is disclosed in the priority document and enjoys the claimed priority, while the subject-matter of alternative (b) is not directly and unambiguously derivable from the priority document and does not enjoy a priority right.

#### 4.7 *Conclusions*

4.7.1 Once the validity of the priority has been determined both for the application under analysis and for document D9, the relevance of D9 under Article 54(3) EPC can be determined.

- 4.7.2 For the subject-matter of claim 1 of the main request for which the priority is valid (alternative (a) in paragraph 4.5.14, above), D9 does not belong to the state of the art under Article 54(3) EPC, as it has no valid date prior to the priority date of the application under analysis. For this subject-matter therefore D9 is of no relevance at all in the analysis of novelty.
- 4.7.3 For the subject-matter of claim 1 of the main request for which the priority is not valid (alternative (b) in paragraph 4.5.14, above), D9 is state of the art under Article 54(3) EPC, however only for the subject-matter for which the priority of D9 is valid (alternative (a) in paragraph 4.6.3, above). However, the subject-matter of alternative (a) of D9 is not novelty destroying for the subject-matter of alternative (b) of claim 1 of the main request, as the former subject-matter has no overlap with the latter.
- 4.7.4 As no lack of novelty arises, there is no need for a disclaimer with respect to document D9.

*Inventive step*

5. *Closest prior art*

- 5.1 Claim 1 of the main request does not concern a pharmaceutical composition *per se* as was the case for the requests on which the decision was based, but is directed to the use of a light protective coating to reduce the rate of formation of photodegradation products of the active ingredient.
- 5.2 Applying to claim 1 the accepted principles of the case law concerning the identification of the closest prior art, namely that the closest prior art must be directed

to the same purpose or effect as the invention, is generally that which corresponds to a similar use requiring the minimum structural modifications and it should relate to the same or a similar technical problem or, at least, to the same or a closely related technical field (Case Law of the Boards of Appeal, 7th edition 2013, I.D.3.2), the closest prior art should be in the present case a document which acknowledges the problem of photodegradation of the active ingredient. Since neither D1 nor D2 make reference to the photodegradation or stability of the agent in general, they are not suitable starting points for the skilled person.

5.3 Although not disclosing the active ingredient of claim 1, D4 generically discloses compounds which are structurally closely related to it and differ therefrom in the nitrogen heterocycle which is a pyran ring according to D4 (page 2, line 11 - page 3, line 8) and a pyrimidine ring in the active ingredient according to claim 1. HMG-CoA reductase inhibitor activity is also mentioned for some of the compounds of D4 (e.g. page 3, lines 9 to 13). D4 is concerned with the preparation of stable oral pharmaceutical formulations of said compounds (page 1, lines 7-12). It is recognised that said compounds are unstable in that they are susceptible to heat, moisture, low pH environment, and *light*; in addition, it is stated that *the hydroxy acids will decompose rapidly when exposed to UV or fluorescent light* (page 4, lines 1-6).

5.4 Thus D4 discloses the problem of photodegradation of active agents *similar* to that of claim 1. Additionally, one of the aims of D4 is to prepare a stabilized pharmaceutical formulation which protects the drug from *inter alia* photochemical decomposition during storage (page 15, line 34 - page 16, line 4), thereby

corresponding to the same technical problem as the application.

5.5 D3 is not a better choice than D4 as closest prior art since although *light sensitivity* of the subject compounds is mentioned generally (page 2, paragraph 3), as is the possibility of applying coating materials (page 8, paragraph 2 - page 9, paragraph 3), D3 does not specifically identify the problem of light sensitivity as being one for which a solution is proposed. Consequently, D4 is identified as the closest prior art for the subject-matter of claim 1.

5.6 Claim 1 differs from the disclosure of D4 in that:

- a) the latter does not disclose the active ingredient of claim 1 but rather compounds which differ in that they comprise a pyran ring.
- b) the latter does not disclose the use of a light protective coating, let alone a coating containing lactose, hydroxypropyl methyl cellulose, triacetin, titanium dioxide and ferric oxide, to reduce the rate of formation of photodegradation products of the active agents.

5.6.1 Although in D4 the preparation of tablets which are film coated to about a 3% weight increase is mentioned (examples 3 on page 21 and example 8 on page 23), the composition of the coating is not disclosed and there is no indication in D4 that the coating may play a role in the prevention of photodegradation of the active ingredients, which according to D4 is provided by the stabilizing effect of the pharmaceutically acceptable alkaline earth metal salt (such as calcium carbonate)

comprised within the compositions (page 5, lines 8 - 29).

6. *Problem solved*

6.1 Since a comparison of the method for reducing photodegradation according to D4 with that of the present application is not available to the Board, no particular advantage or improvement can be attributed to the differences identified. In view of this, the problem solved is the provision of a further method for reducing the rate of formation of photodegradation products of an inhibitor of HMG-CoA possessing a hydroxy acid side chain attached to a nitrogen heterocycle.

6.2 That the problem has been solved is demonstrated by documents D13, D15, D15a and D17, filed by the appellant as evidence of the effect on photodegradation of a tablet coating comprising ferric oxide and titanium dioxide. D13 identifies the major photodegradation products of the active ingredient of claim 1 as the epimeric PDP1 and PDP2 (paragraphs 1.6.3.1 and 1.6.4.2). According to test report D15 and the supplementary experimental detail provided as D17, a coating comprising titanium dioxide was compared with a coating comprising ferric oxide and titanium dioxide. The results, displayed in D15a, demonstrate that coatings comprising titanium dioxide and ferric oxide are effective in protecting the active ingredient against photodegradation: at the same percentage of coating weight gain, coatings comprising titanium dioxide and ferric oxide led to less photodegradation products than coatings comprising only titanium dioxide. Although a comparison was not drawn with a composition of the active ingredient in the absence of a coating, it is reasonable to assume that such a composition would not

demonstrate a lower rate of formation of photodegradation products than if it were surrounded by a coating comprising only titanium dioxide, thereby allowing the indirect comparison of the rate of formation of photodegradation products of the active ingredient according to claim 1 to the rate which would be observed in the absence of a coating.

7. *Obviousness*

7.1 None of the prior art documents on file teaches that a reduction of the rate of photodegradation in compounds similar to the active ingredient of claim 1 may be achieved by using a light protective coating containing the ingredients listed. D3, the only document apart from D4 which mentions the light sensitivity of the subject compounds, refers to the possibility of employing coatings which may comprise as ingredients *inter alia* titanium dioxide and iron oxide (D3, page 9, paragraph 2). However, there is no indication in D3 that using said coating, or a coating of any kind will reduce the rate of formation of photodegradation products in the active ingredients. The skilled person faced with the posed problem, would have therefore no motivation to use a coating as the one indicated in the claim.

7.2 It follows that the subject-matter of claim 1 involves an inventive step.

**Order**

**For these reasons it is decided that:**

1. The decision under appeal is set aside.



2. The case is remitted to the department of first instance with the order to grant a patent on the basis of claims 1 to 12 filed during the oral proceedings before the Board and a description yet to be adapted thereto.

The Registrar:

The Chairman:



N. Schneider

D. Boulois

Decision electronically authenticated