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Case Number: T 0064/12 - 3.3.07

Application Number: 05792891.3

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Language of the proceedings: EN

Title of invention:
COMPOSITIONS COMPRISING 5-AMINO-2-HYDROXYBENZOIC ACID AND A REDUCING SUGAR

Patent Proprietor:
Warner Chilcott Company, LLC

Opponent:
Tillotts Pharma AG

Relevant legal provisions:
EPC Art. 56
RPBA Art. 13(1)

Keyword:
Inventive step - main request (no)
Late-filed auxiliary requests - admitted (yes)
Inventive step - auxiliary requests (no)

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Case Number: T 0064/12 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 30 April 2015

Appellant: (Opponent)	Tillotts Pharma AG Hauptstrasse 27 4417 Ziefen (CH)
Representative:	Beck Greener Fulwood House 12 Fulwood Place London WC1V 6HR (GB)
Respondent: (Patent Proprietor)	Warner Chilcott Company, LLC P.O. Box 1005 Union Street Km I.I. Fajardo Puerto Rico 00738-1005 (PR)
Representative:	O'Connell, Maura FRKelly 27 Clyde Road Ballsbridge Dublin 4 (IE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 17 November 2011 rejecting the opposition filed against European patent No. 1784166 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairwoman	R. Hauss
Members:	A. Usuelli
	W. Ungler

Summary of Facts and Submissions

I. The appeal of the opponent (appellant) lies against the decision of the opposition division to reject the opposition against European patent No. 1 784 166.

The patent was granted with 13 claims. Independent claim 1 read as follows:

"1. A kit characterized in that it comprises:
(a) at least one unit dosage form comprising:
(i) a safe and effective amount of 5-amino-2-hydroxybenzoic acid;
(ii) a reducing sugar; and
(b) a predetermined amount of a desiccant.

II. An opposition was filed against the patent as a whole. It was based on Article 100(a) and (b) EPC on the grounds of lack of novelty and inventive step and insufficiency of disclosure. The opponent relied *inter alia* on the following documents:

D1a: English translation of JP-A-10-15032
D2a: WO 83/00435
D3: Yoshioka, Stella: Stability of Drugs and Dosage Forms, New York 2002, pages 29-33, 113 and 174-176
D4: Maillard reaction and Drug Stability, RSC special publication, 1994, 20-27
D5: Journal of Pharmaceutical Sciences, 51(2), 1962, 106-108
D6: Kibbe: Handbook of pharmaceutical excipients, third edition, 2000, 276-285
D7: EP 474 874 A1
D8: Proc. Natl. Acad. Sci., 1994, 91, 5710-5714
D9: Nephrol. Dial. Transplant., 1996, 11, 1718-1722
D10: Biosci. Biotech. Biochem., 59(2), 307-308, 1995

D10b: Declaration of Mr Kaczanowski dated 20 July 2011
D11: Pharmaceutical and Medical Packaging News Magazine, 1999; A Gorton: Desiccants Enhance Package Performance

III. In its decision the opposition division came to the conclusion that the subject-matter of the patent was sufficiently disclosed and complied with the requirement of novelty.

As to inventive step, two alternative approaches were considered by the opposition division, using either document D2a or document D1a as the closest prior art. In both cases the opposition division concluded that the subject-matter of the claims was not obvious in view of the cited documents.

IV. The appellant lodged an appeal against that decision. The respondent (patent proprietor) replied with letter of 1 August 2012 by requesting the board to dismiss the appeal and to maintain the patent as granted or alternatively to maintain the patent in accordance with one of the sixteen auxiliary requests sent on the same date.

V. With letter dated 24 April 2015 the respondent submitted six new sets of claims as auxiliary requests 1 to 6 and stated that if they were admitted it would withdraw the sixteen auxiliary requests filed with letter of 1 August 2012.

Claim 1 of auxiliary request 1 differed from claim 1 of the main request (see point I above) in the addition of the following features at the end of the claim:

"... wherein the concentration of a degradant that may accumulate during storage in the unit dosage form is no more than 0.15% and wherein the degradant is 5-[2-Formyl-5-(hydroxymethyl)-1H-pyrrol-1-yl]-2-hydroxybenzoic acid".

Claim 1 of auxiliary request 2 differed from claim 1 of auxiliary request 1 in indicating that the unit dosage form maintained a moisture content of 1.1% or less.

Claim 1 of auxiliary request 3 differed from claim 1 of auxiliary request 1 in indicating that the concentration of a degradant was "measured according to a stability testing method recognised by International Conference on Harmonization of technical requirements for registration of pharmaceuticals".

Claims 1 of auxiliary requests 4, 5 and 6 corresponded respectively to claims 1 of auxiliary requests 1, 2 and 3, with the specification that the reducing sugar was lactose.

VI. Oral proceedings were held on 30 April 2015. As there were no objections against admitting the auxiliary requests filed with letter of 24 April 2015 the respondent withdrew the sixteen auxiliary requests submitted on 1 August 2012.

VII. Concerning inventive step, the appellant proposed two different lines of argument, starting from D1a or from D2a as the closest prior art. The relevant arguments in the context of the present decision are those using D2a as the closest prior art which are summarised as follows:

The subject-matter of claim 1 of the granted patent differed from the disclosure of example VI of D2a in the combination of the tablets with a desiccant to form a kit. The tablets of example VI of D2a were substantially identical to the product Asacol®. The effect of the desiccant in the product of the patent in suit was to reduce the browning of the composition. It was known before the priority date that the Maillard reaction could occur also in pharmaceutical products. This was confirmed for instance by documents D3 to D7. The skilled person would have considered this reaction as very likely to occur in the tablet of example VI of D2a in view of the presence of a reducing sugar and of an active ingredient with an amino group. Documents D4 and D5 indicated that the Maillard reaction was mediated by moisture. Accordingly, it would have been obvious for the skilled person seeking to prevent the Maillard reaction to reduce the humidity level. In order to do that he would have added a desiccant to the tablet as suggested by document D11. As to D7, that document did not indicate that the Maillard reaction could not occur with 5-amino-2-hydroxybenzoic acid (5-ASA), as maintained by the respondent. Rather D7 taught the use of 5-ASA for inhibiting the Maillard reaction of proteins because 5-ASA itself reacted competitively in the Maillard reaction.

In claim 1 of the auxiliary requests, the nature and the amount of the degradant were specified. However, possible structures of products formed in Maillard reactions were suggested in D8, D9 and D10. In view of the teachings of these documents, the skilled person would have easily identified the degradation product of tablets containing 5-ASA and lactose. As to the amount of the degradant, there were no effects associated with the percentage 0.15% recited in the claims. The mere

fact of setting an upper limit for the degradant concentration did not involve an inventive step.

The indication of the moisture content did not render inventive claim 1 of auxiliary requests 2 and 5. Moreover, in normal conditions the moisture was very close to the level recited in claim 1.

The feature included in claim 1 of auxiliary requests 3 and 6 concerning the method used for the test of stability had no impact on the assessment of inventive step.

VIII. As far as relevant for the present decision, the respondent's arguments on inventive step can be summarised as follows:

Example VI of D2a disclosed a unit dosage form comprising 5-ASA and lactose. The difference between the subject-matter of claim 1 and D2a was the provision of a predetermined amount of a desiccant in a kit with a unit dosage form comprising the 5-ASA and a reducing sugar such as lactose. The technical effect of this difference was the reduction of the degradation of 5-ASA in the presence of a reducing sugar. Therefore, the objective technical problem was how to reduce degradation of 5-ASA in the presence of a reducing sugar. The skilled person would not have recognised that a reaction could take place between a reducing sugar and 5-ASA. Part of the solution of the technical problem consisted in recognising that said reaction occurred. It was also important to identify the product of said reaction. As affirmed by Mr Kaczanowski in his declaration (D10b), the determination of the structure of the degradation product isolated from Asacol® tablets required a considerable amount of effort.

Although many examples of Maillard reactions were described in the prior-art, none of the documents mentioned by the appellant in relation to the Maillard reaction made reference to 5-ASA. In document D5 it was affirmed that this reaction was very fast with strongly basic amines. However, 5-ASA was a weak base. Document D7 described 5-ASA as an inhibitor of the Maillard reaction. Accordingly, there was no teaching regarding the degradation of 5-ASA in the presence of a reducing sugar.

The chemical structure of the specific degradant recited in all the auxiliary requests was not suggested by any of the prior-art documents. It was clear from documents D8 to D10 that the Maillard reaction could result in the formation of many different products. The skilled person would not have considered the pyrrole derivatives as the inevitable products of a Maillard reaction. The subject-matter of the auxiliary requests was inventive also on account of the identification of the degradation product.

As to the subject-matter of claim 1 of auxiliary requests 2 and 5, figure 3 of the patent showed the importance of maintaining a moisture content of 1.1% or less.

IX. The appellant requested that the decision under appeal be set aside and that the patent be revoked.

X. The respondent requested that the appeal be dismissed and the patent be maintained as granted, or alternatively that the patent be maintained according to the claims filed as auxiliary requests 1 to 6 with letter of 24 April 2015.

Reasons for the Decision

Main request (patent as granted)

1. Inventive step - Claim 1

The patent in suit addresses the problem of limiting the formation of impurities in compositions comprising 5-amino-2-hydroxybenzoic and a reducing sugar such as lactose (see [0003]). 5-amino-2-hydroxybenzoic is also known as 5-aminosalicylic acid and is abbreviated 5-ASA.

Closest prior art

1.1 In the decision under appeal the opposition division followed two alternative approaches for the assessment of inventive step, starting from D1a or D2a as the closest prior art.

Document D1a relates to the problem of avoiding the formation of impurities in pharmaceutical compositions comprising 5-ASA as active ingredient. The impurities considered in this document are those generated by factors like high temperatures or presence of alkali (see [0003]). D1a does not disclose any compositions comprising 5-ASA and a reducing sugar.

D2a relates to the problem of providing pharmaceutical compositions comprising 5-ASA as active ingredient for the treatment of colonic disorders. There is no mention in D2a of any issue concerning the formation of impurities. Example VI of this document discloses a composition comprising 5-ASA and lactose.

Since D1a does not disclose any composition containing a reducing sugar, the problem concerning the formation of impurities due to the presence of a reducing sugar cannot arise. Therefore the board regards D2a as the most suitable starting point for the assessment of inventive step in view of the disclosure in example VI of a composition comprising 5-ASA and a reducing sugar.

1.2 The subject-matter of claim 1 differs from example VI of D2a in that the tablets are combined with a desiccant to form a kit. This finding was not disputed by the parties.

Technical problem

1.3 The technical effects associated with the distinguishing feature can be seen from example 3 of the patent, which shows that tablets comprising 5-ASA and lactose stored for 90 days in a desiccated chamber contain less degradant than tablets stored for the same length of time in a non-desiccated chamber.

1.4 In the context of defining the technical problem, the results of the experiments disclosed in examples 1 and 4 are also relevant.

Example 1 shows the effect of humidity on the formation of the degradant 5-[2-Formyl-5-(hydroxymethyl)-1H-pyrrol-1-yl]-2-hydroxybenzoic acid in compositions comprising 5-ASA and lactose. The results of the experiment, which are reported in the graph of Figure 1, indicate that the samples stored at relative humidity of 60% contain a higher amount of degradant than the samples stored at relative humidity of 10 to 30%. These results are in line with those of example 4 which relates to an experiment in which identical

dosage forms are equilibrated at relative humidity of 15 or 50% and then sealed in hermetic foils. Figure 4 shows that a reduced degradation rate is observed for the product equilibrated at the lower humidity.

1.5 In the board's view these examples make it credible that the formation of the degradation product is dependent on humidity and that the use of desiccants can reduce the formation of the degradant.

In view of these considerations the board holds that the technical problem is to reduce the degradation products in solid dosage forms containing 5-ASA and a reducing sugar.

Obviousness

1.6 A rational approach to tackle this problem is to identify which possible mechanisms of degradation are likely to occur in dosage forms containing 5-ASA and a reducing sugar. In order to do that, a skilled person would consider the chemical structures of the molecules included therein.

As clearly indicated by its chemical name, 5-amino-2-hydroxybenzoic, 5-ASA is a molecule containing an amino group. A reducing sugar is a sugar that contains an aldehyde group. Examples of reducing sugars are lactose, glucose, galactose and sucrose (claim 7 of the patent). As illustrated for instance in documents D3 and D4 it was already known well before the priority date of the patent that compounds containing an amino group may react with reducing sugars in a condensation reaction known as the Maillard reaction.

In document D3, it is stated that "Reducing sugars readily react with primary amines, including those of amino acids, through the Maillard reaction" (page 30, paragraph 2.1.7.2). This document mentions various drugs containing amino groups that undergo this reaction (page 33, lines 2 to 6). In document D4, published in 1994, it is affirmed that "Pharmaceutical preparations containing reducing sugars or other carbonyl containing compounds such as pharmaceutical adjuvants, and amine drugs, frequently show a non-enzymatic browning ("Maillard") reaction during storage" (page 20, "Introduction").

The occurrence of the Maillard reaction in pharmaceutical compositions is also discussed in D5, published in 1961 and in D6 (page 283, paragraph 12).

1.7 The Maillard reaction was therefore extensively investigated before the priority date, in particular in the field of pharmaceuticals. This fact is also acknowledged in the description of the patent in suit (see "Background of the invention").

Accordingly, in the board's view a skilled person concerned with degradation problems of compositions containing an amino derivative such as 5-ASA, and a reducing sugar such as lactose, would be immediately alerted by the presence of these substances to consider the possibility of a Maillard reaction. Indeed, since this reaction has been observed with several amine derivatives of different chemical structures, such as amphetamine, isoniazide, glycine and neomycin (D3, paragraph 2.1.7.2; D4, pages 21 and 22), the skilled person would consider it highly plausible that also 5-ASA undergoes such a reaction. After all, the prior art does not suggest that only a restricted group of

primary amines, having for instance specific properties or specific structural features, can undergo a Maillard reaction. It rather conveys the idea that the reaction is generally occurring whenever a primary amine and a reducing sugar are in contact. Thus, the board agrees with the appellant that a Maillard reaction in a composition containing 5-ASA and lactose would be considered not only possible, but also very likely to occur.

1.8 An important item of information that can be gathered from the prior art concerns the effects of humidity on the Maillard reaction. In document D4 it is explained that the browning of antacid tablets due to the Maillard reaction increases with an increase of the relative humidity (page 21, last paragraph). Similar effects of relative humidity on the browning of medicaments are observed with neomycin tablets (page 22, first paragraph). The same concept is expressed in document D5 where it is observed that tablets containing amine salts combined with lactose become tan in colour and that this effect is dependent *inter alia* on the humidity (page 106, 2nd paragraph of left column). The important role of water in the Maillard reaction is also acknowledged in paragraph [0003] of the patent under appeal where it is mentioned that the presence of water had been suggested as essential for the reaction to occur.

1.9 The knowledge that humidity promotes the Maillard reaction would logically suggest to the skilled person seeking to prevent the degradation caused by this reaction the idea of reducing the humidity level.

As can be derived from document D11, a standard method to achieve this effect is to add a desiccant to the

packaging of the pharmaceutical composition, for instance inside the bottle containing the medicament.

It follows from the above that the skilled person would arrive at the subject-matter of claim 1 without any inventive effort.

1.10 Referring to document D5, the respondent argued that 5-ASA is a weak base and that the Maillard reaction occurs primarily with strongly basic amines.

However, the authors of document D5 simply observe that the susceptibility to browning caused by the Maillard reaction is proportional to the basic strength of the amine (page 107, left column paragraph "Discussion"). Although this consideration suggests that the amines which are also strong bases react more rapidly with reducing sugars than weakly basic amines, it cannot be concluded from D5 that the Maillard reaction occurs exclusively with amines whose basicity is above a minimum threshold. Such a conclusion would be against the prevailing teaching derivable from the prior art as to the general character of the Maillard reaction, which can potentially take place each time a primary amine is in contact with a reducing sugar (see points 1.6 and 1.7 above).

1.11 As regards the respondent's argument that 5-ASA would be an inhibitor of the Maillard reaction according to the teaching of D7, the following is observed.

Document D7 relates to compositions for inhibiting the degradation of proteins caused by the Maillard reaction (page 2, lines 1 to 6). Said compositions comprise a hydroxybenzoic acid derivative such as 5-ASA (page 4, line 23 and example 4). Although D7 does not clarify

how the hydroxybenzoic acid derivative inhibits protein degradation, the board considers highly plausible the explanation provided by the appellant that this occurs because the hydroxybenzoic acid derivative reacts itself with the reducing sugar, thereby preventing the latter from reacting with the protein. In other words, the hydroxybenzoic acid derivatives such as 5-ASA would avoid or reduce protein degradation because they are faster to react with the reducing sugars in the Maillard reaction.

In any case, independently on the correctness of the explanation provided by the appellant, document D7 does not contain any statement suggesting that the hydroxybenzoic acid derivatives would not react with reducing sugars. Hence, the argument of the respondent is not convincing.

1.12 The respondent also relied on the declaration of Mr Kaczanowski to underline the fact that determining the structure of the degradation product isolated from tablets containing 5-ASA and lactose required a considerable amount of effort.

This fact is not disputed by the board. However, for the reasons discussed above, the board is of the opinion that the skilled person would have been able to foresee the possible mechanism of degradation of tablets containing 5-ASA and lactose and also to prevent it. All this would have been possible even without isolating and identifying the structure of the degradant.

1.13 In view of the above, the board concludes that claim 1 of the main request does not comply with the requirements of Article 56 EPC.

Auxiliary requests 1 to 6 - Admittance into the appeal proceedings

2. Auxiliary requests 1 to 6 were filed by the respondent with letter dated 24 April 2015. These requests are to a large extent based on the requests which were submitted on 1 August 2012 and then withdrawn during the oral proceedings. In particular, claims 1 of auxiliary requests 1 to 4 of 24 April 2015 are identical to claims 1 of previous requests 1, 7, 11 and 9 respectively. Claims 1 of auxiliary requests 5 and 6 of 24 April 2015 are based respectively on claims 1 of previous auxiliary requests 8 and 11 and differ therefrom only in that the sugar is specified as being lactose. The remaining claims of each request do not contain any substantial amendment.

Thus, the new requests do not increase the complexity of the case.

No objections were raised by the appellant against the admittance of the new auxiliary requests.

In consideration of the above circumstances, the board decides to admit auxiliary requests 1 to 6 submitted with letter dated 24 April 2015 into the appeal proceedings (Article 13(1) RPBA).

Auxiliary request 1

3. Inventive step - Claim 1

Claim 1 of this request differs from claim 1 of the main request in indicating:

a) that the concentration of a degradant that may accumulate during storage in the unit dosage form is no more than 0.15% and

b) that the degradant is 5-[2-Formyl-5-(hydroxymethyl)-1H-pyrrol-1-yl]-2-hydroxybenzoic acid.

3.1 For the reasons given above in relation to the main request, the skilled person would try to prevent the formation of degradation products by reducing the humidity. This measure is of general applicability due to the fact that the Maillard reaction is always fostered by humidity level. Hence, independently of the maximum tolerated amount of degradant, the skilled person would always reduce the moisture, for instance by adding a desiccant to the packaging of the pharmaceutical composition.

Accordingly, the introduction of feature a) does not render the subject-matter of claim 1 inventive.

3.2 As to feature b), the board observes that reducing the humidity is a method for preventing a Maillard reaction which is independent of the specific primary amine and the specific reducing sugar involved in the reaction. Thus, the applicability of this method is also independent of the chemical structure of the degradant formed. In other words, since the skilled person seeking to prevent the Maillard reaction would always consider reducing the moisture content of the pharmaceutical composition no matter which degradant would be formed, determining the chemical structure of this compound does not appear to be a necessary step to arrive at the idea of adding a desiccant to the packaging of the pharmaceutical composition (see also point 1.12 above).

3.3 Independently of the above considerations, the board is also of the opinion that identifying the degradant formed by 5-ASA in a Maillard reaction is an activity which does not involve an inventive step.

Documents D8, D9 and D10 are concerned with the identification of the degradation products of the Maillard reaction. The chemical structures reported in Figure 1 of D8 and in Figures 2 of D9 and D10 indicate that the reaction may result in the formation of various products. A degradation product observed in all three documents is a pyrraline derivative, i.e. a molecule containing a 2-formyl-5-(hydroxymethyl)-pyrrole radical. This pyrraline derivative is substituted at the nitrogen atom of the pyrrole by a group which is the organic moiety of the amine participating in the Maillard reaction. For instance, the degradation product formed by β-alanine is the pyrraline derivative substituted at the nitrogen atom of the pyrrole by the organic moiety of the β-alanine (see D10, Figure 2).

3.4 The degradation product mentioned in claim 1 of auxiliary request 1, namely 5-[2-Formyl-5-(hydroxymethyl)-1H-pyrrol-1-yl]-2-hydroxybenzoic acid, is the pyrraline derivative substituted at the nitrogen atom of the pyrrole by the organic moiety of 5-ASA.

In the light of the teaching of D8 to D10, it is no surprise that this product originates from the condensation of 5-ASA with a reducing sugar.

3.5 On that basis, claim 1 of auxiliary request 1 does not meet the requirements of Article 56 EPC.

Auxiliary request 2

4. Inventive step - Claim 1

The claim corresponds to claim 1 of auxiliary request 1 but differs therefrom in indicating that the unit dosage form maintains a moisture content of 1.1% or less.

4.1 As discussed above (see point 1.8), the degradation caused by the Maillard reaction increases with an increase of the level of relative humidity. This knowledge would induce the skilled person faced with the problem of preventing or reducing this reaction to decrease the moisture content of the dosage form. Furthermore, since there is no indication in the prior art that a reduction of the moisture content could have any negative effect on 5-ASA, the skilled person would in principle avoid setting any lower limit to the moisture content. On the contrary, he would try to keep the dosage form as dry as possible. Hence, maintaining the moisture content below a given value, such as 1.1%, does not involve any inventive skill.

4.2 The respondent argued that a moisture content of 1.1% or less was associated with a pronounced effect in terms of reduction of the amount of degradant formed. In this respect reference was made to Figure 3 of the patent, which is a graph relating to the experiment disclosed in example 3. The experiment is a comparison of the amount of degradant formed in identical tablets containing 5-ASA and lactose which were stored in a desiccated chamber or under 75% relative humidity. Figure 3 shows that a higher amount of degradant is formed in the tablets stored under 75% relative humidity.

The board notes that in example 3 it is stated that the desiccated chamber maintains a moisture content of about 1.1% or less while in the undesiccated chamber the moisture content ranges from 1.1% to 1.8%. Thus, for both groups of tablets, the moisture content is not necessarily close to 1.1%. It is therefore at least doubtful whether the experiment of example 3 is evidence for the criticality of the value 1.1%.

4.3 No matter whether a moisture level of 1.1% or less is associated with a particular reduction of the degradation of 5-ASA, the board holds that claim 1 of auxiliary request 2 is not inventive since the teaching of the prior art would anyway encourage the skilled person to reduce the moisture content as much as possible.

4.4 For the above reasons, claim 1 of auxiliary request 2 does not fulfil the requirements of Article 56 EPC.

Auxiliary request 3

5. Inventive step - Claim 1

Claim 1 of this request differs from claim 1 of auxiliary request 1 in indicating that the concentration of the degradant is measured according to a "testing method recognised by the International Conference of Harmonisation of technical requirements for registration of pharmaceuticals" (see point V above).

5.1 The feature introduced in auxiliary request 3 was included also in some of the requests filed by the respondent on 1 August 2012 (see point 2 above). As

explained by the respondent in the statement setting out the grounds of appeal, the introduction of this feature was intended to address an objection made by the appellant which concerned the issue of sufficiency of disclosure.

5.2 In paragraph [0022] of the description, it is stated that the International Conference of Harmonisation (ICH) has issued guidelines concerning stability testing of new drug substances. Thus, the feature introduced in claim 1 specifies that the measurement of the concentration of the degradant can be made by any method, provided that this method is in accordance with the ICH guidelines.

The board holds that the mere fact of specifying that a measurement is made according to a recognised procedure does not make any inventive contribution to the subject-matter of the claim. Nor has the respondent put forward any argument in this respect.

5.3 It follows from the above that claim 1 of auxiliary request 3 does not fulfil the requirements of Article 56 EPC.

Auxiliary requests 4 to 6

6. Inventive step - Claim 1

As indicated in the facts and submissions (see point V above), claims 1 of auxiliary requests 4, 5 and 6 differ from claims 1 of auxiliary requests 1, 2 and 3 respectively in specifying that the reducing sugar is lactose.

6.1 Example VI of document D2a, which represents the starting point for the assessment of inventive step, already discloses a composition comprising 5-ASA and lactose. Thus, limiting the reducing sugar to lactose does not result in any further distinguishing feature of the claimed kit over the disclosure of D2a and therefore it does not change the situation with regard to the assessment of inventive step.

Thus, the subject-matter of claims 1 of auxiliary requests 4 to 6 is obvious having regard to the prior art for the same reasons as explained in the context of auxiliary requests 1 to 3 and does not involve an inventive step within the meaning of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairwoman:

S. Fabiani R. Hauss

Decision electronically authenticated