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Datasheet for the decision of 8 February 2021

Case Number: T 1193/18 - 3.3.07

Application Number: 11711688.9

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IPC: A61K9/08, A61K31/055

Language of the proceedings: EN

Title of invention:
METHOD FOR THE PREPARATON OF A LEVOTHYROXINE SOLUTION

Patent Proprietor:
HELM SWISS GmbH

Opponent:
Uni-Pharma Kleon Tsetis
Pharmaceutical Laboratories S.A.

Headword:
Levothyroxine solution / HELM SWISS

Relevant legal provisions:
EPC Art. 123(2), 83, 54, 56

Keyword:

Novelty - main request, auxiliary requests 1-11 (no) - auxiliary request 18 (yes)
Inventive step - auxiliary requests 12-17 (no) - auxiliary request 18 (yes)
Amendments - auxiliary request 18 - intermediate generalisation (allowable)
Sufficiency of disclosure - auxiliary request 18 - (yes)

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Case Number: T 1193/18 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 8 February 2021

Appellant: (Opponent)	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A. 14th Km, National Road 1 145 64 Kifissia (GR)
Representative:	Wibbelmann, Jobst Wuesthoff & Wuesthoff Patentanwälte PartG mbB Schweigerstrasse 2 81541 München (DE)
Respondent: (Patent Proprietor)	HELM SWISS GmbH Bodmerstrasse 7 8002 Zürich (CH)
Representative:	Wittop Koning, Tom Hugo Biopatents IP Consultancy Parkzoom 3 2614 TC Delft (NL)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 14 March 2018 rejecting the opposition filed against European patent No. 2683361 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	A. Usuelli
Members:	J. Lécaillon
	Y. Podbielski

Summary of Facts and Submissions

I. European patent 2 683 361 (hereinafter "the patent") was granted on the basis of 14 claims. The independent claims of the patent as granted read as follows:

"1. Method for the preparation of an oral levothyroxine composition, comprising the steps of:
a) providing a salt of levothyroxine, preferably the sodium salt of levothyroxine
b) mixing levothyroxine with an aqueous solvent, the aqueous solvent being a mixture of water and a water miscible organic solvent, the water-miscible organic solvent comprising glycerol,
c) adjusting the pH to a pH of at least 8 to yield a basic aqueous solvent, and
d) dissolving the levothyroxine in the basic aqueous solvent to yield a levothyroxine solution, and
e) lowering the pH of the levothyroxine solution to between 5-6."

"12. Oral Levothyroxine composition obtainable using the method according to any of the preceding claims."

II. An opposition was filed against the patent on the grounds that its subject-matter lacked novelty and inventive step and it was not sufficiently disclosed.

III. The opposition division took the decision to reject the opposition.

IV. The decision of the opposition division, posted on 14.03.2018, cited *inter alia* the following documents:

D1: US 2004/0266877

D3: Boulton et al., 1996
D6: Report University of Athens of December 22, 2009
D7: J. of the American Pharmaceutical Association, Vol. XLII, 1953, "pHydroxybenzoic Acid Esters as Preservatives".
D8: Report on stability studies of different levothyroxin solutions, K. Lioumis
D9: Report about Stability of Evotrox

V. The opposition division decided in particular as follows:

(a) The subject-matter of the patent as granted was sufficiently disclosed.

(b) The data provided by the proprietor in D6, D8 and D9 were considered to demonstrate that solutions obtained by a process according to granted claim 1 showed an improved stability in comparison to Evotrox and D3. The present process thus conferred a technical property which distinguished the claimed products from those of the prior art.

(c) Starting from D3 as closest prior art, the skilled person would not have considered performing the present pH variations in order to prepare a levothyroxine solution with improved stability.

VI. The opponent (appellant) lodged an appeal against the above decision of the opposition division.

VII. With its reply to the appellant's statement setting out the grounds of appeal the patent proprietor (respondent) defended its case on the basis of the patent as granted as the main request, and on the basis of auxiliary requests 1-23 filed therewith.

The content of the claims upon which the present decision is based can be illustrated as follows:

Claim 12 of auxiliary request 1 read as follows:
"12. Oral Levothyroxine composition having a pH between 5-6, obtainable using the method according to any of the preceding claims."

Claim 12 of auxiliary request 2 read as follows:
"12. Oral Levothyroxine solution having a pH between 5-6, obtainable using the method according to any of the preceding claims."

Claim 12 of auxiliary request 3 read as follows:
"12. Clear oral Levothyroxine solution having a pH between 5-6, obtainable using the method according to any of the preceding claims."

Claim 12 of auxiliary request 4 read as follows:
"12. Clear oral Levothyroxine solution having a pH between 5-6, obtainable using the method according to any of the preceding claims, the solution being clear after an incubation of 2 months at 40°C."

Claim 12 of auxiliary request 5 read as follows:
"12. Clear oral Levothyroxine solution having a pH between 5-6, obtainable using the method according to any of the preceding claims, the solution being clear after an incubation of 2 months at 40°C when in a concentration of 100 µg in 5 ml."

Claims 12 of auxiliary requests 6 and 7-11 correspond to claims 12 of the main request and auxiliary requests 1-5, respectively, wherein the feature "comprising 40-80w/v% glycerol" was added.

Auxiliary request 12 corresponded to the main request wherein the product-by-process claims 12-14 were deleted.

Auxiliary requests 13-17 corresponded to auxiliary request 12 wherein, in claim 1, the oral levothyroxine composition was amended to:
- "an oral levothyroxine composition having a pH between 5-6" (auxiliary request 13),
- "an oral levothyroxine solution having a pH between 5-6" (auxiliary request 14),
- "a clear oral levothyroxine solution having a pH between 5-6" (auxiliary request 15),
- "an oral levothyroxine solution having a pH between 5-6, the solution being clear after an incubation of 2 months at 40°C" (auxiliary request 16), and
- "an oral levothyroxine solution having a pH between 5-6, the solution being clear after an incubation of 2 months at 40°C when in a concentration of 100µg in 5 ml"(auxiliary request 17).

Auxiliary request 18 corresponds to auxiliary request 12 wherein, in claim 1, the levothyroxine composition was amended to "an oral levothyroxine composition comprising 40-80 w/v% glycerol".

VIII. The following items of evidence were filed by the parties during the appeal proceedings:

(a) Documents filed by the appellant with its statement setting out the grounds of appeal:

D10: Statement of Mr. Loukas dated 27 June 2018 and Experimental Report.

(b) Documents filed by the respondent with its reply to the statement setting out the grounds of appeal:

D11: Report of Mr. Lioumis dated 11 January 2019
D12-D14: Stability report Galenica for samples 1-3
D15: Experimental summary Galenica
D16: Preparation of levothyroxine solutions Galenica
D17: DAZ.online 15 December 2015.

(c) Documents filed by the appellant on 7 November 2019:

D18: Experimental Report accompanying D19
D19: Statement of Mr. Loukas dated 4 November 2019.

(d) Documents filed by the respondent on 19 December 2019:

D20-D22: Stability report Galenica for samples 1-3 including 3 and 6 months stability data
D23: Experimental summary Galenica including 3 and 6 months stability data
D24: Graph of the data of D20-D22.

IX. Oral proceedings were held before the Board on 8 February 2021.

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

XI. The respondent requested that the appeal be dismissed and the patent be maintained as granted, or, as an auxiliary measure, that the patent be maintained on the basis of one of auxiliary requests 1-23 filed with the reply to the grounds of appeal.

XII. The arguments of the appellant, as far as relevant for the present decision, can be summarised as follows:

(a) The process of claim 1 of the main request did not confer to the products obtained thereby an increased stability compared to the products of D3. The product-by-process claim 12 of the main request was thus not novel. The additional features introduced in auxiliary requests 1-11 were already disclosed in D3. Said requests were hence also not novel over D3.

(b) The patent specification did not provide sufficient guidance to prepare oral compositions having the alleged stability and the claims would be unduly broad. The requirements of Article 83 EPC were thus not met.

(c) Starting from the closest prior art D3, the ambitious problem of providing oral compositions with improved stability had not been solved, let alone over the whole scope claimed. Varying the pH was a standard practice and it was known that a lower pH was important when using a preservative. An inventive step could thus not be acknowledged for auxiliary request 12. The additional features introduced in auxiliary requests 13-17 did not further differentiate the claimed subject-matter from D3. Said requests did thus also not involve an inventive step.

(d) The concentration of glycerol introduced in claim 1 of auxiliary request 18 amounted to an unallowable intermediate generalisation of the specific compositions of original Tables I-III.

(e) No improved property compared to the closest prior art had been convincingly shown for processes limited to the glycerol concentration range of present auxiliary request 18. For the same reasons as developed for auxiliary request 12, auxiliary request 18 did thus not involve an inventive step.

XIII. The arguments of the respondent, as far as relevant for the present decision, can be summarised as follows:

(a) The compositions obtained by the process of claim 1 of the main request, in particular through the specific pH variation steps c) and e), had improved long-term stability compared to the prior art solutions lacking said pH variation steps, as shown by the various comparative data provided in D8, D12-D16 and D20-D24. In particular the presently claimed solutions were shown to be stable while D3 reported unstable products. The experiments relied upon by the appellant were based on sub-optimal conditions and even under such sub-optimal conditions an effect of the pH variations would be expected. Claim 12 of the main request was thus novel. The same applied to auxiliary requests 1-11.

(b) The appellant did not provide any experimental data in support of the allegation of lack of sufficiency of disclosure.

(c) The specific pH variation steps c) and e), which constituted the distinguishing features *versus* the closest prior art D3, were shown to result in improved long-term stability. Said effect would occur over the whole scope claimed. None of the prior art documents suggested to perform said pH variations to solve the problem of providing

levothyroxine compositions with improved stability. Auxiliary request 12 did thus involve an inventive step. The same applied to auxiliary requests 13-17.

(d) The concentration of glycerol introduced in claim 1 of auxiliary request 18 was disclosed in original Tables I-III. Hence, the requirements of Article 123(2) EPC were met.

(e) The provision of the process for the production of levothyroxine compositions having improved stability according to auxiliary request 18 was inventive for the same reasons as detailed for auxiliary request 12.

Reasons for the Decision

Main request - Granted patent

1. Novelty

1.1 Claim 12 of the main request is a product-by-process claim. Novelty of such a claim can be acknowledged based on novel process features only if said features cause the claimed product to have different properties from the products previously described. The prior art solutions described in D3 include levothyroxine and glycerol. Said prior art solutions thus have the same product features as the presently claimed solutions. It was undisputed among the parties that the process of claim 1 differs from those of D3 on the basis of the specific pH variations defined in steps c) and e). The issue is thus whether said distinguishing feature of the process leads to a property which may distinguish the claimed products from the solutions of D3.

1.2 The respondent argued that the specific pH variation of the present process provides increased stability to the claimed solutions, in particular upon storage for more than 1 month. According to the respondent this would be experimentally substantiated in particular by D8, comparing sample 1 (according to the patent) and sample 3 (differing from sample 1 only in the pH treatment) as well as by D12-D16 and D20-D24.

1.3 The Board notes that none of the numerous stability tests performed allows for a comparison between on the one hand the solutions of D3 and on the other hand solutions obtained following the process of D3 and only further differing therefrom in that the presently claimed pH variations are performed. Such a comparison is however crucial to appropriately establish an improvement in terms of stability over the products of said prior art due to the pH variation. The examples according to the patent on which the respondent based its argument were indeed prepared under very specific process conditions (amount of levothyroxine, temperature used in the first step, concentration of glycerol, presence of a preservative), which differ from those applied in D3. A comparison of these examples with one according to D3 is therefore not appropriate to demonstrate novelty of the present compositions over D3. In particular sample 4 of D8 (according to D3) and sample 1 of D8 (according to the patent) differ from each other not only in the pH variations performed but also *inter alia* in the levothyroxine and glycerol concentrations. No meaningful comparison of said two samples can thus be made. Similarly the sample 1 of D10 (prepared by the appellant according to D3) has not been compared with a product prepared by a process according to claim 1 with the same levothyroxine and glycerol concentrations.

1.4 It appears furthermore from the experiments of D18-D19 provided by the appellant (see samples T4-D19PE, T4-D1902 and T4-D1903) that at least the concentration of glycerol influences the stability of the levothyroxine solutions. Glycerol seems to play a role in *inter alia* the solubilisation of levothyroxine (see letter of the appellant dated 23 July 2020, page 9, 2nd paragraph and paragraph [0016] of the patent), as seem to do the pH and temperature (see paragraphs [0011] and [0017] of the patent). There is no indication on file that the influence of these parameters could be considered independently from each other. There is therefore no evidence which allows to follow the argument of the respondent that for any given concentration of glycerol, even suboptimal ones, the presently claimed pH variation would necessarily lead to an increased stability.

1.5 Additionally the data reported by each party when repeating the example of D3 (see sample 4 of D8 and sample 1 of D10) reveal that some stability is actually achieved for the solutions of D3. The assertion of the respondent that the products prepared in D3 are unstable is thus not convincing in the present context lacking appropriate comparative data (see above 1.3).

1.6 As a consequence it cannot be concluded that the presently claimed variation of pH applied to the process of D3 would indeed lead to an improved stability of the products. Novelty cannot therefore be acknowledged for the subject-matter of claim 12 of the main request.

Auxiliary requests 1-11

2. Novelty

2.1 The Board considers that the finding of lack of novelty of claim 12 of the main request applies *mutatis mutandis* to auxiliary requests 1-11. The further features introduced in auxiliary requests 1-11 do not constitute structural distinguishing features versus D3, for the following reasons:

(a) The limitation to a final pH of 5-6 (auxiliary requests 1-11), a "(clear) solution" (auxiliary requests 2-5 and 8-11), and/or to a glycerol concentration of 40-80w/v% (auxiliary requests 6-11) cannot further distinguish the claimed products from those of D3. D3 indeed describes solutions having a final pH of 5.4 (see page 1160, 1st column, 3rd paragraph), being clear (page 1158, 1st column, 4th paragraph) and containing 40% v/v glycerol (i.e. around 50w/v% glycerol; see page 1160, 2nd column. last paragraph).

(b) The further specification of the conditions under which the claimed solutions shall be clear (auxiliary request 4-5 and 10-11) define a parameter not disclosed in D3. There is however no evidence that this parameter would not be achieved by the solutions of D3 described as being clear.

2.2 The respondent did not provide any specific argument on how these features would overcome the lack of novelty finding for the main request.

2.3 Accordingly, auxiliary requests 1-11 do not fulfill the requirements of Article 54 EPC.

Auxiliary request 12

3. Amendments and novelty

Auxiliary request 12 is limited to the process claims as granted (deletion of the product-by-process claims). The ground for opposition according to Article 100(c) EPC had not been raised by the appellant and no objection of lack of novelty was raised for these process claims.

4. Sufficiency of disclosure

4.1 Claim 1 of auxiliary request 12 defines a process for the preparation of levothyroxine compositions comprising 5 specific steps (steps a) to e)).

4.2 The Board notes that the patent specification provides a detailed description of one general way of performing the process of claim 1.

4.3 The appellant mainly based its line of argument on the lack of guidance to prepare products via said process which would achieve the alleged stability. The Board does not share this view. Improved stability is not a feature of any claim of auxiliary request 12, so that the achievement of said effect, and thus the presence of features potentially essential to its achievement, is not an issue of sufficiency of disclosure.

4.4 Finally the appellant also raised the issue of the breadth of the claims. The Board observes that the mere fact that a claim is broad is not in itself a ground for considering that the patent does not comply with the requirements of sufficiency of disclosure. In the present case there does not appear to be any evidence

supporting the fact that the skilled person could not carry out the claimed process.

4.5 Hence auxiliary request 12 fulfills the requirements of Article 83 EPC.

5. Inventive step

5.1 In agreement with both parties, the Board considers D3 to represent the closest prior art.

D3 discloses the preparation of solutions comprising levothyroxine originating from tablets or from powders (see pages 1158-1159 paragraphs "Methods - Solution preparation and storage", "Methods - Drug assay", and Table 1). The formulations contain levothyroxine sodium, water, glycerol and optionally methylparaben (preservative). Levothyroxine powder (directly as powder or after grounding of tablets) was triturated with glycerol. Water and optionally the preservative were added. There is no mention of any step of pH modification. Merely the apparent pH of the formulations was measured as being 6.7 and 5.4 for tablet- and powder-based formulations without preservative and 6.3 and 4.9 for tablet- and powder-based formulations with preservative (see page 1160, left-hand column).

5.2 The parties agreed that the process of claim 1 of auxiliary request 12 differs from the one of D3 in the pH variations performed in steps c) and e).

5.3 The main point of dispute concerned the presence of a technical effect linked to said distinguishing feature compared to the closest prior art and in its occurrence over the whole scope of the claim.

Following the same reasoning as developed for the novelty of the product-by-process claims, the respondent was of the opinion that the specific pH treatment conferred an improved stability to the obtained solutions, in particular upon storage for more than 1 month (see 1.2).

As already stated in the context of novelty of the main request (see 1.3-1.5), none of the various experimental data on file provides a direct comparison with a process according to D3 and an effect on stability has only been substantiated under specific conditions, in particular a specific glycerol concentration. The experiments on file repeating the process of D3 do furthermore not allow to conclude that the products of D3 are generally unstable (see sample 4 of D8 and sample 1 of D10). Moreover the appellant has provided examples of compositions prepared according to a process falling under the scope of the claims and having a poor stability (see samples T4-D1903 and T4-D1908 in D18/D19). The argument of the respondent that these experiments of D18 would not be relevant, because they were performed at the border of the claimed scope *i.e.* under sub-optimal conditions, is not convincing as these examples do fall under the scope of the claims.

Regarding the substantiation of the presence or absence of an effect over the whole breadth of the claims, the Board notes that while the appellant has not performed a direct comparison with the process of the closest prior art, it has nevertheless substantiated that processes falling under the claims lead to a poor stability. On the other hand, the results of the respondent in D15 and D23 obtained under specific conditions cannot be extrapolated to the entire scope

of the claims (as detailed previously, see 1.4), let alone the conditions used in D3.

The Board is consequently of the opinion that no effect on stability has been substantiated compared to the closest prior art D3, let alone over the whole scope claimed.

5.4 It follows that, starting from D3, the objective technical problem to be solved by the process of claim 1 of auxiliary request 12 lies in the provision of a further process for the preparation of an oral levothyroxine composition.

5.5 According to the respondent there would be no motivation in the prior art to lower the pH once it had reached a higher level to solve the problem posed. The prior art would rather teach to maintain the pH.

The Board notes that the final pH of some of the solutions of D3 falls under the pH defined in present step e). Furthermore, as mentioned by the opposition division under point 4.4 of its decision, dissolving levothyroxine under basic conditions in water and glycerol is disclosed in the examples of D1. The importance of pH when preparing levothyroxine appears thus to be known to the skilled person. This finds confirmation in the closest prior art itself (see D3, first paragraph of the chapter "Discussion"). It follows that modifying the pH, *inter alia* as in present steps c) and e), is considered as one of several known options which the skilled person willing to solve the problem posed would have considered. In the absence of any particular effect, the Board is therefore of the opinion that the solution offered in claim 1 of auxiliary request 12 is obvious for the skilled person.

5.6 As a result, auxiliary request 12 does not fulfill the requirements of Article 56 EPC.

Auxiliary requests 13-17

6. Inventive step

6.1 The features introduced in auxiliary requests 13-17, namely a final pH of 5-6 (auxiliary requests 13-17), a (clear) solution (auxiliary requests 14-17), specific conditions under which the solution shall be clear (auxiliary requests 16-17) do not introduce any further difference *versus* the closest prior art D3, as already detailed above (see 2.1). Consequently, the reasoning developed for auxiliary request 12 applies *mutatis mutandis* to the present auxiliary requests 13-17.

6.2 The respondent did not provide any specific argument on how these features would overcome the finding of lack of inventiveness for auxiliary request 12.

6.3 Accordingly, auxiliary requests 13-17 do not fulfill the requirements of Article 56 EPC.

Auxiliary request 18

7. Amendments

7.1 The feature "comprising 40-80 w/v% glycerol" was introduced in claim 1 of auxiliary request 18. The respondent cited as basis for this feature the original tables I-III.

7.2 The appellant objected that said tables disclosed the glycerol concentration range in the context of specific

compositions (specific further components in specific amounts). The disclosure of the concentration of glycerol in said tables could therefore not be extrapolated to the preparation of any composition according to claim 1.

7.3 The Board does not share this view and is of the opinion that the claimed range of glycerol concentration is directly and unambiguously derivable from the original application as the preferred range therefor. Tables I-III do indeed not relate to individual specific compositions. They rather generally disclose possible compositions for a levothyroxine dose of 25, 50 or 100 mg, respectively. In all three tables the range of glycerol concentration remains identical, namely 40-80w/v%. Moreover the skilled person would have learned from the original application as a whole that the other components listed in said tables are not inextricably linked to glycerol and its concentration. Citric acid and sodium hydroxide are indeed pH adjusting agents, meaning that their amount is conditioned by the desired pH (see original page 4 lines 6-27), and Nipagin M sodium is a preservative described as optional in the original application (see original claims and original page 5, 3rd paragraph).

7.4 The subject-matter of auxiliary request 18 consequently fulfills the requirements of Article 123(2) EPC.

8. Sufficiency of disclosure and novelty

As detailed for auxiliary request 12, no objection of lack of novelty was raised for the process claims. Regarding sufficiency of disclosure the appellant did not provide further arguments directed to auxiliary request 18. The reasoning provided for auxiliary

request 12 therefore applies *mutatis mutandis* to auxiliary request 18, which thus meets the requirements of Article 83 and 54 EPC.

9. Inventive step

9.1 As detailed above for auxiliary request 12, the closest prior art is considered to be D3. As 40% v/v (i.e. around 50 w/v%) glycerol is used in D3, the feature introduced in auxiliary request 18 does not further distinguish the claimed subject-matter from D3. The process of present claim 1 thus still differs from the one of D3 in the pH variations performed in steps c) and e).

9.2 As previously noted, none of the numerous stability tests performed allows for a comparison between on the one hand the process of D3 and on the other hand solutions obtained following the process of D3 and only further differing therefrom in that the presently claimed pH variations are performed. In particular sample 4 of D8 (prepared by the respondent according to D3) and sample 1 of D8 (according to the patent) differ from each other not only in the pH variations performed but also *inter alia* in the levothyroxine and glycerol concentrations. Similarly the sample 1 of D10 (prepared by the appellant according to D3) has not been compared with a product prepared by a process according to claim 1 with the same levothyroxine and glycerol concentrations. In the absence of such a direct comparison with the process of D3, *i.e.* wherein the sole difference would be the present distinguishing feature, no improvement over the closest prior art D3 can be acknowledged.

However, in present auxiliary request 18, the process has been limited to a specific range of glycerol concentration. The data provided in D15 and D23 show that a good stability upon storage is achieved when carrying out the present process within said glycerol concentration range. In particular the samples T4-D1903 and T4-D1908 of D18/D19 (having poor stability) do no longer fall under the scope of the claims (glycerol concentration below the present range). In view of all the experimental data provided by the parties, the Board considers that this effect can furthermore be extrapolated to the entire claimed scope, given that all the examples on file which fall under the present scope exhibit good stability data.

Hence, even if there is no evidence of an improvement over D3, the achievement of a good storage stability remains a property of the present process which cannot be ignored.

9.3 It follows that, starting from D3, the objective technical problem to be solved by the process of claim 1 of auxiliary request 18 lies in the provision of an alternative process for the preparation of oral levothyroxine compositions having good storage stability.

9.4 The Board considers that this problem has been solved by the claimed process (see 9.2).

9.5 As noted under point 4.4 of the first instance decision, the use of a basic pH for dissolving levothyroxine is known in the prior art (see D1, examples and claim 1, pH between 9-10). D3 furthermore describes solutions having a final pH in the presently claimed range of step e). Stability issues upon storage

of levothyroxine solutions appear however to be commonly known (see for example D1 paragraph [0004], D1 paragraph [0004], patent in suit paragraph [0008]). Modifying the pH could appear as a known option when looking for an alternative process, without any particular concern as to the storage stability of the final levothyroxine composition. However, in the Board's view, the skilled person could not have predicted that, starting from the process of D3, solutions maintaining good stability upon storage could be obtained by using a pH of at least 8 in the step corresponding to present step c) and then lowering the pH to between 5 and 6 in a final step. Therefore, when faced with the technical problem defined in point 9.3 above, he would have not modified the process of D3 by performing the pH variations defined in steps c) and e) of claim 1.

The appellant argued that D7 would suggest lowering the pH for solutions containing Nipagin sodium, which is the preservative used in the present examples. The Board cannot follow this argument. Neither nipagin sodium nor any preservative is a feature of claim 1 of auxiliary request 18. Furthermore D7 does not concern the preparation of levothyroxine solutions, so that D7 cannot provide a hint to perform the present steps c) and e) to stabilize a levothyroxine solution.

9.6 As a result, auxiliary request 18 fulfills the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

The decision under appeal is set aside.

The case is remitted to the opposition division with the order to maintain the patent with the following claims and a description to be adapted thereto:

Claims 1-11 according to auxiliary request 18 filed with the letter dated 16 January 2019.

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated