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Datasheet for the decision of 24 February 2015

Case Number: T 0367/11 - 3.3.07

Application Number: 01927763.1

Publication Number: 1267844

IPC: A61K9/50, A23L1/302, A23L1/303

Language of the proceedings: EN

Title of invention:
SUSTAINED RELEASE VITAMIN COMPOSITION

Patent Proprietor:
Omega Pharma NV
allphamed Pharbil Arzneimittel GmbH

Opponent:
Krüger GmbH & Co. KG

Headword:

Relevant legal provisions:
EPC Art. 113, 123(2), 83, 84, 54, 56
RPBA Art. 12(1), 12(4)

Keyword:
Admissibility of documents filed during opposition proceedings - yes
Amendments - added subject-matter (no)
Claims - clarity (yes)
Sufficiency of disclosure - (yes)
Novelty - (yes)
Inventive step - (yes)

Decisions cited:

Catchword:

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Beschwerdekammern
Boards of Appeal
Chambres de recours

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 0367/11 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 24 February 2015

Appellant: (Opponent)	Krüger GmbH & Co. KG Senefelderstr. 44 D-51469 BERGISCH GLADBACH (DE)
Representative:	Von Rohr Patentanwälte Partnerschaft mbB Rüttenscheider Straße 62 45130 Essen (DE)
Respondent: (Patent Proprietor 1)	Omega Pharma NV Venecoweg 26 9810 Nazareth (BE)
Respondent: (Patent Proprietor 2)	allphamed Pharbil Arzneimittel GmbH Hildebrandstrasse 12 37081 Göttingen (DE)
Representative:	Brantsandpatents bvba Pauline Van Pottelsberghelaan 24 9051 Ghent (BE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 23 December 2010 concerning maintenance of the European Patent No. 1267844 in amended form.**

Composition of the Board:

Chairman	J. Riolo
Members:	A. Usuelli
	P. Schmitz

Summary of Facts and Submissions

I. The appeal of the opponent (appellant) lies from the decision of the opposition division concerning the maintenance of European patent No. 1 267 844 in amended form.

II. The patent had been opposed under Article 100(a), (b) and (c) EPC on the grounds that its subject-matter lacked novelty and inventive step, the invention was not sufficiently disclosed and its subject-matter extended beyond the content of the application as filed. The documents filed during opposition proceedings included the following:

D1: EP 208 362
D6: EP 630 646
D8: EP 239 361
D15: US 2,928,770
D16: DE 1 949 894
D24: Technical report of Stefan Heim
D25a: Römpp Lexicon Chemie, 9. Auflage, 1992, 4018-4019
D25d: Internet-link, Wikipedia, Shellac

III. The opposition division's decision was based on the granted patent as main request and on a set of claims filed on 11 August 2010 as auxiliary request 2. A set of claims named auxiliary request 1, filed together with auxiliary request 2, was withdrawn during the oral proceedings.

IV. The relevant request to be considered in the context of the present decision is auxiliary request 2. Claim 1 of this request read as follows:

"1. A therapeutic formulation in the form of a beadlet suitable for oral administration from which medicament is released at controlled rates, the beadlet comprising:

a) an extruded-spheronized inner core containing modified release medicament selected from one or more vitamins, trace elements, minerals or mixtures thereof; and further comprising Vitamin C

b) an outer layer containing immediate release medicament selected from one or more vitamins, trace elements, minerals or mixtures thereof;

c) a pharmaceutically acceptable controlled-release shellac coating between the inner core and the outer layer, which coating controls the release of the inner core modified release medicament and;

d) a second coating between the inner core and the pharmaceutically acceptable controlled-release shellac coating."

V. The opposition division's decision may be summarised as follows:

a) Documents D25a to D25g, submitted by the opponent on 1 September 2010, were not admissible in that they were late-filed and did not represent *prima facie* relevant background art.

b) Document D24 represented a response by the patentee to the remarks made by the opposition division in the preliminary opinion. The experiments described in this document were *prima*

facie relevant, and therefore D24 was to be admitted into the proceedings.

c) Claim 1 of the patent as granted did not comply with the requirements of Article 56 EPC.

d) Document D1 was the closest prior art for the assessment of inventive step of auxiliary request 2. The subject-matter of claim 1 of that request differed from the disclosure of D1 in that it comprised a shellac coating and a further coating between the inner core and the controlled-release coating. The technical report D24 showed that the further coating had the effect of stabilising the formulations. The technical problem was therefore the provision of an improved beadlet composition. The prior art did not suggest the introduction of an additional coating between the inner core and the controlled-release coating. The subject-matter of auxiliary request 2 was therefore inventive.

VI. The appellant lodged an appeal against that decision. In the statement setting out the grounds of appeal submitted on 18 April 2011 he requested that the opposition division's decision be set aside and that the patent be revoked.

VII. The patent proprietor (respondent) replied to the grounds of appeal with a letter sent on 4 November 2011 in which he requested that the appeal be dismissed. With the same letter he submitted three sets of claims as auxiliary requests 1 to 3.

VIII. On 28 January 2015 the respondent informed the board that he would not attend the oral proceedings.

IX. Oral proceedings were held before the board on 24 February 2015.

X. As far as relevant for the present decision, the appellant's arguments may be summarised as follows:

a) *Admissibility of documents D24 and D25a-D25g*

Document D24 submitted by the respondent during the opposition proceedings should not be admitted in the appeal proceedings. The opposition division was wrong to admit this document because it was filed only one month before the oral proceedings and the experiments disclosed therein were not technically relevant, in that the composition used for the comparative test was not a composition disclosed in the closest prior art. Moreover, the admission of D24 into the opposition proceedings constituted a violation of the appellant's right to be heard because the time remaining before the hearing was not sufficient to allow him to verify the experiments described in the document by repeating them and possibly to perform his own tests.

Documents D25a to D25g were submitted by the appellant during the opposition proceedings as a reaction to the filing of document D24. These documents should be admitted into the appeal proceedings.

b) *Main request (auxiliary request 2 in opposition proceedings)*

Article 123(2) EPC

Claim 1 derived from the introduction into original claim 1 of various features disclosed in original claims 2, 7, 11 and 12. However, the original

application did not provide a disclosure of the combination of the features included in claim 1. Additional deficiencies under Article 123(2) EPC were brought about by the deletion of the expression "at least" in original claim 1, the introduction of the feature "and further comprising Vitamin C" and the modification of the expression "coating is shellac" to "shellac coating".

Clarity and sufficiency of disclosure

Claim 1 contained various unclear features such as "controlled release", "released at controlled rates" and "immediate release medicament". Moreover, the description did not provide the skilled person with sufficient instructions to carry out the invention over the whole scope of the claim, in particular with regard to the breadth of certain features such as "pharmaceutically acceptable controlled-release coating". Furthermore, the patent did not provide information concerning the amount of active ingredient to be included in the formulations.

Novelty

The subject-matter of claim 1 was not novel in view of the disclosures of documents D6, D15 and D16.

Document D6 related to a controlled-release dosage form comprising a solid substrate with an active agent and a coating comprising ethylcellulose. The substrate could be in the form of beadlets containing various ingredients, including vitamins. An additional coating could be present between the substrate and the controlled-release layer. In a preferred embodiment, an

additional dose of active ingredient could be included in an outer layer.

Document D15 disclosed pills containing a core and a plurality of layers. Shellac was mentioned as a suitable material for the coatings.

Document D16 related to controlled-release tablets containing vitamin C as possible active ingredient. These tablets could also comprise a coating containing shellac.

Inventive step

The closest prior art D1 related to dietary supplement compositions consisting of a core containing calcium and optionally vitamin C. Said core was surrounded by a delayed-release coating and a further coating containing iron. Furthermore, an outer additional layer could optionally be present. The compositions of the patent in suit differed from the compositions of D1 in the use of shellac as material for the controlled-release coating and in the sequence of the iron coating and of the optional coating. The use of shellac in the formulation according to the opposed patent and the presence of a second coating between the inner core and the shellac layer were not associated with any particular effect. Hence, the technical problem was to be formulated as the provision of an alternative composition containing vitamin C. Documents D25a to D25e indicated that shellac was commonly used in the preparation of controlled-release coatings. Further formulations containing shellac coatings were disclosed in D6, D15 and D16. Accordingly, it would have been obvious for the skilled person to use shellac as material for the outer optional layer in the

compositions of D1. Furthermore, since the technical problem was the mere provision of an alternative composition, the skilled person would have also considered switching the position of the iron layer with the position of the outer coating in the formulation of D1. These obvious modifications of the formulation of D1 would have led to the formulation according to claim 1 of the patent in suit.

As an alternative approach, document D8 could be regarded as the closest prior art. This document disclosed a controlled-release composition consisting of a core coated with two layers. Shellac was explicitly mentioned as material for the outer layer. The formulations of D8 did not include an outer layer containing an immediate-release medicament. However, the addition of such a layer was suggested by D1. Hence, the combination of the teachings of D8 and D1 rendered the subject-matter of claim 1 of the patent in suit obvious.

XI. As far as relevant for the present decision, the respondent's written arguments may be summarised as follows:

a) *Admissibility of documents D24 and D25a-D25g*

Document D24 was filed in response to observations made by the opposition division in its preliminary opinion. It was submitted before expiry of the one-month deadline prior to oral proceedings. The experiments disclosed in D24 provided evidence of an effect disclosed in the application as filed. The opposition division's decision to admit this document was therefore correct. Furthermore, the opposition division

was also correct in deciding not to admit documents D25a to D25g.

b) *Main request (auxiliary request 2 in opposition proceedings)*

Article 123(2) EPC

Original claim 13 provided the basis for the introduction of the feature "...further comprising vitamin C" in claim 1. The requirements of Article 123(2) EPC were therefore met.

Clarity and sufficiency of disclosure

The term "pharmaceutically acceptable controlled-release coating" was well understood in the art. In addition a definition of this expression was provided at paragraph [0023] of the patent. Details of the nature of the second coating were given in paragraph [0025] of the patent. As to the amounts of the medicaments, information was given in paragraph [0022] and in example 1.

Novelty

The subject-matter of the claims was not anticipated by the disclosures of documents D6, D15 and D16 for the following reasons:

There was no disclosure in D6 of an extruded-spheronised inner core containing a modified-release medicament as defined in feature a) of claim 1 of the opposed patent. Furthermore, there was no clear and unambiguous disclosure of an outer layer containing

immediate-release medicament as defined in feature b) of claim 1.

Likewise document D6, and also document D15, did not provide an unambiguous disclosure of a formulation having the features a) and b) of claim 1 of the opposed patent.

The formulations disclosed in D16 were not characterised by the same sequence of layers as claimed in the patent, namely a core, a second coating, a controlled-release coating and an outer layer.

Inventive step

Document D1, identified as the closest prior art by the opposition division, related to a dietary supplement containing iron and enterically coated calcium. The presence of vitamins and other minerals was also envisaged. Taking D1 alone or in combination with the other cited documents, there was no guidance to the person skilled in the art to select shellac in combination with the active ingredients mentioned in claim 1 and with a further coating between the inner core and the controlled-release coating. The requirements of Article 56 were therefore met.

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

XIII. The respondent requested in writing that the appeal be dismissed, or alternatively that the patent be maintained on the basis of one of auxiliary requests 1 to 3 filed with the letter dated 4 November 2011.

Reasons for the Decision

Admissibility of documents D24 and D25a-D25g

1.1 Document D24 is an experimental report submitted during the opposition proceedings by the respondent on 11 August 2010, i.e. about one month before the oral proceedings held on 14 September 2010. This document was admitted into the proceedings by the opposition division since it was regarded as *prima facie* relevant for the assessment of inventive step. In its reasoning the opposition division observed also that the experiments disclosed in D24 addressed the inventive step issues raised by the division itself.

The opposition division referred therefore to a relevant criterion for the admissibility of a late submitted document, namely its *prima facie* relevance. Furthermore, it took into account the fact that document D24 was filed as a reaction to some observations made by the division in its communication.

The board therefore holds that the opposition division exercised its discretion on the basis of the relevant facts, according to the right principle and in a reasonable way.

It follows from the above, that D24 is a document forming part of the basis of appeal proceedings pursuant to Articles 12(1) and 12(4) RPBA. The board sees therefore no reason to exclude this document from the appeal proceedings.

1.2 Documents D25a to D25g were not admitted into the opposition proceedings since they were late-filed and were not regarded as *prima facie* relevant.

In the context of the appeal proceedings these documents are no longer to be regarded as late-submitted. Furthermore, their submission during the opposition proceedings represented a reaction on the appellant's part to the filing of document D24. In the light of these considerations, the board in the exercise of its discretion considers it appropriate to admit documents D25a to D25g into the appeal proceedings.

Right to be heard

2. In the context of his request not to admit document D24 in appeal proceedings, the appellant argued that the admission of this document during the opposition proceedings resulted in a violation of his right to be heard under Article 113 EPC. In particular, he remarked that since the document was submitted shortly before the oral hearing, there was no time for him to verify the experiments described in D24 by repeating them and possibly to perform its own tests.

2.1 The board notes in this respect that during the opposition proceedings the appellant has never expressed a clear intention to repeat the experiments of D24 or to carry out other tests. There is also no indication on file that during the first instance proceedings the appellant requested a postponement of the oral proceedings in order to have more time to react to the filing of document D24. Indeed it is to be remarked that the appellant has never submitted the results of its own experiments, not even during the appeal proceedings. If he had whished to present such experiments, he could have done so. There was no need to wait for an invitation by the board, if he considered this to be of relevance.

2.2 In addition, the board agrees with the remark made by the respondent that the experiments disclosed in D24 provided an evidence of an effect which was disclosed on page 9, lines 9 to 22, of the application as filed. Hence, the results of the experiments of D24 were no surprise to the appellant.

Under these circumstances it is considered that no violation of the right to be heard of the appellant has occurred.

Main request

3. Article 123(2) EPC

3.1 Claim 1 of the main request derives from the incorporation in claim 1 as originally filed of features disclosed in original claims 2, 13, 7, 11 and 12. In particular:

(a) The presence of one or more vitamins, trace elements, minerals or mixtures thereof in the inner core (feature a)) is supported by the disclosure of original claim 2, which depends on claim 1. The incorporation in claim 1 of the wording "one or more", disclosed in original claim 2, renders the words "at least one" redundant. The deletion of these words therefore does not result in any additional information.

(b) The feature "and further comprising Vitamin C" (feature a)) finds support in original claim 13, which depends on claims 1 to 12 and recites "wherein the modified release medicament comprises a water-soluble vitamin(s) comprising Vitamin C". The wording of original claim 13, and in

particular the use of the expression "vitamin(s)" (emphasis added), indicates in the board's opinion that in addition to vitamin C other vitamins are optionally present in the inner core. Furthermore, since original claim 13 also depends on claim 2, further vitamins, not necessarily water-soluble, may also be present in the inner core. Although a different wording is used, claim 1 of the main request likewise indicates that vitamin C may be present in the inner core, as the sole vitamin or together with other vitamins.

(c) The list of active ingredients included in the outer layer (feature b)) is disclosed in original claim 7, which depends on original claim 1. As already discussed in point (a) above, the incorporation of the wording "one or more", disclosed in original claim 7, renders the words "at least one" redundant.

(d) The expression "shellac coating" (feature c)) finds support in original claim 11, which recites "coating is shellac". The board agrees with the opposition division's decision that the different wording used in claim 1 and original claim 11 does not imply any difference in meaning. Furthermore, the wording "shellac coating" (or "shellac coat") is also used in the original application (see page 9, line 17, and page 14, line 3).

(e) Feature d) of claim 1 finds support in original claim 12, which depends on claim 1.

3.2 Concerning feature a), the wording "...selected from one or more..." in combination with "...further comprising Vitamin C..." indicates that the inner core

contains at least two ingredients, one of them being vitamin C. The information that the core contains two or more ingredients is fully supported by original claim 1, which required the presence in the inner core of "at least one" medicament. The wording of claim 1 of the main request excludes the possibility comprised in the original claim of a core containing a single active ingredient.

3.3 The features introduced in claim 1 represent preferred embodiments of the invention. In particular, the active ingredients recited in features a) and b) are described as the preferred medicaments on page 6, lines 14 to 17. The use of shellac as a preferred controlled-release coating is disclosed on page 8, line 23. On page 9, lines 14 to 17, it is indicated that the presence of a further coating (feature d)) is especially preferred when the inner core comprises vitamin C and the controlled-release coating is shellac.

Accordingly, the amendments introduced in original claim 1 reflect the core of the invention, as described in the preferred embodiments of the original application. Therefore the combination of the features included in claim 1 does not amount to the introduction of subject matter extending beyond the content of the application as filed.

3.4 In the light of the above, the board concludes that the amendments introduced in the main request comply with the requirements of Article 123(2) EPC.

4. Article 84 EPC

The objections raised by the appellant concern the clarity of the expressions "controlled-release",

"released at controlled rates" and "immediate release medicament", which are included in claim 1.

The board notes that these expressions were also present in claim 1 as granted, and the appellant did not clarify whether and how the issues of clarity arise from the amendments introduced in claim 1.

Independently of the above, it is considered that the expressions objected to by the appellant are commonly used in the field of formulation technology, as can be seen for instance from document D6 (see e.g. examples 27 to 29). The mere observation that these expressions may cover broad subject-matter is not *per se* a reason that could justify a conclusion of lack of clarity.

Therefore the requirements of Article 84 EPC are met.

5. Article 100(b) EPC

A general procedure for preparing the claimed formulations is illustrated in paragraph [0027] of the patent. This passage provides information on the preparation of the inner core and on the procedures for applying the coatings. Examples 1 and 2 specifically relate to the preparation of formulations in which the controlled-release coating comprises shellac.

As to the appellant's argument concerning the absence of information on the amount of active ingredient to be included in the formulations, it is observed that some indications in this respect are provided in paragraph [0018] of the patent and in the examples. Furthermore, the board considers that the skilled person would be able to retrieve information concerning the dosage of specific active ingredients.

In the absence of any corroborating evidence from the appellant which might support his objection under Article 100(b) EPC, the board concludes that the information contained in the description of the patent would enable the skilled person to carry out the claimed invention.

Therefore the requirement of sufficiency of disclosure is met.

6. Article 54 EPC

6.1 Claim 1 has been objected to under Article 54 EPC in view of the disclosures of documents D6, D15 and D16.

The subject-matter of claim 1 of the main request relates to a formulation suitable for oral administration in the form of a beadlet. Moving from the core to the outer layer, the beadlet comprises:

- an inner core containing a modified release medicament which comprises vitamin C (feature a) of claim 1).
- a coating (defined as "second coating" in claim 1) which is in contact with the inner core (feature d) of claim 1)
- a controlled-release shellac coating which is in contact with the "second coating" (feature c) of claim 1)
- an outer layer containing an immediate release medicament which is in contact with the shellac coating (feature b) of claim 1)

6.1.1 Document D6 discloses controlled-release dosage forms comprising a solid substrate containing an active

ingredient which is coated with a controlled-release layer comprising ethylcellulose (see claim 1). The substrate can include a wide variety of active agents comprising vitamins (page 10, lines 37 to 52). However, no mention at all is made in D6 of vitamin C (see feature a) of claim 1). For this reason alone, claim 1 is novel over this document. Shellac is mentioned as a possible component of the controlled-release coating (page 9, lines 41 to 45). However, D6 does not disclose any composition combining the presence of any vitamin and a shellac coating.

6.1.2 Document D15 relates to sustained-action pills comprising a plurality of medicament layers and control membranes (see claim 1). Vitamin C and shellac are mentioned respectively as a suitable medicament (column 8, lines 58, 59) and as a component of the coating membrane (column 5, line 60). This document does not disclose any composition containing an inner core comprising vitamin C, a shellac layer and an additional coating between the inner core and the shellac layer (see features a), c) and d) of claim 1).

6.1.3 The compositions disclosed in document D16 comprise an active ingredient and a hydrophilic acrylate or methacrylate polymer (claim 1). Vitamin C is mentioned on page 9 as a possible active ingredient. According to a specific embodiment disclosed on page 13 (lines 1 to 7) and Figure 5, the composition is in the form of a tablet which comprises an outer coating that may contain shellac. However, this document does not disclose any composition comprising in combination vitamin C and a shellac coating (features a) and c) of claim 1).

6.2 It follows from the above that none of the documents considered by the appellant to be novelty-destroying for the subject-matter of the main request discloses formulations having the features defined in claim 1.

Accordingly, the subject-matter of the main request meets the requirement of novelty.

7. Article 56 EPC

7.1 The invention relates to therapeutic formulations designed to release medicaments at different rates after ingestion, those medicaments being selected from vitamins, trace elements, minerals and mixtures thereof (paragraphs [0001] and [0008]). The formulations are in the form of beadlets comprising an extruded-spheronised inner core and three layers. The active ingredients are included in the inner core and in the outer layer.

Closest prior art

7.2 The board agrees with the opposition division and with the parties that document D1 represents the closest prior art. This document discloses a dietary supplement which comprises a calcium source surrounded by a delayed-release coating and an iron source (page 5, lines 13 to 21). The composition may further include additional ingredients such as vitamins, including vitamin C, and other minerals (page 11, lines 1 to 11). The supplement can take the form of calcium-containing granules, which can be prepared by a process of extrusion and spheronisation and which are coated by a delayed-release material. The iron source is preferably adhered to the exterior surface of the delayed release coating (page 11, lines 20 to 28). Optionally, a

protective layer can be coated onto the iron source (page 12, lines 14 to 18).

The board concurs with the opposition division's finding that the beadlet defined in claim 1 of the patent in suit differs from the formulation disclosed in D1 on account of the shellac coating (feature c)) and on account of the presence of a "second coating", i.e. the layer between the inner core and the controlled-release coating (feature d)).

7.3 According to an alternative approach, the appellant selected D8 as the closest prior art. This document relates to sustained-release pharmaceutical preparations which preferably comprise as active ingredient aspirin, acetaminophene, dextromethorphan, disopyramide and furosemide (see claims 1 and 4 and the example).

However document D8 does not address the problem of providing compositions for the sustained release of vitamins, minerals and trace elements. Furthermore, the formulations of D8 do not contain an extruded-spheronised inner core and an outer layer containing medicaments. Hence, D8 is not an appropriate starting point

Technical problem

7.4 The patent focuses on the problem of providing controlled-release formulations containing vitamins and minerals. A further problem addressed by the patent concerns the stability of formulations containing vitamin C in the inner core (see [0025]).

7.5 In relation to the issue of stability of the formulations, during the opposition proceedings the patentee submitted document D24. This document relates to an experimental study comparing three different products comprising granules having an extruded-spheronised core containing vitamin C.

Products 2 and 3 are formulations according to claim 1 of the disputed patent. The core of these formulations is coated with three layers consisting of an intermediate "second coating" surrounding the core, a shellac controlled-release coating and an outer layer containing vitamin B and talc. Vitamin B is also contained in the inner core of the formulations, in addition to vitamin C.

Product 1 is a comparative formulation consisting of an inner core containing vitamin C coated with a controlled-release shellac coating.

The three formulations were tested in an experiment consisting in measuring the dissolution of vitamin C after 2, 4 or 6 hours. For each formulation the measurements were made before storage, and after periods of storage of various duration (e.g three months, six months, etc.).

The results for comparative product 1 show that the dissolution profile of vitamin C is very unstable. For instance, the measurements made after 2 hours indicate that the dissolution of vitamin C in a product stored for three months is between around 70% and 80% of the dissolution measured for a product which was not stored. In products stored for 6 or 9 months, the dissolution of vitamin C is higher compared to the dissolution determined for products stored for 3

months. However, dissolution falls when the products are stored for more than 9 months.

The same irregular dissolution profile for product 1 is observed when the dissolution of vitamin C is determined after 4 or 6 hours.

In contrast, the data relating to products 2 and 3 for measurements made after 2, 4 or 6 hours indicates that the dissolution of vitamin C remains relatively constant during storage. For instance, the dissolutions after 2 hours of samples of products 2 and 3 stored for 3, 6 or 9 months differ from the dissolution of a sample which was not stored by less than 5%.

7.6 The results disclosed in D24 allow the following observations to be made:

(a) Products containing a shellac coating in contact with a core containing vitamin C suffer from problems of stability when stored for at least three months. These problems result in an irregular dissolution profile for vitamin C.

(b) These problems of stability disappear when an additional layer is interposed between the core containing vitamin C and the shellac coating.

7.7 The appellant argued that the experiments of D24 were not relevant in that the comparative composition was not disclosed in the closest prior-art document D1. In the board's opinion the fact that product 1 is not a composition disclosed in D1 is not *per se* a valid reason for disregarding the results of the experimental report. As explained above, the experiments of D24 allow observation of the effects of the "second

coating", which represents a distinguishing feature of the claimed formulation over the formulation of the closest prior art. The results disclosed in D24 are therefore relevant in the context of the assessment of inventive step.

7.8 The appellant furthermore contested the relevance of the experiments disclosed in D24, arguing that products 2 and 3 differed from product 1 not only on account of the second coating, but also in the presence of vitamin B in the inner core and in the presence of an immediate-release layer also containing vitamin B.

The appellant's observation is indeed correct. However, it is explained in D24 that the immediate-release coating dissolves in less than 10 minutes, leaving the shellac-coated core. It is furthermore observed that the presence of vitamin B in the core does not affect the rate of dissolution of vitamin C. The author of D24 concludes that "the only difference between products 1, 2, and 3 that could influence ascorbic acid (i.e. vitamin C, note of the board) dissolution is the presence of the intermediate second coating in products 2 and 3."

In the absence of any evidence to the contrary, the board sees no reasons for questioning this statement.

7.9 In the light of the above, the board considers that the technical problem can be formulated as the provision of a controlled-release formulation containing vitamin C and minerals which is stable on storage.

Obviousness

7.10 As mentioned in point 2.5.1 above, the claimed formulation differs from the formulation of D1 on account of the shellac coating and in the presence of a "second coating", i.e. the layer between the inner core and the controlled-release coating (feature d)).

Shellac is a known material for the preparation of controlled-release coatings (see for instance D6, page 9, lines 41 to 44; D25d, 10th paragraph on page 49). Hence, a person skilled in the art would consider this substance as a suitable option for preparing the controlled-release coating surrounding the granules of the formulation of D1.

There is however no indication in D1 that a formulation containing vitamin C in contact with shellac would not be stable when stored for long periods. Indeed, document D1 does not in any way address problems of stability on storage of the compositions disclosed therein. Issues of stability of formulations containing vitamin C in contact with shellac are ignored in the other prior art documents as well. In this respect the board considers that the mere indication contained in D25a (page 4019, left-hand column) that shellac is soluble in organic acids, without any further information as to the nature of the acids considered, is too unspecific to be regarded as a clear indication that shellac is unstable in contact with vitamin C, which is a solid organic acid.

Accordingly, in the absence of any indication as to any possible issue of stability deriving from the interaction between vitamin C and shellac, the skilled person would have no reason to modify the formulation of D1 by introducing a further coating, between the inner core and the controlled-release layer.

7.11 In the appellant's opinion the skilled person starting from the formulation of D1 would arrive at the subject-matter of claim 1 by using shellac as material for the optional outer layer and by interchanging the position of this layer with the position of the iron-containing layer. However, the optional outer layer of D1 has the function of preventing oxidation of the iron (see page 12, lines 13 to 18). Nowhere in D1 is it mentioned that this layer has a controlled-release effect. Hence, a skilled person would have no reason for using shellac, a known controlled-release agent, as a material for this layer.

It is furthermore not clear why the skilled person would change the position of the outer layer, made of shellac, with the position of the iron layer. This modification would result in the presence of two consecutive controlled-release coatings surrounding the core granules. Such an arrangement of layers is not foreseen in D1. Thus, it is only with the benefit of hindsight that a skilled person would perform the sequence of modifications of the formulation of D1 suggested by the appellant.

7.12 In view of the above the board concludes that the subject-matter of the main request meets the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

S. Fabiani J. Riolo

Decision electronically authenticated