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Datasheet for the decision of 11 January 2022

Case Number: T 0263/16 - 3.3.01

Application Number: 08852202.4

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Language of the proceedings: EN

Title of invention:
TREATMENT OF ORAL PHARYNGEAL DYSPHAGIA

Patent Proprietor:
Société des Produits Nestlé S.A.

Opponents:
Ajinomoto Co, Inc.
N.V. Nutricia

Relevant legal provisions:
RPBA Art. 12(4)
RPBA 2020 Art. 13
EPC Art. 123(2), 83, 84, 54, 56

Keyword:

New auxiliary request - admitted (yes)
Amendments - added subject-matter (no)
Claims - lack of clarity no ground for opposition
Sufficiency of disclosure - undue burden (no)
Novelty - (yes)
Inventive step - non-obvious alternative

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Case Number: T 0263/16 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 11 January 2022

Appellant: (Patent Proprietor)	Société des Produits Nestlé S.A. Entre-deux-Villes 1800 Vevey (CH)
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Appellant: (Opponent 2)	N.V. Nutricia Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Wohlfahrt, Jan Günther Gleiss Große Schrell und Partner mbB Patentanwälte Rechtsanwälte Leitzstraße 45 70469 Stuttgart (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 21 December 2015 concerning maintenance of the European Patent No. 2222289 in amended form.**

Composition of the Board:

Chairman	A. Lindner
Members:	R. Hauss
	E. Mille

Summary of Facts and Submissions

I. European patent No. 2 222 289 (patent in suit) derives from European patent application No. 08 852 202.4, which was published as an international application with the publication number WO 2009/067296 A1.

II. The **application as filed** contained the following claims, *inter alia*:

1. An orally-administrable liquid nutritional or medicinal product comprising: at least one vanilloid receptor 1 (VR-1) agonist capable of promoting a swallow reflex in an individual.

7. A method for treating oral pharyngeal dysphagia in an individual, the method comprising: administering to the individual an effective amount of a product selected from the product of claims 1, 2, or 3.

9. The method of claim 7, wherein the at least one VR-1 agonist is selected from a group consisting of: capsaicin, capsiate, dihydrocapsaicin, dihydrocapsiate nordihydrocapsaicin, nordihydrocapsiate, homocapsaicin, homodihydrocapsaicin, vanillylamide of n-nonanoic acid (VNA), anandamide, resiniferatoxin, and olvanil.

III. The **patent in suit** was granted with a set of 11 claims. The independent claims read as follows:

1. A product selected from a liquid nutritional or medicinal product, and a liquid hydration product, for use in the treatment of oral pharyngeal dysphagia in an individual by oral administration, wherein said product comprises:

at least one vanilloid receptor 1 (VR-1) agonist capable of promoting a swallow reflex in an individual, wherein the at least one VR-1 agonist is selected from a group consisting of: capsiate, dihydrocapsaicin, dihydrocapsiate nordihydro-capsaicin, nordihydrocapsiate, homocapsaicin, homodihydrocapsaicin, vanillylamide of n-nonanoic acid (VNA), anandamide, resiniferatoxin, and olvanil.

3. Use of a product as defined in any of claims 1 to 2 for the manufacture of a medicament for the treatment of oral pharyngeal dysphagia in an individual by oral administration.

The remaining claims are dependent claims. Claims 8 and 10 read as follows:

8. The product for use of any of claims 1 to 2 or use of claim 3, wherein the product is selected from a thickened beverage, a coffee or carbonated beverage, an alcoholic beverage or non-alcoholic simulated beverage, a soup, a yogurt beverage, an ice cream beverage, a medicinal beverage, a nutritional supplement, a hydration supplement, a herbal preparation, or a vitamin, mineral or vitamin and mineral supplement.

10. The product for use or use of claim 8, wherein the nutritional supplement is a nutrient-dense beverage.

IV. The patent in suit was opposed under Article 100(a), (b) and (c) EPC on the grounds that the claimed subject-matter lacked novelty and inventive step, was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, and extended beyond the content of the application as filed.

V. In the proceedings before the opposition division, the patent proprietor's main request was that the oppositions be rejected. It also filed a number of auxiliary requests.

VI. The documents cited in the opposition and appeal proceedings included the following:

D1: WO 2007/125717 A1 (8 November 2007)

D1b: EP 2011494 A1 - European patent application corresponding to D1, published in accordance with Article 153(4) EPC

D2: WO 2004/058301 A1

D2b: English Translation of D2

D3: J. Agric. Food Chem. 54, 9303-9311 (2006)

D8: US 2003/0082249 A1

Any reference to D1 or D2 in this decision is based on the translations provided as D1b and D2b, respectively.

VII. The decision under appeal is the opposition division's interlocutory decision, announced on 25 November 2015 and posted on 21 December 2015,

- rejecting the patent proprietor's main request and auxiliary requests 1 and 2,
- and finding that the patent as amended in the version of auxiliary request 3, filed during the oral proceedings before the opposition division, met the requirements of the EPC.

VIII. According to the decision under appeal:

(a) Claim 1 as granted defined subject-matter that extended beyond the content of the application as filed.

(b) The subject-matter of claim 1 of each of the first and second auxiliary requests lacked novelty over the disclosure of prior-art document D1.

(c) The third auxiliary request met the requirements of the EPC. Novelty was established by a limitation in claim 1 which required the claimed product to be formulated as a nutrient-dense beverage. Inventive step was assessed starting from the teaching of document D1, which represented the closest prior art. The objective technical problem was to provide an improved formulation of capsaicins for use in the treatment of oral pharyngeal dysphagia.
The claimed subject-matter involved an inventive step because the claimed product enabled the active agent to be simultaneously administered with food or nutrients, and this was not suggested in the cited prior art.

IX. The patent proprietor and the two opponents each appealed this decision.

X. In its statement setting out the grounds of appeal, the patent proprietor's main request was that the patent be maintained as granted. It also filed two claim requests as auxiliary requests 1 and 2.

XI. With its reply to the opponents' grounds of appeal, the patent proprietor filed further claim requests as auxiliary requests 3 to 10.

XII. In a communication issued in preparation for oral proceedings and advising the parties of its preliminary opinion, the board raised the following issue (communication pursuant to Article 15(1) RPBA dated 24 April 2020, point 11.1.1):

Claim 1 as granted was a purpose-limited product claim drafted in the format of Article 54(5) EPC. Dependent claim 2 as granted related to *"The product for use of claim 1"*. In claim 2 of auxiliary request 1, the term *"for use"* had been deleted. The claim could thus be understood as an independent claim referring to the product of claim 1 *per se*. This was not permissible under Article 123(3) EPC, as products *per se* were not covered by the claims as granted. The same objection applied to dependent claims 4 to 11 of auxiliary request 1 and the corresponding claims of all the other auxiliary requests.

XIII. With its submission of 12 April 2021, the patent proprietor filed further auxiliary claim requests.

These included auxiliary request 7A, which consists of six claims. The independent claims of this request (i.e. claims 1 and 3) are identical to those of auxiliary request 7 filed with the reply to the opponents' grounds of appeal (see point XI above). The dependent claims differ from the corresponding claims of auxiliary request 7 in that all the references to *"The product"* were replaced by *"The product for use"*.

The claims of **auxiliary request 7A** read as follows (differences in comparison with auxiliary request 7 underlined):

1. A liquid nutritional supplement, which is a nutrient-dense beverage, for use in the treatment of oral pharyngeal dysphagia in an individual by oral administration, wherein said product comprises:

at least one vanilloid receptor 1 (VR-1) agonist capable of promoting a swallow reflex in an individual, wherein the at least one VR-1 agonist is selected from a group consisting of:

dihydrocapsaicin, nordihydrocapsaicin, homocapsaicin, homodihydrocapsaicin, vanillylamide of n-nonanoic acid (VNA), anandamide, and olvanil.

2. The product for use of claim 1, further comprising at least one of the following: a protein, a soluble fiber, an insoluble fiber, a fatty acid, a vitamin, a mineral, a sugar, a carbohydrate, a flavor agent, a medicament, and a therapeutic agent.

3. Use of a product as defined in any of claims 1 to 2 for the manufacture of a medicament for the treatment of oral pharyngeal dysphagia in an individual by oral administration.

4. The product for use of any of claims 1 to 2 or use of claim 3, wherein the individual is suffering from oral pharyngeal dysphagia as a consequence of at least one of the following: cancer chemotherapy, cancer radiotherapy, surgery for oral cancer, surgery for throat cancer, a stroke, a brain injury, and a progressive neuromuscular disease.

5. The product for use or use of claim 4, wherein the progressive neuromuscular disease is Parkinson's Disease.

6. The product for use of any of claims 1 to 2 or use of claim 3, wherein the product is a nutritional supplement in the form of a thickened liquid.

XIV. Oral proceedings before the board were held on 11 January 2022. During the oral proceedings, the patent proprietor withdrew all its requests with the exception of auxiliary request 7A, which remained as its sole request.

XV. The opponents' arguments may be summarised as follows:

Admittance of auxiliary request 7A

The patent proprietor should have filed auxiliary request 7 during the proceedings before the opposition division or, at the latest, with its own grounds of appeal. The opponents had not raised any new objections in their grounds of appeal that could have given rise to further auxiliary requests being filed. The request was speculative since the purpose of the amendments (i.e. the deletion of certain VR-1 agonist compounds) was not clear.

Auxiliary request 7A was a new request involving a change to the patent proprietor's case. It had not been filed in direct response to the board's preliminary opinion, but almost a year later, at an advanced stage of the proceedings. Contrary to the patent proprietor's assertion, it was not evident that auxiliary request 7A, rather than auxiliary request 7, reflected the patent proprietor's original intention.

Amendments

The amended claim 1 was presumably based on claim 7 as filed, which recited the administration of an effective amount of the product as a mandatory feature. Omitting this feature from amended claim 1 was an inadmissible generalisation.

The feature "for use by oral administration" did not have any basis in the application as filed.

The combination of features defined in the amended claim 1 was the result of shortening two lists, by

- members having been omitted from the originally envisaged list of VR-1 agonists, and

- a specific product type having been selected from several options.

This resulted in a previously undisclosed invention being singled out.

Clarity

In the claims as granted, the feature "nutrient-dense beverage" had been present in dependent claim 10, which referred back to claim 8 and the product forms listed in this claim. The amendments made to auxiliary request 7A rendered the meaning of the feature "nutrient-dense beverage" unclear, because it was incorporated into claim 1.

Sufficiency of disclosure

Having to determine effective amounts to be administered would be an undue burden on the person skilled in the art, especially as the patent in suit did not indicate specific dosages.

Novelty

Example 2 in D1 ("Amelioration of dysphagia") reported that the onset of the swallow reflex of the test subjects was observed, in terms of movement of the hyoid bone. The choice of this parameter indicated that D1 indeed concerned the treatment of oral pharyngeal dysphagia.

According to D1, a capsinoid-containing oil extracted from the fruit of the capsicum variety "CH-19 sweet" was a preferred material for an agent for ameliorating dysphagia. Paragraph [0023] of D1 disclosed a specific extract which also contained "about 0.005% of capsaicinoid". Figure 1 of document D3 disclosed

that capsaicinoids included the components recited in claim 1 of auxiliary request 7A.

The oral administration of a liquid composition could be derived from the passage in paragraph [0020] of D1, which disclosed liquid formulations that were clearly suitable for oral administration and mentioned oral and nasal administration. The term "nutrient-dense beverage" had no generally accepted meaning and had to be interpreted in a broad sense as a nutrient-containing liquid.

According to a more general approach, any prior art disclosing VR-1 agonists in a beverage was prejudicial to novelty, e.g. the passage in document D3 disclosing the oral intake of diluted samples of *capsicum* fruits by a tasting panel to test pungency (D3: page 9304, right-hand column, lines 5 to 9).

Inventive step

Example 2 in document D1 clearly concerned the treatment of oral pharyngeal dysphagia with a liquid product containing a *capsicum* extract. It could be concluded from Figure 1 of D3, which showed capsaicinoids occurring in peppers, that the extract from D1 presumably contained VR-1 agonists listed in claim 1 of auxiliary request 7A. As Example 2 of D1 described nasal administration and not a beverage, the objective technical problem could be defined as that of providing an alternative product and route of administration for treating oral pharyngeal dysphagia. The claimed subject-matter was obvious, since D1 itself suggested that the agent for treating dysphagia could be ingested by oral administration and in the form of a food composition. Furthermore, document D2 taught that the VR-1 agonist capsaicin could be administered in

nutrient-dense beverages such as milk or orange juice, in order to improve the swallow reflex.

In an alternative approach, inventive step could also be assessed starting from the teaching of document D2. Since other VR-1 agonists were known as potential alternatives to capsaicin in the art, it would have been obvious for the person skilled in the art to replace capsaicin with the compounds recited in claim 1 of auxiliary request 7A.

XVI. The patent proprietor's arguments may be summarised as follows:

Admittance of auxiliary request 7A

Auxiliary request 7 had been filed in a timely manner as part of the patent proprietor's defence against the opponents' appeals. Accordingly, the scope claimed was narrower than that of the claims as upheld by the opposition division.

Auxiliary request 7A had been filed in response to a new issue raised in the board's preliminary opinion. It was an amended version of auxiliary request 7, correcting an error in the dependent claims.
The amendments in auxiliary request 7A did not give rise to any new issues that might have complicated the proceedings.

Amendments

Claim 1 was based on claims 1 and 7, and claim 9 or paragraph [0021], in combination with claim 10 or paragraph [0024] of the application as filed.

The term "by oral administration" derived from the expression "orally administrable", which stated the intended use in product claim 1 as filed. It was

evident throughout the application as filed that the route of administration had always been intended to be oral.

The format of claims 1 and 3 as purpose-limited second-medical-use claims automatically implied that the product which was the subject of the claims was suitable for the use and had to be administered in an effective amount.

The product form of "nutrient-dense beverage" was individualised in the description as a preferred embodiment. The application as filed clearly differentiated between capsaicin (presented as a special case) and the other VR-1 agonists (presented as a preferred group). Contrary to the opponents' assertion, the amendments made were not selections from several lists. They did not result in a change to the nature of the invention, but only in a limitation of the scope.

Clarity

The term "nutrient-dense beverage" was present in the claims as granted and was not open to objection regarding an alleged lack of clarity in opposition appeal proceedings. In addition, its meaning remained the same with or without a reference to the subject-matter of claim 8 as granted.

Sufficiency of disclosure

Dose determination was generally accepted in case law as a matter of routine which did not constitute an undue burden. The opponents had not provided substantiated reasons for doubt in this regard.

Novelty

Since document D1 only mentioned the treatment of dysphagia in general, it was not certain that it really concerned the treatment of oral pharyngeal dysphagia. Furthermore, D1 did not directly and unambiguously disclose the oral administration of a liquid product, let alone a nutrient-dense beverage, or any of the VR-1 agonists specified in claim 1 of auxiliary request 7A. D1 did not disclose that these agents had any benefit in treating oral pharyngeal dysphagia either.

Document D3 did not disclose the treatment of oral pharyngeal dysphagia or a nutritional supplement which was a nutrient-dense beverage.

Inventive step

It was readily apparent from the general context in the patent in suit that the VR-1 agonists were the active ingredients for treating oral pharyngeal dysphagia.

All the compounds known from document D1 had been removed from the list of VR-1 agonists in claim 1 of auxiliary request 7A. Document D2 only related to capsaicin, which was not mentioned in claim 1, either. Hence, irrespective of whether D1 or D2 was chosen as the starting point for the assessment of inventive step, the objective technical problem to be solved was to provide alternative agents.

The prior art did not disclose or suggest the benefit of the VR-1 agonists recited in claim 1 of auxiliary request 7A as equivalent agents for treating oral pharyngeal dysphagia, or their oral application in a nutrient-dense beverage.

XVII. The appellant-patent proprietor requested that the patent be maintained on the basis of the claims according to auxiliary request 7A filed by letter of 12 April 2021.

XVIII. Appellant-opponent 1 and appellant-opponent 2 requested that the decision under appeal be set aside and that the patent be revoked. Within the purview of these requests, the opponents also requested that auxiliary request 7A not be admitted.

Reasons for the Decision

1. Admissibility of the appeals

The appeals comply with Articles 106 to 108 EPC and Rule 99 EPC; they are admissible.

2. Technical background

2.1 As set out in the patent in suit (see paragraphs [0002] to [0004]), dysphagia is a condition typified by a decreased ability to swallow. Normal swallowing involves three distinct phases, namely the oral, pharyngeal and oesophageal phases. Oesophageal dysphagia is considered a less serious condition than oral pharyngeal dysphagia, which presents a serious health risk and is more difficult to treat.

2.2 The patent in suit seeks to provide a treatment for oral pharyngeal dysphagia. The product to be administered contains at least one vanilloid receptor 1 (VR-1) agonist capable of promoting a swallow reflex in an individual (see paragraphs [0008] to [0010]). The product form chosen according to the claims of

auxiliary request 7A is a liquid nutritional supplement which is a nutrient-dense beverage.

3. Admittance of auxiliary request 7A

3.1 To the extent that auxiliary request 7A is based on auxiliary request 7, with identical independent claims 1 and 3 (see points XI to XIII above), its admittance is considered under Article 12(4) RPBA 2007.

As far as the additional amendment made by inserting the words *"for use"* into claims 2 and 4 to 6 is concerned, Article 13 RPBA (revised version) applies.

Article 12(4) RPBA 2007

3.2 Auxiliary request 7 was not part of the patent proprietor's appeal, as its scope is more restricted than that upheld by the opposition division. Instead, it was filed in response to the opponents' appeals.

Whether or not the opponents raised new objections in their grounds of appeal is not decisive for the admittance of auxiliary request 7. The mere fact that the opponents filed appeals at all justifies the submission of defensive requests by the patent proprietor.

Since the patent proprietor filed its reply to the oppositions, including auxiliary request 7, before the the revised version of the RPBA entered into force, the criteria of Article 12(4) RPBA 2007 apply in this case (see Articles 24 and 25(2) RPBA).

3.3 According to Article 12(4) RPBA 2007, the board has the power to hold inadmissible requests which could have been presented or were not admitted in the first-instance proceedings.

3.3.1 In the proceedings before the opposition division, the patent proprietor did not file any requests that were entirely identical to auxiliary requests 7 or 7A filed on appeal.

3.3.2 However, claim 1 of the former auxiliary request 3 of 23 October 2015 recites the same shortened list of VR-1 agonists as auxiliary requests 7 and 7A filed on appeal. The difference is that the claimed product is to be *"selected from a liquid nutritional or medicinal product, and a liquid hydration product"* (as in claim 1 as granted), rather than being restricted to a *"liquid nutritional supplement which is a nutrient-dense beverage"*.

3.3.3 Auxiliary request 3 of 23 October 2015 was later re-named auxiliary request 4 (see the minutes of the oral proceedings of 25 November 2015, page 4, lines 10 to 11). This request was neither withdrawn nor held inadmissible in the first-instance proceedings.

3.3.4 Therefore, a request with the same effect (i.e. restricting the options for selecting the at least one mandatory VR-1 agonist in comparison with the claims as granted) was pursued by the patent proprietor in the first-instance proceedings.

3.3.5 The further restriction that was introduced in auxiliary request 7 on appeal defines the product form as a *"liquid nutritional supplement which is a nutrient-dense beverage"*, thereby adapting the scope to that of claim 1 held allowable in the decision under appeal (see point VIII.(c) above) in order to create a convergent defensive request. The dependent claims that related to product forms (claims 6 to 11 of former auxiliary request 4) were either adapted

accordingly or removed, which does not change the issues to be considered.

3.3.6 Opponent 2 took the view that the request held allowable in the decision under appeal (former auxiliary request 3 filed in oral proceedings on 25 November 2015) should not have been admitted by the opposition division in the first place, since it was filed at a late stage, the limitation to a nutrient-dense beverage was a surprise to the opponents, and this feature was also unsuitable for establishing novelty over D1.

However, as the restriction to a "nutrient-dense beverage" was evidently intended to further distinguish the claimed subject-matter from the prior art, and had already been present in claim 10 as granted, the board does not concur with the opponent's view that the opposition division misapplied its discretion in this instance.

3.3.7 In light of these considerations, the board concluded that it would not be appropriate to hold auxiliary request 7 inadmissible under Article 12(4) RPBA 2007. The same conclusion must apply to auxiliary request 7A to the extent that the same features as in auxiliary request 7 are concerned.

Article 13(1) and (2) RPBA

3.4 Auxiliary request 7A is identical to auxiliary request 7, except for the words *"for use"* added to claims 2 and 4 to 6 (see point XIII above).

3.5 This request was filed in response to the board's preliminary opinion under Article 15(1) RPBA in order to address the board's objection under

Article 123(3) EPC to auxiliary request 7 (see points XII and XIII above).

3.6 This amendment is justified as it was occasioned by a new objection. It was also predictable and does not change the patent proprietor's case with regard to other issues or increase the overall complexity of the case. The fact that auxiliary request 7A was filed one year after the board's preliminary opinion did not result in additional complications or time pressure. Article 13(2) RPBA would have applied in any case.

3.7 In consideration of points 3.1 to 3.6 above, the board exercised its discretion to admit auxiliary request 7A.

4. Amendments (Article 123(2) and (3) EPC)

Claim format

4.1 Oral pharyngeal dysphagia is a pathological condition, and therefore its treatment addressed in the current claims is a medical use.

4.2 Independent claims 1 and 3 of auxiliary request 7A both relate to the same further medical use, namely the use of a product containing at least one specified VR-1 agonist in the treatment of oral pharyngeal dysphagia by oral administration.

4.3 Claims 1 is drafted in the format according to Article 54(5) EPC and claim 3 in the Swiss-type format according to G5/83 (OJ EPO 1985, 64).

Therefore, in both claims 1 and 3, the therapeutic use is to be regarded as a functional technical feature.

In the case of claim 3, this concept still applies since the filing date of the patent in suit is before the end of the transitional period set by decision G 2/08 of the Enlarged Board of Appeal, which abolished

the Swiss-type format but had no retroactive effect (see G2/08, OJ EPO 2010, 456, Order: question 3, point 7.1.4 of the Reasons).

Article 123(2) EPC - added subject-matter

4.4 Claims 1 and 3 of auxiliary request 7A are based on the combination of claims 9, 7 and 1 of the application as filed (see point II above).

4.5 As claims 1 and 3 of auxiliary request 7A relate to a further medical use of a product, it is implicit that this use must necessarily involve the administration of an effective amount of said product.

Nothing else is expressed in claim 7 as filed, which defines a method of treatment that involves administering an effective amount of the product.

Hence, the board is unable to identify any change to the scope of the targeted treatment that might have arisen because the term "effective amount" is not incorporated explicitly in claims 1 and 3 of auxiliary request 7A.

The opponents' objection in this respect must therefore fail.

4.6 The further restriction that the liquid product is formulated as a nutrient-dense beverage finds its basis in paragraph [0024] of the application as filed, in which this is presented as a preferred product form, in the form of a general disclosure:

> *"In a preferred embodiment, one or more VR-1 agonists are administered in a nutritional supplement, such as a nutrient-dense beverage."*

Combining a general disclosure of a preferred product form with a claimed embodiment (in this case, as defined by claims 9, 7 and 1 as filed) that is less

specific in terms of the product form does not result in a combination of features that goes beyond the original disclosure. The product form of a nutritional supplement in the form of a nutrient-dense beverage is individualised in the application as filed and can be pursued individually.

4.7 The term "beverage" already implies the concept of oral administration. In addition, it is evident from the use of the term "orally administrable" in claim 1 as filed that oral administration was intended in the context of the envisaged therapeutic treatment.

4.8 In comparison with the list of VR-1 agonists recited in claim 9 and paragraph [0021] of the application as filed, five compounds have been deleted from the corresponding list in claim 1 of auxiliary request 7A.

The deleted compounds are: capsaicin, capsiate, dihydrocapsiate, nordihydrocapsiate and resiniferatoxin.

4.8.1 Capsaicin is known to be very pungent and is disclosed as a special case in the application as filed. The other VR-1 agonists are presented as a group of less pungent and less toxic alternatives to capsaicin (see paragraph [0021] of the application as filed). Hence, deleting capsaicin from the list of VR-1 agonists to be employed does not add any information which was not already present in the application as filed.

4.8.2 The deletion of the other four compounds does not result in a group of remaining compounds having any specific, previously undisclosed property or effect being singled out. The deletion of alternatives from a list of equally useful elements is permissible under Article 123(2) EPC.

4.9 In conclusion, the subject-matter claimed in auxiliary request 7A does not extend beyond the content of the application as filed.

Article 123(3) EPC - extension of scope

4.10 Neither the board nor the opponents had any objection under Article 123(3) EPC. The issue mentioned by the board in its preliminary opinion was resolved by the amendments in auxiliary request 7A (see points XI to XIII above).

5. Clarity (Article 84 EPC)

5.1 As established by the Enlarged Board's decision G3/14 (see G3/14, OJ EPO 2015, 102), in considering whether, for the purposes of Article 101(3) EPC, a patent as amended meets the requirements of the EPC, the claims of the patent may be examined for compliance with the requirements of Article 84 EPC only when, and then only to the extent that, the amendment introduces non-compliance with Article 84 EPC.

5.2 As the term "nutrient-dense beverage" was already present in claim 10 as granted, it is thus not open to objection regarding an alleged lack of clarity in opposition appeal proceedings.

5.3 Opponent 2 nevertheless argued that the removal, by amendment, of the back-reference in claim 10 to claim 8 as granted affected the meaning of the term "nutrient-dense beverage" so as to result in a lack of clarity (for the wording of claims 8 and 10 as granted, see point III above).

5.4 It is not apparent to the board why this should be the case:

5.4.1 Claim 8 as granted defines the liquid product from claim 1 as a nutritional supplement (one of several alternatives listed in claim 8). Claim 10 as granted further specifies that this nutritional supplement is a nutrient-dense beverage.

5.4.2 In the same way, claim 1 of auxiliary request 7A also refers to a liquid nutritional supplement which is a nutrient-dense beverage. The relationship between these terms is the same. No change in meaning is involved. It is not possible to conclude, on this basis, that the amendments introduce non-compliance with Article 84 EPC.

5.5 As a result of these considerations, the objection raised by opponent 2 under Article 84 EPC does not succeed.

6. Sufficiency of disclosure (Article 83 EPC)

6.1 The only objection of insufficiency pursued by the opponents in these appeal proceedings related to the feature in claim 1 of several of the patent proprietor's claim requests which specified that the claimed product comprised "an effective amount" of the at least one VR-1 agonist. They argued that determining what was an effective amount would be an undue burden on the person skilled in the art.

6.2 Since the patent proprietor withdrew all of the requests concerned, and the feature in question is not mentioned in the claims of auxiliary request 7A, it would seem that this objection is not directly applicable to the current claims.

6.3 Nevertheless, as set out in point 4.5 above, it is an implicit feature of claims 1 and 3 that the medical use defined in these claims must involve administering an effective amount of product. The board therefore considered the issue of "undue burden" with regard to the dosage of the product.

6.4 As correctly pointed out by the patent proprietor, dosage determination for a medical use is, as a rule, considered to be a routine matter for the person skilled in the art. Since, in the present case, the treatment elicits an immediate response, and the swallow reflex is a parameter that is easy to observe, titrating the dosage for individual patients would not be expected to present much difficulty, either, if required.

6.5 The opponents did not raise any serious doubts, substantiated by verifiable facts, that, in this particular case, dosage determination would present an unusual burden going beyond the routine work of a person skilled in the art. The mere fact that the application as filed does not specify a dosage amount is not sufficient as a basis for serious doubt.

6.6 For these reasons, and in the absence of other objections by the opponents, the conclusion is that the subject-matter defined in auxiliary request 7A complies with the requirement of sufficiency of disclosure.

7. Novelty (Articles 52(1) and 54 EPC)

Novelty in relation to the disclosure of D1

7.1 Document D1 does not name or disclose any of the VR-1 agonist compounds recited in claim 1 of auxiliary request 7A.

In particular, it cannot be confirmed on the basis of the information on file that the hexane extract mentioned in paragraph [0023] of D1 contained any of these compounds. The sentence in paragraph [0023] of D1

"(...) the extracted oil was estimated to contain about 0.005% of capsaicinoid"

does not constitute an unambiguous disclosure of any compound in particular. Figure 1 of the entirely unrelated document D3 merely shows the structures of capsaicin, dihydrocapsaicin and "at least nine minor capsaicinoids which have been shown to occur in peppers" (D3: page 9303, left-hand column, lines 4 to 8). There is no connection to the specific extract disclosed in D1.

7.2 Document D1 does not disclose the oral administration of a nutritional supplement which is a nutrient-dense beverage either.

According to D1 (paragraphs [0019] and [0020]), the agent for ameliorating dysphagia may be ingested nasally or orally, in the form of a pharmaceutical composition or food composition, and it may be a liquid; however, D1 does not specifically disclose the oral administration of a liquid composition.

While the term is not explicitly defined in the patent in suit, a *"liquid nutritional supplement which is a nutrient-dense beverage"* (as in claim 1 of auxiliary request 7A) would generally be expected to be suitable for serving a nutritional purpose, in particular by containing a high concentration of nutrients adequate for supplementing a subject's nutrition. No such liquid composition is disclosed in D1. In fact, the only example of a "food" composition mentioned in the document is a troche (D1: claim 5).

7.3 As a consequence, the subject-matter of claim 1 and all the other claims in auxiliary request 7A is novel in relation to the disclosure of document D1.

Novelty in relation to the disclosure of D3

7.4 Document D3 mentions an organoleptic test for estimating pungency using *"diluted samples"* of capsicum fruits and a tasting panel of five persons (D3: page 9304, right-hand column, lines 5 to 10).

7.5 D3 relates to the development of an analytical method for determining capsaicin and dihydrocapsaicin in pepper fruit extracts. It does not relate to the treatment of oral pharyngeal dysphagia and, for that reason alone, cannot anticipate the claimed subject-matter (see point 4.3 above). Furthermore, the cited passage which mentions a tasting panel does not disclose the VR-1 agonists from claim 1 or a nutritional supplement which is a nutrient-dense beverage.

7.6 As a consequence, the claimed subject-matter is also novel in relation to the disclosure of document D3.

8. Inventive step (Articles 52(1) and 56 EPC)

Starting point in the prior art

8.1 The opponents proposed documents D1 or D2 as possible starting points in the prior art for the assessment of inventive step. Both approaches were taken into account.

8.2 Document D1 relates to the use of capsinoids (defined as fatty acid esters of vanillyl alcohol) as active agents for treating dysphagia which can be easily ingested by elderly people. Capsiate, dihydrocapsiate and nordihydrocapsiate are specifically mentioned in D1

as examples of suitable capsinoids (see D1: paragraphs [0006], [0007] and [0009]).

The capsiate(s) can be extracted from fruits of *capsicum* plants, preferably those of the non-pungent variety "CH-19 sweet" (see D1: paragraph [0013]). They can be applied orally or nasally (see paragraph [0019]). A specific oil extract was prepared with a capsinoid content of 9.5% (see D1: paragraph [0023]). This was used in the compositions according to the examples in D1.

According to Example 2 (paragraphs [0026] and [0027]), different concentrations of capsinoid solutions were applied with a catheter to three patients, via the nose up to the uvula, and a latent time between the administration of the solution and the occurrence of the swallowing reflex was measured. D1 reports that in the case of the capsinoid administration group, as compared with the control, the swallow reflex was significantly improved.

8.3 Document D2 relates to a composition for improving swallow reflex failure. It comprises at least two functionally defined components, namely

- a substance P secretion promoter

in combination with

- an angiotensin-converting enzyme inhibitor or substance P decomposition inhibitor
- and/or a dopamine secretion promoter.

The only substance P secretion promoter mentioned in the document is capsaicin, a compound known to improve the swallow reflex function (D2: page 1, first paragraph, page 4, lines 13 to 19, and claims 1 and 2). The composition may be administered in liquid or solid form, for example in a food product (D2: pages 12 and 13). According to the data shown in Table 1 of D2,

a troche containing only capsaicin improved the swallow reflex in test subjects when ingested, but, in this regard, was inferior to a combination composition as proposed in D2.

Objective technical problem and solution

8.4 While this point was in dispute, it will be assumed in the following, in the opponents' favour, that both D1 and D2 address the treatment of oral pharyngeal dysphagia.

8.5 The patent in suit discloses the VR-1 agonists as compounds capable of promoting a swallow reflex in an individual; in other words, they are the active ingredients in the product that is to be administered to treat oral pharyngeal dysphagia (see the patent in suit, paragraphs [0007] and [0017]). It is never suggested that the VR-1 agonists might have any other function in the product. This is also reflected in the wording of claim 1 of auxiliary request 7A, which refers to *"at least one vanilloid receptor 1 (VR-1) agonist capable of promoting a swallow reflex in an individual"*. Therefore, the reader understands that the VR-1 agonists recited in the claim are used as the active ingredients providing the envisaged treatment of oral pharyngeal dysphagia.

8.6 The subject-matter of claim 1 differs from the disclosure of D1 and D2 on account of the dosage form as a nutritional supplement which is a nutrient-dense beverage. Furthermore, none of the options for the at least one mandatory active agent recited in claim 1 is disclosed in D1 or D2.

8.7 The objective technical problem which may be formulated on this basis is to provide an alternative product for use in the treatment of oral pharyngeal dysphagia.

8.8 There is no specific reason to assume that this problem would not be solved by the claimed subject-matter.

Obviousness of the solution

8.9 Document D1 restricts itself to capsinoids (defined as esters of vanillyl alcohol) with regard to the choice of active agents for treating dysphagia (see point 8.2 above and paragraph [0009] of D1). This term does not include any of the compounds recited in claim 1 of auxiliary request 7A. There is also no teaching in D1 to suggest that the compounds according to auxiliary request 7A might be alternative agents effective against dysphagia.

8.10 Document D2 teaches that capsaicin, due to its property as a substance P secretion promoter, can improve the swallow reflex in subjects with swallow reflex failure. D2 does not, however, disclose that any of the compounds recited in claim 1 of auxiliary request 7A are substance P secretion promoters, or that they provide the same therapeutic benefit as capsaicin.

8.11 Opponent 2 also argued that it was disclosed elsewhere in the prior art, in particular in document D8, that the compounds from claim 1 were potential alternatives to capsaicin; however, D8 concerns a different therapeutic indication (the treatment of mucositis) and does not contain any teaching to that effect.

8.12 Since it was not demonstrated that the benefit of the agents recited in claim 1 of auxiliary request 7A in the treatment of oral pharyngeal dysphagia was disclosed or suggested in D1, D2 or any other prior-art document, the agents according to claim 1 are non-obvious alternatives. It is thus not necessary to also consider the question of whether the choice of the

product form as a nutritional supplement which is a nutrient-dense beverage would have been obvious.

8.13 The same reasoning applies, *mutatis mutandis*, to independent claim 3. It also applies to the dependent claims.

8.14 As a consequence, the subject-matter of the claims of auxiliary request 7A involves 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 case is remitted to the opposition division with the order to maintain the patent on the basis of the following documents:

   - claims 1 to 6 of auxiliary request 7A filed by letter of 12 April 2021
   - and a description to be adapted.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated