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Datasheet for the decision of 20 December 2022

Case Number: T 0576/19 - 3.3.04

Application Number: 13736751.2

Publication Number: 2872135

IPC: A61K31/375, A61K36/738, A61P19/02

Language of the proceedings: EN

Title of invention:
PROCESS FOR THE MANUFACTURE OF ROSE HIP POWDER

Patent Proprietor:
Orkla Health A/S

Opponent:
Hyben Vital Licens ApS

Relevant legal provisions:
EPC Art. 56

Keyword:
Inventive step - (no)

Decisions cited:
T 0197/86

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Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 0576/19 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 20 December 2022

Appellant: (Patent Proprietor)	Orkla Health A/S Industrigrenen 10 2635 Ishøj (DK)
Representative:	Inspicos P/S Agern Allé 24 2970 Hørsholm (DK)
Respondent: (Opponent)	Hyben Vital Licens ApS Klavsebøllevej 2 Tullebølle 5953 Tranekær (DK)
Representative:	Larsen & Birkeholm A/S Banegårdspladsen 1 1570 Copenhagen V (DK)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 21 December 2018 revoking European patent No. 2872135 pursuant to Article 101(3)(b) EPC**

Composition of the Board:

Chairwoman	T. Sommerfeld
Members:	R. Hauss
	W. Sekretaruk

Summary of Facts and Submissions

I. European patent No. 2 872 135 (hereinafter referred to as the patent in suit) was granted with a set of four claims. Claim 1 reads as follows:

> *"1. A process for the manufacture of dried rose hip powder comprising the steps of*
>
> *• providing harvested rose hip,*
> *• drying and chopping the rose hip,*
> *• separating the chopped rose hip and isolating the shells,*
> *• grinding the shells, and*
> *• optionally sieving the ground rose hip shells to a particle size below 1 mm,*
>
> *wherein cooling is applied during the grinding step so that the grinding is performed at a constant temperature, said temperature being below 40°C, preferably below 30°C, more preferred below 25°C even more preferred below 20°C."*

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

III. The patent proprietor requested that the opposition be rejected (main request) and also submitted five sets of amended claims (auxiliary requests 1 to 5).

IV. The documents cited in the proceedings before the opposition division included the following:

D1: Int. J. Clin. Rheumatol. 9(3), 267-278 (2014)

D2: US 6,024,960 A

D3: WO 2011/113433 A1

D5: Scand J Rheumatol 34, 302-308 (2005)

V. The decision under appeal is the opposition division's decision revoking the patent in suit, announced in oral proceedings on 3 December 2018 and posted on 21 December 2018.

VI. According to the decision under appeal:

(a) The claimed process met the requirements of sufficiency of disclosure (Article 100(b) EPC) and novelty (Articles 100(a), 52(1) and 54(2) EPC).

(b) Inventive step was assessed starting from the technical teaching of document D2.

Claim 1 of the main request differed from the disclosure of D2 by the requirement for cooling and maintaining the temperature below 40°C during grinding. The objective technical problem was to provide an alternative process for obtaining a rose hip powder. As the prior art (e.g. D3) contained indications that low temperatures should be maintained during the manufacturing process, the claimed subject-matter did not involve an inventive step (Articles 100(a), 52(1) and 56 EPC).

The additional requirement in claim 1 of auxiliary requests 1 and 3 that the cooling applied should be air cooling could not change this assessment.

The addition of vitamin C as according to claim 1 of auxiliary requests 2 and 3 was a further arbitrary process modification which could not change the negative conclusion regarding inventive step.

(c) Auxiliary requests 4 and 5, both of which were filed during the oral proceedings before the opposition division, were not admitted.

VII. The patent proprietor (appellant) filed an appeal against this decision.

VIII. With its statement setting out the grounds of appeal, the appellant requested that the decision under appeal be set aside and that the opposition be rejected (main request). The appellant also submitted four sets of claims according to auxiliary requests 1 to 4.

The claims of the main request and auxiliary requests 1 to 3 are identical to those of the corresponding requests considered in the decision under appeal.

With regard to the wording of claim 1 of the **main request** (i.e. claim 1 as granted), see section I. above.

Claim 1 of **auxiliary request 1** is identical to claim 1 of the main request, except that it also specifies that the cooling applied is air cooling.

Claim 1 of **auxiliary request 2** is identical to claim 1 of the main request, except that it specifies that the process further comprises a step of mixing the ground rose hip with vitamin C added in an amount from 30 mg added vitamin C per g rose hip powder to about 80 mg per g rose hip powder.

Claim 1 of **auxiliary request 3** is identical to claim 1 of the main request, except that it also contains the additional technical features of claim 1 of each of auxiliary requests 1 and 2.

IX. With its statement setting out the grounds of appeal, the appellant filed, *inter alia*, the following document:

Annex 1: Test report "In vitro evaluation of anti-inflammatory effect of rose hip shell powders on hPBMCs stimulated with LPS and IFN-γ"

X. With its reply to the appellant's statement of grounds, the opponent (respondent) filed, *inter alia*, the following document:

D13: Experimental data - milling of rosehip (29 July 2019)

XI. With a letter dated 16 December 2019, the appellant presented new auxiliary requests 5 to 9.

Claim 1 of ***auxiliary request 5*** corresponds to claim 1 of the main request, and claims 1 of ***auxiliary requests 6 to 8*** correspond to claims 1 of auxiliary requests 1 to 3, respectively, except that these claims further specify that the particle size of the ground rose hip shells does not exceed 550 µm.

XII. Oral proceedings before the board were held on 20 December 2022. The appellant withdrew auxiliary requests 4 and 9. The issue of inventive step in relation to the other claim requests was discussed. In the end, the board dismissed the appeal.

XIII. The respondent's arguments on inventive step, as far as they are relevant to the present decision, can be summarised as follows:

Inventive step - main request

There was no evidence of any improvement or surprising technical effect linked to the "cooling" feature which distinguished the process of claim 1 from that

disclosed in D2. The comparative tests described in the examples of the patent in suit and in Annex 1 did not show such a link since the experimental set-ups were unsuitable for that purpose, and relevant details about the test conditions were not divulged. It had not been established that active cooling of the powder during the grinding step was necessary to avoid thermal degradation of the active ingredients. On the contrary, the grinding step in the process according to the closest prior art D2 did not even generate temperatures above 40°C, as was demonstrated in D13.

As it had not been established that the claimed process constituted an improvement, the objective technical problem starting from the technical teaching of document D2 was to provide an alternative process for preparing rose hip shell powder.

Knowing that rose hips contained unstable compounds susceptible to thermal degradation (such as, *inter alia*, vitamin C, which was the most sensitive component), and being aware that the prior art suggested gentle process conditions (see, *inter alia*, D2 and page 303, right-hand column, second paragraph, of D5), the person skilled in the art would have considered implementing measures for temperature control during the process, including during the grinding step. Hence, the claimed process would have been obvious in view of the prior art.

Inventive step - auxiliary requests

The additional requirement in claim 1 of auxiliary requests 1 and 3 that the cooling should be air cooling did not give rise to any particular technical effect that could support an argument in favour of inventive step.

The addition of vitamin C as in auxiliary requests 2 and 3 was a well-known conventional measure for improving the shelf life of a product. Thus, the stabilising effect mentioned in paragraph [0020] of the patent in suit could not be regarded as surprising. No evidence of any other specific technical effect was provided, such as the alleged effect (in paragraph [0018] of the patent in suit) that vitamin C facilitated the uptake in a subject of the active rose hip ingredients. When mentioning the rapid degradation of vitamin C in rose hip, paragraph [0019] of the patent in suit did not associate this problem specifically with the process of claim 1. There was thus no basis for formulating the problem to be solved as compensating for the unusually rapid degradation of vitamin C arising from the claimed process (as proposed by the appellant).

The limitation regarding particle size in auxiliary requests 5 to 8 was not a distinguishing technical feature in comparison with the process in D2 and could not, therefore, provide any contribution to inventive step. Even for these smaller particle sizes, it had not been shown that thermal exposure during the grinding step affected the content of active ingredients in the powdered material.

XIV. The appellant's arguments on inventive step, as far as they are relevant to the present decision, can be summarised as follows:

Inventive step - main request

A comparison of the teaching in document D2 and the patent in suit showed that rose hip shell powder prepared according to the patent in suit must be more potent, since lower amounts of it were required for therapeutic benefit. This distinction was confirmed by

the results of the comparative *in vitro* test described in Annex 1. The technical effect of higher potency resulted from all of the technical features of the claimed process in combination: whether it was attributable to the distinguishing technical feature was not of key importance.

The process by which the comparative sample according to Annex 1 had been prepared was a fair representation of the process according to D2, believed to be realistic with regard to the expected heat exposure. At the least, the data showed that short-term heat exposure of the material mattered.

The data presented in the respondent's test report D13 had been obtained under specific, deliberately gentle process conditions and did not warrant the more general conclusion that heat stress during grinding was going to be negligible in any process within the ambit of D2, or that the temperature would always remain below 40°C even without cooling. It was also doubtful that the temperature of the powder upon exiting the mill, as measured according to the test protocol of D13, correctly reflected the (presumably higher) temperature of the material while in contact with the grinding plates inside the mill. Thus, D13 could not cast doubt upon the inventive concept of controlling the temperature during the grinding step.

Starting from the technical teaching of document D2, the objective technical problem was to provide an improved rose hip powder with higher potency, which could be administered in lower amounts and thus improve patient compliance.

Rather than alter the process conditions during grinding, the person skilled in the art seeking to solve this technical problem would have turned to

document D3, which taught that compositions that also included ground rose hip seeds had better efficacy.

The prior art in D2 and D5 recommended mild temperatures just for drying the rose hip material, but did not discuss process conditions during grinding, let alone suggest that heat exposure during the grinding step could affect the quality of the end product. As grinding required considerably less time than drying, the skilled person would have had no concerns about potential heat exposure during the grinding step. In this context, loss of vitamin C (as invoked by the respondent) would not have been considered problematic as this compound was not responsible for the anti-inflammatory effect of the powder and could in any case have easily been replenished by actively adding any required amounts to the processed powder. Thus, the claimed subject-matter was inventive because, surprisingly, a higher content of active substances in the end product was attained when cooling was applied during the grinding process.

Even if the objective technical problem were formulated as the provision of an alternative rose hip composition, the skilled person would have found no incentive in the prior art to implement temperature control in the grinding step.

Inventive step - auxiliary requests

The arguments in favour of inventive step in auxiliary request 1 were the same as those set out for the main request.

The addition of vitamin C as required in auxiliary requests 2 and 3 was not arbitrary but purposeful. According to paragraphs [0018] and [0019] of the patent in suit, vitamin C enhanced the effect of the other

rose hip components, but it had been found to degrade unusually fast in the claimed process. The addition of vitamin C therefore solved a technical problem arising out of the inventive process itself, namely to compensate for the unexpectedly rapid degradation of vitamin C and maintain the product's good properties.

This problem could not have been derived from the prior art, which did not relate to the same process and did not discuss the stability and degradation of vitamin C.

While it was not contested that the particle size in auxiliary requests 5 to 8 was not a distinguishing technical feature in relation to the disclosure of D2, it was well known that grinding to smaller particle sizes required a higher energy input and gave rise to greater heat exposure of the material, including from the additional heat generated by friction between the particles. The respondent's experiment described in D13 did not cover these small particle sizes, which would be expected to be associated with much higher temperatures during the grinding step. The claimed process prevented this excess heat development and the concomitant thermal degradation of the active ingredients.

XV. The appellant requested that the decision under appeal be set aside and that the patent in suit be maintained as granted, or, in the alternative, that the patent be maintained in amended form on the basis of the claims of any of:

- auxiliary requests 1 to 3 as filed with the statement setting out the grounds of appeal, or
- auxiliary requests 5 to 8 as filed on 16 December 2019.

XVI. The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. Admissibility of the appeal

The appeal complies with Articles 106 to 108 EPC and Rule 99 EPC; it is admissible.

2. Inventive step - main request

Patent in suit

2.1 As acknowledged in the patent in suit, rose hip formulations, including formulations prepared from rose hip shells as described in prior-art document D2, were known to alleviate symptoms associated with inflammation and arthritis (see paragraphs [0003] to [0009] of the patent specification). The patent in suit seeks to provide a process for preparing a composition comprising dried rose hip with anti-inflammatory properties that is improved in the concentration of active ingredients (see paragraphs [0001] and [0010] of the patent specification). This is expected to improve patient compliance, as the same amount of active ingredients can be administered in a lower volume of material, i.e. with fewer tablets or capsules.

2.2 The process defined in claim 1 as granted involves grinding dried and chopped rose hip shells and applying cooling during the grinding process so that the grinding is performed at a constant temperature below 40°C.

The drying and chopping may be performed in any order suitable (see paragraph [0050] of the patent specification).

Starting point in the prior art

2.3 It was common ground that document D2 (cited in the application as filed) represents the closest prior art.

2.4 Like the patent in suit, D2 discloses a process for the preparation of rose hip powder from dried rose hip shells (see D2: claim 20 and column 3, lines 18 to 44). The process according to claim 20 of D2 involves:

- obtaining a plurality of rose hips
- fracturing the rose hips into pieces
- separating the flesh portion of the rose hips from other matter
- drying the flesh portion of the rose hips at temperatures below 50°C to a water content of about 5%
- grinding the dried flesh portion of the rose hips to produce a powder
- providing the powder in a physiologically acceptable form.

It was not in dispute that the term "flesh portion" refers to the rose hip shell.

According to the description (D2: column 3, lines 18 to 44) the drying step may be carried out before the separation step.

2.5 With this process, a powder or granular material having a particle size of below 1 mm, preferably 0.1 to 0.5 mm, can be obtained (see D2: column 3, lines 42 to 43).

Distinguishing technical feature

2.6 Claim 1 as granted differs from the disclosure in D2 by the specification that cooling is applied so that the

grinding of the rose hip shells is performed at a constant temperature below 40°C.

Objective technical problem and solution

2.7 The alleged technical effect of the claimed process in comparison with the process disclosed in D2 is that, because milder process conditions help avoid the degradation of active substances, a higher content of active substances in the ground rose hip shell material may be attained. Thus, the appellant based its reasoning in support of inventive step on an alleged improvement.

2.8 The board considers that the alleged technical effect has not been rendered credible, for the reasons set out below.

2.8.1 According to the jurisprudence of the EPO, the nature of the comparison with the closest prior art must be such that the alleged technical effect is convincingly shown to have its origin in the distinguishing technical feature (see, for instance, T 197/86, OJ 1989, 371). The alleged technical effect must also be credibly attainable over the whole of the claimed scope.

2.8.2 Contrary to the appellant's view, the association of the alleged technical effect with the distinguishing technical feature is a necessary requirement.
If it were not known which technical features were responsible for the technical effect(s) observed in a comparative test, it would not be possible to infer that the claimed subject-matter indeed provides a specific technical effect in comparison with the closest prior art.

2.8.3 A comparison meeting the criteria:

(a) comparison with the closest prior art
(b) alleged technical effect linked to the distinguishing technical feature
(c) technical effect attainable across scope claimed

was provided neither in the patent in suit (or the corresponding passages of the application as filed) nor with the appellant's submissions.

2.8.4 In support of the alleged technical effect, the appellant relied, in one approach, on a comparison of statements about dosing found in the prior art and in the patent in suit. While the powder prepared according to D2 was to be administered in an amount of at least 20 g per day (as stated in D2, column 2, lines 41 to 42), the powder prepared according to the patent in suit could be administered in an amount of 4.5 g or even just 2.25 g per day (see Example 2 of the patent in suit).

However, comparing statements about dosing in D2 and in the patent in suit does not constitute a direct comparison between powders obtained from the same batch of raw material and with process conditions that only differ by applying, or not applying, the cooling defined in claim 1. This means that the difference in dosing cannot be conclusively attributed to the distinguishing technical feature (criterion (b)). Other parameters relating to raw materials, equipment and process conditions may have differed that could have affected the content of active substances in the rose hip shell powders on which the dosing recommendations were based.

2.8.5 The examples described in the patent in suit do not focus on the distinguishing technical feature and (as conceded by the appellant) do not provide a direct

comparison of the claimed process with that of the closest prior art D2.

- Example 1 relates to two preparations that "were prepared according to the present invention and differed only by the type of rose hips used." The example has no comparative embodiment representing the closest prior art (criterion (a)).

- Example 2 relates to a clinical study in patients with osteoarthritis of the knee, in which rose hip powder according to the patent in suit was compared to a commercially available product of the prior art - in other words, a product manufactured from a different batch of raw material under unknown process conditions. For that reason alone, it cannot be acknowledged that Example 2 provides a correct comparison focused on effects linked to the distinguishing technical feature (criterion (b)).

  Furthermore, contrary to the statement in paragraph [0076] of the patent in suit, it also appears that the comparative sample was not a powder according to D2. It was uncontested that document D1 relates to the same clinical study that is also the subject of Example 2 of the patent in suit. According to D1 (see the abstract and page 268, left column, second paragraph), the comparative product was manufactured from whole rose hips and included material from rose hip seeds. Thus, Example 2 does not provide a comparison with the closest prior art D2 (criterion (a)).

  The appellant argued that, in light of the teaching of the prior art (e.g. in D3 or D5), rose hip powder containing seeds, such as the comparative sample in Example 2, would in any case have been

expected to have a higher potency than rose hip powder prepared from shells only, and therefore this choice of comparative sample would not have influenced the outcome in favour of the "inventive" sample. However, this argument remains speculative, since nothing is known about the content of seed material in the comparative sample or about the qualitative and quantitative content of active components in either sample. The appellant's argument, in any case, does not overcome the objection relating to criterion (b).

- Examples 3 and 4 relate to samples of rose hip powder which were "manufactured by conventional processes" that are not defined in detail (Samples A and C), and samples "manufactured according to the process of the present invention", also not defined in detail (Samples B and D). All of the samples were manufactured from rose hips of the species *Rosa canina*, *Rosa moschata* and *Rosa rubiginosa* (see paragraph [0082]). It cannot be inferred from the information provided that all of the samples were produced from the same batch of rose hips or even from rose hips of the same species. Thus, it is unknown also in this case which parameters differed in the preparation of the four powder samples, and it would not be possible to conclude that any observed difference in the content of active ingredients had its origin in the distinguishing technical feature (criterion (b)).

  The main difference between these samples was the content of triacylglycerols and fatty acids, highest in Samples A and C. This was attributed to the presence of seeds in Samples A and C (see paragraph [0097]). Hence, it is evident that the

comparative samples do not represent the closest prior art D2 (criterion (a)).

2.8.6 The appellant's experiment described in Annex 1 does provide a comparison carried out with rose hip shell material from the same batch. A powder obtained by a process according to the patent in suit and a powder obtained by a comparative process were compared with respect to their effect on levels of the pro-inflammatory cytokine TNF-α in an *in vitro* cell culture experiment.

However, the comparative process in Annex 1 is not the process according to D2. Annex 1 states, instead, that rose hip shell powder prepared as described in the patent in suit, i.e. ground at a controlled temperature below 40°C, was split into two batches. One was not subjected to heat and one was subjected to 50°C for five minutes, in order to model heat exposure of the powder during grinding. Thus, rather than directly reproducing the prior-art process by grinding the rose hip shells in the same apparatus without cooling, the appellant made an assumption about heat exposure in the prior-art process and then implemented a process step involving heat exposure subsequent to grinding, to model this assumption.

No technical basis is given for the assumption regarding heat exposure, which must, therefore, be regarded as speculative. There is no evidence that without cooling, the heat exposure of the material during the grinding step might indeed be equivalent to five minutes' exposure to 50°C, in any mill that could have been used to implement the grinding step required in D2:

- The appellant's Annex 1 does not describe the apparatus and process parameters used for the

grinding step, apart from stating that grinding was carried out at a controlled temperature below 40°C. The time required for grinding is not mentioned.

- In document D13 (Experiment 2), the respondent reports that "less than a few seconds" were required for grinding the rose hip shell material under specified process conditions, and the temperature of the powder immediately upon leaving the mill was 30°C.

In conclusion, it cannot be confirmed on the basis of the available information that the comparison in Annex 1 adequately represents a comparison with the closest prior art D2 (criterion (a)).

Moreover, the experiment described in Annex 1 cannot render the attainment of the alleged technical effect credible across the temperature range claimed (criterion (c)), since the document does not reveal the temperature at which the material was maintained during the grinding step. It could have been close to the upper limit of 40°C but it could also have been much lower (preferred temperatures according to claim 1 are "below 20°C"). If the milling temperature in the experiment had been, for instance, 10°C, the same result (in terms of the efficacy of the "inventive" sample) could not necessarily be expected with a milling temperature of 39°C, which is still within the scope claimed.

For these reasons, the results reported in Annex 1 do not show conclusively that the alleged technical effect is linked to the distinguishing technical feature and is attained over the whole scope claimed.

2.9 As the alleged technical effect was not rendered credible, it cannot be taken into account in the formulation of the objective technical problem.

2.10 Thus, the objective technical problem is to provide an alternative process for preparing a dry powder from rose hip shells.

2.11 It was not in dispute that the process defined in claim 1 as granted solves this problem.

Obviousness of the solution

2.12 Seeking to solve the objective technical problem, the person skilled in the art would routinely have considered modifying the process conditions, in particular with the intention of ensuring mild process conditions.

2.13 Plant materials typically contain components which are sensitive to heat and susceptible to thermal degradation. Rose hip is a plant material known to contain such components, such as vitamin C and other vitamins. The presence of vitamin C in food and drug products has, moreover, been known to be advantageous as a nutrient and as a pharmaceutically acceptable antioxidant and stabiliser. While vitamins may not be the active ingredients that bring about the composition's anti-inflammatory effect, their presence may still be desirable. Furthermore, it cannot be ruled out that other relevant rose hip components may be susceptible to thermal degradation.

2.14 D2 recommends drying the rose hip shells at temperatures below 50°C in order to preserve their vitamin content, since above that temperature notable deterioration in vitamin content is possible (see D2: column 3, lines 29 to 37). In a similar context, D5

(see page 303, right-hand column) describes a process for drying material from both shells and seeds, wherein the temperature never exceeds 40°C.

2.15 Hence, it was clear that gentle process conditions were desirable for processing the rose hip material. The person skilled in the art would furthermore have been aware that grinding requires the input of mechanical energy and generates heat. The grinding step might, therefore, expose the material to thermal stress.

2.16 It would thus have been an obvious precautionary measure to implement cooling as defined in claim 1 during the grinding step, in order to ensure gentle process conditions and protect any heat-sensitive components.

2.17 This would have been enough of an incentive, in the absence of a technical prejudice against doing so.

2.17.1 The appellant argued that the prior art only restricted the drying temperature and did not mention grinding as problematic. Still according to the appellant, as drying takes much longer than grinding, the person skilled in the art would not have been concerned about heat exposure during the comparatively short time the material spent in the grinder.

2.17.2 This argument is not necessarily correct, as it considers only the length of time and not the potentially heightened energy input mentioned in point 2.15. In any case, such general speculations do not amount to evidence of a technical prejudice which would have prevented the skilled person from implementing the process modification in question as an obvious precaution.

2.18 For these reasons, the subject-matter of claim 1 as granted does not involve an inventive step within the meaning of Article 56 EPC.

3. Inventive step - auxiliary request 1

3.1 Claim 1 of auxiliary request 1 differs from claim 1 of the main request solely in the requirement that the cooling applied is air cooling.

3.2 Air cooling is a common mode of cooling. This technical feature has not been associated with any particular technical effect or advantage, and accordingly it does not change the objective technical problem or the board's conclusion on obviousness.

3.3 As a consequence, the subject-matter of claim 1 of auxiliary request 1 does not involve an inventive step within the meaning of Article 56 EPC, for the same reasons as set out above with respect to claim 1 of the main request.

4. Inventive step - auxiliary requests 2 and 3

4.1 Claim 1 of auxiliary request 2 differs from claim 1 of the main request, and claim 1 of auxiliary request 3 differs from claim 1 of auxiliary request 1, by the additional process step of mixing the ground powder with 30 mg to 80 mg vitamin C per g rose hip powder. It is not specified what the content of vitamin C should be in the final product.

4.2 The technical effect achieved is that of increasing the content of vitamin C in the ground rose hip shell powder.

4.2.1 No direct comparison with the process and powder according to D2 was provided.

4.2.2 D2 describes its rose hip shell powder as containing a high content of vitamin C, especially when drying was conducted at temperatures below 50°C (see D2: claims 1 and 20; column 3, lines 29 to 37; Table 1). A typical content mentioned in D2 is 560 mg vitamin C per 100 g powder, i.e. 5.6 mg/g.

4.2.3 Thus, it would appear that the process according to auxiliary requests 2 and 3 involves adding relatively high amounts of vitamin C to the ground powder.

4.3 As pointed out by the appellant, the patent in suit, in paragraphs [0018] to [0020], makes the following statements in relation to added vitamin C:

(1) The presence of vitamin C is believed to facilitate the uptake in a subject of the active ingredients of the rose hip complex.

(2) The added vitamin C is also believed to provide for improved stability of the composition, thus improving the shelf life of the product.

(3) In a preferred embodiment, the added vitamin C is a synthetic vitamin as naturally occurring vitamin C in rose hip has shown to degrade too fast. In other words, added vitamin C compensates for vitamin C that was lost in processing the rose hip shells.

4.4 Thus, it has to be determined whether any of these effects attributed to added vitamin C constitutes a reason to modify the objective technical problem, or to formulate an additional technical problem to be solved.

4.5 As to the first effect, no evidence was provided to show that added vitamin C indeed facilitates the uptake of the relevant active ingredients (and ultimately improves the therapeutic efficacy of the powder).

4.6 As to the second effect, the appellant did not provide any evidence in comparison with the closest prior art regarding the effect of added vitamin C on shelf life.

4.7 In connection with the third point, the appellant did not provide any evidence regarding the degradation of vitamin C and whether this occurred faster in the claimed process than in the process according to D2. On the basis of the available information, it is not possible to say under which conditions, and to what extent, it would be necessary to compensate for loss of vitamin C during processing.

4.8 As alleged but unsupported advantages cannot be taken into consideration when determining the objective technical problem, the objective technical problem remains the same as for claim 1 of the main request, namely to provide an alternative process for preparing a dry powder from rose hip shells.

4.9 As an additional observation, the alleged technical effect of vitamin C acting as a stabiliser (see point 4.5 above), if acknowledged, would be plausible owing to the commonly-known properties of vitamin C, but for the same reason it would also not have been surprising and therefore could not contribute to inventive step.

4.10 With regard to the technical feature of temperature control during the grinding step, the same reasoning regarding obviousness applies as set out for claim 1 of the main request.

4.11 With regard to the process step of adding vitamin C to the ground powder, the following considerations are relevant:

4.11.1 As set out in section 2.13 above, the person skilled in the art would have been aware that vitamin C, a natural component of rose hips, had desirable properties as a nutrient and antioxidant/stabiliser, and that it was susceptible to degradation. Accordingly, it would have been logical to attribute some relevance to vitamin C content. In this context, it would have been a routine measure to check the vitamin C content of the processed material and to adjust as needed to the content desired in the final product (as argued by the appellant itself in a different context, see section XIV. above, on page 8, second paragraph). If indeed the degradation of the vitamin were unusually fast in the claimed process, this would have been detected and compensated for in the course of the routine activity of the skilled person.

4.12 For these reasons, the subject-matter of claim 1 of auxiliary requests 1 to 3 does not involve an inventive step within the meaning of Article 56 EPC.

5. Inventive step - auxiliary requests 5 to 8

5.1 Document D2 discloses a range of 0.1 to 0.5 mm, i.e. 100 to 500 µm, as the preferred particle size (see section 2.5 above).

5.2 Hence, the requirement in claim 1 of auxiliary requests 5 to 8 that the particle size of the ground rose hip shells must not exceed 550 µm is not a distinguishing technical feature relative to the disclosure of D2 and cannot contribute to inventive step.

5.3 With regard to the assessment of inventive step, the same reasoning and conclusions apply to auxiliary requests 5 to 8 as set out above for the main request and auxiliary requests 1 to 3.

5.4 The argument that more heat will be generated when milling to a smaller particle size does not overcome the objection that the alleged technical effect has not been rendered credible for any particle size. As set out in detail in section 2.8 above, no conclusive evidence was provided that the claimed process results in a different product on account of cooling the material to a temperature below 40°C during the grinding step. In addition, since the particle size is not mentioned in the examples of the patent in suit or in Annex 1, it cannot be confirmed that any of the samples tested was in conformity with the claims of auxiliary requests 5 to 8.

5.5 For these reasons, the subject-matter of claim 1 of auxiliary requests 5 to 8 does not involve an inventive step within the meaning of Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairwoman:

K. Boelicke T. Sommerfeld

Decision electronically authenticated