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Datasheet for the decision of 5 October 2022

Case Number: T 1776/18 - 3.3.09

Application Number: 12769275.4

Publication Number: 2757898

IPC: A23L2/66, A23L33/00, A23L33/185, A23J3/14, A23J3/16

Language of the proceedings: EN

Title of invention:
POWDERED NUTRITIONAL FORMULATIONS INCLUDING SPRAY-DRIED PLANT PROTEIN

Patent Proprietor:
ABBOTT LABORATORIES

Opponents:
Fresenius Kabi Deutschland GmbH
Cosucra-Groupe Warcoing SA
N.V. Nutricia
Spreepatent Schutzrechtsverwertung und Innovationstransfer GmbH
Société des Produits Nestlé S.A.

Relevant legal provisions:

EPC Art. 56, 113(2), 114(1), 114(2), 123(1)
RPBA Art. 12(4)
RPBA 2020 Art. 13(2)
EPC R. 79(1), 81(3), 116(1), 116(2)
ECHR Art. 6(1)

Keyword:

Inventive step - (no)
Late-filed request - request identical to request not admitted in first instance proceedings
Legal basis for not admitting late-filed requests
Amendment after summons - taken into account (no)

Decisions cited:

G 0002/88, G 0010/91, G 0004/92, G 0007/93, G 0003/14, R 0006/19, J 0014/19, T 0912/91, T 0133/92, T 0202/92, T 0771/92, T 0502/98, T 0706/00, T 0171/03, T 0235/08, T 0811/08, T 1734/08, T 1100/10, T 1732/10, T 1914/12, T 1933/12, T 2288/12, T 2385/12, T 2536/12, T 0487/13, T 1855/13, T 0066/14, T 0108/14, T 1784/14, T 0044/17, T 0525/15, T 1758/15, T 0688/16, T 0754/16, T 0966/17, T 1042/18, T 1078/18, T 1270/18, T 1558/18, T 0085/19, T 0256/19

Catchword:

1.) Article 114(2) EPC provides a legal basis for disregarding claim requests which are not submitted in due time (Reasons 4.5.1-4.5.11).

2.) A claim request which is filed in opposition proceedings after the date set under Rule 116(1) EPC is not submitted in due time within the meaning of Article 114(2) EPC (Reasons 4.6.1-4.6.10).

3.) Rule 116(2) EPC does not limit the Opposition Division's discretionary power under Article 114(2) EPC and Rule 116(1) EPC. As a rule, this discretionary power does not depend on the contents of the Opposition Division's communication under Rule 116(1) EPC. However, if the Opposition Division invites the patent proprietor to file an amended claim request to address a specific objection and the patent proprietor complies with this invitation by filing the required amendments by the date set under Rule 116(1) EPC, the Opposition Division's discretion not to admit that claim request may effectively be reduced to zero (Reasons 4.7.1-4.7.8).

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Case Number: T 1776/18 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 5 October 2022

Appellant: (Patent Proprietor)	ABBOTT LABORATORIES 100 Abbott Park Road Abbott Park, IL 60064-3500 (US)
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Representative:	Vanhalst, Koen De Clercq & Partners cvba E. Gevaertdreef 10a 9830 Sint-Martens-Latem (BE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 31 May 2018 concerning maintenance of the European Patent No. 2757898 in amended form.**

Composition of the Board:

Chairman	A. Haderlein
Members:	F. Rinaldi
	N. Obrovski

Summary of Facts and Submissions

I. This decision concerns the appeals filed by the patent proprietor and opponents 1, 3, 4 and 5 against the Opposition Division's interlocutory decision.

II. In the following, the parties will be referred to by their party status before the Opposition Division.

III. With their respective notice of opposition, the opponents had requested revocation of the patent based on, among other things, Article 100(a) EPC, on the grounds of a lack of novelty and inventive step.

IV. The following documents are relevant to the decision:

D6: WO 2010/100368 A1
D6b: US 2011/0311599 A1

D6 is the publication of an international application filed under the PCT in French. D6b is the US patent application based on this international application. On appeal, the parties agreed to use D6b as prior art instead of D6.

V. In the decision under appeal, the Opposition Division decided, among other things, that claims 1 and 7 of auxiliary request 4 before it lacked novelty over D6. Auxiliary request 4A, which had been filed during the oral proceedings, was not admitted into the proceedings. However, auxiliary request 4B, which had also been filed during the oral proceedings, was admitted and was found to be allowable.

VI. With its statement setting out the grounds of appeal, the patent proprietor filed a main request and auxiliary requests 1, 2, 3 and 4A. The latter is identical to the request that was not admitted in the opposition proceedings. Furthermore, the patent proprietor maintained auxiliary request 4B and filed auxiliary request 4C, with its reply to the opponents' statements setting out the grounds of appeal, and auxiliary request 5, by letter dated 6 June 2022.

VII. The following claims are relevant to this decision:

Main request

Claim 6 reads as follows:

"*A powdered nutritional formulation comprising at least one milk protein and at least one spray-dried pea protein, wherein the spray-dried pea protein comprises up to 50 wt.% of the total protein in the powdered nutritional formulation, and wherein the formulation includes dryblended spray-dried pea protein.*"

Auxiliary requests 1, 2, 3 and 4B

These claim requests include a claim having the same wording as claim 6 of the main request.

Auxiliary requests 4A and 5

Claim 1 of both requests reads as follows:

"*A powdered nutritional formulation comprising a dryblended pea protein, wherein at least a portion of the dryblended pea protein is spray-dried pea protein,*

and further comprising at least one milk protein, wherein said formulation is packaged and sealed in a single or multi-use container."

Auxiliary request 4C

Claim 1 reads as follows:

"*A powdered nutritional formulation comprising at least one milk protein and at least one spray-dried plant protein, wherein the spray-dried plant protein comprises up to 50 wt.% of the total protein in the powdered nutritional formulation, and wherein the formulation includes dryblended spray-dried plant protein, and wherein the plant protein is pea protein or a combination of pea protein with soy protein.*"

VIII. The patent proprietor's arguments, where relevant to the present decision, can be summarised as follows:

- Claim 6 of the main request was inventive. The closest prior art, D6b, did not disclose spray-dried pea protein nor the amount called for in the claim. This protein provided specific technical effects. Even if the technical problem were merely to provide an alternative, the skilled person still would not have arrived at the claimed subject-matter.
- The Opposition Division erred in not admitting auxiliary request 4A. The request was filed in direct reaction to a change in the subject-matter of the proceedings. It was not late-filed. The Opposition Division had no discretion not to admit it. Thus, auxiliary request 4A and auxiliary request 5, which is based on the former, had to be admitted.

IX. The opponents' arguments, where relevant to the present decision, can be summarised as follows:

- Claim 6 of the main request lacked inventive step. D6b was the closest prior art. Claim 6 differed from it only in the amount of spray-dried pea protein. The technical problem was to provide an alternative. Reducing the amount of spray-dried pea protein in the product of D6b would have been an obvious measure for the skilled person.
- The Opposition Division's decision not to admit auxiliary request 4A was correct. Auxiliary request 5 should not be admitted either.

X. Final requests

The patent proprietor requested that the decision under appeal be set aside and that the patent be maintained on the basis of:

- the main request, filed with the statement setting out the grounds of appeal; or
- auxiliary requests 1, 2, 3 or 4A, filed with the statement setting out the grounds of appeal; or
- auxiliary request 4B, filed during the oral proceedings before the Opposition Division on 22 March 2018; or
- auxiliary request 4C, filed with the reply to the opponents' statements setting out the grounds of appeal; or
- auxiliary request 5, filed with the submission dated 6 June 2022.

Opponents 1, 3, 4 and 5 requested that the decision under appeal be set aside and that the patent be revoked.

Reasons for the Decision

1. Patent in suit

The patent relates to powdered nutritional formulations including a plant protein which is dryblended. At least a portion of the plant protein, preferably pea protein, has been spray-dried prior to being dryblended into the nutritional formulation. According to the patent, spray-drying the plant protein prior to dryblending it into the powdered nutritional formulation improves the mouthfeel of the reconstituted formulation (paragraphs [0001], [0011] and [0014]).

2. Main request - inventive step

2.1 In the decision under appeal, the Opposition Division assessed the inventive step of a claim having the same wording as claim 6 of the main request (i.e. claim 1 of what is now auxiliary request 4B). It concluded that the claimed subject-matter involved an inventive step. The prior art used was D6, among other documents.

2.2 Closest prior art

2.2.1 On appeal, the parties used D6b as the closest prior art instead of D6. The Board agrees to do the same.

2.2.2 D6b (e.g. paragraphs [0001], [0216] and [0226] to [0231]) concerns a granulated powder containing vegetable proteins and fibres. Among other things, the powder can be used as a total or partial replacement for animal protein, in particular milk protein. D6b also refers to food formulations comprising the granulated powder. The food formulations are presented in various forms, including mixtures of powders intended for diet products or for sportspersons.

2.2.3 In Example 4 of D6b, the granulated powder is obtained by spray-drying pea protein and branched maltodextrin, at a weight ratio of 60% pea protein composition (at a total protein content of 85%) and 40% branched maltodextrins. The granulated powder is dry-mixed (i.e. dryblended) with specified amounts of other nutritional powders (milk protein, sugar, modified starch, maltodextrin). To this dry composition, oil and water is added to produce a high-protein cream product.

2.2.4 The patent proprietor regarded the resulting dry composition as an intermediate product. In its view, such a product was not suitable as a starting point for assessing the inventive step of claim 6.

2.2.5 This argument is not convincing. It is true that the dry composition of Example 4 is not consumed as such. It requires further process steps, including adding oil and water, before it can be ingested. Yet so does the powdered nutritional formulation of claim 6 of the main request. This requires, for example, reconstitution with an aqueous liquid (patent in suit, paragraph [0013]).

2.2.6 Therefore, the dry composition of Example 4 of D6b is considered the starting point for assessing inventive step. It is the closest prior art.

2.3 Distinguishing feature(s)

2.3.1 There is agreement between the parties that the subject-matter of claim 6 differs from the closest prior art in that the spray-dried pea protein comprises up to 50 wt.% of the total protein.

2.3.2 The patent proprietor maintained that there was a second distinguishing feature. In its view, claim 6 called for a spray-dried pea protein, whereas the closest prior art disclosed a spray-dried mixture of pea protein with something else (i.e. maltodextrin). These were different things.

2.3.3 In particular, the patent proprietor argued as follows:

- The skilled person would not have considered the mixture of the closest prior art to be a spray-dried pea protein.
- The patent specification supported the interpretation that the spray-dried pea protein did not include any other ingredient.
- The use of the terms "dryblended" and "spray-dried pea protein" made it clear that no ingredient was mixed with the pea protein before spray-drying. Thus, the spray-dried pea protein according to claim 6 of the main request was prepared as an individual, single component. The remaining components of the formulation were then dryblended with it.

- Regulatory authorities would not consider the product of Example 4 of D6b to be a spray-dried pea protein.

2.3.4 To deal with these points, it is expedient to first examine the wording of claim 6 and to then turn to the patent proprietor's arguments.

2.3.5 Claim 6 is directed to a powdered nutritional formulation which comprises at least one milk protein and at least one spray-dried pea protein. In addition, the claim specifies two things, the formulation's (maximum) amount of spray-dried pea protein and how to incorporate the spray-dried pea protein into the powdered nutritional formulation.

2.3.6 Claim 6 is drafted using open claim wording - the powdered nutritional formulation comprises specified components. The wording of claim 6 does not specify that the spray-dried pea protein is the sole spray-dried component. Nor does it specify that the pea protein is spray-dried in isolation. Rather, the open wording merely stipulates the mandatory features milk protein and pea protein, the latter having been subjected to a spray-drying process step.

2.3.7 It is entirely consistent with open claim wording that components called for in a claim may be associated with other components not mentioned in the claim. This applies in the present case.

2.3.8 The granulated powder of Example 4 of D6b, which is produced by spray-drying a mixture of pea protein and maltodextrin, is to be considered a spray-dried pea protein within the meaning of claim 6 of the main request. While the spray-drying step in D6b may confer

additional technological properties on the product, it does not change the pea protein into something else. More precisely, the pea protein treated in this way remains a pea protein, which has additionally been subjected to a spray-drying step. Such a product is encompassed by the wording of claim 6.

2.3.9 According to the patent proprietor, the patent specification made it clear that the spray-dried pea protein of claim 6 included no other component. In this context it referred e.g. to paragraphs [0012], [0014], [0022] and [0027] to [0029].

2.3.10 The cited passages relate to spray-dried plant protein, such as pea protein. They do not disclose that specified ingredients are added to the plant protein. At the same time, they describe that pea protein is spray-dried together with other (non-protein) components, such as source material. Moreover, the patent specification does not explicitly exclude other components from being added. Further process steps may be carried out in the preparation of the spray-dried pea protein, such as pasteurising or homogenising (main request, claims 11 and 12). In short, the patent specification does not impose an interpretation of claim 6 that contradicts the one set out above in section 2.3.6.

2.3.11 The patent proprietor argued that the combination of the terms "dryblended" and "spray-dried pea protein" implied a particular sequence of process steps in preparing the product of claim 6.

2.3.12 However, in line with the claim construction set out in section 2.3.6 above, claim 6 simply specifies that the spray-dried pea protein is dryblended into the

nutritional formulation. This does not mean that other process steps may not occur, for instance combining pea protein with other components prior to spray-drying.

2.3.13 Finally, the patent proprietor argued that regulatory authorities would not consider the product of the closest prior art to be a spray-dried pea protein.

2.3.14 However, the question is not how the product of the closest prior art would have to be labelled for marketing it. The issue under investigation is rather whether this product is encompassed by the open wording of claim 6. As explained above, the answer is affirmative.

2.3.15 To conclude, the dry composition of the closest prior art comprises both powdered milk protein and a pea protein which has undergone a spray-drying step, i.e. a spray-dried pea protein.

2.3.16 Therefore, the only distinguishing feature over the closest prior art is that the spray-dried pea protein comprises up to 50 wt.% of the total protein.

2.4 Technical problem

2.4.1 The next question to be addressed is what technical problem is solved.

2.4.2 No specific technical effect is associated with the distinguishing feature. According to both the patent as granted and the application as filed, spray-dried pea protein could be added in any amount to the powdered nutritional formulation. It could even be the sole source of protein used. This fact underscores that the

restricted amount of spray-dried pea protein is arbitrary. It does not provide a technical effect.

2.4.3 The patent proprietor also argued that the spray-dried pea protein provided technical effects, namely that it reduced the formulation's viscosity and improved its mouthfeel. These effects should be taken into account when formulating the technical problem, as the Opposition Division did in the decision under appeal.

2.4.4 However, this is not correct, for several reasons.

2.4.5 First, the closest prior art itself already includes spray-dried pea protein. Therefore, this component does not provide a technical contribution to be taken into account when formulating the technical problem.

2.4.6 Second, there is no evidence in the patent that the spray-dried pea protein causes the alleged effects. The only example in the patent in which mouthfeel is assessed is Example 11. However, in this example all of the formulations, including the control formulation, were prepared using spray-dried pea protein. Thus, the example's results cannot be used to demonstrate any technical effects.

2.4.7 Third, there is no evidence that any effect on the viscosity is achieved.

2.4.8 Therefore, it can be concluded that the technical problem is merely to provide a further composition.

2.5 Obviousness

2.5.1 The patent proprietor argued that the skilled person would not be motivated to reduce the amount of spray-

dried pea protein in the closest prior art. Rather, the teaching therein would lead them away from doing so.

2.5.2 However, the Board fails to see any teaching preventing the skilled person from using higher concentrations of milk protein in combination with the spray-dried pea protein of D6b.

2.5.3 The examples in D6b set out to demonstrate what can be achieved when applying the document's teaching. Throughout the disclosure of D6b, the straightforward teaching is that a total or partial replacement of milk protein can be achieved. The skilled person would understand that they would be at liberty to adjust or modify the amounts of the milk protein and spray-dried pea protein. In particular, reducing the amount of a component which is difficult to handle when used at a high concentration would be a measure that the skilled person would consider. There is nothing that would prevent them from doing so in the context of the specific dry composition of Example 4, i.e. the closest prior art.

2.5.4 Therefore, the solution would have been obvious for the skilled person.

2.6 In conclusion, the subject-matter of claim 6 of the main request does not involve an inventive step (Article 56 EPC).

3. *Auxiliary requests 1, 2, 3, 4B and 4C - inventive step*

3.1 Auxiliary requests 1, 2, 3 and 4B include a claim having the same wording as claim 6 of the main request. This means that all these requests include a claim which lacks an inventive step for the reasons set out

above in section 2. It follows from this that none of these requests is allowable (Article 56 EPC).

3.2 As to auxiliary request 4C, claim 1 of this request is based on claim 6 of the main request. However, claim 1 is not restricted to spray-dried pea protein. Instead, it refers to one spray-dried plant protein, which is pea protein or a combination of pea protein with soy protein.

3.2.1 This claim was filed with the reply to the opponents' statements setting out the grounds of appeal to address objections other than those relating to inventive step. The patent proprietor provided no separate inventive-step argument with respect to this claim.

3.2.2 In substance, claim 1 still encompasses the same subject-matter as claim 6 of the main request, namely a powdered nutritional formulation which comprises at least one milk protein and at least one spray-dried pea protein. Therefore, claim 1, like claim 6 of the main request, lacks an inventive step.

3.3 It follows from this that none of auxiliary requests 1, 2, 3, 4B and 4C is allowable under Article 56 EPC.

4. *Admittance of auxiliary request 4A*

4.1 The patent proprietor filed auxiliary request 4A at the oral proceedings before the Opposition Division, which decided not to admit the request. The patent proprietor requested that this decision be set aside.

4.2 The patent proprietor argued that auxiliary request 4A was not late-filed. It could not have been filed earlier. Instead, the request had been filed in direct

reaction to the Opposition Division's conclusion that the claim under scrutiny lacked novelty over Example 4 of D6. This objection had been raised for the first time in one of the opponents' submissions filed on the last day fixed under Rule 116(1) EPC. Under these circumstances, the Opposition Division had no discretion not to admit the request. The reasoning of T 754/16 was applicable by analogy. According to the cited decision, auxiliary requests filed during oral proceedings in direct response to a reversal of the Opposition Division's preliminary opinion had to be admitted.

4.3 In short, the patent proprietor's view was that auxiliary request 4A, once filed, was in the proceedings. Under the circumstances of the case before it, the Opposition Division had no discretionary power. It simply had to admit the request.

4.4 The Opposition Division decided on the admittance of auxiliary request 4A under Article 114(2) EPC. In view of the patent proprietor's allegation that the Opposition Division did not have any discretionary power for its decision not to admit auxiliary request 4A, the Board will firstly assess whether Article 114(2) EPC provides a legal basis for such a discretionary decision. Secondly, it will be analysed whether the concept of "not submitted in due time" in Article 114(2) EPC relates to *fixed criteria* such as a certain point in time in the proceedings or, as alleged by the patent proprietor, to *relative criteria* such as individual procedural developments. Thirdly, it will be assessed whether Rule 116(2) EPC should, as alleged by the patent proprietor with reference to T 754/16, be understood as making the exercise of the Opposition Division's discretionary power subject to conditions

other than that the amended claim request was not submitted in due time. Fourthly, the Opposition Division's way of exercising its discretion will be reviewed.

4.5 Article 114(2) EPC - legal basis for not admitting amended claim requests

4.5.1 There is a long line of case law (e.g. T 171/03, Reasons 5; T 811/08, Reasons 4.2; T 1100/10, Reasons 8 and 11; T 1933/12, Reasons 4.1; T 2385/12, Reasons 1.8; T 108/14, Reasons 3; and T 44/17, Reasons 2) according to which claim requests may be disregarded under Article 114(2) EPC. In T 1855/13, Reasons 1.8.1, a submission containing a claim request was explicitly considered to be a fact within the meaning of Article 114(2) EPC. Likewise, in T 604/01, Reasons 6.1, both the patent as granted and the claims as amended were considered facts. Examples of case law in which the Opposition Division's discretion not to admit claim requests was considered to have its legal basis in Article 114(2) EPC in conjunction with Rule 116(1) EPC include T 1270/18, Reasons 2 and 3, and T 85/19, Reasons 1.2.

4.5.2 There is also an alternative view. In a petition for review case before the Enlarged Board of Appeal, the petitioner had argued that a Board of Appeal had no power not to admit claim requests because claim requests were neither facts nor evidence within the meaning of Article 114(2) EPC. Against this background, the Enlarged Board referred to the first sentence of Article 123(1) EPC, according to which a patent may be amended in accordance with the Implementing Regulations. The Enlarged Board noted that the applicant's right under the second sentence of

Article 123(1) EPC to be given at least one opportunity to amend the application was not applicable in opposition proceedings and that under Rule 81(3) EPC, in opposition proceedings, an opportunity to amend must only be given where necessary. The Enlarged Board deduced from this that the first sentence of Article 123(1) EPC provided a legal basis for the EPO's discretion as to whether or not to admit claim requests. It left open whether or not Article 114(2) EPC constituted such a legal basis as well (R 6/19, Reasons 5 to 11; cf. also T 966/17, Reasons 2.2.1). In T 256/19, Reasons 4.7, the Board stated that discretion to disregard an amended version of a patent could only emanate from Article 123(1) EPC in conjunction with Rule 79(1), 81(3) or 116(2) EPC.

4.5.3 There are further views in the case law (see Case Law of the Boards of Appeal, 10th edition, 2022, IV.C.5.1.4 a)) on the legal basis for not admitting amended claim requests, including that Rule 116(2) EPC is the only legal basis (see T 688/16, Reasons 2.1), under this approach apparently without any corresponding provision in the articles of the EPC. There are also decisions in which Article 114(2) EPC in conjunction with Rule 116(2) EPC was considered to be the legal basis for not admitting amended claim requests (e.g. T 2536/12, Reasons 2.8, T 525/15, Reasons 1.2, and T 1758/15, Reasons 1.1.4).

4.5.4 In decision T 754/16, referred to by the patent proprietor, the Board was of the view that Article 114(2) EPC did not provide a legal basis for not admitting amended claim requests. This was reasoned by reference to a legal commentary. In the corresponding passage of the current, 8th edition of this commentary reference is made to T 1914/12. In

T 1914/12, last paragraph of Reasons 7.1.3.a), it is stated that new sets of claims are not facts within the meaning of Article 114 EPC. This is reasoned by references to previous decisions, namely to T 912/91, Reasons 10; T 133/92, Reasons 7; T 771/92, Reasons 7, and T 235/08, Reasons 6.1. However, all of these decisions are concerned with a very specific question, namely the question of whether Article 113(1) EPC and the Enlarged Board's opinion in G 4/92 prevent a Board from deciding on the maintenance of a patent on the basis of auxiliary requests made during oral proceedings in which the opponent was absent. Against this background, the Board is of the view that in particular the statements in T 912/91 and T 133/92 that the submission of auxiliary requests is not a fact "within the meaning of the above decision" (i.e. opinion G 4/92) cannot be generalised. As highlighted in T 202/92, Reason 6, the question to be asked in the context of G 4/92 is whether an opponent can expect a patent proprietor to try to overcome the objections on file by filing an auxiliary request in the oral proceedings. In T 235/08, Reasons 6.1, which is the most recent decision cited in T 1914/12, it was accordingly held that G 4/92 did not prevent the admittance of amended claim requests filed at the oral proceedings "where the amendments made amount to clarifying restrictions made to avoid objections raised in the written proceedings and the amendments are of a nature that the absent opponents might have expected". This statement appears to indicate that the Board in T 235/08 considered amended claim requests as facts under G 4/92. Otherwise the Board would not have had to explain the specific circumstances which did not prevent the admittance of these amendments under G 4/92. In any case, opinion G 4/92 itself does not

contain any statement as to the legal nature of claim requests in relation to Article 114(2) EPC.

4.5.5 The present Board agrees with the case law according to which Article 114(2) EPC constitutes a legal basis for not admitting claim requests. Under Rule 43(1) EPC, a patent claim defines the matter for which protection is sought in terms of the technical features of the invention. In G 2/88, Reasons 2.5, the Enlarged Board referred to an invention's technical features as physical features, namely as the physical parameters of the claimed entity or the physical steps of the claimed activity. For the purposes of Article 114(2) EPC, the present Board thus considers a patent claim to be a statement of technical facts in legal terms. This is also apparent in claim interpretation. While determining the subject-matter of a patent claim is overall a question of law, it also involves questions of fact, such as the meaning of a certain technical term at a certain point in time. Due to the technical expertise of the technically qualified members of the Boards of Appeal (and of the examiners in the Examining and Opposition Divisions) such questions of fact can usually be resolved without gathering evidence, but they are still questions of fact, and must at least implicitly be answered when interpreting a claim to assess whether a given claim request is allowable or not.

4.5.6 Moreover, even if one were of the opinion that a patent claim as such does not qualify as "facts or evidence" within the meaning of Article 114(2) EPC, an amended claim request must be substantiated in order to become effective (see, for example, T 1732/10, Reasons 1.5, T 2288/12, Reasons 3.1, and T 1784/14, Reasons 3.5). Unsubstantiated claim requests are not considered

validly filed and do not form part of the proceedings (T 1784/14, Reasons 3.7). In view of Rule 80 EPC, according to which an amended claim request must be occasioned by a ground for opposition, a claim request must be substantiated by submitting why the amendment is suitable for overcoming one or more grounds of opposition. For novelty and inventive-step objections, this substantiation is usually provided through submissions which relate the amendment to prior-art documents, and for objections on sufficiency of disclosure and added subject-matter, through submissions which relate the amendment to the application documents. Submissions referring to such documentary evidence necessarily involve factual elements. Moreover, substantiating an amendment of a claim and explaining its technical meaning necessarily involves the view of the skilled person, which depends on their common general knowledge. While the skilled person *per se* is a fictitious character and therefore a legal construct, their common general knowledge is a question of fact. Even claim requests addressing a clarity objection raised in line with G 3/14 usually involve references to factual elements in some form or other, for example on the meaning of a certain technical term in a particular technical field. Exceptionally, an amended claim request may not be explicitly substantiated but may still be considered to have been validly filed because it is self-explanatory. Legally, however, this does not mean that such a claim request is not substantiated at all. Rather, the minimum substantiation required for any valid claim request is in such cases implicitly provided (cf. T 1078/18, Reasons 2.5), and is thus present in the form of an implied statement. In conclusion, in submissions containing claim requests which are explicitly or implicitly substantiated, factual

elements are present. The presence of these factual elements allows Article 114(2) EPC to be relied on as a legal basis for disregarding claim requests which are not filed in due time (see J 14/19, Reasons 1.6 and 1.7).

4.5.7 Most of the case law on the need to substantiate claim requests concerns claim amendments submitted in appeal proceedings, and in these cases reference is often made to Article 12(2) RPBA 2007 (cf. Article 12(3) RPBA 2020). While this provision is not applicable in opposition proceedings, the principle that a party must contribute to the conduct of the proceedings by substantiating its own requests in a minimum way is not limited to appeal proceedings. This can in particular be deduced from Rule 76(2)(c) EPC, according to which an opponent requesting the revocation of a patent must also provide substantiation for at least one ground of opposition (see Case Law of the Boards of Appeal, 10th edition, 2022, IV.C.2.2.8 a)). Accordingly, it was confirmed in T 44/17, Reasons 2, that claim requests are deemed to be validly submitted only as of the date of their substantiation in opposition proceedings as well. Correspondingly, it is also standard practice in opposition proceedings to substantiate claim requests explicitly.

4.5.8 A teleological interpretation of Article 114(2) EPC supports the understanding that substantiated claim amendments are facts within the meaning of this provision. The purpose of Article 114(2) EPC is to provide the deciding body with an effective means to prevent parties from unnecessarily protracting the proceedings. This serves the principle of procedural economy, which requires, *inter alia*, that the best possible use is made of a given legal system's limited

resources. Excessively lengthy proceedings are also at odds with the right to a fair trial under Article 6(1) ECHR, which includes the right to have cases heard and adjudicated within a reasonable time. Clearly, amended claim requests which a patent proprietor does not submit in due time can unnecessarily protract the proceedings. Hence, the purpose underlying Article 114(2) EPC is only served if the deciding body has discretion not to admit late-filed claim requests. Moreover, as to whether a late-filed submission may unnecessarily protract the proceedings, there is no principal difference between objections submitted by an opponent and amended claim requests submitted by a patent proprietor. Applying Article 114(2) EPC to both types of party submissions thus also ensures that the parties are treated equally and according to the same criteria, which guarantees equality of arms.

4.5.9 A systematic interpretation does not lead to any other result either. According to the second subclause of Article 114(1) EPC on *ex officio* examination the EPO is not restricted to the "facts, evidence and arguments provided by the parties and the relief sought". Article 114(2) EPC on late-filed submission refers, on the other hand, only to "facts or evidence". The omission of the term "arguments" in Article 114(2) EPC has been invoked in favour of the view that late-filed arguments may not be equated with facts and may therefore not be disregarded under this provision (T 1914/12, Reasons 7.2.1.a); see also J 14/19, Reasons 1.10). This reasoning, however, cannot be applied in analogy to claim requests in view of the omission of the term "relief sought" ("Anträge" and "demandes", respectively, in the German and French versions) in Article 114(2) EPC, as this term cannot be

understood as encompassing claim requests. In particular, Article 114(1) EPC provides that the EPO is in its examination not restricted to the "relief sought". Under 113(2) EPC, however, the EPO may only examine the patent in the text submitted or agreed by the patent proprietor. Hence, patent claim requests actually *do* restrict the EPO's power of *ex officio* examination (T 706/00, Reasons 2.1; T 1558/18, Reasons 1), and therefore they cannot be subsumed under the "relief sought" referred to in the second subclause of Article 114(1) EPC. In conclusion, a systematic interpretation of the term "facts" in Article 114(2) EPC is therefore also in line with considering substantiated claim requests as falling thereunder.

4.5.10 As to Article 123(1) EPC as a possible legal basis for not admitting claim requests, it does not seem straightforward that the first sentence of this provision is concerned with any discretionary power conferred to the EPO. While the word "may" in Article 114(2) EPC clearly refers to a discretionary power of the EPO, the wording in Article 123(1) EPC instead suggests that it is the applicant or patent proprietor itself which "may" amend its patent in accordance with the Implementing Regulations. Rule 81(3) EPC as such does not appear to confer any discretionary power to the EPO either; rather, it concerns certain non-mandatory ("where necessary") contents of a communication of an Opposition Division under Article 101(1) EPC. Moreover, the requirement for a submission to not have been "submitted in due time" as a precondition for the exercise of discretion by the EPO only exists under Article 114(2) EPC, and not under Article 123(1) EPC. While it may be possible to address this issue by relying on the differences in the wording

of Rules 79(1) and 81(3) EPC (see T 966/17, Reasons 2.2.1), it appears preferable to ensure the equal treatment of opponents and patent proprietors in respect of the admittance of their submissions by relying on the same legal basis and the same precondition for the exercise of discretion, namely that the submission in question was "not submitted in due time". However, if considered necessary, this result can also be achieved by relying on Article 114(2) EPC in conjunction with Article 123(1) EPC (see J 14/19, Reasons 1.6: "ergänzend"), as the latter provision is complementary to the former in that it only requires an applicant to be given one opportunity to amend the application.

4.5.11 As an interim conclusion, Article 114(2) EPC provides a legal basis for disregarding claim requests which are not submitted in due time. Thus, provided that auxiliary request 4A was not submitted in due time, the Opposition Division had discretion under Article 114(2) EPC not to admit this request.

4.6 Article 114(2) EPC - the concept of "not submitted in due time"

4.6.1 The question of *whether* the deciding body has discretion not to admit a certain submission under Article 114(2) EPC must be distinguished from the question of *how* that discretion should be exercised.

4.6.2 When answering the question of whether the deciding body has discretion not to admit a certain submission, one can either rely on *fixed criteria*, such as a certain point in time in the proceedings after which submissions are considered late, or, alternatively, on *relative criteria*, such as whether the submission was

made according to the principle of procedural economy or in direct response to a new submission by another party. Relative criteria are necessarily a moving target.

4.6.3 Article 114(2) EPC applies both to proceedings before the departments of first instance and to proceedings before the Boards of Appeal. For appeal proceedings, the RPBA 2020 implement Article 114(2) EPC in a manner which in principle is binding (T 1042/18, Reasons 4.7) and rely on fixed criteria in order to determine whether a Board has discretion not to admit a certain submission. Under Article 12(2) and (4) RPBA 2020, a submission constitutes an amendment, the admittance of which is subject to a Board's discretion if it is not directed to the requests, facts, objections, arguments and evidence on which the decision under appeal was based. The only exception to this concerns a party's demonstration that this part was already admissibly raised and maintained in the first-instance proceedings. As a result, any submission which has not been made during the first-instance proceedings is in the appeal proceedings considered not to have been submitted in due time within the meaning of Article 114(2) EPC. Accordingly, in appeal proceedings the fixed point in time after which a certain submission is late-filed is the end of the first-instance proceedings. Considerations such as whether a party could not have adequately reacted to a request or document filed at a late stage of the first-instance proceedings do not determine *whether* a submission is late-filed, but are instead relevant to the question of *how* a board should exercise its discretion (see also CA/3/19, pages 35 and 36, explanatory remarks on Article 12(4) RPBA 2020).

4.6.4 For opposition proceedings, there are also fixed points in time which allow the deciding body to determine whether a submission was filed in due time within the meaning of Article 114(2) EPC. In particular, evidence submitted by an opponent after the end of the opposition period under Article 99(1) EPC may be considered to not have been filed in due time (T 1734/08, Reasons 2; see also T 66/14, Reasons 2.3). For the patent proprietor, a corresponding point in time would be the end of the period under Rule 79(1) EPC. Accordingly, the admittance of party submissions made after these points in time would generally be subject to the Opposition Division's discretion under Article 114(2) EPC. This, however, does not mean that such submissions should in principle not be admitted.

4.6.5 In the present case, the patent proprietor filed auxiliary request 4A not only after the expiry of the period set under Rule 79(1) EPC, but also after the final date for making written submissions specified according to Rule 116(1) EPC. Hence, even if not the expiry of the period under Rule 79(1) EPC but the date specified under Rule 116(1) EPC is considered to be the relevant fixed point in time that determines whether a certain submission is "not submitted in due time" within the meaning of Article 114(2) EPC, auxiliary request 4A would have been late-filed.

4.6.6 According to an alternative view, the question of whether a submission is not submitted in due time - which determines whether or not an Opposition Division has discretion under Article 114(2) EPC not to admit that submission - does not depend on fixed points in time but rather on relative criteria. Such criteria are, in particular, whether the party making the

submission acted "in accordance with the principle of procedural economy" and observed "a fair degree of procedural vigilance", which is assumed to be the case if a submission was filed, for example, as a reaction to an unforeseeable development (T 502/98, Reasons 1.5) or in direct response to a change in the subject of the proceedings (T 487/13, Reasons 6.2).

4.6.7 An approach relying on relative criteria for determining whether an Opposition Division has discretion not to admit an amended claim request does not seem to be compatible with considering Article 123(1) EPC and Rules 79(1) and 81(3) EPC to be the only legal basis for not admitting claim requests in the opposition proceedings, as these provisions seem to provide for a fixed point in time after which such requests are considered late-filed (see T 966/17, Reasons 2.2.1). In any case, an approach relying on relative criteria tied to individual procedural circumstances has, in the Board's view, the grave disadvantage that the Opposition Division's discretionary power is then not clearly and predictably delimited by the law itself. Accordingly, an approach relying on fixed points in time is also preferable when considering Article 114(2) EPC as providing the legal basis for disregarding claim requests.

4.6.8 Furthermore, under Rule 116(1), fourth sentence, EPC, facts and evidence filed after the final date referred to in Rule 116(1) EPC "need not be considered, unless admitted on the grounds that the subject of the proceedings has changed." Firstly, the phrase "facts and evidence" in Rule 116(1) EPC must be understood, as in Article 114(2) EPC, as encompassing substantiated claim requests. Secondly, the word "admitted" expresses the exercise of discretionary power, and the phrase "on

the grounds" indicates a criterion for exercising this discretionary power. Rule 116(1), fourth sentence, EPC thus confirms that a change in the subject of the proceedings must be taken into account by the Opposition Division in the course of *exercising* its discretion. It is therefore not compatible with Rule 116(1) EPC to make the *existence* of the Opposition Division's discretion under this provision subject to the condition that there was no change in the subject of the proceedings, as the approach relying on relative criteria does. Hence, at least as of the final date referred to in Rule 116(1) EPC, the approach described in section 4.6.6 cannot, in the Board's view, be applied.

4.6.9 As to the exercise of its discretion, the Opposition Division must bear in mind that in opposition proceedings more weight must be given to examination *ex officio* under Article 114(1) EPC than in appeal proceedings (cf. G 9/91 and G 10/91, Reasons 18). Depending on the specific circumstances, it may also be the case that the Opposition Division has very little discretion not to admit a certain submission which is provided at a certain point in time in reaction to a certain development in the proceedings. In this context, aspects such as procedural economy and procedural vigilance can and should be taken into account. However, this concerns *how* the Opposition Division exercises its discretion rather than *whether* it has any discretion in the first place. The correct exercise of discretion is subject to review by the Boards of Appeal (see section 4.8.1 below).

4.6.10 As an interim conclusion, a claim request which is filed in opposition proceedings after the date set under Rule 116(1) EPC is not submitted in due time

within the meaning of Article 114(2) EPC. In the present case, auxiliary request 4A was therefore not submitted in due time.

4.7 Rule 116(2) EPC - notification of the grounds prejudicing the grant or maintenance of the patent

4.7.1 Rule 116(2) EPC is applicable in both examination and opposition proceedings. As to opposition proceedings, the Board has the following observations.

4.7.2 In the first subclause of Rule 116(2) EPC, reference is made to the patent proprietor having "been notified of the grounds prejudicing the [...] maintenance of the patent". The appellant referred in this regard to decision T 754/16, Reasons 1.3.2, in which it is stated that "requests filed after the final date set for making written submissions, can only then not be admitted if the patent proprietor had been notified of the grounds prejudicing the maintenance of the patent". In T 754/16 this was not considered to have been the case because the Opposition Division had changed its previously positive written preliminary opinion on certain claim requests during the oral proceedings. In T 754/16, the Board was of the view that amended claim requests which were filed during the oral proceedings in response to such a change of the Opposition Division's opinion were not late-filed as a matter of principle. Accordingly, the Board in T 754/16 opined that the Opposition Division, which had considered the amended claim requests to not be *prima facie* allowable under Articles 56, 84 and 123(2) EPC, did not have any discretion whatsoever not to admit these requests.

4.7.3 The present Board does not share the views expressed in T 754/16. Rule 116(2) EPC concerns a very specific

situation, as is made clear in the first sentence of the provision, namely a situation where the Opposition Division decides to notify the patent proprietor of grounds prejudicing the maintenance of the patent. The first subclause of Rule 116(2) EPC ("if the applicant or patent proprietor has been notified of the grounds prejudicing the grant or maintenance of the patent") is not a condition for the Opposition Division having discretionary power not to admit amended claim requests. Rather, the condition in the first subclause is linked to whether the Opposition Division may invite the patent proprietor to present amended claims ("he may be invited to submit [...] documents"). The first subclause in the first sentence of Rule 116(2) EPC thus expresses nothing other than that the Opposition Division should only invite the patent proprietor to present amended claim requests if it has notified it of grounds of opposition which may, in its view, prejudice the patent's maintenance. In other situations, no such invitation should be made.

4.7.4 The primary purpose of inviting the patent proprietor to file amended claim requests under Rule 116(2) EPC is to expedite the opposition proceedings, and to prevent the patent proprietor from filing such requests after the date specified in Rule 116(1) EPC. This is also confirmed by the *travaux préparatoires* (CA/12/94, pages 11 and 12), according to which Rule 116(2) EPC (i.e. former Rule 71a(2) EPC) is "also designed to speed up the procedure, and to prevent parties being unfairly confronted with new facts in oral proceedings." As the term "facts" in this sentence refers to amended claim requests, the Board notes that also the legislator apparently understood this term to include amended claim requests when introducing former Rule 71a EPC. This confirms the conclusion reached in

section 4.5.11 above that Article 114(2) EPC provides a legal basis for disregarding claim requests which are not submitted in due time.

4.7.5 In view of its wording and purpose, Rule 116(2) EPC does therefore not limit the Opposition Division's discretionary power under Article 114(2) EPC and Rule 116(1) EPC. The *travaux préparatoires* also confirm that "Rule 71a does not restrict EPO discretion under Article 114" (CA/12/94, page 11).

4.7.6 Furthermore, the second sentence of Rule 116(2) EPC, according to which the third and fourth sentences of Rule 116(1) EPC apply *mutatis mutandis* to the situation described in the first sentence of Rule 116(2) EPC, does not support the view that claim requests do not fall under Rule 116(1) EPC. This statement rather clarifies that even amended claim requests which are submitted in reply to an invitation of the Opposition Division under Rule 116(2) EPC are subject to the Opposition Division's discretion under Rule 116(1) EPC. The Board understands the term "*mutatis mutandis*" to primarily take account of the possibility that if the Opposition Division invites the patent proprietor to file an amended claim request to address a specific objection and the patent proprietor complies with this invitation by filing the required amendments by the date set under Rule 116(1) EPC, its discretion not to admit that claim request may effectively be reduced to zero. The *travaux préparatoires* on Rule 116 EPC, according to which amended claim requests are to be understood as facts (see section 4.7.4 above), also confirm that Rule 116(2) EPC is not to be understood as an indication that claim requests would not fall under Rule 116(1) EPC. The above also speaks against considering Rule 116(2) EPC to be a self-standing legal

basis for an Opposition Division's discretion not to admit claim requests (see section 4.5.3 above), which would also be at odds with the need to root the Opposition Division's power of discretion in an article of the EPC instead of only in an implementing rule.

4.7.7 The Board further notes that if, as opined in Reasons 1.3.2 of T 754/16, an Opposition Division had no discretion not to admit an amended claim request whenever it had not notified the patent proprietor "of the grounds prejudicing the maintenance of the patent", this would mean that any such claim request - regardless of its contents and regardless of when it was made - would automatically be admitted into the opposition proceedings. A certain development in the opposition proceedings does not, however, justify the submission of any kind of claim request - possibly including claim requests which are not even related to the specific procedural development in question - at any point in time. Such a result must be avoided, which speaks additionally against this approach.

4.7.8 As an interim conclusion, Rule 116(2) EPC does not limit the Opposition Division's discretionary power under Article 114(2) EPC and Rule 116(1) EPC. In particular, the existence of this discretionary power does not depend on the contents of the Opposition Division's communication under Rule 116(1) EPC. In the present case, auxiliary request 4A was filed during the oral proceedings before the Opposition Division in response to the novelty objection based on Example 4 of D6, which was submitted by one of the opponents before the final date indicated in the Opposition Division's communication under Rule 116(1) EPC. Applying the principles set out above, the Opposition Division had discretionary power not to admit auxiliary request 4A,

even though it had not included in its communication under Rule 116(1) EPC the novelty objection based on Example 4 of D6.

4.8 Review of the Opposition Division's exercise of discretion

4.8.1 When exercising its discretionary power, a department of first instance has a certain margin of discretion. When reviewing a department of first instance's exercise of discretion, the Boards of Appeal therefore usually limit themselves to a review of whether the discretion was exercised according to the right principles, in a reasonable way and without exceeding the proper limits of discretion (see J 14/19, Reasons 8.3 and 10.2, with reference to G 7/93, Reasons 2.6).

4.8.2 The amendment in claim 1 of auxiliary request 4A contains a feature taken from the description ("wherein said formulation is packaged and sealed in a single or multi-use container"). How the formulation is packaged or suitable containers for the composition were aspects that were never discussed in the opposition proceedings. They came up for the first time with the amendment. The opponents objected to the admittance of auxiliary request 4A, stating that they had been taken by surprise and that this amendment would require a new and time-consuming search which could only be undertaken if the oral proceedings were adjourned. The opponents further argued that auxiliary request 4A was *prima facie* not allowable and noted that document D6 had been in the opposition proceedings from the beginning.

4.8.3 Against this background, the Opposition Division's conclusion that the very late filing of the amended claim request introducing features from the description gave rise to a number of new issues and surprised the opponents (Decision under appeal, Reasons for the decision, section II.7) does not indicate an exercise of discretion according to the wrong principles, in an unreasonable manner or in excess of the limits of discretion. As to the patent proprietor's argument that it submitted auxiliary request 4A at the earliest opportunity, the Board notes that the patent proprietor could and should have submitted this claim request already in advance of the oral proceedings before the Opposition Division. Instead, it did so only during the oral proceedings, and even then only after the Opposition Division had found that none of the higher-ranking requests was allowable.

4.8.4 The Board also notes that the Opposition Division admitted auxiliary request 4B. The patent proprietor filed this request right after the Opposition Division decided not to admit auxiliary request 4A. The Opposition Division reasoned its decision by explaining that the request was "done in response to the novelty objections based on D6 and that its claims 1 and 2, already present in Auxiliary Request 4 (as claims 5 and 6), do not create unexpected issues" (Reasons for the decision, section II.8).

4.8.5 The way the opposition division dealt with the two auxiliary requests, 4A and 4B, demonstrates that it duly assessed the case before it. It considered relevant aspects such as the point of time when the amendment was filed and the impact the amendment would have on the proceedings and on the parties, as well as whether the amendment gave rise to new issues. It

concluded that auxiliary request 4B, which was not based on features taken from the description, was to be admitted, whereas auxiliary request 4A was not. This shows to the Board's satisfaction that the Opposition Division exercised its discretion in a reasonable way.

4.8.6 Therefore, the Board sees no reason to set aside the Opposition Division's discretionary decision.

4.9 In view of the fact that the Opposition Division exercised its discretion not to admit auxiliary request 4A correctly, the Board did not admit this request under Article 12(4) RPBA 2007 either. Under this provision, the Board is empowered to hold inadmissible requests filed on appeal which were not admitted in the first instance proceedings.

5. *Admittance of auxiliary request 5*

5.1 Auxiliary request 5 was filed after notification of the summons to oral proceedings and is therefore subject to Article 13(2) RPBA 2020. The request is based on auxiliary request 4A, with some claims having been deleted, but with the same wording of claim 1.

5.2 In view of the fact that auxiliary request 4A is not admitted into the appeal proceedings, there is no reason to admit auxiliary request 5, which was filed even later.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

M. Schalow A. Haderlein

Decision electronically authenticated