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Datasheet for the decision of 28 October 2021

Case Number: T 2899/18 - 3.3.04

Application Number: 06778012.2

Publication Number: 1913138

IPC: A61K38/54

Language of the proceedings: EN

Title of invention:
Processes for the manufacture of pancreatin powder with low virus content

Patent Proprietor:
Abbott Laboratories GmbH

Opponent:
Nordmark Pharma GmbH

Headword:
Pancreatin powder/ABBOTT

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

Keyword:
Sufficiency of disclosure - main request (no)
Amendments - added subject-matter - auxiliary request (yes)

Decisions cited:
G 0001/04, T 1208/03, T 1050/09, T 2619/11, T 0491/13

Catchword:

Europäisches Patentamt
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Beschwerdekammern

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Case Number: T 2899/18 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 28 October 2021

Appellant: (Patent Proprietor)	Abbott Laboratories GmbH Freundallee 9A 30173 Hannover (DE)
Representative:	Miller, David James Mathys & Squire The Shard 32 London Bridge Street London SE1 9SG (GB)
Respondent: (Opponent)	Nordmark Pharma GmbH Pinnauallee 4 25436 Uetersen (DE)
Representative:	RGTH Patentanwälte PartGmbB Neuer Wall 10 20354 Hamburg (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 9 November 2018 revoking European patent No. 1913138 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chair	G. Alt
Members:	B. Rutz
	L. Bühler

Summary of Facts and Submissions

I. An appeal was lodged by the patent proprietor (appellant) against the decision of the opposition division revoking European patent No. 1 913 138 ("the patent"). The patent is entitled "*Processes for the manufacture of pancreatin powder with low virus content*" and is based on European patent application 06 778 012.2 published under the PCT as WO 2007/014896 ("the application").

II. The patent was opposed on the grounds of Article 100(a) EPC, in relation to novelty (Article 54 EPC) and inventive step (Article 56 EPC), and of Article 100(b) EPC, in relation to disclosure of the invention.

III. In its decision, the opposition division held that the subject-matter of claim 1 of the main request (patent as granted) lacked an inventive step over the disclosures of document D8 or document D1, taking into account common general knowledge as evidenced by document D13 (Article 56 EPC).

With regard to auxiliary requests I, III and IV, the opposition division found that the subject-matter claimed lacked an inventive step for the same reasons as the main request.

With regard to auxiliary request II, the opposition division found that the invention to which its claims related was not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 83 EPC).

IV. With the statement of grounds of appeal, the appellant filed a new main request and new auxiliary requests 1 to 11 and submitted document D21.

V. The opponent (respondent) replied to the statement of grounds of appeal and submitted document D22.

VI. The board summoned the parties to oral proceedings by videoconference, as requested by both parties, and informed them of its preliminary opinion in a communication pursuant to Article 15(1) RPBA.

VII. With a letter dated 15 September 2021 in reply to the board's communication, the appellant withdrew auxiliary requests 2, 3, 5, 8, 9 and 11 and renumbered auxiliary requests 4, 6, 7 and 10 as auxiliary requests 2, 3, 4 and 5 respectively.

VIII. During the oral proceedings, the appellant withdrew all claim requests except auxiliary request 3 (formerly auxiliary request 6), which became the main request, and auxiliary request 5 (formerly auxiliary request 10), which became the auxiliary request.

At the end of the oral proceedings the Chair announced the board's decision.

IX. Claim 1 of the main request (auxiliary request 6 filed with the statement of grounds of appeal) reads as follows.

"1. A process for the manufacture of pancreatin which is decreased in viral contaminants, comprising the steps of

(a) pre-heating a dispersed form of pancreatin containing one or more solvents to a temperature of from 85 °C to 100 °C, and
(b) continuing heating of the dispersed form of pancreatin at a temperature of from 85 °C to 100 °C for a period of from 18 hours to 30 hours, and obtaining a total solvents content in the dispersed form of pancreatin of equal to or less than 3.5% by weight at any point during process step (b),
wherein the dispersed form of pancreatin is selected from powders, pellets, micropellets, microspheres, granules and granulates,
wherein the titer leve[l] of any viral contaminant present in the dispersed pancreatin after heating is at least 1000 times less than the titer level of said viral contaminant present in the dispersed pancreatin prior to heating,
and wherein the pancreatin lipase activity after heating is at least 50% of the lipase activity prior to heating."

Claim 1 of the auxiliary request (auxiliary request 10 filed with the statement of grounds of appeal) reads as follows (differences to claim 1 of the main request are underlined).

"1. A process for the manufacture of pancreatin which is decreased in viral contaminants, comprising the steps of
(a) pre-heating a dispersed form of pancreatin containing one or more solvents to a temperature of from 85 °C to 95 °C, wherein the solvents content at the end of step (a) is from 0.1% to 1.6% by weight, and
(b) continuing heating of the dispersed form of pancreatin at a temperature of from 85 °C to 95 °C for a period of from 18 hours to 30 hours, and obtaining a

total solvents content in the dispersed form of pancreatin of equal to or less than 1.6% by weight at any point during process step (b),
wherein the dispersed form of pancreatin is selected from powders, pellets, micropellets, microspheres, granules and granulates,
wherein the titer leve[l] of any viral contaminant present in the dispersed pancreatin after heating is at least 1000 times less than the titer level of said viral contaminant present in the dispersed pancreatin prior to heating,
and wherein the pancreatin lipase activity after heating is at least 50% of the lipase activity prior to heating."

X. The appellant's arguments are summarised as follows.

Main request - claim 1
Claim construction

Claim 1 had to be construed with a mind willing to understand and having regard to the teaching of the patent as a whole.

The total solvents content of 3.5% or less had to be interpreted as being obtained over the whole of step (b). This was also apparent from paragraph [0029] and the examples in the patent (see for example paragraph [0060]), where a constant solvents content was disclosed.

Although the solvents content in step (a) was not explicitly defined, it was connected to the solvents content in step (b), and the skilled person would therefore consider that it was not different from that in step (b).

Sufficiency of disclosure (Article 83 EPC)

Even if the claim was given a broader interpretation, i.e. including higher solvents contents, the invention was disclosed in a manner sufficiently clear for the skilled person to carry it out over the whole scope of the claim.

The claim only covered processes that attained a dispersed form of pancreatin having at least 50% of the lipase activity prior to heating, and thereby excluded methods that did not satisfy this requirement.

Methods which satisfied this limitation could be readily identified by a person skilled in the art, in view of the technical guidance provided by the patent. The patent was based on the finding that a specific subset of conditions could maintain high levels of enzyme activity (and thus pancreatin activity) whilst at the same time reducing viral concentration.

For example, the skilled person understood that pancreatin could be exposed to a temperature of 100°C for a period of up to and including 24 hours, provided that there was a solvents content of 1% (see Table 1 in the patent). Similar logic could also be applied to the other conditions recited in the claim. Thus, the patent provided sufficient guidance on the conditions necessary to enable the skilled person to carry out the claimed invention. Accordingly, the requirements of Article 83 EPC were satisfied.

Case law (see for example decisions T 1263/18, T 103/09, T 1753/15, T 1077/17, T 1094/10, T 2222/09 and T 731/00) consistently showed that the existence of

non-working embodiments was of no harm under Article 83 EPC as long as the specification included sufficient information on the relevant criteria for finding appropriate alternatives over the claimed range with reasonable effort. In addition, the case law was clear that Article 83 EPC did not require all possible combinations of parameters to produce the desired result (see decision T 2222/09). Instead, it was only necessary for the skilled person to be able to identify suitable conditions that were capable of producing the claimed effect (see for example decisions T 1753/15 and T 2222/09).

Auxiliary request
Amendments (Article 123(2) EPC)- claim 1

A basis for the claimed subject-matter could be found in the original claims 1, 3, 5, 8, 14 and 18, and in the description: page 7, lines 19 and 33; page 8, line 26; page 9, lines 15 to 19. The feature "less than 0.16%" was disclosed on page 7, lines 16 to 19 as a combination of the lower limit in line 17 ("less than") and the upper limit in line 19 ("1.6%"). The feature "18 to 30 hours" was disclosed on page 9 as a combination of the upper limit ("to 30 hours") in line 11 and the lower limit ("18 hours") in line 17.

It could be derived from a number of decisions of the Boards of Appeal, e.g. T 2619/11, T 667/18, T 491/13, T 1050/09 and T 1208/03, that, when assessing the conformity of amended claims with the requirements of Article 123(2) EPC, the focus should be on what was actually disclosed to the skilled person and not disproportionally on the structure of the claims.

Applying these principles to the present case, the skilled person would combine the subject-matter of original claim 18 with the disclosure on pages 7, 8 and 9 of the application as filed, and would therefore directly and unambiguously derive the subject-matter of claim 1 of the auxiliary request.

XI. The respondent's arguments are summarised as follows.

Main request - claim 1
Claim construction

Step (a) of the process was not limited with regard to the pre-heating time and the total solvents content.

Step (b) required "obtaining a total solvents content in the dispersed form of pancreatin of equal to or less than 3.5% by weight at any point during process step (b)". This meant that the total solvents content of "equal to or less than 3.5%" could be reached at the beginning, at the end or at any (time) point during step (b). It also meant that after this total solvents content was reached it could change during the remainder of the process and indeed rise above 3.5% again.

In conclusion, except for a single point in time during step (b) at which the total solvents content was defined as "equal to or less than 3.5% by weight", the total solvents content was not limited during the entire process.

Since the pre-heating in step (a) was not limited in time and a distinction between pre-heating and heating was not possible, the duration of the whole heating process was not limited.

Sufficiency of disclosure (Article 83 EPC)

The process was to be performed such that the lipase activity remained at least 50% of that prior to heating.

The patent showed that, within the limits defined by the parameters mentioned in the claim (i.e. temperature, time, total solvents content), only a very small number of combinations achieved the effect of maintaining the necessary lipase activity.

For example, for a total solvents content of 9% the lipase activity dropped to 50% after only 1 hour at 80°C. For a total solvents content of 12% the lipase activity dropped to less than 40% after only 0.5 hours at 80°C (see Table 3 and Figure 3). This showed that a higher solvents content had a drastic effect on the activity, even at lower temperatures and much shorter incubation times than those allowed by the claimed process.

Similarly, Figure 2 showed that even at a solvents content of 3% an incubation of 30 hours at 95°C reduced the activity to 50%. Incubation at higher temperatures or for longer times, both of which were permitted in the claimed process, would therefore necessarily reduce the activity to less than 50% (see also Figure 1).

The pre-heating time, which was not limited in the claim, was not even considered in the examples given in the patent.

In conclusion, the claim did not correspond to the invention and its contribution to the state of the art,

because it did not define the necessary parameters such as a low and constant total solvents content, or limit the time of incubation.

This could not be compensated by the introduction of functional features into the claim, which represented only a result to be achieved.

Over a large part of the claimed process a lipase activity of at least 50% could only be maintained with additional measures, but these were not detailed in the claim or disclosed in the description.

Auxiliary request
Amendments (Article 123(2) EPC)- claim 1

Original claim 18, which related to at least 50% lipase activity after heating, only referred back to claims 1 and 2. The missing features of claim 1 were thus not disclosed in combination with the 50% lipase activity.

Some of those features could be found in the original dependent claims, but not in combination, while others were only disclosed in the description (e.g. "18 to 30 hours", "0.1 to 1.6%").

The combination involved several selections from lists, e.g. 18 to 30 hours, solvents content equal to or less than 1.6%, temperature from 85°C to 95°C, lipase activity of at least 50%.

The feature "18 hours" was only disclosed in a passage which referred to heating at a temperature of at least 85°C. This could not be generalised to heating at a temperature between 85°C and 95°C as required in the claim.

The subject-matter of claim 1 therefore extended beyond the content of the application as filed.

XII. The appellant requested that the decision under appeal be set aside and that the case be remitted to the opposition division for further prosecution based on the main request or the auxiliary request, filed as auxiliary requests 6 and 10 with its statement of grounds of appeal, in the event that the requirements of Article 83 EPC were found to be met. In the alternative, the appellant requested that the patent be maintained on the basis of the main request or the auxiliary request.

The respondent requested that the appeal be dismissed.

Reasons for the Decision

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

Main request - claim 1
Claim construction

2. The claim relates to a process for the manufacture of pancreatin comprising process steps (a) and (b) and resulting in a product wherein, amongst other things, the "pancreatin lipase activity after heating is at least 50% of the lipase activity prior to heating".

3. The pre-heating step (a) is neither limited in time nor in the total solvents content of the pancreatin. Since the wording of the claim is clear and not unreasonable, the board cannot see any reason to give the claim a more restricted interpretation by relying on passages

in the remainder of the patent. This would also be contrary to the principle of legal certainty. According to established case law, the meaning of the terms of a claim should be clear from the wording of the claim alone (see decision G 1/04, OJ EPO 2006, 334, Reasons point 6.2 and Case Law of the Boards of Appeal of the European Patent Office, 9th edition 2019, II.A.3.1).

4. The board is not persuaded by the appellant's argument that the total solvents content required for the heating step (b) would limit the total solvents content of step (a). The skilled person, based on common general knowledge, would know that the total solvents content decreases during heating and can therefore be higher in the pre-heating step than in the heating step. This is also supported by paragraph [0029] of the patent, which states that the process may start "*with an initial solvents content of 9% by weight or less*" and that "[d]*uring the initial pre-heating phase, the solvents content in the pancreatin will typically decrease as a function of time and temperature*".

5. Thus, the skilled person would conclude that the pre-heating step can start with a higher total solvents content (e.g. 9%), which will gradually decrease during the pre-heating and heating steps, and that the total solvents content of 3.5% to be obtained at (at least) one point in step (b) must not yet be reached during the pre-heating step.

6. The board therefore finds that the pre-heating step (a), while limited in respect of the temperature to be reached ("85 °C to 100 °C"), is not limited in time or total solvents content.

7. The heating step (b) is limited in time ("18 to 30 hours") and temperature ("85 °C to 100 °C") and contains the requirement "obtaining a total solvents content in the dispersed form of pancreatin of equal to or less than 3.5% by weight at any point during process step (b)". The skilled person would read the expression "obtaining a total solvents content" in this context to mean that the total solvents content is a result of the heating and can occur at "any point during process step (b)".

8. The board does not consider the interpretation by the appellant, that the total solvents content of 3.5% or less has to be reached at the beginning of the process step (b) and has to remain constant during the rest of the heating step, to be a compelling reading of step (b), less still the only possible one.

9. Furthermore, the wording "obtaining ... at any point" does not exclude the possibility that the total solvents content can increase again after the required total solvents content of 3.5% or less has been reached.

10. The board therefore finds the heating step (b) to be limited to a temperature of 85°C to 100°C, a time of 18 to 30 hours, and a total solvents content which at least once during this process step (b) reaches 3.5% by weight or less.

11. The temperature range for the pre-heating step (a) is the same as for the heating step (b) ("85 °C to 100 °C"), and both steps involve the same starting composition ("dispersed form of pancreatin").

12. The board therefore finds that the skilled person reading the claim cannot distinguish between the pre-heating step (a) and the heating step (b), and is thus also unable to determine when step (a) has finished and step (b) starts. The skilled person might, based on common general knowledge, consider that the pre-heating step has finished when the required temperature, i.e. 85°C to 100°C, is reached. However, there is no definition of either the time to reach this temperature range or of the exact temperature between 85°C and 100°C at which step (a) ends and step (b) starts. In consequence, because the duration of the pre-heating step (a) is not limited, the duration of the whole process is not limited either.

13. The process is functionally limited by two features:

(i) "the titer level of any viral contaminant present in the dispersed pancreatin after heating is at least 1000 times less than the titer level of said viral contaminant present in the dispersed pancreatin prior to heating" and

(ii) "the pancreatin lipase activity after heating is at least 50% of the lipase activity prior to heating".

Hence, the process has to be conducted such that the viral titer level is reduced in accordance with this and lipase activity is maintained at the required level.

Processes resulting in less than 1000-fold viral reduction or less than 50% lipase activity are not covered by the claim.

14. In conclusion, the claim relates to processes in which a dispersed form of pancreatin is heated to 85°C to 100°C for at least 18 hours and, at least once during this process, reaches a total solvents content of 3.5% by weight, while its viral load is reduced 1000-fold and at least 50% of its lipase activity is retained.

Sufficiency of disclosure (Article 83 EPC)

15. It follows from the claim construction, set out above in points 2. to 14., that the claim encompasses a large number of conceivable alternatives for conducting the process, given the many possible combinations of different parameters for the pre-heating and heating steps. This number of conceivable alternatives is limited to those embodiments which also fulfil the functional features that "the titer leve[l] of any viral contaminant present in the dispersed pancreatin after heating is at least 1000 times less than the titer level of said viral contaminant present in the dispersed pancreatin prior to heating" and "the pancreatin lipase activity after heating is at least 50% of the lipase activity prior to heating".

16. It can be deduced from Table 3 and Figures 2 and 3 that not all of the conceivable process alternatives do in fact result in the required effect.

17. Article 83 EPC requires the application to disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. As established by the case law of the Boards of Appeal, the skilled person must be able to carry out the invention without undue burden, over the whole scope of the claim and based on the application as a whole, including examples, furthermore taking into

account the common general knowledge of the skilled person (see Case Law of the Boards of Appeal of the European Patent Office, 9th edition 2019, section II.C.1).

18. In view of the observation in point 16. above, the question to be addressed is whether the skilled person is able to identify, out of all the conceivable process alternatives, those which fulfil the functional features "1000 times less" titer level of any viral contaminant and "at least 50%" pancreatin lipase activity after heating without undue burden, when taking account of the application as a whole and the common general knowledge of the skilled person.

19. The examples relate either to low constant total solvents content and relatively long incubation times (see Table 1 and paragraph [0059]: "*1% solvents content*"; up to 30 hours; Table 2 and paragraph [0061]: "*3% solvents content*"; up to 48 hours) or to high constant total solvents content and relatively short incubation times (see Table 3 and paragraph [0063]: "*3%, 6%, 9% and 12%*", "*0.5, 1.0 and 3.0 hours*").

20. However, the claimed process alternatives encompass, for example, the alternative of carrying out the process at high total solvents content combined with relatively long incubation periods.

21. The experiments and results in Table 3 show that, at 9% or 12% total solvents content, the lipase activity is already below 50% after an incubation of 1 hour at a temperature lower than those defined in the claim (e.g. 80°C).

22. The board has not been referred to a disclosure in the application or to common general knowledge that could give guidance on how, for example, to incubate pancreatin with a higher total solvents content at the temperatures defined in the claim ("85 °C to 100 °C") and for the time defined in the claim ("18 hours to 30 hours") without reducing lipase activity to below the required limit of 50%.

23. The appellant's argument that the skilled person would understand from the teaching of the application *"that pancreatin can be exposed to a temperature of 100°C for a period of up to and including 24 hours, provided that it has a solvents content of 1 %. Similar logic can also be applied to the other conditions recited in the claim*" is not found to be persuasive. The argument suggests that, in the event of failure with higher total solvents contents, high temperatures and longer incubation times, the skilled person is taught to resort to low solvent contents. However, this is not the kind of guidance the skilled person will seek when wanting to carry out the invention in an area covered by claim 1, namely at high solvent contents.

24. The board concludes that the application includes guidance on achieving the required effect that "the pancreatin lipase activity after heating is at least 50% of the lipase activity prior to heating" only for a very selective set of process conditions.

25. Hence, the disclosure in the application is not such that the claimed invention can be carried out without undue burden over the whole scope of the claim.

Auxiliary request
Admission

26. In view of the finding that the auxiliary request is not allowable under Article 123(2) EPC (see below), there is no need to provide a reasoning as to why the request was admitted.

Amendments (Article 123(2) EPC) - claim 1

27. Claim 1 of the auxiliary request reads as follows (differences from claim 2 as originally filed, which refers back to claim 1 as originally filed, are underlined).

"1. A process for the manufacture of pancreatin which is decreased in viral contaminants, comprising the steps of
(a) pre-heating a dispersed form of pancreatin containing one or more solvents to a temperature of from 85 °C to 95 °C, wherein the solvents content at the end of step (a) is from 0.1% to 1.6% by weight, and
(b) continuing heating of the dispersed form of pancreatin at a temperature of from 85 °C to 95 °C for a period of from 18 hours to 30 hours, and obtaining a total solvents content in the dispersed form of pancreatin of equal to or less than 1.6% by weight at any point during process step (b),
wherein the dispersed form of pancreatin is selected from powders, pellets, micropellets, microspheres, granules and granulates,
wherein the titer leve[l] of any viral contaminant present in the dispersed pancreatin after heating is at least 1000 times less than the titer level of said viral contaminant present in the dispersed pancreatin prior to heating,

and wherein the pancreatin lipase activity after heating is at least 50% of the lipase activity prior to heating."

28. With regard to the pancreatin lipase activity after heating, the appellant referred to claim 18 as filed as the basis ("*pancreatin lipase activity after heating is at least 50% of the lipase activity prior to heating*"). However, this claim refers back to claims 1 and 2 and not to other claims, such as claims 5, 9, 14 and 16, the subject-matter of which has been incorporated into claim 1.

29. The same applies to original claim 16 ("*powders, pellets, micropellets, microspheres, granules and granulates*"), which refers back to original claims 1 and 2, but not to original claims 5 or 9. The same also applies to original claim 9 ("*temperature in process step a) and the temperature in process step b) is both from 85 °C to 95 °C*"), which refers back to original claims 1 and 2, but not to original claim 5.

30. This lack of interdependencies in the original set of claims means that separate sets of combinations of features are disclosed, but not a combination of all those features. There is thus no combined disclosure in the claims as filed of the parameters of duration, temperature, titer level of viral contaminant, form of pancreatin and remaining lipase activity (which are individually disclosed in dependent claims 5, 9, 14, 16 and 18 respectively).

31. The passage in the description on page 12, lines 11 to 13, referred to by the appellant, is not pertinent in this regard because it does not relate to lipase activity but to enzyme activity in general. The

following passage (page 12, lines 14 to 18), which mentions lipase activity, relates to the experiments that were conducted, and so it cannot serve as a basis for a general disclosure of lipase activity after heating either.

32. The total solvents content in steps (a) and (b) and the lower limit of the duration of step (b) is not disclosed in the claims as filed, but can be found in further passages from the description (e.g. page 8, line 1: "*solvents content of 0.1% to 1.6% by weight reached at the end of the pre-heating phase*"; page 7, line 19: "*even more preferably from 0.1% to 1.6% by weight*"; page 8, line 17: "*18 hours*"), which do not disclose these parameters in combination with the other parameters in the claim either.

33. The appellant cited a number of decisions by the Boards of Appeal of the EPO which, in its opinion, allowed the subject-matter of dependent claims to be combined even if they did not refer to each other (e.g. decisions T 2619/11, T 491/13, T 1050/09 and T 1208/03). The respondent counter-argued that all of the cited decisions also relied on passages in the description or drawings which disclosed the combination of the respective features.

34. The board agrees with the respondent (and finds support for its view in the cited decisions), that in the absence of dependencies in the claims as filed, the skilled person needs to be provided with an indication or pointer in the remainder of the application to render the combination of features from those dependent claims directly and unambiguously derivable. In the present case, however, the board has not been directed to any passage in the application as filed which would

prompt the skilled person to combine the subject-matter of the respective dependent claims with each other and with the above-indicated further passages from the description.

35. Furthermore, the lower limit of "18 hours" for the heating time in step (b) is derived from a list of 36 individual values (see page 8, line 17). This lower limit is combined with the upper limit of "30 hours" disclosed on the same page (line 11), or in claim 5 as part of "8 hours to 30 hours". However, the value "18 hours" is only disclosed in combination with a temperature of "at least 85 °C" (see page 8, lines 10 to 21), but not with the range 85°C to 95°C, which is only disclosed in combination with the broader time range of 10 hours to 30 hours (see for example page 9, lines 15 to 19). The subject-matter of claim 1 thus combines further individual embodiments of the application as filed in a way which is not disclosed therein.

36. The board concludes that, although all the features of the claim can be found in isolation in the application as filed, the combination of the features in the claim results in subject-matter extending beyond the content of the application as filed.

37. Hence, claim 1 of the auxiliary request does not fulfil the requirements of Article 123(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

I. Aperribay G. Alt

Decision electronically authenticated