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Datasheet for the decision of 20 September 2022

Case Number: T 2444/18 - 3.3.04

Application Number: 12852587.0

Publication Number: 2786750

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Language of the proceedings: EN

Title of invention:
AGENT FOR REDUCING ADVERSE SIDE EFFECTS OF KINASE INHIBITOR

Patent Proprietors:
EA Pharma Co., Ltd.
Yamaguchi University

Opponent:
N.V. Nutricia

Relevant legal provisions:
EPC Art. 56, 83, 123(2), 123(3)
EPC R. 80
RPBA Art. 12(4)
RPBA 2020 Art. 13(2)

Keyword:
Sufficiency of disclosure - after amendment
Inventive step - (yes)

Decisions cited:
T 0946/16, T 0021/16

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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 2444/18 - 3.3.04

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

Appellants: (Patent Proprietor 1)	EA Pharma Co., Ltd. 2-1-1, Irifune Chuo-ku Tokyo 104-0042 (JP)
(Patent Proprietor 2)	Yamaguchi University 1677-1, Yoshida Yamaguchi-shi Yamaguchi 753-8511 (JP)
Representative:	Mewburn Ellis LLP Aurora Building Counterslip Bristol BS1 6BX (GB)
Appellant: (Opponent)	N.V. Nutricia Eerste Stationsstraat 186 2712 HM Zoetermeer (NL)
Representative:	Nederlandsch Octrooibureau P.O. Box 29720 2502 LS The Hague (NL)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 26 July 2018 concerning maintenance of the European Patent No. 2786750 in amended form.**

Composition of the Board:

Chair	J. Molina de Alba
Members:	R. Hauss
	R. Romandini

Summary of Facts and Submissions

I. European patent No. 2 786 750 (patent in suit) derives from European patent application number 12852587.0 (application as filed).

The patent in suit was granted with a set of 15 claims. Claims 1, 4, 7, 12 and 13 read as follows:

1. At least one branched-chain amino acid selected from among isoleucine, leucine and valine, or a salt thereof, for use in reducing a side effect of a kinase inhibitor.

4. The branched-chain amino acid, or salt thereof, for use according to any of claims 1 to 3 which comprises all three branched-chain amino acids: isoleucine, leucine and valine.

7. The branched-chain amino acid, or salt thereof, of any one of claims 1 to 6 for use according to any one of claims 1 to 6 in a liver cancer patient.

12. A food composition for use in reducing a side effect of the kinase inhibitor, wherein the food composition comprises the branched-chain amino acid, or salt thereof, according to any one of claims 1 to 8.

13. The food composition for use according to claim 12, wherein the food composition is contained in a container.

II. The patent in suit was opposed under Article 100(a), (b) and (c) EPC on the grounds that the claimed subject-matter lacked novelty and inventive step, was not disclosed in a manner sufficiently clear and

complete for it to be carried out by a person skilled in the art, and extended beyond the content of the application as filed.

III. In the course of the opposition proceedings, the patent proprietors requested that the patent be maintained in amended form. In addition to the amended main request, they filed a number of substantive auxiliary requests.

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

D3: US 2005/0197398 A1

D4: Community Oncology 3(9), 559 (2006)

D5: WO 2004/026294 A1

D6: Int. J. Immunopathol. Pharmacol. 23(1), 143-151 (2010)

V. The decision under appeal is the opposition division's interlocutory decision, announced on 11 June 2018 and posted on 26 July 2018, which rejected the patent proprietors' main request and auxiliary requests 1 to 4 and found that the patent as amended in the version of auxiliary request 5 met the requirements of the EPC.

VI. Claims 1 of the main request and auxiliary request 1 considered in the decision under appeal are identical and read as follows:

> *1. A branched-chain amino acid, or salt thereof, which comprises all three branched-chain amino acids: isoleucine, leucine and valine, for use in reducing a side effect of a kinase inhibitor.*

Claim 1 of auxiliary request 5 considered in the decision under appeal differs from claim 1 of the main

request by stating that the side effect is at least one of hand-foot syndrome and bleeding.

These requests contain further independent claims relating to a pharmaceutical composition or a food composition for use in reducing a side effect of a kinase inhibitor and an agent for use in anticancer therapy, all comprising the branched-chain amino acid of claim 1.

VII. As set out in the decision under appeal, the opposition division ruled, *inter alia*, as follows:

(a) The subject-matter claimed in the main request did not meet the requirement of sufficiency of disclosure (Article 83 EPC). The same objection applied to auxiliary requests 1 to 4.

(b) Auxiliary request 5, filed during the oral proceedings, was admitted.

(c) The amendments made in auxiliary request 5 did not add subject-matter or introduce a lack of clarity (Articles 84 and 123(2) EPC).

(d) Owing to the limitation of the targeted side effects to hand-foot syndrome and bleeding, the claims of auxiliary request 5 met the requirement of sufficiency of disclosure.

(e) Document D6 disclosed that a composition comprising L-leucine, L-lysine, L-proline and glycine as collagen precursors, in combination with sodium hyaluronate, reduced oral mucositis (a frequent side effect of chemotherapy and radiotherapy). Starting from this technical teaching, the objective technical problem was to provide an alternative composition for treating bleeding or hand-foot syndrome. The claimed subject-matter

would not have been obvious to the person skilled in the art, who would not have had an expectation that a composition comprising the amino acids according to claim 1 would have the desired effect.

VIII. The patent proprietors and the opponent both filed appeals against this decision.

IX. With their statement setting out the grounds of appeal, the patent proprietors submitted 28 sets of claims as their main request and auxiliary requests 1 to 27. They also submitted the following documents:

D9: Pfizer Labs: SUTENT® (sunitinib malate) capsules - Highlights of Prescribing Information (issued May 2011)

D10: Hepatology Research, 44, 302-312 (2014)

X. Claims 1, 11 and 12 of the **main request** read as follows:

1. A branched-chain amino acid, or salt thereof, which comprises all three branched-chain amino acids: isoleucine, leucine and valine, for use in reducing a side effect of a kinase inhibitor.

11. A food composition for use in reducing a side effect of the kinase inhibitor, wherein the food composition comprises the branched-chain amino acid, or salt thereof, according to any one of claims 1 to 7.

12. The food composition according to claim 11, wherein the food composition is contained in a container.

XI. Claim 1 of **auxiliary request 1** only differs from claim 1 of the main request by specifying that:

(...) the side effect is selected from one or more of hand-foot syndrome, exfoliative dermatitis, mucocutaneous ocular syndrome (Stevens-Johnson syndrome), erythema multiforme, bleeding, acute hepatitis, liver function disorder or jaundice, liver failure, hepatic encephalopathy, acute lung injury, interstitial pneumonia, hypertensive crisis, reversible posterior leukoencephalopathy syndrome, myocardial ischemia or myocardial infarction, congestive heart failure, gastrointestinal perforation, gastrointestinal ulceration, hemorrhagic enteritis, ischemic enteritis, leukopenia, neutropenia, lymphopenia, thrombopenia, anemia, pancreatitis, renal failure, shock, anaphylactic reaction and rhabdomyolysis, hypersensitivity, elevated INR, prolonged prothrombin time, rash, hair loss, pruritus, erythema, dry skin, acne, skin scale, eczema, redness, depression, sensory peripheral neuropathy, tinnitus, dizziness, joint pain, muscular pain, hoarseness, rhinorrhea, hypertension, QT prolongation, diarrhea, nausea, vomiting, elevated amylase, elevated lipase, constipation, mouth stomatitis, indigestion, dysphagia, gastroesophageal reflux disease, gastritis, elevated AST (GOT), elevated ALT (GPT), elevated bilirubin, elevated Al-P, gallbladder inflammation, cholangitis, elevated LDH, fatigue, pain, hypophosphatemia, asthenia, fever, influenza-like symptoms, erectile dysfunction, folliculitis, infection, gynecomastia, hypothyroidism, hyponatremia, dehydration, dysgeusia,

hyperthyroidism, radiation recall reaction, hyperkalemia and edema.

XII. Claim 1 of **auxiliary request 2** only differs from claim 1 of the main request by specifying that:

(...) the side effect is selected from one or more of hand-foot syndrome, bleeding and redness.

XIII. The independent claims of **auxiliary request 3** and dependent claims 5 and 11 of this request read as follows (differences in comparison with the claims of former auxiliary request 5, i.e the request that was held allowable by the opposition division, marked by the board):

1. A branched-chain amino acid, or salt thereof, which comprises all three branched-chain amino acids: isoleucine, leucine and valine, for use in reducing a side effect of a kinase inhibitor, wherein the side effect is selected from one or more of: hand-foot syndrome and bleeding.

5. The branched-chain amino acid, or salt thereof, of any one of claims 1 to **6** ***5*** *for use according to any one of claims 1 to 4 in a liver cancer patient.*

9. A pharmaceutical composition for use in reducing a side effect of a kinase inhibitor, wherein the pharmaceutical composition comprises the branched-chain amino acid, or salt thereof, according to any one of claims 1 to 6, and wherein the side effect is at least one of: hand-foot syndrome and bleeding.

10. A food composition, for use in reducing a side effect of the kinase inhibitor, wherein the food composition comprises the branched-chain amino

acid, or salt thereof, according to any one of claims 1 to 6, *and wherein the side effect is at least one of: hand-foot syndrome and bleeding.*

11. The food composition ***~~for use~~*** *according to claim 10, wherein the food composition is contained in a container.*

12. An agent for use in anticancer therapy comprising:

the branched-chain amino acid, or salt thereof, according to any one of claims 1 to 6, and a kinase inhibitor, wherein

the branched-chain amino acid, or salt thereof, and the kinase inhibitor are arranged for administration as a combination drug, or for separate, simultaneous or sequential administration; and wherein

the branched-chain amino acid is for use in reducing a side effect of the kinase inhibitor wherein the side effect is at least one of: hand-foot syndrome and bleeding.

XIV. In a communication under Article 15(1) RPBA issued in preparation for oral proceedings and advising the parties of its preliminary opinion, the board pointed out, *inter alia*, that claim 12 of the main request and claim 11 of auxiliary request 3 contravened the requirement of Article 123(3) EPC (see point 2.2 of the board's communication dated 22 August 2022). This was because, in comparison with claim 13 as granted, the purpose limitation ("for use" feature) had been deleted.

XV. With a letter dated 7 September 2022, the patent proprietors filed further sets of claims as auxiliary requests 28 to 64.

The independent claims of **auxiliary request 28** are identical to the independent claims of the main request. Claim 12 reads as follows:

12. The food composition for use according to claim 11, wherein the food composition is contained in a container.

The independent claims of **auxiliary request 29** are identical to the independent claims of auxiliary request 1. Claim 12 reads as follows:

12. The food composition for use according to claim 11, wherein the food composition is contained in a container.

Claim 1 of **auxiliary request 30** only differs from claim 1 of the main request by specifying that:

(...) the side effect is selected from one or more of hand-foot syndrome, bleeding, redness and loss of appetite.

Claim 1 of **auxiliary request 31** is identical to claim 1 of auxiliary request 2 (see point XII. above).

XVI. The claims of **auxiliary request 32** are identical to those of auxiliary request 3, with the exception of dependent claims 5 and 11, which read as follows (differences in comparison with the claims of auxiliary request 3 marked by the board):

*5. The branched-chain amino acid, or salt thereof, of any one of claims 1 to ~~**5**~~ **4** for use according to any one of claims 1 to 4 in a liver cancer patient.*

*11. The food composition **for use** according to claim 10, wherein the food composition is contained in a container.*

XVII. Oral proceedings before the board were held on 20 September 2022.

XVIII. The opponent's arguments may be summarised as follows.

Extension of scope (Article 123(3) EPC)

The patent proprietors' interpretation of claim 12 of the main request was not correct as there was no implicit back-reference to the use according to claim 11. Reference was made to the current Guidelines for Examination in the EPO, G.VI-7.1.5, regarding the correct wording of dependent claims for the claim format pursuant to Article 54(5) EPC.

Admittance of auxiliary request 28

The necessity that claim 12 of the main request and the corresponding claims of auxiliary requests 1 to 27 must retain the purpose-limiting feature "for use" was not a new aspect of the case. This same issue had been discussed during the oral proceedings before the opposition division, and former auxiliary request 5 (that was ultimately upheld by the opposition division) had been filed to include the feature "for use" in claims 11 and 12. Careless drafting of the requests filed with the grounds of appeal did not constitute exceptional circumstances under Article 13(2) RPBA.

Sufficiency of disclosure

The data provided in the patent in suit supported the claimed medical use only in the narrow context of the experimental conditions reported in example 1 (amounts and ratios of isoleucine, valine and leucine; sorafenib

as the kinase inhibitor; only specific side effects of sorafenib). Extrapolation of these results to different kinase inhibitors and side effects, low amounts and different ratios of branched-chain amino acids was not warranted.

Admittance of auxiliary request 30

The addition of "loss of appetite" to the side effects recited in claim 1 constituted an amendment, at an advanced stage of the proceedings, of the patent proprietors' case not justified by exceptional circumstances.

Admittance of auxiliary request 31

No reason was apparent why this request could not have been filed in the proceedings before the opposition division.

Admittance of auxiliary request 32

There were no exceptional circumstances that justified bringing back the term "for use" in claim 11 at an advanced stage of the proceedings.

Auxiliary request 32 - criterion of Rule 80 EPC

The correction of a claim dependency or back-reference in claim 5 (*"of any one of claims 1 to 4"*) was not an amendment occasioned by a ground for opposition under Article 100 EPC.

Auxiliary request 32 - added subject-matter

The absence of the term "agent" in independent claim 1 generated added subject-matter. Furthermore, independent claims 9 and 10 also contained added subject-matter. The objection relating to claims 9

and 10 should be admitted as it responded to point 1.3 of the board's written preliminary opinion.

Auxiliary request 32 - inventive step

The subject-matter of claim 1 did not involve an inventive step starting from the teaching of documents D5 or D6. The inventive-step reasoning starting from D5 was not a change of case as the opponent had also argued this in the proceedings before the opposition division. An alternative approach using document D4 as the starting point was no longer pursued.

Starting from the technical teaching of D6, the objective technical problem was to provide an alternative composition. Isoleucine and valine were known from documents D3 and D5 as further candidate compounds for reducing side effects. No particular motivation or inventive skill would therefore have been required to modify the composition taught in D6 to include isoleucine and valine.

XIX. The patent proprietors' arguments may be summarised as follows.

Extension of scope (Article 123(3) EPC)

In claim 12 of the main request, which read: "The food composition according to claim 11 [...]", the use of the definite article "the" implied to the reader that the back-reference to claim 11 related to all aspects of the composition defined in claim 11, i.e. to both the composition and its use. As a consequence, the wording of claim 12 did not extend the scope of the claims in the patent as granted.

Admittance of auxiliary request 28

Auxiliary request 28 addressed the objection under Article 123(3) EPC that had been raised for the first time in the board's preliminary opinion. The request corresponded to the main request but reinstated the "for use" language in claim 12. If the board considered this an amendment to the patent proprietors' case (which was disputed), then exceptional circumstances justified its admittance.

Sufficiency of disclosure

The data provided in the patent showed efficacy against some of the most commonly encountered side effects of kinase inhibitors. Certain side effects (e.g. bleeding) could be observed for all kinase inhibitors. Also, the treatment's efficacy against a variety of side effects suggested a general mechanism of action. For these reasons, it was plausible that the envisaged administration of branched-chain amino acids would provide prophylactic or curative treatment of at least one side effect. Furthermore, the opponent had not provided any evidence to show that the same side effects induced by kinase inhibitors other than sorafenib could not be blocked with the same treatment.

Admittance of auxiliary request 30

This request had been filed in response to the board's preliminary opinion, according to which the data in the patent rendered it credible that also the side effect of loss of appetite could be reduced by administering branched-chain amino acids.

Admittance of auxiliary request 31

The claims of auxiliary request 31 (corresponding to those of auxiliary request 2) established an intermediate position with regard to the selection of side effects to be targeted and had been inserted in reaction to developments in the first-instance proceedings. Auxiliary request 31 did not introduce a new aspect to the case since redness was included in the list of side effects according to auxiliary request 1.

Admittance of auxiliary request 32

Except for minor corrections (the term "for use" was restored in claim 11, and a back-reference in claim 5 was adapted), this request corresponded to auxiliary request 3 filed with the statement setting out the grounds of appeal and to former auxiliary request 5 held allowable by the opposition division. It should therefore be admitted.

Auxiliary request 32 - criterion of Rule 80 EPC

The adaptation of the back-reference in claim 5 was a consequence of other amendments that were occasioned by a ground for opposition and that resulted in a reduced number of claims preceding the claim in question.

Auxiliary request 32 - added subject-matter

Neither the references to the composition in the application nor the wording of the claims as filed implied the need to use additional ingredients alongside the branched-chain amino acids and their salts. As a consequence, the opponent's objection to claim 1 under Article 123(2) EPC must fail.

The opponent's new objection relating to claims 9 and 10 should not be admitted under Article 13(2) RPBA.

Auxiliary request 32 - inventive step

In the oral proceedings before the opposition division, the opponent had not challenged the choice of D6 as the only starting point for the assessment of inventive step. Hence, there was no basis on which the opponent could challenge this point on appeal, and the opponent's inventive-step approach using D5 as the starting point in the prior art should not be admitted under Article 12(4) RPBA 2007.

Starting from the technical teaching of document D6, the objective technical problem was to provide an alternative composition for treating bleeding or hand-foot syndrome, which permitted enteral administration. There was nothing in the prior art that would have led the skilled person to a composition having isoleucine and valine alongside leucine.

XX. The patent proprietors requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of:

- the claims of the main request (filed with the statement setting out the grounds of appeal)

or, in the alternative:

- the claims of one of auxiliary requests 1 to 27, all filed with the statement setting out the grounds of appeal

or, in the further alternative:

- the claims of one of auxiliary requests 28 to 64, all filed with the patent proprietors' letter dated 7 September 2022

The patent proprietors requested, furthermore, that D9 and D10 be admitted into the proceedings, to the extent that they would rely on these documents.

XXI. The opponent requested that the decision under appeal be set aside and that the patent be revoked.

The opponent also requested that auxiliary requests 2, 5 to 7, 9 to 11, 13 to 16, 18 to 23 and 25 to 62 not be admitted and that documents D9 and D10 not be admitted.

Reasons for the Decision

1. Admissibility of the appeals

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

2. Claim analysis

2.1 Claim 1 of the current main request reads as follows:

> *"1. A branched-chain amino acid, or salt thereof, which comprises all three branched-chain amino acids: isoleucine, leucine and valine, for use in reducing a side effect of a kinase inhibitor."*

2.2 Thus, it appears that the same term "a branched-chain amino acid" is used with two different meanings, namely:

(a) to designate any individual substance which is a branched-chain amino acid (BCAA) (*"all three branched-chain amino acids: isoleucine, leucine, and valine"*)

(b) to designate a composition which is a mixture of different individual branched-chain amino acids

(BCAAs) (*"a branched-chain amino acid [...] which comprises all three branched-chain amino acids"*)

These different meanings are also present in the same way in claim 4 as granted, as acknowledged in the decision under appeal. The opponent did not appeal the opposition division's finding that, taking into account the criteria established in the Enlarged Board of Appeal's decision G 3/14 (OJ EPO 2015, A102), this issue is not open to examination under Article 84 EPC.

2.3 The board is of the view that the scope of the term "a branched-chain amino acid" when used to designate a mixture (meaning (b)) would not be commonly understood to include compositions comprising further components other than branched-chain amino acids (meaning (a)). The product according to claim 1 can, nevertheless, be formulated with or without additional components to put the use according to claim 1 into practice, as also envisaged in the independent claims relating to a pharmaceutical composition or food composition.

2.4 The skilled person's understanding of the feature "for use in reducing a side effect of a kinase inhibitor" would be that the condition to be addressed is a side effect arising from treatment with a kinase inhibitor, i.e. that claim 1 is restricted to therapeutic situations in which treatment with a kinase inhibitor takes place.

3. Extension of scope (Article 123(3) EPC)

3.1 Independent claim 12 as granted is a purpose-related product claim drafted in the format in accordance with Article 54(5) EPC (see point I. above).

Dependent claim 13 as granted accordingly refers back to:

"The food composition for use according to claim 12, (...)"

3.2 Claims 11 and 12 in the current main request are the claims corresponding to claims 12 and 13 as granted. Claim 12 of the current main request (see point X. above) reads:

"The food composition according to claim 11, wherein the food composition is contained in a container."

3.3 Since claim 12 of the current main request refers back only to the food composition but not to its use as defined in claim 11 (namely reducing a side effect), this claim is effectively an independent claim. It defines a product comprising a container and a food composition (required to be located inside the container) that comprises the amino acid mixture defined in claim 1.

3.4 The deletion of the purpose limitation in claim 12 of the main request, in comparison with claim 13 as granted, would result in an extension of protection. This amendment, therefore, contravenes the requirement of Article 123(3) EPC.

3.5 The patent proprietors' argument that a back-reference to the use of claim 11 is implied by the definite article "the" employed in claim 12 (*"The food composition according to claim 11,..."*) is not convincing.

- There is no linguistic convention on the basis of which it might be assumed that this is what a reader would understand. In the absence of an explicit reference to the use, the reader would

have no reason to construe such a reference or would at least be left in doubt about the drafter's intention.

- A look at established EPO practice (as reflected in the Guidelines for Examination in the EPO, G.VI-7.1.5, (March 2022) cited by the opponent) also shows that the patent proprietors' interpretation is not self-evident. As a rule, a dependent claim must clearly reflect its dependency on the independent claim. If the independent claim is drafted in the format of Article 54(5) EPC, this means that back-references not only to the substance or composition in question but also to its therapeutic use must be stated.
- The patent proprietors did follow this practice in dependent claims 2 to 9 of the same set of claims, all of which refer back to the BCAA, or its salt, "for use" according to claim 1. Since, in contrast to this, the use according to claim 11 is not mentioned in claim 12, a reader must infer that a back-reference to the use was not intended.

3.6 Each of auxiliary requests 1 to 27 contains a claim corresponding to claim 12 of the main request. None of these corresponding claims includes a purpose limitation (by back-reference or otherwise) to the use of the composition in reducing a side effect of a kinase inhibitor. As a consequence, the same objection under Article 123(3) EPC applies.

3.7 Under these circumstances, it is not necessary to address the issue of admittance of auxiliary requests 2, 5 to 7, 9 to 11, 13 to 16, 18 to 23 and 25 to 27.

3.8 In conclusion, none of the main request and auxiliary requests 1 to 27 is allowable under Article 123(3) EPC.

4. Auxiliary request 28 - admittance (Article 13(2) RPBA)

4.1 Auxiliary request 28 differs from the main request by including the feature "for use" in claim 12. This change, by inserting a purpose limitation, constitutes an amendment to the patent proprietors' appeal case. Indeed, as discussed above (see points 3.2, 3.3 and 3.6), none of the claim requests filed earlier in the appeal proceedings include a purpose limitation in the respective claim in question. The criteria of Article 13(2) RPBA apply.

4.2 The limiting feature "for use" was also present in the corresponding claim (i.e. claim 11) of former auxiliary request 5 held allowable by the opposition division. It had been added in the context of a discussion of inventive step, to delimit the claimed scope (see the decision under appeal, Reasons 6.5.2.4).

4.3 According to the patent proprietors, this feature should have been included but was omitted by error in the claim requests filed with the grounds of appeal.

4.4 In any case, claim 12 of the main request was never challenged during the written appeal proceedings for breadth of scope until the board, in its written preliminary opinion, raised a new objection under Article 123(3) EPC (see point XIV. above). In response, the patent proprietors filed auxiliary request 28 reinstating the feature "for use" in the claim concerned.

4.5 In these circumstances, the board acknowledged that the filing of auxiliary request 28 had been occasioned by a new development, and exercised its discretion under Article 13 RPBA to admit this request.

5. Auxiliary request 28 - sufficiency of disclosure (Article 83 EPC)

5.1 Example 1 provided in the application as filed (and in the identical passage in paragraphs [0050] to [0055] of the patent in suit) investigates the effects of the combined intake of the kinase inhibitor sorafenib and a mixture of isoleucine, leucine and valine (weight ratio 1:2:1.2) in a rat model of liver cancer.

In the sorafenib-only intake group, redness was noted on the legs, trunk and skin, and a tendency for bleeding to occur in the gastrointestinal tract, including the anal region, was observed. A loss of appetite due to gastrostenosis was also observed.

In contrast, in the group with the combined intake of sorafenib and BCAAs, the symptoms of redness, bleeding and loss of appetite were all improved significantly (see paragraph [0054] of the patent in suit).

5.2 Thus, it is rendered credible that a mixture of isoleucine, leucine and valine may reduce certain side effects of sorafenib.

5.3 The board agrees, however, with the opponent's view that this teaching cannot be extended to different side effects for the following reasons.

5.3.1 Paragraph [0030] of the patent in suit provides an extensive list of possible side effects of kinase inhibitors to be reduced by administration of the BCAAs. In addition to hand-foot syndrome, gastrointestinal bleeding and redness, side effects as diverse as cerebral hemorrhaging, acute hepatitis, liver function disorder, interstitial pneumonia, congestive heart failure, anaphylactic reaction, depression, tinnitus, anorexia, fever, influenza-like

symptoms, infection, hyperthyroidism and hypothyroidism are, *inter alia*, mentioned.

5.3.2 A common underlying mechanism causing all these symptoms is not apparent and can be derived neither from the information given in the patent in suit nor from common general knowledge. The patent proprietors' argument is speculative and remains unsubstantiated by data or a theoretical scientific concept. If the data in example 1 shows some success of BCAA administration in reducing several different side effects, namely skin redness, bleeding in the gastrointestinal tract and loss of appetite due to gastrostenosis, it does not follow that the same treatment would reduce presumably unrelated side effects such as tinnitus, fever or congestive heart failure. There is no persuasive scientific basis for drawing that conclusion.

5.3.3 The patent proprietors filed D10 as post-published evidence to show that BCAA treatment during sorafenib therapy may also contribute to maintaining liver function by increasing serum albumin levels (see the statement setting out the grounds of appeal, page 2). Even if admitted, the disclosure of document D10 on the potential utility of BCAAs against one further side effect would not remedy the absence of a substantiated general concept that would allow the teaching of example 1 to be extended to all conceivable side effects.

5.4 The patent proprietors also argued that the wording of claim 1 "for use in reducing a side effect" required only one side effect to be reduced. The side effects observed in example 1 were common. Since a side effect such as bleeding would be observed for all kinase inhibitors at least to some extent, the requirement in claim 1 would always be met as the administration

of the BCAAs according to claim 1 would reduce, or prophylactically prevent, bleeding.

5.5 The board arrives at a different conclusion for the following reasons.

5.5.1 Claim 1 of the main request does not specify a particular side effect. If BCAAs as defined in claim 1 are administered to a patient to reduce or prevent a side effect other than bleeding, e.g. tinnitus, this is an alternative embodiment covered by claim 1.
The therapeutic efficacy of BCAAs in preventing or treating tinnitus (and other side effects not covered by example 1) is not supported by evidence and is not rendered credible in the application as filed.

5.5.2 The allegation that bleeding, hand-foot syndrome and loss of appetite are prevalent side effects of kinase inhibitors that are inevitably and invariably addressed cannot be verified on the basis of the available evidence. The patent proprietors cited documents D4 and D9, both in relation to known side effects of sunitinib, i.e. one other kinase inhibitor. These documents do not, however, provide any information on the general prevalence of specific side effects in all kinase inhibitors. Thus, assuming D9 (the prescribing information for sunitinib) had been admitted, its teaching could not change the board's conclusions on sufficiency.

5.6 In conclusion, the subject-matter of claim 1 of auxiliary request 28 is 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).

5.7 In its reasoning set out above (see points 5.3.3 and 5.5.2), the board considered D9 and D10 to the extent the patent proprietors relied on them in presenting

their case, without taking a formal decision on admittance.

6. Auxiliary request 29 - sufficiency of disclosure (Article 83 EPC)

6.1 Claim 1 of auxiliary request 29 (see points XI. and XV. above) differs from claim 1 of auxiliary request 28 by specifying a list of various side effects to be targeted, based on the list provided in paragraph [0028] of the application as filed, which corresponds to paragraph [0030] of the patent in suit.

6.2 Irrespective of the issue of admittance of this request, the assessment on sufficiency of disclosure as set out in section 5 for claim 1 of auxiliary request 28 also applies to claim 1 of auxiliary request 29.

6.3 Hence, auxiliary request 29 is not allowable because the subject-matter of claim 1 of auxiliary request 29 is 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).

7. Auxiliary request 30 - admittance (Article 13(2) RPBA)

7.1 According to claim 1 of auxiliary request 30, the targeted side effects are hand-foot syndrome, bleeding, redness and loss of appetite.

7.2 This constitutes an amendment to the patent proprietors' case since none of the claim requests submitted earlier in the appeal proceedings specified that the targeted side effects included loss of appetite.

7.3 The fact that the board summarised the known results of example 1 in point 4.1 of its written preliminary opinion, mentioning the observation made in example 1 that, *inter alia*, the symptom of loss of appetite was improved, is not a new development that could justify filing auxiliary request 30 at this advanced stage of the proceedings.

7.4 Furthermore, the addition of "loss of appetite" in claim 1 of auxiliary request 30 does not respond to a new objection but is merely an attempt by the patent proprietors to create a further intermediate position between auxiliary request 31 (corresponding to auxiliary request 2 and listing hand-foot syndrome, bleeding and redness as the targeted side effects) and auxiliary request 28 (corresponding to the main request and referring to "a side effect" in general).

7.5 Finally, the data and observations presented in example 1 of the application as filed were known to the patent proprietors. Hence, they should have filed this intermediate request during the proceedings before the opposition division.

7.6 For these reasons, the board decided not to admit auxiliary request 30.

8. Auxiliary request 31 - admittance (Article 12(4) RPBA 2007)

8.1 Auxiliary request 31 corresponds to auxiliary request 2, with an amendment in claim 12 made for compliance with Article 123(3) EPC. For the same reasons as set out in section 4 above, the amendment in claim 12 re-instating a purpose limitation for that claim is permissible under Article 13(2) RPBA.

8.2 For the other amendments, admittance is assessed under Article 12(4) RPBA 2007 since auxiliary request 31 is otherwise identical to auxiliary request 2 filed with the patent proprietors' grounds of appeal.

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

8.4 Claim 1 of auxiliary requests 2 and 31 specifies that the targeted side effect is to be selected from one or more of hand-foot syndrome, bleeding and redness.

8.5 Claim 1 in the requests filed in the proceedings before the opposition division states that the following side effects of a kinase inhibitor were to be targeted:

- "a" side effect (former main request and auxiliary requests 1 to 3 and 7)
- a longer list of side effects, as in current auxiliary request 29 (former auxiliary requests 4 and 8)
- at least one of hand-foot syndrome and bleeding (former auxiliary requests 5 and 6)

The requests filed in the first-instance proceedings did not include any claim specifying that the side effect was to be selected from one or more of hand-foot syndrome, bleeding and redness.

8.6 Auxiliary request 2 filed upon appeal does not respond to any objection that arose in the proceedings before the opposition division. Rather, this request occupies an intermediate position between claim requests that refer only to hand-foot syndrome and bleeding and claim requests that refer to "a side effect" or a longer list

of side effects. The same goes for auxiliary request 31.

8.7 The patent proprietors had the opportunity to establish such an intermediate position, if desired, during the proceedings before the opposition division, and they should have done so at that time. The board is not aware of any reason that would have prevented the patent proprietors from filing a request listing hand-foot syndrome, bleeding and redness.

8.8 For the reasons set out in points 8.2 to 8.7, the board decided not to admit auxiliary request 31.

9. Auxiliary request 32 - admittance

9.1 Auxiliary request 32 corresponds to auxiliary request 3, with an amendment in claim 11 made for compliance with Article 123(3) EPC. For the same reasons as set out in section 4 above (for claim 12 of auxiliary request 28), the amendment in claim 11 re-instating a purpose limitation for that claim is permissible under Article 13(2) RPBA.

9.2 Apart from the amendment in claim 11, the issue of admittance is assessed under Article 12(4) RPBA 2007 since auxiliary request 32 is otherwise identical to auxiliary request 3 filed with the patent proprietors' grounds of appeal, except for a corrected back-reference in dependent claim 5 (see points XIII. and XVI. above).

9.3 The independent claims of auxiliary requests 3 and 32 are identical to the corresponding claims of former auxiliary request 5 deemed allowable by the opposition division (see points VI., XIII. and XVI. above). The

opponent did not object to the admittance of auxiliary request 3.

9.4 Taking these circumstances into account, the board saw no reason to hold auxiliary request 32 inadmissible under Article 12(4) RPBA 2007.

10. Auxiliary request 32 - criterion of Rule 80 EPC

10.1 Claim 7 as granted reads as follows:

> *7. The branched-chain amino acid, or salt thereof, of any one of claims 1 to 6 for use according to any one of claims 1 to 6 in a liver cancer patient.*

It is thus readily apparent that the back-reference in this claim is to all preceding claims (claims 1 to 6).

10.2 The corresponding claim in former auxiliary request 5 held allowable by the opposition division reads as follows:

> *5. The branched-chain amino acid, or salt thereof, of any one of claims 1 to 6* [sic] *for use according to any one of claims 1 to 4 in a liver cancer patient.*

10.3 The corresponding claim in current auxiliary request 3 reads as follows:

> *5. The branched-chain amino acid, or salt thereof, of any one of claims 1 to 5* [sic] *for use according to any one of claims 1 to 4 in a liver cancer patient.*

10.4 The corresponding claim in auxiliary request 32 reads as follows:

> *5. The branched-chain amino acid, or salt thereof, of any one of claims 1 to 4 for use according to any one of claims 1 to 4 in a liver cancer patient.*

10.5 Like granted claim 7, claim 5 of auxiliary request 32 refers back to all claims preceding it (i.e. in this case, claims 1 to 4). The back-references have been adapted to the reduced number of preceding claims resulting from other amendments. This is normal practice and cannot in any case infringe Rule 80 EPC since this adaptation does not result in a change of content but merely preserves the still applicable back-references.

10.6 The opponent did not state an objection under Rule 80 EPC to any amendment that involved the deletion of preceding claims.

10.7 As can be seen in points 10.2 and 10.3 above, the back-references were not adapted correctly in earlier versions of this claim according to former auxiliary request 5 and current auxiliary request 3. However, the fact that there was an error in certain amended claim requests cannot be used to prevent the patent proprietors from stating the back-references correctly in another claim request.

In the board's view, Rule 80 EPC does not apply to such a situation as it concerns amendment(s) of a European patent, i.e. a comparison of an amended version to the granted version rather than a comparison between different amended versions.

A different understanding of the legal framework would create a legal asymmetry. On the one hand, any amended text would have to comply with all the requirements of the EPC. On the other hand, any subsequent amendments of that text could be allowed only if they were prompted by a ground for opposition. This legal asymmetry would have unfair consequences (see already T 946/16 of 23 October 2019, point 3.4 of the Reasons). For example, the opponent could raise a lack of clarity

based on the introduction of an amendment, which itself meets the requirements of Rule 80 EPC, while the patent proprietor could not respond by filing a further amended text because this amendment would not comply with Rule 80 EPC (T 946/16, *ibidem*). However, the purpose of the latter provision is to prevent the proprietor from using the opposition procedure to improve the text of the granted patent in a way and to an extent that is not necessary to overcome a ground of opposition (see also T 21/16 of 9 April 2019, point 6 of the Reasons). In accordance with this purpose and its title, which refers to the European patent, Rule 80 EPC cannot apply to amendments concerning features (or errors) which were not already in the granted claims.

10.8 For these reasons, auxiliary request 32 is allowable under Rule 80 EPC.

11. Auxiliary request 32 - amendments (Article 123(2) EPC)

11.1 The opponent argued that the absence of the term "agent" in independent claim 1 generated added subject-matter since the claim now encompassed embodiments which consisted of BCAAs.

11.2 This argument cannot succeed for the following reasons.

11.2.1 Claims 1 and 4 of the application as filed read as follows:

> *1. An agent for reducing a side effect of a kinase inhibitor, the agent comprising at least one branched-chain amino acid selected from among isoleucine, leucine and valine or a salt thereof as an active ingredient.*

4. The agent for reducing a side effect according to any one of Claims 1 to 3, comprising three branched-chain amino acids isoleucine, leucine and valine.

11.2.2 The terms "agent" and "comprising", employed in claims 1 and 4 of the application as filed, do not imply the mandatory (as opposed to optional) presence of ingredients other than BCAAs and their salts.

11.2.3 In any case, however, the application as filed teaches that the BCAAs (or their salts) are the active ingredients that bring about the effect of reducing various side effects of a kinase inhibitor (see, for instance, claim 1 and paragraphs [0014] and [0019] as filed). Thus, a claim directed to the further medical use of these active ingredients for this purpose does not go beyond the content of the application as filed, and claim 1 meets the requirements of Article 123(2) EPC.

11.3 At the oral proceedings before the board, the opponent also argued that claims 9 and 10 of auxiliary request 32 contained added subject-matter.

11.3.1 These claims had been on file from the outset of the appeal proceedings (as claims 9 and 10 of auxiliary request 32 are identical to claims 9 and 10 of auxiliary request 3 filed with the statement setting out the grounds of appeal). In its written appeal submissions, the opponent never objected to these claims in relation to added subject-matter. Raising this objection for the first time at the oral proceedings before the board constitutes a change of the opponent's case under Article 13(2) RPBA.

11.3.2 The opponent stated that the objection arose in reaction to point 1.3 of the board's communication under Article 15(1) RPBA on claim analysis.

11.3.3 In its communication, the board stated its preliminary view that the scope of the term "a branched-chain amino acid" when used to designate a mixture (meaning (b), see point 2.2 above) would not be commonly understood to include compositions comprising further components other than BCAAs (meaning (a)).

11.3.4 The question whether the claimed embodiments required the presence of components other than BCAAs (or their salts) had always been in dispute. Hence, it could not have been surprising that the board addressed this issue. That the board's opinion might not confirm the opponent's view should also have been anticipated as an eventuality by the opponent, which should have filed any objections on this basis at an earlier stage, rather than wait for the board's communication.

11.3.5 Furthermore, the board's interpretation does not give rise to a new situation. Indeed, it does not result in a different scope of claims 9 and 10 in comparison to the one which results from the interpretation endorsed by the patent proprietors and the opposition division, since both held that the presence of components other than BCAAs or their salts was possible but not required or implied by claim 1. In either case, the pharmaceutical composition of claim 9 and the food composition of claim 10, defined as comprising the product of claim 1, may or may not comprise further components.

11.3.6 In view of the above, the reason given by the opponent did not justify the admittance of the late-filed objection against claims 9 and 10 on added subject-

matter. The board decided, therefore, not to admit this objection.

12. Auxiliary request 32 - sufficiency of disclosure

12.1 The limitation of the targeted side effects to hand-foot syndrome and bleeding, as in claim 1 of auxiliary request 32, overcomes the objection of insufficiency under points 5.3 to 5.6 above because the specified side effects are covered by example 1 disclosed in the application as filed (see points 5.1 and 5.2 above).

Hand-foot syndrome is a side effect of some cancer treatments which manifests itself in redness, swelling and pain in the palms of the hands and/or the soles of the feet. The treatment of hand-foot syndrome is reflected and rendered credible by the observation that redness of the legs was reduced in the rat model employed according to example 1.

12.2 The opponent's argument that the disclosure in the application as filed does not support the treatment of side effects caused by kinase inhibitors other than sorafenib cannot succeed for the following reasons.

12.2.1 In the animal study described in example 1, the animals were treated with sorafenib as the kinase inhibitor. As set out above, example 1 renders it credible that the administration of BCAAs may be effective in the treatment of hand-foot syndrome and bleeding as side effects of sorafenib treatment.

12.2.2 The opponent has not provided an explanation why the same side effects, when caused by a different kinase inhibitor, should not be susceptible to the same treatment with BCAAs, i.e. why hand-foot syndrome and bleeding caused by other kinase inhibitors would differ from the same side effects caused by sorafenib. Hence,

the opponent has not succeeded in raising serious doubt, substantiated by verifiable facts, about the efficacy of BCAA administration in such cases.

12.3 The opponent's further argument that efficacy may be lacking at low doses or certain ratios of the BCAAs cannot succeed as dose optimisation is within the ordinary scope of ability of the skilled person. Furthermore, the opponent did not provide any evidence that altering the ratios of the amino acids would lead to a loss of efficacy. Hypothetical "literal embodiments" involving doses clearly outside the scope of practical application would not be considered, and nor are they claimed.

12.4 For these reasons, the claimed subject-matter is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, as required by Article 83 EPC.

13. Auxiliary request 32 - inventive step

Starting point in the prior art

13.1 At the oral proceedings before the opposition division, inventive step of claim 1 of former auxiliary request 5, filed during the oral proceedings, was discussed. As mentioned above, the independent claims of former auxiliary request 5 are identical to the independent claims of current auxiliary request 32. The minutes of the oral proceedings show, in point 6.1, that the opponent relied in its reasoning exclusively on document D6 as the starting point in the prior art and did not request any other approach to be considered. Thus, it is readily apparent that the opponent at that stage did not pursue an inventive-step objection based on D5 as the starting point.

13.2 Upon appeal, the opponent alleged that the claimed subject-matter lacked an inventive step starting from the disclosure of document D6 or, alternatively, starting from the disclosure of document D5 (see the opponent's statement setting out the grounds of appeal).

13.3 The objection is based on statements of fact or mixed statements of fact and law, namely that this document has a specific content in that it advocates the use of the same BCAAs for the treatment of cancer cachexia, that the claims may have a specific differentiating feature in view of this document, and that the application of the problem-solution approach would lead to the formulation of a specific problem. Therefore, this new line of attack is not limited to a new argument with the consequence that its admissibility is subject to the board's discretion under Article 12(4) RPBA 2007.

13.4 The board is not aware of any reason why the opponent could not have presented the alternative inventive-step assessment based on D5 at the oral proceedings before the opposition division to obtain a first-instance ruling on this point. The board therefore decided to hold this line of reasoning inadmissible under Article 12(4) RPBA 2007.

13.5 It was common ground that document D6 was suitable as a starting point for the assessment of inventive step as it was directed to the same purpose as the patent in suit.

13.6 D6 is a scientific journal article on controlling oral mucositis as a frequently occurring side effect of chemotherapy and radiotherapy. It discloses that a composition comprising L-leucine, L-lysine, L-proline

and glycine as collagen precursors, in combination with sodium hyaluronate (page 144, right-hand column, third paragraph), reduces oral mucositis.

One patient in the study population of D6 received the kinase inhibitor sorafenib, followed by sunitinib (see D6: Table III).

Objective technical problem and solution

13.7 The product ("a branched-chain amino acid, or salt thereof") defined in claim 1 differs from the composition disclosed in D6 by the presence of isoleucine and valine.

13.8 In light of the board's understanding of the term "a branched-chain amino acid" when used to designate a mixture (meaning (b)), claim 1 also differs from the composition proposed in D6 by excluding components other than BCAAs and their salts.

13.9 This is not the case, however, for claim 9, which is directed to a pharmaceutical composition that "comprises" the BCAA, or salt thereof, of claim 1. The term "comprising" implies that the composition may also include further components, while the general term "pharmaceutical composition" imposes no restrictions on such further components except their suitability for pharmaceutical purposes.

13.10 Although the topic discussed at the oral proceedings before the board was inventive step of claim 1 and the parties did not present separate lines of reasoning for the other independent claims, claim 9 will be considered in the board's reasoning in this decision for being the claim with the broader scope. This approach favours the opponent (i.e. the losing party, see below).

13.11 The therapeutic indication of reducing hand-foot syndrome as a side effect of a kinase inhibitor is a further feature distinguishing the claimed subject-matter from the disclosure of D6.

13.12 As far as the therapeutic indication of reducing bleeding as a side effect of a kinase inhibitor is concerned, the opponent pointed out that oral mucositis addressed in D6 is a side effect of the cancer medication and is "clinically characterized by", *inter alia*, bleeding (see D6: page 144, left-hand column, first paragraph). Healing oral mucositis would thus also reduce or prevent bleeding.

13.13 With respect to the technical effects linked to the distinguishing features, the patent proprietors contended that the claimed compositions could be used to treat side effects of a kinase inhibitor even in the absence of hyaluronic acid and that it was possible to achieve this through enteral administration, including in the form of a food.

13.14 However, the absence of hyaluronic acid is not reflected in any technical feature of claim 9, nor is enteral administration. As a consequence, these alleged technical effects cannot be relied on in the formulation of the objective technical problem.

13.15 Taking the therapeutic indications into account, two separate objective technical problems may be formulated for claim 9 starting from the disclosure of D6:

(a) to provide an alternative pharmaceutical composition for use in reducing a side effect of a kinase inhibitor, where the side effect is bleeding

(b) to provide a pharmaceutical composition for use in reducing a further side effect of a kinase inhibitor

13.16 The solution to both technical problems is provided by the pharmaceutical composition according to claim 9, which includes isoleucine and valine (or their salts), in combination with leucine.

Obviousness of the solution

13.17 Except for leucine, D6 teaches mandatory components different from those required in the patent in suit. These components were chosen for being collagen precursors and for their role in tissue healing, to be applied topically to the affected areas of the oral mucosa in the form of a spray composition.

In particular, D6 teaches that hyaluronic acid, or sodium hyaluronate, plays an important role in tissue healing and enhances the healing process, and that the collagen precursors (proline, leucine, lysine and glycine) are added to promote and accelerate this activity (see D6: page 144, right-hand column, lines 4 to 7 and page 149, left-hand column, second paragraph).

13.18 D6 provides no incentive for the skilled person to use modified compositions comprising isoleucine and valine in addition to leucine. Furthermore, D6 is only concerned with the alleviation of oral mucositis and does not discuss other potential side effects of kinase inhibitors such as hand-foot syndrome. Hence, D6 alone cannot point the skilled person to the subject-matter of claim 9.

13.19 Nor has it been made clear why, starting from the teaching in D6 of a specialised topical composition for oral mucositis, the skilled person would have consulted documents D3 (therapeutic agent for liver disease) or

D5 (nutritional compositions), which were cited by the opponent as supplementary documents.

13.19.1 Document D3 relates to a therapeutic agent for liver disease (including liver cancer) which comprises isoleucine, leucine, valine and alanine as active ingredients. D3 says nothing about kinase inhibitors and their side effects, or about topical compositions similar to those of D6. The board therefore considers that the person skilled in the art, starting from the disclosure in D6 and seeking to solve one of the objective technical problems, would not have consulted document D3.

13.19.2 Document D5 does not mention kinase inhibitors or their side effects, either. D5 is not concerned with reducing the side effects of cancer medication but relates to the treatment of cachexia (tumour-induced weight loss and malnutrition), which is a symptom of the cancer itself (D5: page 1, lines 1 to 20). D5 proposes nutritional supplements containing essential amino acids and teaches that high amounts of leucine stimulate muscle protein synthesis (D5: page 2, lines 4 to 26; claims 18 to 20; examples; page 2, lines 5 to 8). Since the teaching of document D5 is entirely unrelated to the objective technical problem and the teaching of D6, the person skilled in the art would not have considered D5 as a secondary document.

13.20 In conclusion, the opponent failed to show that the subject-matter of claim 9 would have been obvious to the person skilled in the art, based on D6 in combination with D3 or D5, as a solution to either of the objective technical problems formulated above.

13.21 The subject-matter of claim 1 is even more removed from the disclosure of D6 as it requires the absence of components other than BCAAs and their salts (see

point 13.8 above). The same reasoning applies as set out for claim 9. Moreover, the person skilled in the art would not have expected the desired activity against oral mucositis, or bleeding, to be attained with a composition not containing sodium hyaluronate and most of the "collagen precursors" regarded as essential in D6.

13.22 As a consequence, the subject-matter of claims 1 and 9 of auxiliary request 32 involves an inventive step within the meaning of Article 56 EPC. The opponent did not raise any objection against any other independent claim.

14. Adaptation of the description

The board did not consider any amendment to the description necessary (pages 2 to 9 filed during the oral proceedings of 11 June 2018). None of the parties disagreed in this respect at the oral proceedings.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent as amended in the following version:

   - Claims: claims 1 to 13 according to auxiliary request 32 filed with the letter dated 7 September 2022
   - Description: pages 2 to 9 filed during the oral proceedings of 11 June 2018
   - Drawings: sheets 1/2 to 2/2 of the patent specification

The Registrar: The Chair:

I. Aperribay J. Molina de Alba

Decision electronically authenticated