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Datasheet for the decision of 28 September 2021

Case Number: T 0138/17 - 3.3.07

Application Number: 10776328.6

Publication Number: 2493482

IPC: A61K33/00, A61P3/00

Language of the proceedings: EN

Title of invention:
THERAPEUTIC GAS FOR THE TREATMENT OF MITOCHONDRIAL DISORDERS

Patent Proprietor:
Löffler, Bernd-Michael

Opponent:
Ai Mediq S.A.

Headword:
Treatment of mitochondrial disorders / LÖFFLER, BERND-MICHAEL

Relevant legal provisions:
RPBA Art. 12(4)
RPBA 2020 Art. 11, 13(2), 25(1), 25(2)
EPC Art. 100(a), 54, 56

Keyword:

Sub-authorisation - validity
Oral submissions by patent proprietor - (yes)
Late-filed evidence - admitted (no)
(Late-filed) request - admittance in appeal proceedings (yes)
Novelty - (yes)
Inventive step - (no)
Remittal - special reasons for remittal (no)

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Case Number: T 0138/17 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 28 September 2021

Appellant: (Patent Proprietor)	Löffler, Bernd-Michael Knesebeckstrasse 68/69 10623 Berlin (DE)
Representative:	Dr. Klemens Schubert Patentanwalt Schlüterstraße 37 10629 Berlin (DE)
Respondent: (Opponent)	Ai Mediq S.A. 19 Rue de Bitbourg 1273 Luxembourg (LU)
Representative:	Jeck, Anton Jeck, Fleck & Partner mbB Patentanwälte Klingengasse 2 71665 Vaihingen/Enz (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 14 November 2016 revoking European patent No. 2493482 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	A. Usuelli
Members:	J. Lécaillon
	A. Jimenez

Summary of Facts and Submissions

I. European patent 2 493 482 (hereinafter "the patent") was granted on the basis of 10 claims. The independent claim of the patent as granted read as follows:

"1. Therapeutic gas comprising oxygen for use in the intermittent hypoxia-hyperoxia therapy of mitochondrial disorders or coenzyme Q10 deficiencies by inhalation and by a patient who has been identified as a person with a mitochondrial disorder or a coenzyme Q10 deficiency."

II. An opposition was filed against the patent on the grounds that its subject-matter lacked novelty, inventive step and industrial applicability, it was not sufficiently disclosed and it extended beyond the content of the application as originally filed.

III. The opposition division took the decision to revoke the patent.

IV. The decision of the opposition division, posted on 14 November 2016, cited *inter alia* the following document:

D2: Intermittent Hypoxic Therapy/Training (IHT) as etiological and pathogenic anti-ageing treatment, A. Prokopov and T. Voronina at SENS3 conference,Queens' College, Cambridge, UK, 6-10 September 2007, retrieved online from http://www.sens.org/outreach/conferences/intermittent-hypoxic-therapytraining-iht-etiological-and-pathogenetic-anti

V. In its decision the opposition division came to the conclusion that document D2 disclosed the treatment of patients with oxidative stress by use of an intermittent hypoxia and normoxia or hyperoxia therapy (IHT) and taught that this therapy had a therapeutic effect on mitochondrial activity. Consequently the subject-matter of claim 1 of the patent was not novel over D2.

VI. The patent proprietor (appellant) lodged an appeal against the above decision of the opposition division.

VII. With its statement setting out the grounds of appeal the appellant defended its case on the basis of the patent as granted as the main request, and on the basis of four auxiliary requests filed therewith.

The content of the claims of the auxiliary requests upon which the present decision is based can be illustrated as follows:

Claim 1 of auxiliary request I read as follows (emphasis added):

"Therapeutic gas comprising oxygen for use in the intermittent hypoxia-hyperoxia therapy of mitochondrial disorders or coenzyme Q10 deficiencies by inhalation, wherein cycles of inhalation of hypoxygenic and hyperoxygenic gases follow each other, and by a patient who has been identified as a person with a mitochondrial disorder or a coenzyme Q10 deficiency."

Claim 1 of auxiliary request II differed from claim 1 of the main request in that the feature "wherein the plasma level of Q10 in the patient is elevated" was added at the end of the claim.

Claim 1 of auxiliary request III differed from claim 1 of auxiliary request II in that the feature "up to the therapeutic range of 2.5 mg/l" was added at the end of the claim.

Claim 1 of auxiliary request IV read as follows (emphasis added):

"Therapeutic gas comprising oxygen for use in the intermittent hypoxia-hyperoxia therapy of mitochondrial disorders or coenzyme Q10 deficiencies by inhalation using cycles of inhalation of hypoxygenic and hyperoxygenic gases and by a patient who has been identified as a person with a mitochondrial disorder or a coenzyme Q10 deficiency, wherein the plasma level of Q10 in the patient is elevatedelevated *[sic]* up to the therapeutic range of 2.5 mg/l."

VIII. The following items of evidence were filed by the parties during the appeal proceedings:

(a) Documents filed by the appellant with its statement setting out the grounds of appeal:

D21: Reddy and Los, Hepat Mon. 2012; 12(8):e6159
D22: Thomas and Cookson, Int J Biochem Cell Biol. Author manuscript; available in PMC 2010 October 1.
D23: Dewhirst, Radiat. Res. Author manuscript; available in PMC 2010 December 1.

(b) Documents filed by the respondent with its reply to the statement setting out the grounds of appeal:

D24: Wikipedia article "Metabolic syndrome"

(c) Document submitted by the appellant during the oral proceedings on 28 September 2021:

D25: Article "Intermittent Hypoxia and Health: from Evolutionary Aspects to Mitochondria Rejuvenation" by Arkadi F. Prokopov

IX. Oral proceedings were held before the Board on 28 September 2021.

X. The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted or, alternatively, that the patent be maintained on the basis of one of the auxiliary requests I-IV filed on 23 March 2017 with the statement setting out the grounds of appeal. It further objected to the validity of the authorisation of Mr. Christian Störle to represent the respondent in the oral proceedings.

XI. The respondent requested that the appeal be dismissed. The respondent further requested not to admit auxiliary requests I-IV into the appeal proceedings and that the case be remitted to the opposition division should auxiliary requests I-IV be admitted into the appeal proceedings. During oral proceedings, it also requested that the patent proprietor, Mr Bernd-Michael Löffler, not be allowed to make oral submissions and the document D25 not be admitted into the appeal proceedings.

XII. The arguments of the appellant, as far as relevant for the present decision, can be summarised as follows:

(a) The representative present at the oral proceedings for the respondent was not duly authorised due to

an inconsistency in the names of the patent law firm initially authorised and the one which issued the sub-authorisation.

(b) The patent proprietor should be allowed to make submissions during the oral proceedings.

(c) The appellant became aware of D25 when preparing for oral proceedings. D25 was a post-published document by the same author as D2 filed to further explain the disclosure of D2. As the patent in suit actually contained a reference thereto, D25 was to be admitted into the appeal proceedings.

(d) D2 was limited to intermittent hypoxia / normoxia therapy and did not disclose the use of an intermittent hypoxia / hyperoxia therapy, let alone for use in the treatment of mitochondrial disorders or coenzyme Q10 deficiencies in patients having such disorders. The subject-matter of claim 1 of the main request was novel over D2.

(e) D2 represented the closest prior art. D2 focused on intermittent hypoxia / normoxia therapy and mitoptosis. An intermittent hypoxia / hyperoxia therapy for increasing the coenzyme Q10 levels in patients for use in the treatment of coenzyme Q10 deficiencies and mitochondrial disorders was thus not derivable from D2 nor from any further cited prior art. The subject-matter of claim 1 of the main request thus involved an inventive step.

(f) Auxiliary requests I-IV were filed in reaction to the decision of the first instance and were therefore to be admitted into the appeal

proceedings. A remittal of the case to the first instance was not required.

(g) The features relating to the elevation of plasma level of coenzyme Q10 introduced in auxiliary requests II-IV were neither disclosed nor suggested in D2, which was silent about coenzyme Q10. The subject-matter of claim 1 of auxiliary requests II-IV therefore involved an inventive step.

XIII. The arguments of the respondent, as far as relevant for the present decision, can be summarised as follows:

(a) The representative present at the oral proceedings for the respondent had been duly authorised by way of a sub-authorisation.

(b) The patent proprietor should not be allowed to make submissions during oral proceedings. It had not been specified on which aspects the patent proprietor would make submissions. In addition, the subject-matter underlying the present case was technically not so complicated as to require statements of an expert.

(c) The filing of D25 at such a late-stage of the appeal proceedings constituted an abuse of proceedings, as it should have been filed earlier in response to the objection based on D2. Furthermore D25 was not *prima facie* relevant. It was thus not to be admitted into the appeal proceedings.

(d) D2 disclosed alternative therapies, one of them being intermittent hypoxia / hyperoxia therapy. D2 further pertained to oxidative stress and taught

effects on mitochondrial therapy. D2 finally mentioned that experimental studies on more than 100 patients suffering from oxidative stress were performed and beneficial effects were obtained. A link between oxidative stress and mitochondrial disorders was disclosed in both D2 and the patent in suit. The subject-matter of claim 1 of the main request was thus anticipated by D2.

(e) D2 represented the closest prior art. D2 would not specifically disclose the presently claimed therapeutic use. D2 disclosed intermittent hypoxia / hyperoxia therapy and provided unequivocally a link between the mentioned beneficial clinical effects and mitochondrial activity. Furthermore no particular effects were reported in the patent in suit. It was thus obvious starting from D2 to apply the disclosed intermittent hypoxia / hyperoxia therapy in the treatment of mitochondrial disorders. The subject-matter of claim 1 of the main request did consequently not involve an inventive step.

(f) Auxiliary requests I-IV were not to be admitted into the appeal proceedings because they should have been filed already in the first instance proceedings in reaction to the novelty objection *versus* D2 raised since the filing of the notice of opposition. Moreover auxiliary requests I-IV did *prima facie* not overcome the objections regarding the main request and raised further issues. In particular the introduction of features from the original description in some auxiliary requests created a fresh case. Should the Board be of an opposite opinion, in order to ensure the possibility of having said auxiliary requests

examined by two instances, the case was to be remitted to the first instance.

(g) The features relating to the elevation of plasma level of coenzyme Q10 introduced in auxiliary requests II-IV did not further distinguish the claimed subject-matter from the one described in D2. As D2 encouraged the skilled person to perform the same therapy as presently claimed for the treatment of the same disease (*i.e.* mitochondiral disorders), an elevation of the coenzyme Q10 level would then also necessarily occur. The modifications introduced in claim 1 of auxiliary requests II-IV did therefore not overcome the objection of lack of inventive step of the main request.

Reasons for the Decision

1. Authorisation of the respondent's representative

1.1 At the beginning of the oral proceedings the appellant questioned the validity of the authorisation of Mr. Christian Störle, the representative present for the respondent. A difference in the names of the patent law firm which filed the sub-authorisation to Mr. Christian Störle compared to the patent law firm initially authorised by the respondent would render the validity of the sub-authorisation doubtful.

1.2 The Board notes that, with the authorisation dated 13 July 2017 filed with the letter dated 24 July 2017, the respondent appointed "Jeck and Fleck, Klingengasse 2/1, 71665 Vaihingen/Enz / DE" as its representative.

This authorisation included the possibility of giving a sub-authorisation. The Board takes the view that the indication of a law firm amounts to the appointment of all the professional representatives within this law firm under Rule 152(10)EPC. With the letter dated 23 November 2020, a sub-authorisation was given by Anton Jeck, Patentanwälte "Jeck, Fleck & Partner mbB, Klingengasse 2, D-71665 Vaihingen/Enz" to Mr. Christian Störle, professional representative, for the oral proceedings before the EPO on 28 September 2021. According to the footer of their respective letters filed in the present proceedings before the EPO, the tax identification numbers, namely tax numbers and VAT numbers, of the patent law firm having the name "Jeck and Fleck" and the one having the name "Jeck, Fleck & Partner mbB" are identical. The Board therefore concludes that both names refer to one and the same company. There is consequently no reason to doubt that the law firm initially authorised by the respondent is the same as the one mentioned in the sub-authorisation for Mr. Christian Störle. Accordingly, Mr Anton Jeck, as a professional representative belonging to this law firm, was entitled to file the sub-authorisation to Mr Christian Störle.

1.3 The Board therefore concludes that Mr. Christian Störle was validly authorised to represent the respondent at the oral proceedings before the Board.

2. Submissions by the patent proprietor

2.1 As announced with the letter dated 19 August 2021, the appellant requested the patent proprietor, Mr. Bernd-Michael Löffler, to be allowed to make submissions during the oral proceedings. The respondent objected to this request.

2.2 The Board notes that Mr. Bernd-Michael Löffler is the proprietor of the patent in suit, *i.e.* a party to the proceedings. He is therefore not to be treated as an accompanying person. The Board concludes that, as a direct party to the proceedings, Mr. Bernd-Michael Löffler is entitled to his own right to make oral submissions in support of his case (see Case Law of the Boards of Appeal, 9th Edition, III.V.5.2.3).

3. Admittance of D25

3.1 D25 was filed by the appellant during the oral proceedings before the Board on 28 September 2021. As the summons to oral proceedings before the Board were issued on 29 July 2020, *i.e.* after the entry into force of the revised Rules of Procedure of the Boards of Appeal (RPBA 2020, OJ EPO 2019, A63), the admittance of D25 is to be decided on the basis of Article 13(2) RPBA 2020 (Article 25(1) RPBA 2020). Pursuant to Article 13(2) RPBA 2020, D25 shall not be admitted unless there are exceptional circumstances which have been justified with cogent reasons by the appellant.

3.2 The appellant argued that he became aware of D25 only during the preparation of the oral proceedings. According to the appellant, D25 is a document published in 2010 which would provide further explanations regarding the disclosure of D2. D25 would correspond to the entire study whose abstract is presented in D2. There would be furthermore a reference to D25 in paragraph [0030] of the patent in suit.

3.3 The Board cannot identify in the reasoning of the appellant any exceptional reason justifying the late

filing of D25. According to the appellant, said document has been published more than 10 years before the oral proceedings before the Board. Furthermore, as the patent in suit contained a reference to the book containing the chapter filed as document D25 (see paragraph [0030] of the patent), the appellant must have been aware of the existence of the D25 since the filing of the patent in suit. In this context the Board further notes that the reference to the book containing the chapter filed as D25 in the patent in suit is a general reference and cannot be considered as an incorporation of said specific chapter in the patent in suit. Finally, the objections based on D2 have been raised already in the notice of opposition and the first instance decision. The appellant has not indicated any new or surprising aspect in relation thereto that would justify the filing of D25 at the present late stage.

3.4 Thus, the Board sees no exceptional circumstances let alone ones that have been reasoned that would justify the late filing of D25. Accordingly, D25 is not admitted into the appeal proceedings (Article 13 (2) RPBA 2020).

Main request - Patent as granted

4. Novelty with regard to D2

4.1 D2 relates to interval hypoxic training (IHT) wherein hypoxic phases and normoxic or hyperoxic phases are alternated (see third paragraph of D2) for use in the treatment of oxidative stress. The following main issues were discussed:

(i) whether D2 actually discloses an intermittent hypoxia/hyperoxia therapy or merely an interval hypoxia/normoxia therapy, and
(ii) whether D2 actually discloses the presently claimed medical use, in particular the treatment of mitochondrial disorders of a patient that has been identified as a person with a mitochondrial disorder or a coenzyme Q10 deficiency, with an intermittent hypoxia/hyperoxia therapy.

4.2 Disclosure of an intermittent hypoxia/hyperoxia therapy (point (i)).

4.2.1 The appellant argued that the term hyperoxic in D2 would have to be understood as a mere equivalent to normoxic (a normoxic gas being hyperoxic when compared to a hypoxic gas). Furthermore the appellant stated during oral proceedings that, according to his personal knowledge, the author of D2 had concentrated his researches on interval hypoxia/normoxia therapy, in particular by studying whales. According to the appellant D2 was thus limited to an interval hypoxia/ normoxia therapy.

4.2.2 The Board cannot follow this approach. The skilled person reporting the study of D2 would be aware of the commonly accepted meaning of each of the terms hypoxic, normoxic and hyperoxic and would not equate one to the other. It is further noted that, as argued by the respondent, the terminology used for the training (IHT versus IHHT) is, on the contrary, not uniformly used in the field. The Board does thus not share the opinion of the appellant that the acronym IHT would necessarily exclude the presence of hyperoxic phases. Finally, the considerations of the appellant relating to the field

of research of the author of D2 are not substantiated by verifiable facts.

4.2.3 Furthermore the appellant argued that the use of the term "intermittent" in granted claim 1 excludes any further steps such as gaps including normoxic episodes. This would constitute a further distinguishing feature over D2. Independently of the interpretation of the term "intermittent", the Board notes that, as underlined by the respondent, no gaps appear to be explicitly defined in D2 (see D2 third paragraph wherein hypoxic phases are interspersed with either normoxic or hyperoxic phases). Moreover the Board observes that D2 actually uses the same terminology as the patent in suit namely "Intermittent Hypoxic Therapy/Training" (see D2 second paragraph).

4.2.4 The Board concludes therefore that D2 generally discloses in one alternative an intermittent hypoxia/ hyperoxia therapy as defined in present claim 1.

4.3 Disclosure of the claimed medical use (point (ii))

4.3.1 According to the respondent and the opposition division, D2 relates to the treatment of patients with oxidative stress and discloses a therapeutic effect on mitochondrial therapy, *i.e.* on mitochondrial disorders, thus anticipating the medical use of the patent in suit.

4.3.2 The Board notes that a variety of cellular and systemic effects of the disclosed therapy are generally discussed in D2, including rejuvenation of mitochondria *via* mitoptosis but also, for example, decrease of reactive oxygen species generation or increased enzymatic antioxidative defense, which overlap at least

to some extent with the effects on oxidative stress described in the patent in suit (see paragraphs [0005]-[007]). It appears furthermore that mitoptosis has on a large scale a beneficial effect on mitochondrial activity as a whole (see D2, second paragraph).

The Board however observes that no detailed results are provided for the exemplified methods in D2. D2 merely states that the described training "gradually induces beneficial clinical effects" which are "clearly noticeable in patients, suffering from oxidative stress" (see paragraph 3). No details are provided as to which specific beneficial clinical effects were actually observed. It cannot therefore be concluded with certainty that the latter were directly linked to the cellular and systemic effects listed in paragraph 2, let alone whether all of them or only part thereof were indeed observed. The Board is therefore of the opinion that D2 does not unambiguously disclose the achievement of beneficial cellular and systemic effects linked to mitochondrial activity.

4.3.3 Moreover, D2 does not detail which alternative therapy(ies) provided the generally mentioned results. Hence, it cannot be unambiguously ascertained either that the mentioned beneficial results were indeed obtained with intermittent hypoxia/hyperoxia therapy.

4.3.4 In this context the respondent brought forward during oral proceedings that the disclosure in D2 of the theoretical possibility of treating patients with oxidative stress with an intermittent hypoxia/hyperoxia therapy would be sufficient to deny novelty over D2. The question of whether the method had in fact been carried out in D2 would not be relevant, as the medical use was reproducible. The Board cannot share this view.

It is established jurisprudence of the Boards of Appeal that, for a prior art citation to anticipate a therapeutic use, it has to disclose the actual existence of the claimed therapeutic use, *i.e.* the actual effectiveness of the therapy (see Case Law of the Boards of Appeal, 9th Edition, I.C.4.1., pages 113-114 of the English version). It follows that, in the present case, it cannot be decided that D2 is prejudicial to novelty on the basis of a theoretical possibility.

4.3.5 Finally, as argued by the respondent, D2 states that the study was performed on patients suffering from oxidative stress (see third paragraph) and oxidative stress is addressed in the patent in suit (see paragraph [0005]). During oral proceedings, the appellant has however explained that it is common general knowledge that oxidative stress is not limited to a mitochondrial disorder and may have other origins (it may for example be due to a dysfunction of cytosol located superoxide dismutases). It is consequently not possible to unambiguously conclude that the patients of D2 are persons with a mitochondrial disorder as required in present claim 1.

4.4 The Board thus concludes that D2 does not directly and unambiguously disclose an intermittent hypoxia/ hyperoxia therapy for use in the treatment of a mitochondrial disorder. Furthermore D2 is silent about coenzyme Q10 deficiencies. Accordingly the subject-matter of claim 1 of the main request is novel over D2.

5. Inventive step

5.1 Closest prior art and distinguishing feature

5.1.1 In agreement with both parties, the Board considers D2 to represent the closest prior art.

5.1.2 D2 pertains to intermittent hypoxia / (hyperoxia or normoxia) therapy for use in the treatment of oxidative stress. As detailed above (see point 4.3), D2 fails to unambiguously disclose the effective use of specifically intermittent hypoxia/hyperoxia therapy for the treatment of mitochondrial disorders. Furthermore, D2 is silent about coenzyme Q10 deficiencies. The parties did not dispute the nature of said distinguishing feature in the context of inventive step.

5.2 Objective technical problem

5.2.1 Starting from D2, the Board considers that the objective technical problem to be solved lies in the provision of an alternative therapeutic use of intermittent hypoxia/hyperoxia therapy.

5.2.2 The Board is satisfied that the experimental results provided in the patent in suit render credible the solving of said problem by treating mitochondrial disorders or coenzyme Q10 deficiencies. In particular, the difference in increase of mitochondrial activity between the control and the treatment group, objected to by the respondent during oral proceedings, appears to be significant even if moderate.

5.3 Obviousness of the solution

5.3.1 As stated in the discussion on novelty, the Board considers that an intermittent hypoxia / hyperoxia therapy is disclosed in D2 (see points 4.2.2 - 4.2.4) and that D2 generally describes a positive effect thereof on mitochondrial activity (see point 4.3.2 first paragraph). While an effective treatment of mitochondrial disorders with this specific therapy is not unambiguously disclosed in D2, it remains without any doubt that D2 suggests it. Hence, the Board is of the opinion that it would have appeared obvious to the skilled person willing to solve the problem posed to apply the therapies described in D2, including the intermittent hypoxia / hyperoxia therapy, to the treatment of mitochondrial disorders.

5.3.2 In relation with the arguments of the appellant in support of the inventiveness of the claimed subject-matter, the Board notes the following:

(a) Purposively treating mitochondrial disorders necessarily imply to perform the therapy on persons which have a mitochondrial disorders. It follows that the argument of the appellant, that D2 would not describe patients identified as persons with a mitochondrial disorder, is irrelevant in the present context of inventive step.

(b) The appellant argued that mitoptosis, which is the programmed death of a mitochondrion, would not constitute a treatment of a mitochondrial disorder (see statement setting out the grounds of appeal, page 19, second full paragraph). The Board does not share this opinion. As previously stated, it actually appears that mitoptosis has on a large

scale a beneficial effect on mitochondrial activity as a whole (see D2 second paragraph). As the expression "mitochondrial disorder" is not further defined in the patent in suit, it has to be interpreted in the broadest possible manner. It follows that the various effects on mitochondrial activity, including mitoptosis but not limited thereto, described in D2 are considered to address mitochondrial disorders.

(c) According to the appellant, D2 would be limited to intermittent hypoxia / normoxia therapy for use in the rejuvenation of mitochondria through mitoptosis. D2 would therefore not have provided any incentive to use intermittent hypoxia / hyperoxia therapy to increase coenzyme Q10 levels in patients and thus treat coenzyme Q10 deficiencies and mitochondrial disorders. The Board observes that claim 1 of the main request defines the treatment of mitochondrial disorder and of coenzyme Q10 deficiencies as alternative treatments. For the reasons detailed above (see point 5.3.1), the treatment of mitochondrial disorders is considered obvious in view of D2. The fact that one alternative of the claim lacks an inventive step is enough to deny inventiveness.

5.4 The Board therefore concludes that the ground of opposition under Article 100(a) EPC in combination with Article 56 EPC prejudices the maintenance of the patent in suit.

Auxiliary requests

6. Admittance

6.1 Auxiliary requests I-IV were filed with the statement setting out the grounds of appeal on 23 March 2017 in reaction to the decision of the opposition decision considering the main request not novel. Their admittance must be decided on the basis of Article 12(4) RPBA 2007 (Article 25(2) RPBA 2020).

6.2 The Board preliminarily observes that, as argued by the respondent, novelty over D2 has been contested since the notice of opposition. However, the annex to the summons to oral proceedings in opposition did not provide any detailed preliminary opinion regarding novelty of the main request and mentioned as main issue the disclosure of the group of patients as claimed in the patent in suit. This issue does not correspond to the reasons provided in the decision of the opposition division regarding the lack of novelty over D2. The Board therefore considers that there were no compelling reasons for the appellant to file auxiliary requests I-IV already in the first instance proceedings. Furthermore, the features of the present auxiliary requests incorporated from the description (see auxiliary requests I and III-IV) do not amount to a new case but rather further concentrate on preferred embodiments of the patent in suit. Said requests thus represent a legitimate and direct response to the first-instance decision. Finally the Board observes that the *prima facie* relevance, which the respondent objected to, is not a requirement for admittance of amendments mentioned in Article 12(4) RPBA 2007.

6.3 Accordingly, auxiliary requests I-IV are admitted into the appeal proceedings.

7. Remittal

7.1 The respondent requested that the case be remitted to the first instance for further examination of the auxiliary requests, to safeguard the possibility of evaluation of these requests by two instances.

7.2 Article 11 RPBA 2020 which applies in the present case according to Article 25(1) RPBA 2020 provides that the Board shall not remit a case to the department whose decision was appealed for further prosecution, unless special reasons present themselves for doing so.

7.3 In the present case the auxiliary requests have been filed with the aim to overcome the finding of lack of novelty of the opposition division. The novelty issue, in particular with regard to the closest prior art D2, has been extensively discussed in opposition proceedings. Moreover, as stated above (see point 7.2), the features of the present auxiliary requests incorporated from the description do not amount to a new case. The Board therefore considers that special reasons according to Article 11 RPBA 2020 are not apparent in the present case.

7.4 The request of the respondent to remit the case to the opposition division for further prosecution is rejected.

8. Inventive step

8.1 Auxiliary request I

The Board considers that the reasoning developed concerning the main request (see point 5.) applies *mutatis mutandis* to the subject-matter of auxiliary request I, because the feature introduced in said request, namely "wherein cycles of inhalation of hypoxygenic and hyperoxygenic gases follow each other", does not further distinguish the claimed subject-matter from the one of D2. As stated in the context of novelty (see point 4.2.3), the Board indeed considers that D2 does not disclose any gaps either. During oral proceedings the appellant acknowledged that auxiliary request I would not be appropriate to overcome the objection of lack of inventive step raised for the main request.

8.2 Auxiliary requests II-III

8.2.1 Auxiliary requests II-III differ from the main request in that it was specified that the plasma level of Q10 in the patient is elevated (Auxiliary request II) up to a given level (Auxiliary request III).

8.2.2 The appellant's explanations in writing (see statement setting out the grounds of appeal, page 19, third full paragraph and page 20, fifth paragraph) and at the oral proceedings indicate that the claimed medical use, independently of whether it pertains to the treatment of mitochondrial disorders or coenzyme Q10 deficiencies, is based on said elevation of coenzyme Q10 levels following intermittent hypoxia / hyperoxia therapy. This means that the elevation of coenzyme Q10 levels is to be understood as the mechanism of action

through which the therapy is achieved. There is however no evidence that this particular mechanism would provide for a different therapeutic application, *i.e.* the treatment of mitochondrial disorders distinct from those of D2. The appellant has merely stated during oral proceedings that mitochondria have many different effects than those in relation with coenzyme Q10. This does however not constitute an evidence that the presently claimed therapeutic application would be distinct from the one suggested in D2. D2 does indeed suggest to apply the exact same therapy (intermittent hypoxia / hyperoxia therapy) for the treatment of the same disease (mitochondrial disorder) as presently claimed. The elevation of coenzyme Q10 levels as defined in claim 1 of auxiliary request II is therefore considered a mechanism inherent to the use of the intermittent hypoxia / hyperoxia therapy even if this mechanism was not known or explained in the prior art. The mere explanation of this mechanism does not result in a different therapeutic application of the intermittent hypoxia / hyperoxia therapy.

8.2.3 The Board considers that, in view of the wording used for the amendment (*i.e.* "up to the therapeutic range of 2.5 mg/l", emphasis added), the value introduced in auxiliary request III is to be understood as an upper-limit, so that auxiliary request III does not exclude lower values. The appellant made the same interpretation during its submission at oral proceedings. The same reasoning as in auxiliary request II therefore applies to auxiliary request III.

8.2.4 The features introduced in auxiliary requests II and III cannot thus involve an inventive step as they do not result in a distinct therapeutic application. The

reasoning developed for the main request applies consequently *mutatis mutandis* to the present requests.

8.3 Auxiliary request IV

Auxiliary request IV corresponds to auxiliary request III wherein the feature "using cycles of inhalation of hypoxygenic and hyperoxygenic gases" has been introduced. This feature does not further distinguish the subject-matter of claim 1 of auxiliary request III from the one of D2, as such cycles are already disclosed in D2 (see third paragraph). The reasoning provided for auxiliary request III (see point 8.2) therefore applies *mutatis mutandis* to the auxiliary request IV.

8.4 Accordingly, auxiliary requests I-IV do not fulfill the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated