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Datasheet for the decision of 4 February 2014

Case Number: T 1805/09 - 3.3.02

Application Number: 02023126.2

Publication Number: 1310249

IPC: A61K31/232, A61K31/202, A61P9/00, A61P9/04, A61P9/10

Language of the proceedings: EN

Title of invention:
Use of polyunsatured fatty acids for the primary prevention of major cardiovascular events

Patent Proprietor:
PRO APARTS - INVESTIMENTOS E CONSULTORIA LDA

Opponents:
MOCHIDA PHARMACEUTICAL CO. LTD.
IBSA INSTITUT BIOCHIMIQUE S.A.

Headword:
Polyunsaturated fatty acids/PRO APARTS

Relevant legal provisions:
EPC Art. 114(2), 54, 56, 123(2)
RPBA Art. 12(2), 13, 12(4)

Keyword:
Late-filed evidence - admitted (no): not more relevant than documents already on file
Novelty and inventive step - second (or further) medical use
Late-filed request
Amendments - added subject-matter (yes)

Decisions cited:
T 1955/09, T 0836/01, T 1642/06

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern
Boards of Appeal
Chambres de recours

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 1805/09 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 4 February 2014

Appellant: (Patent Proprietor)	PRO APARTS - INVESTIMENTOS E CONSULTORIA LDA Avenida do Infante, 50 9004-521, Funchal Madeira (PT)
Representative:	Bounaga, Sakina De Clercq & Partners cvba Edgard Gevaertdreef 10a 9830 Sint-Martens-Latem (BE)
Respondent: (Opponent 1)	MOCHIDA PHARMACEUTICAL CO. LTD. 7, Yotsuya 1-chome Shinjuku-ku TOKYO 160 (JP)
Representative:	Grünecker, Kinkeldey, Stockmair & Schwanhäusser Leopoldstrasse 4 80802 München (DE)

Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 3 July 2009 revoking European patent No. 1310249 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman:	H. Kellner
Members:	T. Sommerfeld
	R. Cramer

Summary of Facts and Submissions

I. European patent EP 1310249, based on application No. 02023126.2, was granted with nine claims.

Claim 1 as granted reads as follows:

"1. Use of polyunsaturated fatty acids of the ω-3 series, for the preparation of a drug, to be administered orally, in the primary prevention of death from a cardiological cause in subjects affected by cardiac decompensation, who have not undergone previous infarct episodes, wherein the fatty acids comprise eicosapentaenoic acid (EPA) and/or docosahexaenoic acid (DHA) and/or at least one C_1-C_3 alkyl ester thereof, in a content between 75 and 95% by weight on the total fatty acid weight."

II. Two oppositions were filed, both opponents requesting revocation of the patent in its entirety on the grounds of lack of novelty and inventive step (Articles 54(2) and 56 EPC and Article 100(a) EPC); additionally, opponent 2 requested revocation on the grounds of lack of industrial applicability (Article 52(1) and (4) EPC 1973 and Article 100(a) EPC) and lack of sufficiency of disclosure (Article 100(b) EPC).

III. The documents cited during the proceedings before the opposition division and the board of appeal include the following:

D12 McCarty, Medical Hypotheses 46, pp.400-406, 1996
D44 Butterworths Medical Dictionary (excerpt), 1978, pp.469, 785-786
D49 Declaration of F. McCarty, dated 02.11.2009
D50 Declaration of M. Gheorghiade, dated 01.11.2009

D51 Declaration of T. Bruzzese, dated 27.10.2009
D52 Declaration of M. Filippo, dated 16.11.2009
D53 Declaration of P. Silvestri, dated 17.11.2009
D54 Declaration of T. Francesco, dated 19.11.2009

IV. By decision pronounced at oral proceedings on 9 June 2009 and posted on 3 July 2009, the opposition division revoked the patent under Article 101(3)(b)EPC.

The opposition division decided that the claim sets according to the main request (claims as granted) and to the first auxiliary request lacked inventive step, and that the claim set according to the second auxiliary request added subject-matter contrary to Article 123(2) EPC. The subject-matter of the main request was considered to fulfil the requirements of Article 83, Article 52(4) EPC 1973 (at the time of the decision Article 53(c) EPC) and Article 54(2)(3) EPC.

V. The patent proprietor (hereinafter appellant) lodged an appeal against that decision. With the statement of the grounds of appeal, the appellant requested that the patent be maintained as granted (main request) or alternatively according to the first or second auxiliary requests, both filed with the grounds of appeal. New documents were submitted.

VI. Opponent 1 (hereinafter respondent) did not submit any direct reply to the grounds of appeal.

VII. Opponent 2 did not submit any substantive reply either, but instead, with letter dated 29 October 2010, withdrew its opposition.

VIII. Summons for oral proceedings before the board were issued on 7 August 2013, scheduling oral proceedings for 4 February 2014.

IX. With letter dated 4 December 2013, the appellant submitted "new" auxiliary requests 1 to 6, adding new auxiliary requests 1 to 4 and renumbering the auxiliary requests on file as auxiliary requests 5 and 6. New documents D49a (a corrected version of D49), D52, D53 and D54 were also submitted.

The **main request** consists of the claims as granted.

In **auxiliary request 1** the feature "wherein the drug is to be administered at a dose of 0.1-3.0 g per day" of claim 7 of the main request was incorporated into claim 1.

In **auxiliary request 2** the feature "wherein the drug is to be administered at a dose of 0.3-2.0 g per day" of claim 8 of the main request was incorporated into claim 1.

In **auxiliary request 3** the feature "wherein the drug is to be administered at a dose of 1 g per day", corresponding to claim 9 of the main request, was incorporated into claim 1.

In **auxiliary request 4**, claim 1 was amended in relation to the main request by addition of the word "sudden" before "death": "(...) in the primary prevention of sudden death from a cardiological cause (...)".

Auxiliary request 5 is the renumbered first auxiliary request filed with the statement of the grounds of appeal. Claim 1 of this request differs from claim 1 of

the main request by addition of the feature "characterized by the reduction in the contractile capacity of the myocardium and of the ejection fraction":

"... in subjects affected by cardiac decompensation characterized by the reduction in the contractile capacity of the myocardium and of the ejection fraction, ..."

Auxiliary request 6 is the renumbered second auxiliary request filed with the statement of the grounds of appeal. Claim 1 of this request differs from claim 1 of auxiliary request 5 by the replacement of the term "death" by "sudden death", thus incorporating the features of claim 2 of auxiliary request 5 into claim 1:

"... in the primary prevention of sudden death from a cardiological cause in subjects affected by cardiac decompensation ..."

X. With letter dated 2 January 2014 - the respondent's first submission during the appeal proceedings -, the respondent requested that the appeal be dismissed and that the patent be revoked in full. It further requested that new auxiliary requests 1 to 6 and new documents D49a, D52, D53 and D54 not be admitted into the proceedings as late-filed.

XI. The appellant replied with letter dated 27 January 2014.

XII. Oral proceedings before the board took place on 4 February 2014. At the end of the oral proceedings, the decision of the board was announced.

XIII. The appellant's submissions, in so far as relevant for the present decision, may be summarised as follows:

Admissibility of documents D52, D53 and D54

D52, D53 and D54 were declarations of cardiologists, submitted in due time two months before oral proceedings, to supplement declarations D49/D49a and D50, in order to further strengthen the arguments in respect of the difference between cardiac decompensation (or heart failure) and congestive heart failure. Since they were short and similar to declarations already on file, they did not add to the complexity of the case.

Admissibility of auxiliary requests 1 to 4

The amendments to claim 1 did not change the subject of the proceedings since they consisted in the incorporation of subject-matter of granted dependent claims which had already been discussed before the department of first instance. These amendments, which served to answer to objections under novelty, did not add to the complexity of the case and had been filed in due time two months before oral proceedings.
The basis for the feature introduced to form claim 1 of auxiliary request 4 could be found on page 3, lines 10 to 14, and page 5, lines 30 to 32, of the application as originally filed, wherein the feature was inherently present.

Admissibility of auxiliary requests 5 and 6

Auxiliary requests 5 and 6, although introducing amendments derived from the description, were similar

to requests that were already on file before the department of first instance. At oral proceedings before the opposition division, the patentee was not in a position to propose further amendments but submitted them in due time with the grounds of appeal, as a reaction to the decision. The opponent did not react to the grounds of appeal, and did not raise an objection against the filing of these requests until one month before oral proceedings.

Main request - Novelty

Document D12 disclosed patients with congestive heart failure without specifying their previous clinical background; in particular it did not disclose the subgroup of patients not having previously suffered myocardial infarction. This subgroup effectively constituted a new subgroup of patients and thus represented a new clinical situation.

Congestive heart failure was not encompassed by the term "heart failure", as apparent from declarations D49/D49a and D50. The term "heart failure" referred to non-congestive heart failure and this was the scope of the term "cardiac decompensation" as claimed. Heart failure should not be considered as overlapping with congestive heart failure, as the latter was only one of the multitude of different conditions which could originate from the former. As such, D12 which referred to congestive heart failure deviated from claim 1.

There was also no disclosure in D12 of prevention of death, but only a description of hypothetical roles for fatty acids. Distinction had to be made between direct and indirect effects (T 1955/09, T 836/01, T 1642/06, wherein an effect upstream or downstream of the claimed

effect was not considered anticipatory). It was not claimed that heart failure or myocardial infarctions or arrhythmia were prevented or treated as in the prior art. Instead it was claimed that death from a cardiological cause (but not necessarily myocardial infarction or arrythmia or heart failure) was prevented, which was a new clinical situation/subgroup of patients: specifically those subjects which otherwise would have died were singled out, in contrast to document D12 which indiscriminately related to the prevention/treatment of conditions which may or may not result in death.

Moreover, document D12 did not disclose the composition of fatty acids EPA and DHA and their content percentage.

Main request - Inventive step

The closest prior art should be directed to the same use, but such a document was not on file. D12 was not directed to the same technical problem as the patent, as it related exclusively to congestive heart failure and did not refer at all to heart failure. D12 was focused on decreasing the risk of arrhythmia and myocardial infarction in patients affected by congestive heart failure, while the technical problem underlying the patent was the prevention of death. Experimental report D51 showed that, conversely to the teachings of document D12, there was no benefit in treating congestive heart failure with an omega-3 composition in terms of reduction of number of deaths or mortality; the skilled person would not consider document D12 as providing a hint for treating heart failure with an omega-3 composition, in view of the known differences between heart failure and congestive

heart failure, and even if he had followed the suggestion he would have found the "fish oil" to have no effectiveness towards congestive heart failure: document D12 would thus have taught away from the invention. Moreover D12 did not disclose use of EPA and/or DHA, but only generally referred to fish oils. The inventors surprisingly found that the composition provided prevention of death in patients with cardiac decompensation and no history of infarct.
The experiments of the patent were performed with animals for ethical and time constraint reasons. However, expert-conducted clinical trials, of which the results were unfortunately not on file, confirmed that the problem was solved.
Moreover the data of experimental report D51 supported that the claimed compositions were capable of reducing mortality in subjects affected by heart failure as opposed to congestive heart failure, and that subjects not affected by previous myocardial infarction had an increased survival rate upon administration of the claimed compositions compared to subjects previously affected by myocardial infarction. The differences between the claimed subject-matter and the prior art (document D12) were thus linked to a technical effect and not arbitrarily chosen, in particular the intended uses and the specified patient population.

Auxiliary requests 1 to 3 - Inventive step

Document D12, if anything, taught a daily dose of fish oils ranging from 3 to 6 g, which did not correspond but even taught away from the claimed daily dose of auxiliary requests 1 to 3.
These doses were those of the most effective drug, but unfortunately evidence therefor was not on file. This was not an arbitrary choice but instead the dose which

had been used. A formulation corresponding to this dose was shown in Example 2 of the patent.

Auxiliary requests 5 and 6 - Added matter

The amendments to claim 1 found a basis in Test 5 (page 7, lines 51-52, of the patent in suit). There was no dependency between the results of this experiment and the other parameters mentioned in Test 5, and therefore the further features of the test (dose, the way that the cardiac decompensation was achieved) did not need to be incorporated.

XIV. The respondent's arguments, in so far as relevant for the present decision, may be summarised as follows:

Admissibility of late-filed documents D52, D53 and D54

Documents D52, D53 and D54 should not be admitted into the proceedings, as they were late-filed and not more relevant than other documents on file.

Admissibility of auxiliary requests 1 to 4

Auxiliary requests 1 to 4 should not be admitted into the proceedings, as they were late-filed and would require discussion of new subject-matter.
In relation to auxiliary request 4, no basis could prima facie be found for the new combination of features.

Admissibility of auxiliary requests 5 and 6

Auxiliary requests 5 and 6 contained subject-matter taken from the description, which had only been introduced at appeal proceedings despite the fact that

there had been plenty of opportunity for the patentee to introduce these claims at first instance.

Main request - Novelty

Document D12 disclosed the use of fish oil in the treatment of congestive heart failure, which was a specific form of heart failure. Document D44 showed that the terms were used interchangeably in the prior art, and it was clear from all documents on file that congestive heart failure was a form of heart failure. Absence of previous myocardial infarction was not disclosed, but since D12 referred to decrease of risk for myocardial infarction (conclusion on page 403, line 11), it was most likely that the target population had not suffered myocardial infarction.

A content of 75 to 95 wt% of omega-3 fatty acids could not render the subject-matter of claim 1 novel over document D12 since it was not shown in the patent that this range was critical and thus it did not fulfil the criteria for purposive selection. In claim 1 of the requests it was also not clear what the meaning of this percentage was, since the composition might contain other ingredients.

Intake of ω-3-rich fish oil was recommended in document D12 to decrease the risk of arrythmia and myocardial infarction, which were cardiological causes for death. The prevention of death could not be the therapeutical indication, since death was not a disease: therapy was thus directed at prevention of major cardiac incident (including heart failure).

Thus the subject-matter of the main request was not new in view of document D12.

Main request - Inventive step

The only examples in the patent relating to the claimed subject-matter were Test 1 and Test 5. However, none of these tests referred to subjects affected by cardiac decompensation, since healthy subjects were first treated with an EPA+DHA composition and only subsequently administered a cardiotoxic agent (Test 1) or submitted to ligature of the circumflex coronary artery (Test 5). Thus, the experimental data of the patent did not support the granted claims.

Auxiliary requests 1 to 3 - Inventive step

In auxiliary requests 1 to 3, the omega-3 fatty acid content was defined in relation to the total amount of fatty acids, and there was no link between this content and the dose of drug: thus, the doses were not comparable to those of prior-art documents that referred to absolute amounts of omega-3 fatty acids.

Auxiliary requests 5 and 6 - Added subject-matter

Adding the feature "characterized by the reduction in contractile capacity of the myocardium and of the ejection fraction" in the context of claim 1 contravened Article 123(2) EPC, because it was disclosed in the application as filed in the specific context of Test 5, which did not even support the subject-matter of claim 1 of the main request.

XV. The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request (claims as granted), or alternatively on the basis of one of

the auxiliary requests 1 to 6 filed with the letter of 4 December 2013.

XVI. The respondent (opponent) requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. Admissibility of late-filed documents D52, D53 and D54

Documents D52, D53 and D54 are late-filed. They do not add any further information to what is on file. Moreover, they do not represent what was the knowledge of the skilled person at the priority date of the application, since they were written much later and provide no link to the knowledge before the priority date. Therefore the board does not admit documents D52, D53 and D54 into the proceedings (Article 114(2) EPC).

3. Main request

3.1 Novelty

3.1.1 Claim 1 is in the form of a second medical use claim as allowed by the Enlarged Board of Appeal in decision G 5/83 (OJ EPO 1985, 64), i.e. in the form of the use of a substance or composition for the manufacture of a medicament for a defined therapeutic application. This claim form is also allowable when taking into consideration the findings of the Enlarged Board in its decision G 2/08 (OJ EPO 2010, 456; reasons 7.1.4 and Order, last paragraph).

3.1.2 The therapeutic application is defined in claim 1 as "the primary prevention of death from a cardiological cause" in "subjects affected by cardiac decompensation, who have not undergone previous infarct episodes".

3.1.3 The expression "primary prevention" is further defined in paragraph [0010] of the published patent specification as being "prevention in subjects who, while affected by various pathologies of the cardiocirculatory and/or cardiorespiratory systems, have not yet suffered an infarct episode", in contrast to "secondary prevention", which is also defined in the same paragraph of the application as being "aimed at protecting a subject who has already suffered an infarct".

3.1.4 The patent provides however no definition for "prevention of death from a cardiological cause". In the absence of a specific definition in the patent, this term is to be regarded as having the general meaning that a skilled person would have given it at the priority date. In fact, any measure directed to preventing the occurrence of cardiac events which are known to be associated with a high mortality risk (such as myocardial infarction and arrythmia) is to be considered as a measure to prevent death from a cardiological cause. In the context of the claimed subject-matter, which is directed to patients with cardiac decompensation, this also includes any measure aimed at treating this underlying condition. Thus the presently claimed aim of the treatment is not such as to distinguish it from any treatment directed to cardiac decompensation.

3.1.5 As regards "cardiac decompensation", there is also no specific definition in the published patent specification. Document D44, an extract from a medical dictionary in an edition which is part of the prior art, provides the following definition (D44, page 469, left column, entry under "decompensation"): "**Cardiac decompensation.** Heart failure; inability of the heart to fulfil the demands made upon it. In clinical practice, the term is often used to describe congestive cardiac failure." Thus, according to document D44, the term "cardiac decompensation" means heart failure and is also used to describe congestive cardiac failure. None of the many documents submitted by the appellant in this respect is convincing evidence that the designation "cardiac decompensation" does not include congestive heart failure: most of these documents discuss differences between non-congestive heart failure and congestive heart failure but do not define "cardiac decompensation" at all; the same is true for the further entry in the dictionary extract D44 on page 785, right column, last two lines, to page 786, left column, line 16. Moreover, some of these documents are dated much later than the priority date of the patent application and provide no support for how the term was understood at the relevant date. The board thus adopts the definition given by document D44 *supra* for the term "cardiac decompensation" throughout the present decision, and thus considers that this term encompasses any form of heart failure, be it congestive or not.

3.1.6 Notwithstanding the above considerations, the board finds that the claimed subject-matter is novel over document D12.

While D12 discloses the treatment of patients with congestive heart failure (which is encompassed in the term "cardiac decompensation", see above), it is silent

in relation to the patients' past cardiological history: a group of patients with cardiac decompensation who have not suffered myocardial infarction is thus not explicitly disclosed in D12.

Additionally, a further distinction is that the particular percentage range of the content of omega-3 fatty acids as claimed is not disclosed.

3.1.7 None of the other documents on file discloses the full set of features of claim 1 of the main request either. The present claims are thus novel over the prior art (Article 54(2) and (3) EPC).

3.2 Inventive step

3.2.1 The closest prior art is document D12, which discloses the therapeutical use of omega-3 fatty acids in the context of treating patients with congestive heart failure. D12 further teaches that the administration of the omega-3 fatty acids decreases the risk of arrhythmia and of myocardial infarction (D12, page 403, right column, last paragraph), which are both well-known cardiological causes of death (*supra*).

3.2.2 As set out above, document D12 differs from the claimed subject-matter in that there is no explicit disclosure of the subgroup of patients that have not undergone myocardial infarction and in that a particular percentage range of the content of omega-3 fatty acids as claimed is not disclosed.

3.2.3 There is no evidence in the patent or elsewhere on file supporting any improvement linked to the differences to the closest prior art (see section 3.2.5 of this decision). Thus the technical problem is formulated as

the provision of a further formulation of polyunsaturated fatty acids of the omega-3 series, enriched to a content of >50% omega-3, for the preparation of a drug for use in the prevention of death from a cardiological cause in patients with cardiac decompensation.

3.2.4 The proposed solution is the subject-matter according to claim 1 of the patent in suit, involving the use of omega-3 fatty acids which comprise *inter alia* eicosapentanoic acid (EPA) and/or docosahexaenoic acid (DHA) in a content between 75 and 95% by weight of the total fatty acid weight for the preparation of a drug to be administered to patients with cardiac decompensation who have not undergone myocardial infarction. The board is satisfied that the technical problem as formulated above is plausibly solved.

3.2.5 Neither the examples of the patent (Tests 1 to 5) nor the experiments set out in document D51 represent the claimed subject-matter, as they do not make use of models of cardiac decompensation at all: instead the animals which are treated with the omega-3 fatty acid compositions are healthy at the onset of the treatment. There is also no data in the application or elsewhere on file providing evidence that a particular effect is linked to the claimed content of 75 to 95%, as all examples in the application, as well as in the post-published experimental report D51, use contents within this range and there are no comparative examples with other contents according to the closest prior art (>50% omega-3). Therefore, the results of the experiments on file do not demonstrate that patients with cardiac decompensation and not having undergone previous infarct episodes can be treated as well as or better than those with such episodes, nor do they show any

difference concerning a treatment with a drug containing 75 to 95% omega-3 compared to one containing >50% and not 75 to 95%.

3.2.6 Consequently, in the absence of any specific effect linked to the differences over the closest prior art, these features cannot **per se** justify an inventive step. The board thus concludes that the subject-matter of claim 1 lacks inventive step, and thus the main request does not fulfil the requirements of Article 56 EPC.

3.3 The appellant's further arguments as regards novelty and inventive step cannot succeed:

3.3.1 The appellant argued that a further difference to the prior art, and in particular to document D12, was that none of the prior-art documents disclosed prevention of death from a cardiovascular cause but instead only treatment of the cardiological disease. In this context, the appellant referred to decisions T 1955/09 of 12 June 2013, T 836/01 of 7 October 2003 and T 1642/06 of 23 August 2007, as evidence that a distinction has to be made between direct and indirect effects and that known effects which are upstream or downstream of the claimed effect should not be considered anticipatory.

3.3.2 In decision T 1955/09, "the use of [the same] peptidic compounds for the purpose of inhibiting or neutralizing toxins produced by bacteria or fungi" was considered as a direct effect on the produced toxins and different to the technical effect relied on by the claimed invention, which was "the indirect influence of the peptidic compounds on the production of the toxins via their antibiotic action against the toxin producing bacteria or fungi" (reasons 9). In T 836/01, the board

also observed that, while both the claimed subject-matter and the prior art disclosed the use of the same composition for the treatment of the same disease, the claimed invention relied on a novel effect of the composition, namely a direct effect on tumor cell growth and terminal differentiation, while the prior art relied on an indirect effect on activation of the immune system of the patient (reasons 5 to 8). As regards T 1642/06, again it was noted that, although the same composition was used to treat the same disease in both the application and the prior art, the prior art relied on a direct effect on cancer cells (induction of apoptosis), while the claimed subject-matter relied on an indirect effect, namely the inhibition of neovascularization of the tumors (reasons 2.1.1).

3.3.3 The board however notes that the present patent does not disclose any new mechanism of action nor any other effect associated with the use of the same composition in the same disease. On the contrary, the patent refers very generally to the prevention of death by a cardiological cause, and no underlying effect is disclosed at all. All the above decisions make clear that, in order for an effect to be considered novel, it has to identify a new clinical situation and translate into a new industrial/commercial application (T 836/01, reasons 8; T 1642/06, reasons 2.1.1; T 1955/09, reasons 10). The patent has not shown how to prevent death from a cardiological cause independently of treating the underlying cardiological disease, and as such no new effect can be identified.

4. Auxiliary requests 1, 2 and 3

4.1 Admissibility

4.1.1 All these requests were filed after oral proceedings had been arranged, and thus their admission is governed by the principles of Article 114(2) EPC in conjunction with Article 13 RPBA, which states that it is at the board's discretion to admit any amendment to a party's case after it has filed its grounds of appeal or reply thereto.

4.1.2 These requests differ from the granted claims merely in that features from dependent claims have been incorporated into claim 1. The amendments were made in order to further distinguish the claimed subject-matter from the prior art, with the aim of overcoming novelty objections.

4.1.3 Moreover, the respondent's request not to admit auxiliary requests 1 to 3 was filed one month before the oral proceedings, with its first submission during the whole appeal proceedings. According to Article 12(2) RPBA, the reply to the statement of grounds of appeal shall contain the respondent's complete case; thus the respondent's request was in itself late-filed and its admission into the proceedings was at the board's discretion (Article 12(4) RPBA).

4.1.4 The board considers these claim sets as an attempt to provide a reply to the possible objections of the respondent, that might only have been brought forward during the oral proceedings, and to file respective requests "in due time".

4.1.5 In view of these circumstances of the case, the board admits auxiliary requests 1 to 3 into the proceedings (Article 13 RPBA).

4.2 Novelty and inventive step

4.2.1 For the same reasons as given above in relation to the main request, the claimed subject-matter of auxiliary requests 1, 2 and 3 is not anticipated by any of the prior-art documents on file.
The board thus concludes that the claims of auxiliary requests 1, 2 and 3 fulfil the requirements of Article 54(2)(3) EPC.

4.2.2 Claim 1 of each of these requests has been restricted in relation to claim 1 of the main request by indication of the dose of the drug to be administered. The board notes however that this further restriction does not have any impact on the board's arguments above relating to inventive step, as there is no particular effect linked to the specific doses. Neither the examples of the patent nor those of document D51 support the existence of such an effect, as they are not representative of the claimed subject-matter (*supra*).
The board thus concludes that the claims of auxiliary requests 1, 2 and 3 do not fulfil the requirements of Article 56 EPC.

5. Auxiliary request 4 - Admissibility

5.1 Auxiliary request 4 was filed at the same time as auxiliary requests 1 to 3, i.e. after oral proceedings had been arranged. Its admission is thus also governed by the principles laid down in Article 13 RPBA.

5.2 Auxiliary request 4 introduces an amendment into claim 1 which is not *prima facie* allowable under Article 123(2) EPC. Although the feature "sudden death" was incorporated from dependent claim 2 as granted, new

claim 1 is now directed to an aim which is not readily apparent in the application as filed: "prevention of sudden death from a cardiological cause" is not explicitly disclosed in the application, since original claims 4 and 5, as well as page 4, lines 4 to 13, and page 5, lines 25 to 32, of the originally filed application presented "death from a cardiological cause" and "sudden death" as two distinct alternatives. Thereby it is apparent that new complex considerations would arise if auxiliary request 4 were to be admitted into the appeal proceedings.

5.3 The board thus makes use of its discretionary power under Article 13 RPBA and decides not to admit auxiliary request 4 into the proceedings.

6. Auxiliary requests 5 and 6

6.1 Admissibility

6.1.1 These requests are identical to the first and second auxiliary requests filed with the statement of the grounds of appeal. The amendments therein are directed at overcoming the objections raised in the appealed decision. It is moreover noted that the respondent did not reply to the statement of the grounds of appeal and objected to the admissibility of these requests only one month before oral proceedings.

6.1.2 The board thus decides to admit auxiliary requests 5 and 6 into the proceedings (Article 12(4) RPBA).

6.2 Added subject-matter

6.2.1 The wording characterising the feature added to form claim 1 of both requests - a feature which further

defines cardiac decompensation - is to be found in Test 5, paragraph [0045] of the published patent application (page 10, lines 8 to 10, of the originally filed application).

6.2.2 However this passage cannot constitute an adequate basis for the introduction of said feature within the context of claim 1, since this feature is disclosed in the specific context of one example, which, as discussed above (section 3.2.5), is not even representative of the claimed subject-matter.

6.2.3 The board thus concludes that claim 1 of both auxiliary requests 5 and 6 contravenes the requirements of Article 123(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

N. Maslin H. Kellner

Decision electronically authenticated