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Datasheet for the decision of 16 April 2015

Case Number: T 0523/11 - 3.3.02

Application Number: 01924998.6

Publication Number: 1272204

IPC: A61K35/34, A61P43/00

Language of the proceedings: EN

Title of invention:
SOFT TISSUE AND BONE AUGMENTATION AND BULKING UTILIZING MUSCLE-DERIVED PROGENITOR CELLS, COMPOSITIONS AND TREATMENTS THEREOF

Patent Proprietor:
UNIVERSITY OF PITTSBURGH

Opponent:
DE CLERCQ, BRANTS & PARTNERS

Headword:
Muscle-derived progenitor cells for treatment/UNIVERSITY OF PITTSBURGH

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

Keyword:
Amendments - added subject-matter (yes)
Second auxiliary request not admitted -
not examined by the opposition division
Fourth auxiliary request not admitted -
submitted during oral proceedings and creating complexity

Decisions cited:
G 0009/91

Catchword:

Europäisches Patentamt
European Patent Office
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Case Number: T 0523/11 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 16 April 2015

Appellant: (Patent Proprietor)	UNIVERSITY OF PITTSBURGH 200 Gardner Steel Conference Center Pittsburgh, PA 15260 (US)
Representative:	Cowley, Catherine Mary Venner Shipley LLP 200 Aldersgate London EC1A 4HD (GB)
Appellant: (Opponent)	DE CLERCQ, BRANTS & PARTNERS E. Gevaertdreef 10a 9830 Sint-Martens-Latem (BE)
Representative:	Dehmel, Albrecht Dehmel & Bettenhausen Patentanwälte Herzogspitalstrasse 11 80331 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 29 December 2010 concerning maintenance of the European Patent No. 1272204 in amended form.**

Composition of the Board:

Chairman	U. Oswald
Members:	T. Sommerfeld
	L. Bühler

Summary of Facts and Submissions

I. European patent No. 1272204, based on European patent application No. 01924998.6, which was filed as an international patent application published as WO 2001/078754, was granted with 22 claims.

II. An opposition was filed against the granted patent, the opponent requesting revocation of the patent in its entirety on the grounds of lack of novelty and inventive step (Articles 52, 54 and 56 EPC and Article 100(a) EPC), lack of sufficiency of disclosure (Article 100(b) EPC) and added subject-matter (Article 100(c) EPC).

III. By an interlocutory decision pronounced at oral proceedings on 26 October 2010 and posted on 29 December 2010, the opposition division decided that the patent be maintained in amended form on the basis of the second auxiliary request, filed during oral proceedings as "twice amended" second auxiliary request (Articles 101(3)(a) and 106(2) EPC). As regards the main request and the first auxiliary request, the opposition division considered that these claims contravened the requirements of Article 123(2) EPC.

IV. Both the patent proprietor and the opponent lodged an appeal against that decision.

V. With the statement of grounds of appeal, the appellant-proprietor requested that the patent be maintained on the basis of the main request or, alternatively, of the first or second auxiliary requests, both filed with the statement of grounds of appeal, or alternatively according to the "twice amended" second auxiliary request as maintained by the opposition division.

VI. With the statement of grounds of appeal, the appellant-opponent requested that the decision be set aside and the patent be revoked in its entirety.

VII. Both appellants submitted replies to each other's statement of grounds of appeal. With its reply, the appellant-proprietor requested that the appellant-opponent's objection under Article 123(2) EPC, raised in the statement of grounds of appeal in relation to the maintained claim set, not be allowed.

VIII. A summons for oral proceedings was issued by the board. In the accompanying communication sent under Article 15(1) RPBA, the board expressed its preliminary opinion *inter alia* on the admission of the second auxiliary request, and on the admission of the objection under Article 123(2) EPC in relation to the maintained claims ("twice amended" second auxiliary request).

IX. Oral proceedings before the board took place as scheduled. At the oral proceedings, the appellant-proprietor submitted a new third auxiliary request (replacing the claims as maintained by the opposition division) and a fourth auxiliary request.

Claim 1 of the **main request** reads as follows:

"1. Use of a composition comprising (i) isolated, desmin-expressing, muscle-derived progenitor cells (MDC) having long-term survivability *in situ*, or a clonal population thereof, and (ii) a physiologically-acceptable carrier, excipient, or diluent, for the manufacture of a medicament for use in augmenting or bulking esophageal muscle tissue or gastroesophageal muscle tissue in a mammal, wherein the composition is

present in an amount sufficient to augment or bulk the esophageal or gastroesophageal muscle tissue."

Independent claims 2, 3, 5, 6 and 8 differ from claim 1 in that different tissues are given (for the same indication of "augmenting or bulking").

Independent claim 11 differs from claim 1 essentially in that a different medical indication is claimed, namely for use in restoring or improving contractility of gastrointestinal smooth muscle tissue.

The **first auxiliary request** differs from the main request in that the MDC cells are further characterised in the independent claims as follows:

"1. (...), and wherein the MDC express at least desmin, M-cadherin, MyoD, myogenin, CD34 and Bcl-2."

The **second auxiliary request** differs from the main request in that the MDC cells are further characterised in the independent claims as follows:

"1. (...), and wherein the MDC are isolatable by a method comprising: (a) plating a suspension of muscle cells from skeletal muscle tissue in growth medium (DMEM supplemented with 10% fetal bovine serum, 10% horse serum, o.5% chick embryo extract, and 2% penicillin/streptomycin) in a first collagen-coated flask to which fibroblast cells of the muscle cell suspension adhere; (b) re-plating non-adherent cells from step (a) in a second collagen-coated flask, wherein the step of re-plating is after 30-40% of cells have adhered to the first flask; (c) repeating serial plating step (b) approximately 5-6 times to enrich for a population of viable, desmin-expressing cells having

long-term survivability *in situ*; and (d) isolating the MDC as the population of viable, desmin-expressing cells having long-term survivability *in situ*."

The **third auxiliary request** is based on the second auxiliary request, differing therefrom in that the feature "gastroesophageal muscle tissue" has been deleted from claim 1, and in that claims 3 and 4 have been deleted.

The **fourth auxiliary request** is based on the main request, whereby the feature "gastroesophageal muscle tissue" in claim 1, as well as claims 3 and 4, have been deleted. Moreover, the MDC cells are further defined as follows:

1. "(...) wherein the MDC express cell markers comprising at least desmin, CD34, Bcl-2, Sca-1 and Flk-1, and do not express CD45 and c-kit cell markers, (...)"

X. The appellant-proprietor's submissions, in so far as relevant to the present decision, may be summarised as follows:

Main request - Article 123(2) EPC

In the claims, the MDC cells were defined not only by desmin expression but also by their survivability and this was also the characteristic referred to on page 1, lines 8 to 16, of the application as filed. On page 6, the markers were listed as optional, as made clear by the use of the wording "such as". Likewise, page 50, lines 10 to 17, used expressions such as "characteristic", "for example" and "preferably", thus indicating that the listed markers were examples only.

On page 16, line 28 to page 17, line 12, there was a reference to high levels of desmin but not to other cell markers. Indeed, cell markers being transiently expressed, this would not be a reliable way to define the cells. Tables 2 and 4 on pages 34 and 51, respectively, showed that not all PP6 cells expressed all markers: in particular, CD34 was expressed only in >95% and >98%, respectively, of the cells. Another example were the mc13 cells, a clonal population of the PP6 cells (page 44, lines 25 to 26) which did not express CD34 (Table 4). The fact that the cells had been obtained by enrichment (page 6; Example 1, page 33) further supported the fact that not all cells had the same markers, whether being fibroblasts or other muscle cells. Some of the listed markers were skeletal muscle markers, while the invention was not limited to this tissue source. Also, in originally filed claim 74 no markers were disclosed at all. Even if this claim was directed to other uses, the cell compositions were still the same, since the application disclosed only one way of producing the cells.

First auxiliary request - Article 123(2) EPC

A basis for the amendments could be found on page 6, first and second full paragraphs: this particular group of markers was mentioned separately, meaning that they had a higher ranking in terms of cell definition. Other markers were to be considered optional.

Second auxiliary request - Admissibility

This request had indeed been presented at first instance during the oral proceedings and was even mentioned in the decision, as well as discussed in the

minutes of the oral proceedings. It was thus in compliance with Article 12(4) RPBA.

Third auxiliary request - Admissibility and Article 123(2) EPC

This request was submitted as a direct reaction to an objection raised by the board during oral proceedings, and contained a simple amendment consisting of the deletion of the alternative that had been objected to.

As regards the basis for the amendment, only one method was disclosed in the application, and this was the one in Example 1. Concerning the animal source, it was known that the structure of skeletal striated muscle was highly conserved between different species: thus any preparation method applied to any source would produce the same result. In any case, the cell culture conditions were not even specific to skeletal muscle or to a specific source, but instead were general cell culture conditions. All other method features were intrinsic to plating and thus inherent in the claim, and were not essential features. Further basis could also be found on page 17, line 3 to page 18, line 14.

Fourth auxiliary request - Admissibility

This request was also reactive to issues only brought up at oral proceedings before the board. The definition of the MDC cells was as in the original claims and thus it constituted an obvious attempt to solve issues which had been discussed since the beginning of the opposition proceedings.

XI. The appellant-opponent's arguments, in so far as relevant to the present decision, may be summarised as follows:

Main request - Article 123(2) EPC

The definition of the MDC cells was given on page 6 in the first two paragraphs of the Summary of the Invention and it invoked 12 markers (10 positive and 2 negative). The whole description was thus to be interpreted on basis of this initial definition, as there was no different definition in the rest of the description. Only in the claims was there a different definition, e.g. claim 1 only referred to 7 markers. Thus, selection of desmin as the only cell marker was arbitrary. Even if further defined by the feature survivability, the disclosures of pages 6, 16 and 17 still required other markers. As regards the mc13 cells, these were a clonal isolate obtained by stable transfection and thus it was not surprising that they no longer expressed CD34; nevertheless the inventor did not conclude that CD34 did not have to be expressed: page 50, lines 7 ff. again stated that CD34 should be expressed. Nowhere in the application as filed was the skilled person taught that the markers were to be arbitrarily chosen. Even if Tables 2 and 4 showed that only 95% or 98% of the cells expressed desmin and CD34, this was due to the fact that the process was an enrichment process (Example 1, page 33; page 6, line 19). Therefore, the obtained populations were not clonal but instead enriched populations, wherein other cells might be comprised, including fibroblasts which were negative for CD34. Originally filed claim 74 referred to one therapeutical indication only, and was thus not a suitable basis for all the other therapeutic indications.

First auxiliary request - Article 123(2) EPC

The markers still constituted an arbitrary selection, as was apparent in the Table on page 7 of the opponent's letter of 15 September 2011.

Second auxiliary request - Admissibility

The opponent had no submissions in this respect.

Third auxiliary request - Admissibility and Article 123(2) EPC

This request was submitted too late and it was *prima facie* not allowable.

As regards the basis for the amendments, the features were only present in Example 1 and thus their combination with the features of claim 1 amounted to an inadmissible generalization. Claim 1 was generally directed to any skeletal muscle tissue from any mammal source; however, the skilled person would know that cells from different sources required different culture conditions and plating rounds. In addition, not all method steps of Example 1 were present in claim 1. Furthermore, even in Example 1 the MDCs were also disclosed by the markers listed, and these were not in the claims. Finally, the MDC cells of Example 1 were not disclosed in combination with all the claimed therapeutical indications.

Fourth auxiliary request - Admissibility

This request should not be admitted because it constituted an amendment of case. Since a new

combination of markers, which had not been presented at first instance, was in the claims, a new situation was created also in relation to Articles 54 and 56 EPC.

XII. The appellant-proprietor requested that the decision under appeal be set aside and that the patent be maintained on the basis of the claims of the main request or, alternatively, of the first or second auxiliary requests, filed with the statement of grounds of appeal, or, alternatively, of the third or fourth auxiliary requests filed during the oral proceedings of 16 April 2015.

XIII. The appellant-opponent requested that the contested decision be set aside and that European patent No. 1272204 be revoked.

Reasons for the Decision

1. Both appeals are admissible.

2. Main request - Article 123(2) EPC

2.1 According to Article 123(2) EPC, a European patent application or a European patent may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed.

In accordance with the established case law of the boards, the relevant question to be decided in assessing whether an amendment adds subject-matter extending beyond the content of the application as filed is whether the proposed amendments are directly and unambiguously derivable from the application as

filed, meaning that they must not result in the introduction of technical information which a skilled person would not have objectively derived from the application as filed. In the present case, wherein a product is defined by a combination of features, it is necessary not only for each of the features, as well as their combination as claimed, to be disclosed in the application as filed, but also that there is a direct and unambiguous disclosure of a product which is defined by the particular combination of features.

2.2 In the claims of the main request, the muscle-derived progenitor cells (MDC cells) are defined as being "desmin-expressing, muscle-derived progenitor cells (MDC) having long-term survivability *in situ*".

2.2.1 Nowhere in the original application as filed is an explicit disclosure of such a definition to be found. Instead, the cells are generally disclosed as being "muscle-derived progenitor cells that show long-term survival following introduction into soft tissues and bone" (page 1, lines 11 to 13) or more specifically disclosed as comprising "early progenitor muscle cells, i.e., muscle-derived stem cells, that express progenitor cell markers, such as desmin, M-cadherin, MyoD, myogenin, CD34, and Bcl-2" (page 6, lines 11 to 15), and which, "[i]n addition, (...) express the Flk-1, Sca-1, MNF, and c-met cell markers, but do not express the CD45 or c-kit cell markers" (page 6, lines 15 to 17). The same definition is repeated on the same page in lines 22 to 26. Reference to the "long-term survival rates following transplantation into body tissues, preferably soft tissues" is made again on page 16, lines 18 to 19, but without any indication of the markers which should be expressed, let alone desmin. Page 18 then discloses the PP6 population as being a

preferred embodiment; this population is disclosed as being muscle-derived progenitor cells which "express the desmin, CD34, and Bcl-2 cell markers" (page 18, lines 15 to 16), and then as having "long-term survivability following transplantation" (page 18, lines 18 and 19). A further definition of the PP6 cells on page 18 states that this population "comprises a significant percentage of cells that express progenitor cell markers such as desmin, CD34, and Bcl-2" and "[i]n addition, PP6 cells express the Flk-1 and Sca-1 cell markers, but do not express the CD45 or c-kit markers" (page 18, lines 20 to 25). This latter definition of the PP6 cells is again put forward on page 19 (lines 14 to 18) in relation to "the muscle-derived progenitor cells of this invention" in general.

2.2.2 As regards the experimental part of the description, in Example 1, a method is disclosed for "MDC enrichment, isolation and analysis", wherein cells designated as PP6 cells are obtained by serial plating of cell cultures derived from muscle explants. Table 2 on page 34 shows the results of the immunohistochemical analysis performed on the PP6 cells: desmin, CD34, Bcl-2, Flk-1 and Sca-1 are each detected in more than 95% of the cells, M-cadherin in 5 to 50% of the cells, and MyoD and myogenin in 40 to 80% of the cells. Example 9 then discloses a PP6-derived clone, mc13, which was obtained by stable transfection of the PP6 cells with a plasmid containing the LacZ, mini-dystrophin, and neomycin resistance genes. While observing that the mc13 cells did not express CD34 or CD45 (page 50, lines 2 to 7), the inventors state that the PP6 cells can be used to "obtain clonal isolates that express cell markers characteristic of the muscle-derived progenitor cells" and further clarify that "[f]or example, the clonal isolates express progenitor

cell markers, including desmin, CD34, and Bcl-2" and "[p]referably, the clonal isolates also express the Sca-1 and Flk-1 cell markers, but do not express the CD45 or c-Kit cell markers" (page 50, lines 10 to 17). Again, Table 4 shows the results of the immunohistochemical analysis peformed on the PP6 and the mc13 cells: desmin, CD34, Bcl-2, Flk-1 and Sca-1 are each expressed in more than 98% of the PP6 cells, M-cadherin and MyoD in 5 to 30%, and myogenin in 40 to 80%; the results for the mc13 cells are similar, with the exception of CD34, which is not expressed, and Bcl-2, which is expressed only on 40 to 80% of the cells; no data is given for MyoD expression on mc13 cells.

2.2.3 Finally, as regards the claims as originally filed, all independent claims - except claim 74 - characterise the MDC cells to be used as having long-term survivability *in situ*, and as expressing cell markers comprising at least desmin, CD34, Bcl-2, Sca-1 and Flk-1, and as not expressing CD45 and c-Kit cell markers. Originally filed claim 74, on the other hand, refers only to "muscle-derived progenitor cells", without further characterisation.

2.3 Taking into account the above disclosure in the application as filed, the cells of the invention are disclosed to the person skilled in the art either generally as just being muscle-derived progenitor cells (as in original claim 74) or as muscle-derived progenitor cells with long-term survivability after transplantation (pages 1 and 16 supra) or specifically by reference to their cell marker expression, wherein the cell markers include not only desmin but also a number of other markers. Even if the passages on page 6 were to be interpreted as meaning that only one of

desmin, M-cadherin, MyoD, myogenin, CD34, and Bcl-2 has to be present, the definition would still require that Flk-1, Sca-1, MNF, and c-met cell markers are also expressed, and that the CD45 or c-kit cell markers are not expressed.

2.4 The board thus concludes that the main request contravenes the requirements of Article 123(2) EPC.

3. First auxiliary request - Article 123(2) EPC

3.1 In this claim set, the muscle-derived progenitor cells are defined by their long-term survivability together with expression of at least desmin, M-cadherin, MyoD, myogenin, CD34 and Bcl-2.

3.2 The relevant passages on page 6 describing the MDC cells of the invention clearly require that Flk-1, Sca-1, MNF, and c-met cell markers are also expressed, and that the CD45 or c-kit cell markers are not expressed: "[i]n addition, these early progenitor muscle cells express Flk-1, Sca-1, MNF and c-met cell markers, but do not express the CD45 or c-kit cell markers" (page 6, lines 15 to 17); "[t]his MDC population also expresses Flk-1, Sca-1, MNF and c-met cell markers, but does not express the CD45 or c-kit cell markers" (page 6, lines 24 to 26). Contrary to the appellant-proprietor's arguments, these passages cannot be interpreted as referring to optional markers.

3.3 Since there is no other disclosure in the application as filed which could constitute a basis for this amendment, as evident from the discussion above (sections 2.2.1 to 2.2.3), the claims of the first auxiliary request add subject-matter, contrary to the requirements of Article 123(2) EPC.

4. Second auxiliary request - Admissibility

4.1 Article 12(4) RPBA leaves it to the board's discretion to hold inadmissible requests which could have been presented in the first instance proceedings. When exercising its discretion, the board takes into account the circumstances of the particular case and the arguments put forward by the parties.

4.2 The second auxiliary request, submitted with the statement of grounds of appeal, corresponds to the "amended" second auxiliary request which was filed during oral proceedings before the opposition division and then withdrawn to be replaced by the "twice amended" second auxiliary request. Notwithstanding the fact that the opposition division made reference to this request in both the decision and the minutes of the oral proceedings, there is nevertheless no reasoned decision by the opposition division on this set of claims.

4.3 If the second auxiliary request was to be admitted, the board would have to decide on an issue for which no decision was given by the opposition division. Even though it might not have been the appellant-proprietor's intention to avoid a decision by the opposition division, the inevitable result of the withdrawal of the request was that it was not the subject of the reasoned decision of the opposition division. The purpose of the appeal proceedings is to review what has been decided at first instance and not to review what has not been decided. No further reason was given why the board should deal with the second auxiliary request on appeal. The board therefore uses its discretionary power according to Article 12(4) RPBA

not to admit the main request into the appeal proceedings.

5. Third auxiliary request

5.1 Admissibility

5.1.1 Article 13(1) RPBA leaves it to the board's discretion to admit any amendment to a party's case after it has filed its grounds of appeal. This discretion shall be exercised in view of *inter alia* the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy.

5.1.2 The third auxiliary request was only submitted at the oral proceedings, in reaction to the board's preliminary opinion on the main request as regards Article 123(2) EPC. It was based on the second auxiliary request, with deletion of the feature "gastroesophageal muscle tissue" in claim 1 and deletion of claims 3 and 4. It is thus almost identical to the claim request which was considered allowable by the opposition division, only differing therefrom by deletion of the feature "gastroesophageal muscle tissue".

5.1.3 In the notice of opposition, the opponent had objected to the feature "gastroesophageal muscle tissue" under Article 123(2) EPC. The opposition division, however, came to the conclusion that said feature did not add subject-matter, and the opponent did not pursue this objection during appeal. It was only with the communication accompanying the summons to oral proceedings that the parties were informed that this could be an issue to discuss. Thus, while this amendment could have been introduced earlier, the

appellant-proprietor had in fact no reason to do so until receiving the summons to oral proceedings. Certainly it could then have replied to the summons and submitted the amendment in writing rather than wait until the oral proceedings. However, in view of the fact that the amendment just consists of the removal of one alternative from a claim which has already been thoroughly analysed by the opposition division and by the appellant-opponent, its admission does not lead to increased complexity nor does it run counter to the need for procedural economy.

5.1.4 The third auxiliary request is thus admitted to the proceedings (Article 13 RPBA).

5.2 Article 123(2) EPC

5.2.1 With the statement of grounds of appeal, the appellant-opponent raised an objection under Article 123(2) EPC to the claims as maintained - which merely differ from the claims of the present fourth auxiliary request by the presence of the feature "gastroesophageal muscle tissue" in claim 1 (*supra*). Contrary to the appellant-proprietor's observations that this objection had not been raised at first instance, the board notes that it is in fact apparent from the minutes of the oral proceedings before the opposition division (page 2, section entitled "AR2-Article 123(2)EPC") that the opponent had indeed raised an objection under Article 123(2) EPC to the then second auxiliary request in relation to the same amendment. Thus, the appellant-proprietor's request not to admit this objection, on the basis that it constitutes a new objection, is unfounded.

5.2.2 Moreover, the board remarks that, according to G 9/91, in the case of amendments to the claims or other parts of a patent in the course of opposition or appeal proceedings, such amendments are to be fully examined as to their compatibility with the requirements of the EPC (G 9/91, point 19 of the Reasons). Thus, independently of any objection by the opponent, the board has to assess Article 123(2) EPC.

5.2.3 In the third auxiliary request, the MDC cells are characterised by process features taken from Example 1 of the application as filed. The opposition division found that said amendment fulfilled the requirements of Article 123(2) EPC, being correctly based on Example 1. In the decision of the opposition division, reference was also made to page 16, line 20 and to page 19, lines 9 and 10, to justify that it was not required to include in the claims the exact source of muscle cells given in Example 1.

5.2.4 The board, however, notes that there is no indication in the application as filed that the method of Example 1, which is disclosed in relation to specific skeletal muscle cell sources, will always produce cells with the characteristics of the cells of the invention (as defined in the description; see above) when using different cells from skeletal muscle tissue from any possible mammal source, as encompassed in the claim. On the contrary, the application provides evidence that when using e.g. transfected cells - which are not excluded from the claim - clonal isolates can be obtained which do not express the cell markers that should be expressed by the cells of the invention (mc13 cells in Example 9). Moreover, cells from different sources may express other cell markers, as admitted by the appellant-proprietor. Hence, the cells defined by

the process as now in the claims may indeed include the cells of the invention (e.g. the PP6 cells), but they certainly also include other cells which are not part of the cells of the invention.

5.2.5 The disclosure of Example 1 thus cannot be generalised to any cell source, and in particular cannot be combined with each of the therapeutic indications claimed. Indeed, the specific method of producing the cells is only disclosed in the Examples and not in the general part of the description; such cells are then used for specific applications disclosed in the Examples. For the more generally defined uses in the claims, the application only provides a basis for MDC cells which are defined by reference to their marker expression profile, including the specific cell population PP6 (page 17, line 13 to page 18, line 26).

5.2.6 Accordingly, the board comes to the conclusion that the claims of the third auxiliary request do not fulfil the requirements of Article 123(2) EPC.

6. Fourth auxiliary request - Admissibility

6.1 Like the third request, this request was only submitted during oral proceedings before the board and thus its admissibility is also governed by Article 13 RPBA. In this context, the need for procedural economy requires that amended claims submitted at such a late stage as oral proceedings be only admitted if it can be quickly ascertained that they might overcome the outstanding issues without raising new ones.

6.2 In this request, the MDC cells have been defined by reference to their expression of markers desmin, CD34, Bcl-2, Sca-1 and Flk-1, and the absence of expression

of markers CD45 and c-Kit, the amendment being based on the definition of the originally filed claims (e.g. claim 1).

6.3 The board notes that objections under Article 123(2) EPC concerning the definition of the MDC cells have been on file since the very beginning of the opposition and have been maintained throughout the proceedings including the appeal. While the opposition division found that the definition contained in the claims of the then "twice amended" second auxiliary request was allowable, the fact that the appellant-opponent raised again an objection under Article 123(2) EPC against the maintained claims should have prompted the appellant-proprietor to react and produce amended claims, preferably with its reply to the opponent's appeal. At the very latest, such amendments should have been submitted in writing in reaction to the summons to oral proceedings, where the board expressed its preliminary opinion that the claims as maintained did not fulfil Article 123(2) EPC.

6.4 The board further notes that, contrary to appellant-proprietor's statement, the present amendment does indeed increase the complexity of the case, creating a new examination burden on both the appellant-opponent and the board. In view of the fact that not all other features now in the claims, such as some therapeutic indications (e.g. "augmenting or bulking sphincter muscle tissue" - claim 2; "augmenting or bulking tissue comprising one or more of a cutaneous depression, ...," - claim 3) as well as "clonal population", were part of the originally filed claims, it would still have to be examined whether all new combinations now in the claims are also disclosed as such in the application as filed. Moreover, in view of the new definition of the cells,

it is conceivable that new issues under Articles 54 and / or 56 EPC could arise, which might even require to return to written proceedings.

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

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

N. Maslin U. Oswald

Decision electronically authenticated