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**Datasheet for the decision  
of 24 August 2020**

**Case Number:** T 1031/16 - 3.3.01

**Application Number:** 08169379.8

**Publication Number:** 2075002

**IPC:** A61K35/34, C12N5/0775,  
A61P13/02

**Language of the proceedings:** EN

**Title of invention:**

Use of myoblasts in the manufacture of a medicament for  
treating stress urinary incontinence

**Patent Proprietor:**

University of Pittsburgh - Of the Commonwealth  
System of Higher Education

**Opponent:**

Innovacell Biotechnologie AG

**Headword:**

Myoblasts for treating the urinary sphincter muscle /  
UNIVERSITY OF PITTSBURGH

**Relevant legal provisions:**

EPC Art. 123(2)  
RPBA Art. 12(4)

**Keyword:**

Amendments - added subject-matter - all requests (yes)



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Case Number: T 1031/16 - 3.3.01

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.01**  
**of 24 August 2020**

**Appellant:** University of Pittsburgh - Of the Commonwealth  
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**Decision under appeal:** **Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
2 March 2016 concerning maintenance of the  
European Patent No. 2075002 in amended form.**

**Composition of the Board:**

**Chairwoman** T. Sommerfeld  
**Members:** S. Albrecht  
M. Blasi

## **Summary of Facts and Submissions**

I. European patent No. 2 075 002 ("the patent") is based on European patent application 08 169 379.8 ("application as filed") which is a divisional application of earlier European patent application 05 000 057.9. This earlier application is itself a divisional application of European patent application 99 920 202.1 ("the earliest application as filed"). The latter issued as European patent No. 1 113 807 and derived from international patent application PCT/US99/09451 (published as WO 99/56785).

The patent was granted on the basis of a set of five claims.

Claim 1 as granted reads as follows:

"1. Autologous myoblasts for use in an in vivo method of repair of urinary sphincter muscle."

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 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. The opposition division decided that the patent in amended form in the version of the third auxiliary request and the invention to which it related met the requirements of the EPC.

In its decision, the opposition division also concluded that the subject-matter of claim 1 of each of the main and the first auxiliary requests contravened the requirements of Article 123(2) EPC. Claim 1 of the second auxiliary request was found to infringe Article 123(3) EPC.

IV. The patent proprietor ("the appellant-patent proprietor") and the opponent ("the appellant-opponent") both lodged an appeal against the opposition division's decision.

With its statement setting out the grounds of appeal, the appellant-patent proprietor requested that the opposition division's decision be set aside and that the patent be maintained as granted (main request), implying that the opposition be rejected, or, alternatively, that the patent be maintained in amended form on the basis of one of the sets of claims of the following auxiliary requests:

- (a) the first auxiliary request forming the basis of the decision of the opposition division
- (b) the new first auxiliary request (1) as filed with its statement setting out the grounds of appeal
- (c) the new first auxiliary request (2) as filed with its statement setting out the grounds of appeal
- (d) the second auxiliary request forming the basis of the decision of the opposition division
- (e) the third auxiliary request forming the basis of the decision of the opposition division

(f) the fourth to seventh auxiliary requests as filed with the letter of 22 July 2015

Claim 1 of the first auxiliary request is identical to claim 1 of the main request.

The claim set of the new first auxiliary request (1) consists of one single claim, the latter being identical to claim 1 of the main request.

The sole claim of the new first auxiliary request (2) reads as follows:

"1. Autologous myoblasts for use in an *in vivo* method of enhancing coaptation and improving the urinary sphincter muscle."

The sole claim of the second auxiliary request differs from claim 1 of the main request by adding the following passage at the end of the claim:

*"and to bulk up the urethral wall thereby enhancing coaptation and improving the urinary sphincter muscle, wherein the myoblasts are injected into a specific urinary stress incontinence patient from which they are harvested and for which they are cultured"*.

The sole claim of the third auxiliary request reads as follows:

"1. Autologous primary myoblasts for use in an *in vivo* method of repair of urinary sphincter muscle, wherein said myoblasts are introduced in an amount effective to ameliorate stress urinary incontinence."

Claim 1 of the fourth auxiliary request differs from claim 1 of the third auxiliary request by inserting the wording "from skeletal muscle" after the first occurrence of the term "myoblasts".

Claim 1 of the fifth auxiliary request reads as follows:

"1. Autologous myoblasts for use in an in vivo method of repair of urinary sphincter muscle via myoblast mediated gene therapy."

Claim 1 of the sixth auxiliary request and claim 1 of the seventh auxiliary request are identical and read as follows:

"1. Autologous primary myoblasts from skeletal muscle for use in an in vivo method of repair of urinary sphincter muscle, via myoblast mediated gene therapy, wherein said myoblasts are introduced in an amount effective to ameliorate stress urinary incontinence."

With its statement setting out the grounds of appeal, the appellant-opponent requested that the opposition division's decision be set aside and that the patent be revoked in its entirety.

V. The board issued summons for oral proceedings. In a communication pursuant to Article 15(1) RPBA 2020 issued on 22 January 2020, the board drew the parties' attention to the points to be discussed during the oral proceedings and to the circumstance that the patent term had expired.

VI. In a letter dated 17 February 2020, the appellant-patent proprietor confirmed that it

maintained all requests and informed the board that it would not be attending the oral proceedings.

- VII. Likewise, in a letter dated 21 February 2020, the appellant-opponent informed the board that it would not be attending the oral proceedings. In addition, the appellant-opponent withdrew its request for oral proceedings and requested continuation of the proceedings.
- VIII. In a letter dated 5 March 2020, the appellant-patent proprietor equally withdrew its request for oral proceedings.
- IX. On 12 March 2020, the board cancelled the oral proceedings and informed the parties that the proceedings would be continued in writing.
- X. The appellant-patent proprietor's submissions in relation to the issue of added subject-matter, as far as they are relevant for the present decision, may be summarised as follows:

*Claim 1 of each of the main request; the first auxiliary request; the new first auxiliary request (1); the new first auxiliary request (2); the second, third and fourth auxiliary requests*

Contrary to the opposition division's finding set out in paragraph 2.1.8 of its decision, the passages on page 17, lines 8 to 15, and page 30, line 28, to page 31, line 11, as well as the second and third paragraphs of example 12 of the earliest application as filed (i.e. page 6, lines 35 to 39, page 11, lines 13 to 21, and the second and third paragraphs of example 12 of the application as filed), when read together as a



whole with the rest of the application, directly and unambiguously disclosed the treatment of a patient with any condition that would benefit from repair of the urinary sphincter using simple autologous myoblast transplantation without an accompanying gene therapy. Whilst it was true that these passages did not explicitly disclose "repair" of the urinary sphincter muscle, this did not render these deficient in terms of Article 123(2) EPC. As set out in items 2.1.2, 2.1.7 and 5.3.3 of the impugned decision, the skilled person would have considered the terms used in these passages, that is "enhancing coaptation and improving" and "coaptation and closure" of the urinary sphincter muscle, to equate to "repair" of the urinary sphincter muscle. Furthermore, the term "transplantation" at page 17, line 14, of the earliest application as filed (i.e. page 6, line 38, of the application as filed) provided basis for modes of administration of these cells other than injection.

*Claim 1 of each of the fifth, sixth and seventh auxiliary requests*

Basis for the feature "via myoblast mediated gene therapy" could be found on page 16, line 30, to page 17, line 15, and in examples 3 and 12 of the earliest application as filed (see items 6, 7 and 8 of Appendix II of appellant-patent proprietor's statement setting out the grounds of appeal; the passages referred to corresponding to page 6, lines 30 to 39, and examples 3 and 12 of the application as filed).

- XI. The appellant-opponent's submissions in relation to the issue of added subject-matter, as far as they are relevant for the present decision, may be summarised as follows:

*Claim 1 of each of the main request; the first auxiliary request; the new first auxiliary request (1); the second, third, fourth, fifth and sixth auxiliary request*

The passages relied upon by the appellant-patent proprietor required injection of the myoblasts. Moreover, none of these passages disclosed an in vivo method of repair of the urinary sphincter muscle. The terms "enhancing coaptation and improving the urinary sphincter muscle" through urethral wall bulking used in these passages could not serve as basis for the claimed "repair" of the urinary sphincter muscle since the application as filed taught that repair of the urinary sphincter muscle was strictly correlated with gene therapy. Hence, it did not use the terms "repair" and "enhancing coaptation and improving the urinary sphincter muscle" synonymously. Furthermore, contrary to the opposition division's opinion expressed in item 2.1.2 of its decision, the paragraph on page 30, line 28, to page 31, line 11, of the earliest application as filed (i.e. page 11, lines 13 to 21, of the application as filed) referred to a single uniform embodiment in which transduced muscle-derived cells, preferably myoblasts, were injected into the urethral wall, acting in parallel as nonallergenic agent to bulk up the urethral wall.

A combination of the passages relied upon by the appellant-patent proprietor did not provide basis for the subject-matter of claim 1 either because it did not overcome the deficiencies identified in respect of the individual passages. Furthermore, it was not directly and unambiguously derivable from the application as filed that individual features of these distinct

passages could be combined to form a specific new embodiment of the invention.

*Claim 1 of the new first auxiliary request (2)*

The passages referred to by the appellant-patent proprietor in this regard were all limited to genetically-engineered myoblasts, injection and/or treatment of patients with stress urinary incontinence. Accordingly, the subject-matter of claim 1 consisted of an inadmissible generalisation of these disclosures, contrary to the requirements of Article 123(2) EPC.

XII. The parties' final requests, as far as relevant for the present decision and as understood by the board, are as follows:

(a) The appellant-patent proprietor requests:

- (i) that the decision under appeal be set aside and that the patent be maintained as granted, i.e. the opposition be rejected, or, alternatively, that the patent be maintained in amended form on the basis of one of the sets of claims of the auxiliary requests as set out under point IV above, whereby maintenance on the basis of the third auxiliary request implies that the appeal of the appellant-opponent be dismissed; and
- (ii) that all the submissions made on its behalf during the preceding opposition proceedings be taken into account by the board where relevant.

(b) The appellant-opponent requests that the decision under appeal be set aside and that the patent be revoked in its entirety.

The appellant-opponent further requests that the new first auxiliary request (2) not be admitted into the appeal proceedings.

### **Reasons for the Decision**

1. The appeals are admissible. They comply, *inter alia*, with the requirements pursuant to Article 108 and Rule 99 EPC.

*Main request (patent as granted)*

2. Amendments - Article 100(c) EPC

2.1 The subject-matter of the European patent must not extend beyond the content of the application as filed (see Article 100(c) EPC).

2.2 In accordance with established case law of the boards of appeal, the relevant question to be decided in this context is whether the skilled person would have derived the subject-matter of the patent directly and unambiguously from the application as filed, meaning that it must not have resulted in the addition of technical information which a skilled person would not have objectively derived from the application as filed.

Moreover, the content of the application as filed must not be seen as a reservoir of features from which features pertaining to separate embodiments can be combined to artificially create a particular embodiment.

2.3 Claim 1 is directed to autologous myoblasts for use in an in vivo method of repair of the urinary sphincter muscle. As argued by the appellant-opponent (see section III.1 on page 3 of its statement setting out the grounds of appeal), these autologous myoblasts include genetically-engineered as well as non-genetically-modified cells. The board moreover notes that claim 1 does not further define the route of administration of the claimed myoblasts.

2.4 The appellant-patent proprietor submitted that the following passages, when read together as a whole with the rest of the application, directly and unambiguously disclosed the subject-matter of claim 1:

(a) page 17, lines 8 to 15, of the earliest application as filed (i.e. page 6, lines 35 to 39, of the application as filed)

(b) page 30, line 28, to page 31, line 11, of the earliest application as filed (i.e. page 11, lines 13 to 21, of the application as filed)

(c) example 12 of the earliest application as filed (i.e. example 12 of the application as filed)

2.5 Accordingly, it needs to be analysed whether the passages relied upon by the appellant-patent proprietor provide a basis for the subject-matter of claim 1 of the main request within the meaning of Article 100(c) EPC.

In this context, the board notes that whilst the objection related in substance to an extension beyond the application as filed, the parties and the

opposition division referred to passages in the earliest application as filed.

The board notes that the cited passages are identical to passages in the application as filed. Thus, for the sake of consistency, reference is made to the corresponding passages in the application as filed.

2.6 *With regard to the passage on page 6, lines 35 to 39, of the application as filed*

2.6.1 This disclosure is embedded in paragraph [0047] of the application as filed. As submitted by the appellant-opponent (see item III.2.1 of its statement setting out the grounds of appeal), this paragraph can be divided in two parts as follows.

The first part corresponds to page 6, lines 30 to 35, of the application as filed and reads as follows ("first part of paragraph [0047]"):

30 [0047] Yet another object of the present invention is to provide a simple treatment method for women and men with stress urinary incontinence by using autologous, transfected muscle-derived cells to enhance their urinary sphincters. Such muscle-derived cell-mediated gene therapy allows repair and improvement of the urinary sphincter. In accordance with the present invention the treatment comprises a simple needle aspiration to obtain muscle-derived cells, for example, and a brief follow-up treatment to inject cultured and prepared cells into the patient via an outpatient endoscopic  
35 procedure.

This first part of paragraph [0047] is immediately followed by the disclosure relied upon by the appellant-patent proprietor (i.e. page 6, lines 35 to 39, of the application as filed; "second part of paragraph [0047]"), which reads as follows:

35           Also according to the present invention, autologous muscle cell injections using myoblasts and muscle-derived stem cells harvested from and cultured for a specific stress incontinence patient can be employed as a non-allergenic agent to bulk up the urethral wall, thereby enhancing coaptation and improving the urinary sphincter muscle. In this aspect of the invention, simple autologous muscle cell transplantation is performed, preferably without an accompanying gene therapy.

2.6.2       The board notes that this latter disclosure differs from the subject-matter of claim 1 of the main request at least in that:

- (a) it does not report on any urinary sphincter repair effect ("difference (a)")
- (b) it is restricted to the administration of the autologous muscle cells by injection ("difference (b)")

In view of these differences, this disclosure does not, by itself, provide adequate basis for the subject-matter of claim 1 of the main request.

2.6.3       The appellant-patent proprietor contended in this respect that:

- (a) the skilled person would have read the aforementioned statement at page 6, lines 35 to 37, in conjunction with page 6, line 32, of the application as filed ("*Such muscle-derived cell-mediated gene therapy allows repair and improvement of the urinary sphincter.*") and concluded that repair of the urinary sphincter muscle could also be achieved through administration of non-transfected autologous myoblasts (see difference (a) above)
- (b) the term "transplantation" at page 6, line 38, of the application as filed encompassed any suitable

method such as injection or surgery (see difference (b) above)

2.6.4 However, these arguments cannot be accepted for the following reasons.

The first part of paragraph [0047] relates to the repair of the urinary sphincter muscle by means of muscle-derived cell-mediated gene therapy (see page 6, lines 30 to 35, of the application as filed).

The second part of paragraph [0047] reports on the effects of enhanced coaptation and improvement of the urinary sphincter muscle through urethral bulking with the latter being achieved by injecting autologous muscle cells into the patient (see page 6, lines 35 to 37, of the application as filed). These injections are referred to as "simple autologous muscle cell transplantation" on page 6, line 38, and are performed "preferably without an accompanying gene therapy" (see page 6, lines 38 and 39, of the application as filed).

Hence, as submitted by the appellant-opponent, paragraph [0047] explicitly discloses a correlation between the medical use of urinary sphincter muscle repair and muscle-derived cell-mediated gene therapy (see page 3, first two paragraphs, of the appellant-opponent's reply to the appellant-patent proprietor's statement setting out the grounds of appeal in conjunction with page 6, penultimate paragraph, of the appellant-opponent's own statement setting out the grounds of appeal). Enhanced coaptation and improvement of the urinary sphincter muscle, on the other hand, are preferably achieved in the absence of such gene therapy, that is by injecting autologous, non-genetically-modified muscle cells into the patient



(see page 6, lines 38 and 39, of the application as filed).

The board therefore concurs with the appellant-opponent that the skilled person would have considered the first and the second part of paragraph [0047] as two separate embodiments of the invention described in the application as filed and would therefore not have considered the disclosure relating to enhanced coaptation and improvement of the urinary sphincter muscle to be synonymous with the disclosure directed to repair of the urinary sphincter muscle. Given this, the board cannot accept the appellant-patent proprietor's argument that the skilled person would have considered the teaching at page 6, line 32, of the application as filed relating to the repair of the urinary sphincter muscle to be applicable to non-transfected autologous myoblasts.

Furthermore, as far as difference (b) is concerned, the board notes that the feature "simple autologous muscle cell transplantation" is an integral part of the passage relied upon by the appellant-patent proprietor, i.e. page 6, lines 35 to 39, of the application as filed. As submitted by the appellant-opponent (see page 3, first full paragraph, of the appellant-opponent's reply to the appellant-patent proprietor's statement setting out the grounds of appeal), this passage discloses the effects of enhanced coaptation and improvement of the urinary sphincter muscle in the specific context of autologous muscle cell injections. In view of the foregoing, the board cannot accept the appellant-patent proprietor's interpretation of the term "transplantation" at page 6, line 38, as relating to any suitable method of administration.

2.6.5 From the above it follows that the disclosure on page 6, lines 30 to 39, of the application as filed cannot serve as basis for the subject-matter of claim 1 in the claimed generality.

2.7 *With regard to the passage on page 11, lines 13 to 21, of the application as filed*

2.7.1 This passage corresponds to paragraph [0088] of the application as filed. This paragraph consists of four sentences and reads as follows:

**[0088]** In a particular embodiment of the present invention, muscle-derived cell injection, preferably autologous myoblast injection, into the urethral wall is employed as a treatment for stress urinary incontinence to enhance, improve, and/or repair the urinary sphincter. Muscle-derived cells, preferably myoblasts, carrying one or more transduced or transfected heterologous nucleic acids encoding a bioactive molecule and/or a trophic factor, are injected into the urethral wall and survive and differentiate into myofibers to improve sphincter function. The feasibility and survival of myoblast injection into the urethral wall is demonstrated in Example 2. In accordance with this embodiment, autologous muscle-derived cell injections (i.e., muscle-derived cells harvested from and cultured for a specific stress incontinence patient) can be used as a nonallergenic agent to bulk up the urethral wall, thereby enhancing coaptation and improving the urinary sphincter muscle.

2.7.2 In agreement with the appellant-patent proprietor, the board considers that the final sentence of this paragraph at lines 18 to 21 is to be read in conjunction with the preceding sentence at lines 17 to 18. This sentence includes an explicit reference to example 2 of the application as filed. Accordingly, the skilled person would have read this passage in light of this example and infer from it that the embodiment described in the final sentence of this paragraph covers both genetically-engineered and non-genetically-modified myoblasts. However, as observed by the appellant-opponent on page 3, second full paragraph, of its reply to the appellant-patent proprietor's statement setting out the grounds of appeal, the entire disclosure of paragraph [0088] of the application as filed concerns medical uses in which

the desired therapeutic effects are achieved by means of injecting autologous myoblasts directly into the urethral wall. The subject-matter of claim 1, on the other hand, is not limited to this mode of administration. For this reason, the passage on page 11, lines 13 to 21, of the application as filed cannot provide a basis for the subject-matter of claim 1 of the main request in the claimed generality.

2.8 *With regard to example 12 of the application as filed ("example 12")*

As submitted by the appellant-patent proprietor, example 12 generally pertains to two different applications of muscle-derived cells, namely muscle-derived cell-mediated gene therapy and muscle-derived cell-mediated tissue engineering and bulking (see the first and the fifth paragraph of example 12). A practical example of tissue engineering and bulking involving the urinary sphincter muscle is described in the second and third paragraph of example 12. In this practical example, autologous myoblasts harvested from and cultured for a patient with stress urinary incontinence are injected into the urethral wall to provide urethral coaptation and closure. Hence, this disclosure is limited to the administration of the myoblasts by means of injection. Furthermore, it does not pertain to repair of the urinary sphincter muscle.

2.9 Referring to items 2.1.2, 2.1.7 and 5.3.3 of the impugned decision, the appellant-patent proprietor argued in this regard that the term "coaptation and closure" disclosed in the third paragraph of example 12 could be considered to equate to repair of the urethral sphincter.

- 2.10 Nevertheless, this argument is not convincing. In item 2.1.2 of the appealed decision, the opposition division concluded that the final sentence of paragraph [0088] of the application as filed taken in combination with the first sentence of it provided basis for repair of the urinary sphincter muscle by injection of autologous myoblasts without accompanying gene therapy. However, as submitted by the appellant-opponent (see item III.2.2 of its statement setting out the grounds of appeal), the first sentence of paragraph [0088] discriminates between enhancing, improving and/or repairing the urinary sphincter. The same differentiation is made in paragraph [0047] of the application as filed (see point 2.6.4 above). Accordingly, the board concurs with the appellant-opponent that the application as filed does not directly and unambiguously disclose that "this" embodiment referred to in the final sentence of paragraph [0088] relates to the "particular embodiment" directed to the repair of the urinary sphincter muscle mentioned in the first sentence of this paragraph.
- 2.11 The board therefore concludes that example 12 cannot provide a valid basis for the subject-matter of claim 1 of the main request either.
- 2.12 The same conclusions apply if all of the passages of the application as filed referred to by the appellant-patent proprietor in support of its argument are read together as a whole with the rest of the application as filed. As explained above, the aforementioned passages are concerned with medical treatments of the urinary sphincter muscle by means of injection of muscle-derived cells and do not contain any indication that the aforementioned specific route of administration, i.e. injection, could be generalised

to other modes of administration. Such an indication can also not be derived from the overall teaching of the application as filed. The application as filed generally focuses on medical uses of genetically-engineered muscle-derived cells (e.g. page 13, lines 23 to 28, and page 15, lines 21 to 26, of the earliest application as filed which correspond to page 5, lines 26 to 29, and page 6, lines 5 to 8, of the application as filed, respectively), and hence does not provide any basis for generalising to modes of administration of autologous, non-genetically-modified myoblasts other than injection.

- 2.13 In relation to the appellant-patent proprietor's request that all submissions made on its behalf during the opposition proceedings be taken into account by the board where relevant, the board notes that pursuant to Article 12(2) RPBA 2007, the statement of grounds of appeal and the reply shall contain a party's complete case. They shall set out clearly and concisely the reasons why it is requested that the decision under appeal be reversed, amended or upheld, and should specify expressly all the facts, arguments and evidence relied on.

The appellant-patent proprietor's general reference to "all of the submissions" made before the opposition division "where relevant" does not comply with the requirement that the party's submissions be clear and concise. It is neither for the board nor for the other party to speculate whether at all and, if so, which parts of the submissions before the opposition division might be considered relevant.

Hence, this request of the appellant-patent proprietor was not acceded, and its submissions made during the

proceedings before the opposition division were not taken into account by the board (see Article 12(4) RPBA 2007, applicable to this case pursuant to Article 25(2) RPBA 2020).

- 2.14 The board therefore concludes that claim 1 of the main request contains subject-matter which extends beyond the content of the application as filed. The ground for opposition under Article 100(c) EPC therefore prejudices the maintenance of the patent as granted.

*First auxiliary request and new first auxiliary request (1)*

3. Amendments - Article 123(2) EPC

3.1 Claim 1 of each of these requests is identical to claim 1 of the main request and therefore comprises added subject-matter.

3.2 Accordingly, claim 1 of both of these auxiliary requests does not fulfil the requirements of Article 123(2) EPC for the same reasons as set out for claim 1 of the main request.

*New first auxiliary request (2)*

4. Amendments - Article 123(2) EPC

4.1 Claim 1 of the new first auxiliary request (2) differs from claim 1 of the main request in that the phrase "repair of the urinary sphincter muscle" has been replaced with "enhancing coaptation and improving the urinary sphincter muscle". The remaining features of claim 1 of the main request have not been amended. In particular, claim 1 of this auxiliary request is not restricted to a particular route of administration of

the claimed myoblasts.

- 4.2 The passages relied upon by the appellant-patent proprietor to support the amendment made, i.e. the same passages as those cited in respect of claim 1 of the main request (see point 2.4 above), are all restricted to medical uses of muscle-derived cells involving a particular mode of administration, i.e. injection. Accordingly, these cannot serve as a basis for the subject-matter of claim 1 of the new first auxiliary request (2) for the reasons set forth above.
- 4.3 The appellant-patent proprietor did not identify any further passage of the application as filed in support of the amendment made. It merely stated that basis for this amendment could be found throughout the application as filed. This is a general, unspecific statement which would require the board to scrutinise the application on its own and make up the party's case. This would be contrary to the board's obligation to be neutral and impartial.
- 4.4 Under these circumstances, the board considers that the subject-matter of claim 1 of the new first auxiliary request (2) does not find basis in the application as filed, contrary to the requirements of Article 123(2) EPC. This auxiliary request is thus not allowable either.

*Second auxiliary request*

5. Amendments - Article 123(2) EPC
- 5.1 Claim 1 of the second auxiliary request differs from claim 1 of the main request by adding the following passage at the end of the claim:

*"and to bulk up the urethral wall thereby enhancing coaptation and improving the urinary sphincter muscle, wherein the myoblasts are injected into a specific urinary stress incontinence patient from which they are harvested and for which they are cultured".*

- 5.2 As submitted by the appellant-opponent in item VI.2 of its reply to the appellant-patent proprietor's statement setting out the grounds of appeal, the subject-matter of claim 1 of the second auxiliary request is not limited to autologous myoblasts for use in the methods recited in this claim in the context of gene therapy. Thus, the subject-matter of claim 1 also includes myoblasts for use in an in vivo method involving the repair of the urinary sphincter muscle for which the myoblasts have not been genetically engineered.
- 5.3 In the decision under appeal, the opposition division identified page 17, lines 8 to 15, page 30, line 28, to page 31, line 11, and example 12 of the earliest application as filed (i.e. page 6, lines 35 to 39, paragraph [0088] and example 12 of the application as filed) as basis for the subject-matter of claim 1 of the second auxiliary request.
- 5.4 The appellant-patent proprietor did not rely on any further passages of the application as filed in support of the claimed subject-matter from which circumstance the board derived that it solely relied on the passages mentioned in the decision under appeal. Accordingly, it needs to be assessed whether the passages referred to by the opposition division directly and unambiguously disclose the subject-matter of claim 1 of the second auxiliary request.



5.5 In the board's judgement, this is not the case. The passages on page 6, lines 35 to 39, paragraph [0088] and example 12 of the application as filed describe means to provide coaptation, improvement and closure of the urinary sphincter muscle involving autologous myoblasts in general terms, i.e. myoblasts that may or may not be genetically modified. However, as explained under points 2.6.4 and 2.10 above, the application as filed does not provide any basis for considering these effects to be synonymous with the effect of repairing the urinary sphincter muscle. Accordingly, the aforementioned passages cannot serve as basis for the subject-matter of claim 1 relating to autologous, non-genetically modified myoblasts for use in an in vivo method of repair of the urinary sphincter muscle.

Concerning paragraph [0088] of the application as filed, the board further observes that the entire disclosure of this paragraph is limited to medical uses of autologous myoblasts injected into the urethral wall (see point 2.7.2 above). By contrast, claim 1 of the second auxiliary request does not specify the site of injection. Accordingly, also for this reason, paragraph [0088] of the application as filed cannot serve as a basis for the subject-matter of claim 1 of the second auxiliary request within the meaning of Article 123(2) EPC.

The same holds true when the aforementioned passages are considered as a whole with the rest of the application as filed for the reasons outlined above under point 2.12.

- 5.6 The board therefore concludes that the subject-matter of claim 1 of the second auxiliary request does not comply with the requirements of Article 123(2) EPC.

*Third and fourth auxiliary requests*

6. Amendments - Article 123(2) EPC

- 6.1 Claim 1 of the third auxiliary request differs from claim 1 of the main request in that the autologous myoblasts are primary cells and in that the following feature has been added at the end of the claim:

*"wherein said myoblasts are introduced in an amount effective to ameliorate stress urinary incontinence".*

Compared to claim 1 of the third auxiliary request, claim 1 of the fourth auxiliary request specifies that the autologous myoblasts are from skeletal muscle.

- 6.2 Hence, like claim 1 of the main request, claim 1 of these two auxiliary requests is directed to autologous myoblasts which may or may not be genetically modified. Furthermore, these myoblasts may be administered by any means to the patient. Accordingly, for the same reasons as set out above in relation to claim 1 of the main request, neither the subject-matter of claim 1 of the third auxiliary request nor of claim 1 of the fourth auxiliary request find basis in the application as filed.

- 6.3 Claim 1 of these two auxiliary requests thus also fails to comply with the requirements of Article 123(2) EPC.

*Fifth, sixth and seventh auxiliary request*

7. Amendments - Article 123(2) EPC

7.1 Claim 1 of the fifth auxiliary request differs from claim 1 of the main request by adding the following passage at the end of the claim:

*"via myoblast mediated gene therapy".*

Compared to claim 1 of the fifth auxiliary request, claim 1 of the sixth auxiliary request further specifies that the autologous myoblasts are primary cells from skeletal muscle and that these are introduced in an amount effective to ameliorate stress urinary incontinence.

Claim 1 of the seventh auxiliary request is identical to claim 1 of the sixth auxiliary request.

7.2 As basis for the amendments made, the appellant-patent proprietor relied on page 16, line 30, to page 17, line 15, of the earliest application as filed (i.e. paragraph [0047] on page 6, lines 30 to 39, of the application as filed) and examples 3 and 12 of the application as filed (Appendix II to the appellant-patent proprietor's statement of grounds of appeal).

7.3 However, as indicated above under point 2.6.4, paragraph [0047] of the application as filed refers to two separate embodiments of which the first embodiment pertains to a "simple treatment method" for repairing the urinary sphincter. This treatment involves the injection of cultured and prepared autologous muscle-derived cells into the patient (see page 6,

lines 30 to 35, of the application as filed). Likewise, as set out by the appellant-opponent in the final paragraph of page 12 of its statement setting out the grounds of appeal, the disclosure of example 12 is limited to medical uses of autologous myoblasts administered to the patient by injection. The same holds true for example 3 of the application as filed.

- 7.4 Accordingly, the subject-matter of claim 1 of the fifth, sixth and seventh auxiliary requests, in so far as it relates to modes of administration of the claimed myoblasts other than injection, extends beyond the content of the application as filed, contrary to the requirements of Article 123(2) EPC.
8. Since none of the claim requests is allowable, the patent has to be revoked.

**Order**

**For these reasons it is decided that:**

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairwoman:



M. Schalow

T. Sommerfeld

Decision electronically authenticated