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Datasheet for the decision of 22 January 2018

Case Number: T 1050/12 - 3.3.01

Application Number: 05000057.9

Publication Number: 1604674

IPC: A61K35/34, C12N5/08, 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

Opponent:
Innovacell Biotechnologie AG

Headword:
Treatment of stress urinary incontinence/UNIVERSITY OF PITTSBURGH

Relevant legal provisions:
EPC Art. 112(1)(a), 111(1), 54(2), 123(2)
RPBA Art. 13

Keyword:
Referral to the Enlarged Board of Appeal - (no)
Remittal to the department of first instance - (no)
Novelty - (no)
- meeting abstracts available to library users before priority date
- enabling disclosure for medical indication
Amendments - intermediate generalisation
Late-filed auxiliary requests

Decisions cited:
T 0834/09, T 1140/09, T 0381/87, T 0314/99, T 0433/11, G 0003/98, G 0001/12, T 0609/02, T 1993/07

Catchword:
Meeting abstracts published in a supplement to a regular volume of a scientific journal found to be publicly available before the priority date of the patent on the basis of library date-stamps and accompanying declarations of the librarians (see Reasons 3.1 to 3.5).

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Case Number: T 1050/12 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 22 January 2018

Appellant: (Opponent)	Innovacell Biotechnologie AG Mitterweg 24 6020 Innsbruck (AT)
Representative:	Dehmel, Albrecht Dehmel & Bettenhausen Patentanwälte PartmbB Herzogspitalstraße 11 80331 München (DE)
Respondent: (Patent Proprietor)	UNIVERSITY OF PITTSBURGH 200 Gardner Steel Conference Center Pittsburgh, PA 15260 (US)
Representative:	Gill, Siân Victoria Venner Shipley LLP 200 Aldersgate London EC1A 4HD (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 5 March 2012 rejecting the opposition filed against European patent No. 1604674 pursuant to Article 101(2) EPC**

Composition of the Board:

Chairman	A. Lindner
Members:	T. Sommerfeld
	P. de Heij

Summary of Facts and Submissions

I. European patent No. 1 604 674, based on application 05000057.9 and entitled "Use of myoblasts in the manufacture of a medicament for treating stress urinary incontinence", was granted with seven claims.

II. Notice of 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(2) 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. In its decision announced at oral proceedings, the opposition division rejected the opposition under Article 101(2) EPC.

IV. The opponent (appellant) lodged an appeal against that decision. With its statement of grounds of appeal, the appellant requested that the opposition division's decision be set aside and that the patent be revoked in its entirety. Documents D12 and D13 were submitted.

V. By letter of reply, the patent proprietor (respondent) requested that the appeal be dismissed. As a subsidiary request, the respondent requested that the case be remitted to the department of first instance for further prosecution.

VI. The appellant submitted a reply to the respondent's submissions, requesting that the case not be remitted to the opposition division.

VII. The respondent replied in a letter dated 5 June 2013, requesting that the appellant's late-filed submissions not be admitted.

VIII. The board sent a communication indicating its preliminary opinion that the late-filed submissions were admissible and setting a time limit for the respondent to reply thereto.

IX. The respondent submitted a reply dated 21 October 2013, maintaining its requests that the appeal be dismissed (main request) or that the case be remitted to the department of first instance. Alternatively, it requested maintenance of the patent on the basis of the first, second or third auxiliary requests, all filed with the same letter. It further requested referral to the Enlarged Board of Appeal.

X. Oral proceedings before the board took place on 22 January 2018 as scheduled. During the oral proceedings, the respondent filed a fourth auxiliary request. At the end of the oral proceedings, the chairman announced the board's decision.

XI. The **main request** consists of the claims as granted. Claims 1 and 3 read as follows:

"1. Use of skeletal muscle-derived myoblasts histocompatible to a recipient in the preparation of a medicament for use in the repair of smooth muscle dysfunction in the urinary tract."

"3. The use according to claim 1 or 2, wherein the medicament is adapted to be injected into the bladder wall to improve detrusor contractility or into the

urethral wall as a treatment for urinary stress incontinence."

Claim 1 of the **first auxiliary request** differs from claim 1 of the main request by introduction of the following amendment:

"1. Use of skeletal muscle-derived primary myoblasts ..."

Claim 1 of the **second auxiliary request** differs from claim 1 of the first auxiliary request by insertion of a further amendment as follows:

"1. ..., wherein said primary myoblasts have been isolated by preplating."

Claim 1 of the **third auxiliary request** differs from claim 1 of the second auxiliary request by insertion of a further amendment as follows:

"1. ..., ... and exhibit long-term survival following transplantation."

In the **fourth auxiliary request**, claim 1 derives from the combination of granted claims 1 and 3 (partially) as follows:

"1. Use of skeletal muscle-derived myoblasts histocompatible to a recipient in the preparation of a medicament for use in the repair of smooth muscle dysfunction in the urinary tract~~.~~
~~3. The use according to claim 1 or 2~~, wherein the medicament is adapted to be injected into the bladder wall to improve detrusor contractility ~~or into the~~

~~urethral wall as a treatment for urinary stress incontinence~~."

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

D3 Tirney et al. 1998, J. Urol. 159(5) Suppl., p. 327, abstract No. 1256
D5 Extract from Lexikon Medizin 1997, p. 1180
D7 Huard et al. 1998, J. Urol. 159(5) Suppl., p. 16, abstract No. 62
D8 Internet printout of list of volumes of The Journal of Urology
D9 Volume cover "Journal of Urology 159,II 1998 + Suppl."
D10 Declaration of Ms Niehoff
D12 Declaration of Mr James
D13 Declaration of Mr Lee

XIII. The appellant's submissions which are relevant for the present decision may be summarised as follows:

Referral to the Enlarged Board of Appeal
There was no divergent case law, T 834/09 having even discussed the earlier case law. In the present case it was apparent that at least the librarian (as part of the public) had gained access to the document, since he or she had received and stamped it, as evidenced by the date stamp. In the cited earlier decisions the question whether a librarian was part of the public had not been an issue.

Public availability of D3 and D7
The opposition division had used the wrong standard of proof and had not applied it correctly. T 1140/09

confirmed that the standard to be applied for published printed evidence was the balance of probabilities and not absolute certainty. The fact that declaration D10 was made by someone who was not in the library at the relevant date was not a reason to doubt its reliability: T 834/09 also accepted a declaration by a librarian who had not started working at the library in question until seven years later; otherwise novelty would depend on the age of the evidence and the corresponding availability of witnesses. Also, the fact that D10 referred to what normally happened and not to what necessarily happened was not a reason to doubt that what normally happened was, in the absence of evidence to the contrary, very likely to be what in fact did happen (T 381/87). There was confirmatory evidence for D10, in the form of a date stamp on D9; the same type of evidence (date stamps) also accompanied declarations D12 and D13. As to the argument, based on D8, that the public would not know of the existence of the supplement, the situation was not comparable to that of decision T 314/99: anyone requesting the regular volume would be given this supplement as well. D10, D12 and D13 confirmed that the publication arrived in April at different libraries, in Munich, Texas and London, as confirmed by the corresponding date stamps. According to T 834/09, the librarian receiving the publication was already part of the public. Moreover, D12 and D13 confirmed the date when the publication was made available to the libraries' users, i.e. the public in general. There was no issue of confidentiality, as three different covers from three different libraries bore no such indication.

Remittal for further prosecution

There was no reason to remit, because the opposition division had already decided on novelty and inventive

step, albeit on other documents. The patent was due to expire in 2019 and hence it would not be likely that a second appeal could still be settled before expiry.

Main request: novelty over D3

D3 was the abstract of a presentation at a meeting, and both authors were inventors of the patent. All features of granted claim 3 were disclosed in D3, including injection into the urethral wall for treatment of urinary stress incontinence (Title, Methods). The source of autologous myoblasts was always skeletal muscle. This feature was therefore inherent. As to D3's enablement, D3 taught how to obtain the composition and how to use it (administration mode, concentration), and it was undisputed that the skilled person would be able to obtain the myoblasts for transplantation. Model experiments were acceptable to show an effect, especially in therapy. Moreover, D3 also disclosed use of primary myoblasts and that they survived over 30 days (last sentence of Results). D3's results also taught that regenerative myofibrils developed, a precondition for the development of new muscle tissue. There was also reference to a bulking effect, which was known in the prior art for treatment of incontinence (bulking agents: page 11 of the application as originally filed); clearly, autologous myoblasts as bulking agents would not have the disadvantages described in the patent for the bulking agents of the prior art. Even if the patent demonstrated further (functional) effects, the mere elucidation of an effect, by explanation of the underlying mechanism, did not render it novel (T 433/11).

First to third auxiliary requests: admissibility

The auxiliary requests should not be admitted, because they were late-filed, having not been submitted with

the reply to the grounds of appeal. They could have been filed earlier, because in fact they had already been submitted in the first-instance proceedings.

First auxiliary request: novelty
Use of primary myoblasts was also disclosed in D3 (Results, second sentence; Conclusions; Title). The Conclusions referred to "autologous myoblast injections", and there was no indication that these cells should first be transformed into a cell line.

Second and third auxiliary requests: added subject-matter
The patent only disclosed "preplating" in the Examples. However, the examples gave further information, including process details which were not in the claim; this was also true of paragraph [0087], which belonged to Example 1. Moreover, the description for Figures 7A-7H on page 8 showed that not all preplating phases were suitable for the invention. The amendment thus constituted an unallowable generalisation.

Fourth auxiliary request: admissibility
The request was late-filed and would require discussion of inventive step over D7, meaning a new discussion that would delay proceedings.

XIV. The respondent's arguments which are relevant for the present decision may be summarised as follows:

Referral to the Enlarged Board of Appeal
T 834/09 represented a significant change in the definition of the public, by making a librarian a member of the public. Earlier decisions in contrast required evidence that the document was on a shelf or catalogued in order to be considered accessible to the

public, implicitly meaning that the librarian was not part of the public. T 834/09 required less than the public at large, instead requiring only one person, which was a conceptual shift; it promoted the librarian to part of the public, while in the old case law the librarian had held a non-public status. This was a legal point of fundamental importance.

Public availability of D3 and D7
The public was required to be able to gain access to a document not just in theory, but also in practice. In the present case this would not have been possible, as the public would be aware that the journal had a May edition, but might not have known of the supplement's existence, since it was not listed on the website of the Journal of Urology, as evidenced by D8. D10 therefore referred only to what in theory could have happened, but not to what had happened in practice. In addition, it referred only to the journal, and did not once refer to the supplement to the journal.

The opponent had failed to provide corroborating contemporaneous records, as required by case law. Like D10, D12 and D13 were items of evidence in which a librarian made a declaration to the best of his knowledge of what would routinely have happened in the past with normal journals, but not necessarily with a supplement consisting of a collection of abstracts for a future conference. It was not excluded that such issues were to be dealt with confidentially. Also, the routine practice might have changed in the years which had passed.

The standard of evidence had to be very high, "up to the hilt", since the issue was quite fundamental for novelty and inventive step, which required certainty.

Remittal for further prosecution

The case should be remitted for proper consideration of D3 and D7, since there had been no substantial decision on these documents and no preliminary opinion from the board. For fairness, the patent proprietor should have the right to two instances, since a negative decision would mean the end of the road. It was not the patentee's fault that the patent was old, and remittal should not be dependent on the patent's age.

Main request: novelty over D3

D3 did not disclose a therapeutic effect of the myoblasts and was not enabling. It was merely an abstract promoting a presentation, and accordingly it provided only limited information on preliminary experiments. An undefined myoblast cell line was used, which was marked with a reporter gene so as to be able to locate the cells. The results showed that the cells were still present after two to four days, which was not long enough for treatment. While it was shown that the cells could be injected, D3 did not allow any conclusion to be drawn on the effect that they had on the smooth muscle. Example 2 of the patent corresponded to the beginning of the experimentation, namely to background experiments, but the inventors went on to investigate further aspects such as functional testing: Table 1 showed urethral studies on animals which had had injuries and the effect of treatment on those functional parameters; such results, which confirmed that there was an improvement of function of the urinary tract, were not even suggested in D3. Paragraph [0131] of the patent demonstrated the treatment. It was not clear in 1998 what would happen with the myoblasts, especially in terms of function. D3's title did not teach a therapeutic effect, but instead only raised a

hypothesis based on initial experiments. As to page 11 of the application, bulking agents were described as just one possibility for incontinence treatment, among many other alternatives described above, including physical supports and medical devices, and there were no pointers to myoblasts as bulking agents. Bulking agents would anyway have to remain in place for a considerable time (e.g. six months as described in the patent), and not just two to four days as disclosed in D3.

First to third auxiliary requests: admissibility
These requests were the same as before the department of first instance and had never been withdrawn. They raised no complex issues and had been filed well in advance of the oral proceedings.

First auxiliary request: novelty
The primary myoblasts in D3 were mentioned in the context of experiments completely different to those disclosed in the Methods, and there was no linkage between this sentence and the rest of the disclosure, including injection into the urethral wall or treatment of incontinence. There was no indication of where the mice were injected. Also, the second sentence of the Conclusions remained no more than a hypothesis, since there was no linkage to the cell line experiment.

Second and third auxiliary requests: added subject-matter
The amendment had a basis e.g. in paragraph [0087] of the patent (page 43, lines 3 to 26, of the applicationas filed), and the skilled person would recognise, when reading the whole specification, that preplating could be used to prepare the myoblasts of

the invention. Also, Example 11, referring back to Example 1, mentioned preplating.

Fourth auxiliary request: admissibility
The request was filed as a reaction to the surprising view with regard to novelty, for which there had been no preliminary opinion from the board, despite a very positive opinion and decision from the opposition division. The amendments did not raise new issues that would be surprising for the opponent.

XV. The appellant requested that the decision under appeal be set aside and that the patent be revoked; that no questions be referred to the Enlarged Board of Appeal; that the case not be remitted to the opposition division; that the first to third auxiliary requests as filed with the respondent's letter of 21 October 2013 be held inadmissible; and that the fourth auxiliary request, filed during oral proceedings, be held inadmissible.

The respondent requested that the appeal be dismissed (main request) or, alternatively, that the patent be maintained on the basis of the first to third auxiliary requests, filed with the letter of 21 October 2013, or the fourth auxiliary request, filed during oral proceedings; that the case be remitted to the opposition division in the event that the board were to conclude that documents D3 and D7 had been made available to the public before the priority date of the patent; and that questions concerning the availability to the public according to Article 54(2) EPC of a document in a library be referred to the Enlarged Board of Appeal.

Reasons for the Decision

1. The appeal is admissible.

2. Referral of a question to the Enlarged Board of Appeal

2.1 According to Article 112(1)(a) EPC, a board of appeal shall, during proceedings on a case and either of its own motion or following a request from a party to the appeal, refer any question to the Enlarged Board of Appeal if it considers that a decision is required in order to ensure uniform application of the law or to clarify a point of law of fundamental importance.

2.2 The respondent based its request for a referral to the Enlarged Board of Appeal on the fact that decision T 834/09, cited by the appellant in support of arguments concerning the public availability of documents D3 and D7, had reached conclusions which were divergent from the earlier case law and represented a conceptual shift by promoting the librarian to a member of the public.

2.3 As argued by the respondent, T 834/09 states that "[t]he reception and date stamping of an incoming document by a staff member of a public library makes the document available to the public" (Catchword). In point 6.1 of the Reasons, T 834/09 explains that, in view of the established case law that "the theoretical possibility of having access to information renders it available to the public (T 444/88, point 3.1 of the reasons)", it followed that "a printed document received by mail at a public library is clearly rendered available to the public, since the staff member in charge of its reception and date stamping is not bound by any obligation to maintain secrecy and is

thus free to pass the document on to others — which is precisely his or her job." Point 6.2 of the Reasons then clarifies that "date stamping an incoming document in a public library is the point of time at which the document is leaving the non-public domain and entering the public domain. Once placed in the public domain, there is no longer anything that restrains or obstructs access to said information, since the content of the document can be freely reproduced, distributed, transmitted, or otherwise exploited."

2.4 The board does not agree that the conclusions of T 834/09 contradict the earlier jurisprudence. Rather, the earlier decisions cited by the respondent as having reached conclusions divergent from those of T 834/09 were concerned with different aspects of public availability, as discussed in T 834/09 itself (Reasons 4): "none of the aforementioned decisions T 381/87, T 314/99 or T 186/01 addressed the question of the public availability of a document by reception and date stamping by a staff member in a public library."

2.5 Moreover, the admissibility of a referral under Article 112(1)(a) EPC presupposes that an answer to the question is necessary in order for the referring board to be able to decide on the appeal (cf. G 3/98, OJ 2001, 62; Reasons 1). In the present case, regardless of whether or not the librarian is a member of the public, there is evidence on file supporting the conclusion that the document was made available to the public in general (i.e. the users of three libraries) before the priority date (see below). Accordingly, even if the board were to come to the conclusion that there was divergent case law as regards the status of a librarian as a member of the public, it would still be able to reach a decision in the present case without

the need for an answer on this point from the Enlarged Board of Appeal.

2.6 The respondent's request for referral of questions to the Enlarged Board of Appeal is therefore refused.

3. Public availability of documents D3 and D7

3.1 Documents D3 and D7 are meeting abstracts, both published in the same supplement to the Journal of Urology, volume 159, number 5. As is apparent from the cover, the supplement consists of a collection of abstracts of presentations at the AUA 93rd Annual Meeting, which took place in San Diego from 30 May to 4 June 1998. The supplement provides no exact publication date, but its cover carries the date "May 1998".

3.2 Hence D3 and D7 relate to a meeting that undoubtedly took place after 1 May 1998, the priority date of the patent. As to the date of public availability of D3 and D7, the following evidence is available on file:

3.2.1 D10 is a declaration, dated 6 October 2011, by Ms Niehoff, who states that she was a librarian at the Munich University Library (Universitätsbibliothek München) in 1998. In it she declares that: "The Journal of Urology, Volume 159, May 1998, Number 5" was receipted at the library on 30 April 1998, as made evident by the receipt stamp ("Eingangsstempel"). She further states that she could not say exactly when the journal would have been made available to the public, since she had been on holiday on 30 April 1998. Nevertheless, she states that, at that time, scientific publications were generally made available to library visitors, upon request, on the very same day on which

they were date-stamped. As corroborating evidence for D10, a copy of the cover of the journal was submitted as D9. The first page of D9 appears to be an internally used volume cover and carries the designation "Journal of Urology 159, II 1998 + Suppl."; the second page is a copy of the original cover of the supplement in question (as present in D3 and D7), but further carries a stamp with the following information: "Eingangsstempel / 30. APR. 1998 / Univ.-Bibl.- München / Med. Lesehalle"; a magnified version of the page is provided on the last page of D9. As the stamp is placed on the supplement to the journal, it is clear that Ms Niehoff is referring specifically to the supplement.

3.2.2 Document D12, entitled "Statement of public availability", is a signed declaration by a librarian at the Texas Medical Center (TMC) Library. In D12, the usual practice of the library is explained as being that "[j]ournals that are physically received at the library are date-stamped using a stamp that is adjusted each working day to the appropriate date, and then the journals are placed on the shelves and made available to the public. According to the practices currently in place and those in practice in 1998, at the latest, a journal would be placed on the shelves no more than 48 hours after being date-stamped as received." D12 further confirms that "[t]he Library is in possession of a copy of the supplement to the May 1998 (Vol. 159, No. 5, Supp. 1) issue of the Journal of Urology, and this supplement shows a TMC Library date stamp for April 15, 1998 (a Wednesday in 1998). Accordingly, the journal supplement would have been shelved and made available to the public by Friday, April 17, 1998 at the latest." Corroborating evidence is provided in the form of copies of the abstracts in question, of the

journal cover (identical to that of D3 and D7) and of the content page, which carries the library stamp with the date 15 April 1998.

3.2.3 Document D13 is entitled "Public availability date request" and comprises a declaration by Mr Lee of the British Library, wherein it is stated that the British Library received two copies of the "Journal of Urology, Volume 159, Part 5, Supplement 1". According to D13, "Copy 1 was receipted by The British Library on 22 April 1998. It was then catalogued on 27 April 1998 and would have been available for public use from that date. Copy 2 was receipted and catalogued by The British Library on 23 April 1998 and would have been available for public use from that date." Corroborating evidence was attached in the form of "[f]acsimiles of the date stamps of both these copies, indicating the dates of availability". This evidence consists of: one copy of the cover with what appears to be a sticker on the top with the date "22-APR-1998", and just below a stamp with the date "27 APR 1998"; a copy of the "Table of Contents" page is also present, with a stamp with the date "27 APR 1998"; another copy of the cover, apparently with no date stamp; another copy of the "Table of Contents" page, with an almost illegible stamp at the top; a highly magnified copy of the stamp on the same page allows the date to be read as "23 APR 1998".

3.3 In summary, there is evidence on file from three different libraries around the world (Germany, USA and UK) that copies of the journal comprising documents D3 and D7 were available to library users and that the dates of public availability would very likely have been: 30 April 1998 in the Munich Library; 17 April 1998 in the Texas Library; and 27 April 1998

(copy 1) and 23 April 1998 (copy 2) in the British Library. There is corroborating evidence in the form of date-stamped copies for the dates of receipt and/or cataloguing, and the board has no reason to doubt that what the librarians describe as being the usual routines in their libraries would indeed have happened as regards the journal at issue in practice. There is no evidence on file supporting the alleged possibility, raised by the respondent, that the journal supplement, disclosing meeting abstracts for a future conference, was not to be disseminated freely; nor is there any evidence that journal supplements publishing meeting abstracts are not to be made publicly available as soon as they are distributed to libraries and subscribers. Hence, regardless of whether or not the librarian is considered a member of the public (as was the issue in decision T 834/09), the board considers that there is persuasive evidence that documents D3 and D7 were made available to the public before the priority date of the present patent. Whether or not the supplement can be found on the website of the Journal of Urology does not alter the fact that copies of the journal comprising documents D3 and D7 were available to library users.

3.4 Contrary to the respondent's argument that, in view of the issue's relevance to novelty and inventive step, the standard of proof had to be very high, the board notes that even though different concepts as to the standard of proof have developed in the case law of the boards, they all have in common that a judgement is to be made on the basis of the application of the principle of free evaluation of evidence (see in particular decision G 1/12, OJ EPO 2014, A114, reasons 31). The board therefore takes the view that what matters is whether or not the deciding body, here the board, is - having regard to all evidence and arguments

put forward by the parties - convinced that the alleged facts, i.e. the public availability of the documents prior to the priority date, have indeed occurred. In the case of published documents, the standard of proof for public availability is usually the less strict one of the "balance of probabilities" (T 1140/09, reasons 3.2). But even though the present case falls into the category of "balance of probabilities", the board did not form its opinion solely on the basis of whether the alleged facts were just slightly more likely to have occurred than not, but on the basis of whether it was convinced that they had indeed occurred.

3.5 D3 and D7 are thus considered to form part of the prior art, available to the public before the priority date of the patent.

4. Request for remittal to the department of first instance

4.1 Under Article 111(1) EPC the board of appeal may either itself decide on the appeal or remit the case to the department of first instance for further prosecution. Remittal may be justified in the case of new relevant evidence only filed at appeal proceedings, in order to allow any fresh case to be examined at two levels of jurisdiction and to give the other party a reasonable opportunity to react. However, according to the established jurisprudence of the boards of appeal, there is no absolute right to have each individual issue considered at two instances, Article 111(1) EPC leaving it to the discretion of the board whether to exercise any power within the competence of the department of first instance or to remit the case to that department.

4.2 In the present case, no new relevant prior-art documents were submitted. Instead, the same novelty objections over D3 which had been raised during opposition proceedings were maintained by the appellant. To support the public availability of D3 and D7, which had been denied by the opposition division, the appellant provided more evidence in the form of documents D12 and D13. These are of the same nature as document D10, which had already been considered by the opposition division, i.e. they consist of librarians' declarations, accompanied by documentary evidence from the respective libraries. Hence the appellant has not raised a fresh case but rather has merely provided further evidence, in a legitimate attempt to redress the appealed decision.

4.3 While it is true, as argued by the respondent, that there has been no substantial decision by the opposition division concerning documents D3 and D7 because they were not considered to form part of the prior art, this does not per se justify remittal to the department of first instance, since these documents were in fact extensively discussed during the opposition proceedings. Also, the fact that revocation of the patent is the "end of the road" for the respondent cannot be a reason for justifying remittal: otherwise, this would put patent proprietors in an advantageous position over opponents at appeal proceedings, because revocation could be avoided or at least delayed by remittal to the opposition division. In the present case, the fact that the patent already expires in 2019 further speaks against remittal to the department of first instance, since remittal would make it unlikely that a final decision could be reached before expiry of the patent's term.

4.4 Hence the respondent's request for remittal of the case to the department of first instance is refused.

5. Main request - novelty over D3

5.1 Claim 1 of the main request is a second medical use claim, wherein the pharmaceutical composition consists of "skeletal muscle-derived myoblasts histocompatible to a recipient" and the medical indication is "repair of smooth muscle dysfunction in the urinary tract". According to dependent claim 2, the histocompatible skeletal muscle-derived myoblasts are autologous to the recipient, and according to dependent claim 3, the "medicament", i.e. the myoblasts, is to be "adapted to be injected into the bladder wall to improve detrusor contractility or into the urethral wall as a treatment for urinary stress incontinence".

5.2 Document D3 is entitled "Myoblast periurethral injection for the treatment of stress urinary incontinence". It consists of a meeting abstract reporting on experiments which, according to the first paragraph "Objective", aim at exploring "the potential use of myoblasts or satellite cells, the precursors of muscle fibers, as an alternative injection agent for the treatment of stress urinary incontinence". The "Methods" section reports on experiments which make use of a myoblast cell line (not further defined) which was transduced with adenovirus carrying the β-galactosidase reporter gene; the cells were injected into the proximal urethral wall of adult female S-D rats; and the tissue was harvested two to four days after injection and analysed for the presence of the reporter gene. The "Results" section describes how "a large number of cells expressing β-galactosidase" were observed in the urethral wall, as well as "[m]any

regenerative myofibers expressing β-galactosidase". It also states that "[p]rimary myoblasts injected into the SCID mouse survived for over 30 days". Finally, in the "Conclusions" section, the authors state that they "have demonstrated the feasibility and survival of myoblast injection into the urethral wall" and that they "hypothesize that autologous myoblast injections (myoblasts harvested from and cultured for a specific stress incontinence patient) can be used as a nonallergenic agent to bulk up the urethral wall, enhancing coaptation and improving the urinary sphincter muscle."

5.3 The board considers that document D3 discloses all features of claim 1. Autologous myoblasts as mentioned in D3 are, by definition, "myoblasts histocompatible to a recipient", as is also apparent from dependent claim 2, whereas the urethral wall is made up of smooth muscle, as follows from claim 3. It was also common ground among the parties that the myoblasts of D3 were derived from skeletal muscle tissue. As to the medical indication, D3 explicitly discloses injection into the urethral wall for treatment of stress urinary incontinence.

5.4 The respondent essentially argued that D3's disclosure was not enabling for the claimed medical use, because it only disclosed preliminary experiments for which it lacked many details, and it only hypothesised on a therapeutic effect. Contrary thereto, the patent provided data which made the therapeutic effect plausible.

5.5 The board notes that enablement of disclosure for medical uses does not require that a therapeutic effect is demonstrated in vivo but rather that it is made

plausible (T 609/02, reasons 9). Hence, while D3 does indeed not show that injected myoblasts as claimed do exert a therapeutic effect in the context of stress urinary incontinence, it nevertheless does provide data and information which render said therapeutic effect plausible. Contrary to the respondent's arguments, the experiments with the myoblast cell line transduced with a reporter gene did not aim at showing that the injected cells would have a long survival, but rather that they could be injected into the urethral wall and develop therein into "regenerative myofibers". As to cell survival, D3 reports that "[p]rimary myoblasts injected into SCID mice [immunodeficient mice] survived for over 30 days", hence rendering credible that when immune-related effects such as rejection and allergy are avoided, the injected myoblasts are able to survive for a long time: this observation thus renders plausible the hypothesis in the "Conclusions" that "autologous myoblast injections (...) can be used as a nonallergenic agent to bulk up the urethral wall". The use of bulking agents was recognised in the prior art as one of the therapeutic possibilities for treatment of stress urinary incontinence, as reviewed in the patent on paragraph [0032], corresponding to page 11 of the application as originally filed. It is true that the patent presents functional data supporting a therapeutic effect which are not part of D3's disclosure: however, even in the absence of such data, D3 enables and renders plausible a medical use in stress urinary incontinence based on at least a mechanical (bulking) effect, which was accepted in the prior art as a way of treating the disease. Regardless of any further possible mechanism underlying the therapeutic effect, the effect disclosed in D3 is thus enabling for the suggested therapeutic application.

5.6 Hence, the board comes to the conclusion that at least claims 1 to 3 of the main request lack novelty over D3. The main request is thus not allowable for lack of compliance with Article 54(2) EPC.

6. First auxiliary request

Admissibility

6.1 The admission of late-filed requests in appeal proceedings is governed by the Rules of Procedure of the Boards of Appeal. According to Article 12(2) RPBA, the statement of grounds of appeal and the reply thereto must contain a party's complete case. 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 is to 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.

6.2 The present first auxiliary request was not submitted with the reply to the grounds of appeal but only later, with a letter filed as a reaction to further submissions of the appellant. However, the board notes that the present auxiliary request was, although late-filed, still submitted quite early during the appeal proceedings and had in fact already been in the proceedings before the department of first instance. Moreover, it was submitted in reaction to a further letter of the appellant, itself already late-filed and not part of the submissions provided for under Article 12(2) RPBA.

6.3 Hence the first auxiliary request is admitted into the proceedings (Article 13 RPBA).

Novelty over D3

6.4 The only difference between claim 1 as granted and claim 1 of the first auxiliary request is that the latter is restricted to the use of primary myoblasts (rather than myoblasts in general).

6.5 As discussed above (section 5.2), D3 also reports the use of "primary myoblasts" and suggests using "autologous myoblast injections" (hence cells derived from the recipient - by definition, primary - and not from a cell line). Hence, this amendment does not render the subject-matter of claim 1 novel over D3.

6.6 Regarding the respondent's argument that the sentence in D3 mentioning use of primary myoblasts was directed to different experiments with no connection to the rest of the disclosure, the board notes that, in view of D3's whole disclosure, including the Title, it is apparent that the experiments also constituted a model for the use of myoblasts, administered by urethral wall injection, in the treatment of stress urinary incontinence, even if the details of the experiment are missing. Moreover, not only this sentence but also the second sentence of the Conclusions discloses the use of primary myoblasts, "autologous myoblasts" clearly being primary myoblasts (as opposed to myoblasts from cell lines). In this further sentence it is explicitly stated that they are to be used as "a nonallergenic agent to bulk up the urethral wall, enhancing coaptation and improving the urinary sphincter muscle", which is exactly the context of D3's disclosure in general.

6.7 The first auxiliary request is thus not allowable for lack of novelty over D3 (Article 54(2) EPC).

7. Second auxiliary request

Admissibility

7.1 This request was submitted at the same time as the first auxiliary request and also corresponds to a request which had already been presented before the department of first instance. Hence, for the same reasons as discussed above for the first auxiliary request, the second auxiliary request is also admitted into the proceedings (Article 13 RPBA).

Added subject-matter

7.2 Apart from the amendment to the first auxiliary request, claim 1 of the second auxiliary request has been further amended by insertion of the feature that the myoblasts have been isolated by preplating. According to the respondent, a basis for that amendment is to be found in the patent in paragraph [0087], corresponding to page 43 of the application as filed.

7.3 The board notes that the indicated paragraph, entitled "Purification of Primary Myoblasts", first teaches how a muscle cell extract is prepared from the forelimbs and hindlimbs of neonatal mice and is then "pre-plated on collagen-coated flasks". It then discloses that different populations of muscle-derived cells are isolated based on the number of preplates performed on collagen coated flasks, and goes on to disclose the characteristics of each preplate. It further describes how the myogenic populations in each flask are evaluated and what culture media are used. All these

details are not part of the claim, and hence the presently claimed subject-matter (without any restriction as to the preparation) is considered an intermediate generalisation of the specific disclosure of this passage, wherein not only "preplating" but also many other details of the method of myoblast preparation are given, including details specified by reference to other documents.

7.4 The respondent's argument that the skilled person would recognise from the disclosure of the patent as a whole that preplating could be used to prepare the myoblasts of the invention is not persuasive, because there is in fact no single part of the general disclosure that allows this conclusion to be reached, nor is there any reference to "preplating" in general. The reference to "preplating" in Example 11 (paragraph [0257] of the patent, corresponding to page 100, lines 17 to 18, of the application as filed) specifically states that "[t]his technique, termed preplating is described in Example 1, Purification of Primary Myoblasts, herein", hence again making clear that it is defined by the method steps, materials and parameters given in Example 1. Moreover, Example 11 (indicated as being "for information only") is again only one specific example, directed at demonstrating that skeletal muscle could be induced to differentiate into bone, which itself includes further method details which are not part of the claim.

7.5 The second auxiliary request is thus not allowable for lack of compliance with Article 123(2) EPC.

8. Third auxiliary request

Admissibility

8.1 For the same reasons as discussed above for the first and second auxiliary requests, the third auxiliary request is also admitted into the proceedings (Article 13 RPBA).

Added subject-matter

8.2 Claim 1 of this request also comprises the same amendment discussed above for the second auxiliary request. Hence the third auxiliary request does not comply with Article 123(2) EPC and is therefore not allowable.

9. Fourth auxiliary request - admissibility

9.1 The fourth auxiliary request was filed during the oral proceedings, after discussion of the requests already pending. Its admission is hence at the board's discretion, pursuant to Article 13 RPBA. Moreover, amended claims submitted at such a late stage as oral proceedings should be admitted only if clearly allowable, in the sense that it can be quickly ascertained that they overcome all outstanding issues without raising new ones (T 1993/07, reasons 4.4.3).

9.2 Claim 1 of the fourth auxiliary request results from the combination of claim 1 as granted with one alternative of granted claim 3, namely injection into the bladder wall to improve detrusor contractility. Unlike the first to third auxiliary requests, this request had not been filed before.

9.3 The novelty objections raised against the main request and the first auxiliary request were based on the alternative embodiment of injection into the urethral

wall for treatment of stress urinary incontinence. By restriction to the other alternative, the novelty objection over document D3 is indeed prima facie overcome. However, another document, namely D7, would become relevant and would have to be discussed anew, in the context of inventive step, hence increasing the complexity of the case and going against procedural economy. The reasons given by the respondent for not having filed this request earlier were not found convincing: the board's conclusions with regard to the higher-ranking requests, in particular the main request, could not be considered surprising, since the corresponding objections had been raised by the appellant at the very beginning of the opposition proceedings, reiterated with the grounds of appeal and maintained throughout the appeal proceedings. Despite the fact that the opposition division had decided in the respondent's favour, the respondent should nevertheless have considered the possibility that the appellant might succeed with its objections. Hence it should have submitted any further requests earlier. Such a course of action at this advanced stage of the oral proceedings hinders the efficient conduct of the case.

9.4 Accordingly, the fourth auxiliary request is not admitted into the proceedings (Article 13 RPBA).

Order

For these reasons it is decided that:

1. The appealed decision is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated