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# Datasheet for the decision of 17 March 2015

**Case Number:** T 2496/10 - 3.3.02

**Application Number:** 02797144.9

**Publication Number:** 1446129

**IPC:** A61K31/70, A61K39/00, A61P3/10, A61P5/48, A61P25/28

**Language of the proceedings:** EN

**Title of invention:**
POLYNUCLEOTIDE THERAPY

**Applicant:**
The Board of Trustees of the Leland Stanford Junior University

**Headword:**

**Relevant legal provisions:**
EPC Art. 123(2)

**Keyword:**
Amendments - added subject-matter (yes)

**Decisions cited:**
G 0010/93, T 0296/96, T 2619/11, T 1269/06, T 0667/08, T 0783/09, T 0012/81

**Catchword:**

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**Case Number: T 2496/10 - 3.3.02**

# D E C I S I O N
# of Technical Board of Appeal 3.3.02
# of 17 March 2015

| | |
|---|---|
| **Appellant:** (Applicant) | The Board of Trustees of the Leland Stanford Junior University<br>1705 El Camino Real<br>Palo Alto, CA 94306-1106 (US) |
| **Representative:** | Brasnett, Adrian Hugh<br>Mewburn Ellis LLP<br>33 Gutter Lane<br>London EC2V 8AS (GB) |
| **Decision under appeal:** | **Decision of the Examining Division of the European Patent Office posted on 13 July 2010 refusing European patent application No. 02797144.9 pursuant to Article 97(2) EPC.** |

**Composition of the Board:**

| | |
|---|---|
| **Chairman** | U. Oswald |
| **Members:** | T. Sommerfeld |
| | R. Cramer |

## Summary of Facts and Submissions

I. The appeal lies from the decision of the examining division pronounced on 27 May 2010 and posted on 13 July 2010, in which European patent application 02797144.9, based on the international application published as WO 03/045316 (hereinafter: the application as filed), was refused under Article 97(2) EPC.

II. The decision of the examining division was based on the set of claims of the sole request, which was filed with letter of 20 May 2010.

This set of claims comprised 5 claims, of which independent claim 1 read as follows:

"1. A method of preparing a plasmid vector for use in a method of treating insulin dependent diabetes mellitus (IDDM) in a subject, said method comprising:

providing a DNA plasmid vector comprising a polynucleotide encoding insulin, preproinsulin, or proinsulin; and

incorporating into the vector immune modulatory sequences selected from the group consisting of 5'-Purine-Pyrimidine-[X]-[Y]-Pyrimidine-Pyrimidine-3' and 5'-Purine-Purine-[X]-[Y]-Pyrimidine-Pyrimidine-3' wherein X and Y are any naturally occurring nucleotide, except that X and Y cannot be cytosine-guanine."

III. The examining division decided that the claims of the sole request fulfilled the requirements of Article 123(2) EPC but not those of Articles 84, 83 and 56 EPC.

IV. The applicant (hereinafter: the appellant) lodged an appeal against the decision of the examining division. With the statement of the grounds of appeal, it

requested that the appealed decision be set aside and that a patent be granted on the basis of the claim request of 20 May 2010 (re-filed with the grounds of appeal); or, alternatively, that the decision be set aside "on the basis that it is a substantial procedural violation" and that the appeal fee be refunded.

V. As an annex to the summons to oral proceedings, the board issued a communication pursuant to Article 15(1) RPBA.

In said communication, the board summarised the situation and expressed a detailed negative opinion under Articles 123(2) EPC and 84 EPC (clarity).

VI. The appellant did not file any reply to the board's communication.

VII. Oral proceedings took place as scheduled. The appellant maintained its requests as set out in the grounds of appeal, its sole claim request being identical to the one which has been the subject of the appealed decision.

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

Although the originally filed claims were indeed directed to methods of treatment rather than to methods for preparing a plasmid vector, the application nevertheless disclosed a new method for preparing a plasmid vector which also deserved patent protection. Clearly the skilled person first had to obtain the vector in order to be able to use it for treatment, and the application did in fact disclose how to prepare the vector with the features as claimed, e.g. at page 32

lines 8 to 9 and 33 to 34, as well as page 36, from line 26 on. A basis for further features of the vector could also be found in the claims as filed: claims 1, 6 to 11 and 16. The fact that claims 6 and 7 were only dependent on claim 1 should not be taken restrictively; rather the approach of decision T 2619/11 should be followed. Article 123(2) EPC did not require a verbatim disclosure; a semantic approach or a "literal wording test" were not appropriate (T 1269/06, T 667/08). Plasmids were individually disclosed in e.g. page 28, from line 16 on, line 20, lines 26 and 27, line 29; page 37, lines 15 and 25, disclosed a vector as a carrier for the immune stimulatory sequences; the Examples also used plasmids. Regarding the selection of features from two lists, T 783/09, referring back to T 12/81, clarified that objections under Article 123(2) EPC may - but need not - arise according to the circumstances. Pages 13 and 14 provided a list of proteins and it was immediately apparent that each of them was to be used in a plasmid.

IX. The appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the sole request filed with the statement of the grounds of appeal. Alternatively, the appellant requested that the decision be set aside on the basis that the examining division had committed a substantial procedural violation and that the appeal fee be refunded.

## Reasons for the Decision

1. The appeal is admissible.

2. According to the Order of decision G 10/93 of the Enlarged Board of Appeal (OJ EPO, 1995, page 172) "in an appeal from a decision of an examining division in which a European patent application was refused, the board of appeal has the power to examine whether the application or the invention to which it relates meets the requirements of the EPC. The same is true for requirements which the examining division did not take into consideration in the examination proceedings or which it regarded as having been met. If there is reason to believe that such a requirement has not been met, the board shall include this ground in the proceedings".

3. Thus, the board is not limited to the examination of the objections raised in the decision under appeal but has to examine whether appellant's requests fulfil all requirements of the EPC. In this context, the present decision addresses issues under Article 123(2) EPC which were not raised by the department of first instance.

4. Article 123(2) EPC

4.1 According to Article 123(2) EPC, the European patent application or the 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 established board case law, the relevant question to be decided in assessing whether an amendment adds subject-matter extending beyond the content of the application as filed is not only whether the proposed amendments are directly and unambiguously derivable from the application as filed, but also whether they result in the introduction of technical

information which a skilled person would not have objectively derived from the application as filed. Moreover, the content of a document as originally filed may not be seen as a reservoir of features from which features pertaining to separate embodiments can be combined in order to artificially create a particular embodiment (T 296/96 of 12 January 2000, point 3.1 of the Reasons for the Decision).

4.2 Present claim 1 is directed to a method of preparing a plasmid vector. The board could not find any explicit disclosure in the application as filed of methods for preparing a plasmid vector, let alone such a method which is further characterised by the features of present claim 1. Indeed, the disclosure of the application as filed - including the originally filed claims - is directed to methods of treatment rather than to methods of production of plasmid vectors.

4.2.1 Section 1 of the description (page 1 to page 2, line 5), which generally discloses the invention, does not refer at all to methods of production of the compositions intended for the medical uses. The same is also true for the section "Summary of invention" on pages 9 and 10. The "aspects" of the invention are disclosed in the second to sixth paragraphs of this section as being, respectively: "a method for treating or preventing autoimmune diseases such as..."; "a method for treating neurodegenerative diseases such as ..."; "means and methods for identification of self-protein(s), -polypeptide(s) or peptide(s) (...) and for modulating an immune response to the self-protein(s), -polypeptide(s) or peptide(s)"; "means and methods for diagnosing and monitoring disease associated with self-protein(s), -polypeptide(s) or peptide(s)..."; and "means and methods for monitoring therapy comprising

the administration of a polynucleotide encoding self-protein(s), -polypeptide(s) or peptide(s)...". The same aspects are then covered in more detail in the section entitled "Detailed description of the invention", starting on page 12: paragraph 2 on page 13 provides further general statements defining the scope of the invention as "... a method of treating or preventing a disease in an animal associated with one or more self-protein(s), -polypeptide(s) or peptide(s)...". After a discussion of several diseases which can be treated according to the methods of the invention, the description then provides a more detailed disclosure on the compositions to be used in the claimed polynucleotide therapy, namely the "self-vectors" (page 28 to 32, line 4) and the "immune modulatory sequences" (from page 32, line 5 on). While some aspects of vector and immune modulatory sequence (IMS) preparation are then mentioned in the following pages of the description, they cannot be put together into one method for preparation of a vector according to claim 1, as further discussed below (point 4.4). Finally, none of the 35 examples of the application discloses a method of preparing a plasmid vector according to claim 1, and the same is true for the originally filed claims, which are all directed to methods of treatment.

4.2.2 The skilled person would thus not recognise in the application as filed that a method of preparing a plasmid vector was at all an embodiment of the invention. Thus the present amendments result in the introduction of technical information which the skilled person would not have objectively derived from the application as filed.

4.3 The board is also not convinced by the appellant's arguments that such a method is implicitly disclosed in the application as filed. First, contrary to the appellant's arguments, the disclosure of subject-matter directed to therapeutical uses does not imply that the methods for production of the medicament (in this case, a plasmid vector) are also disclosed in the application: actually patent applications directed at second medical use claims usually rely on products which are already available as medicaments and thus already disclosed in the prior art. Thus the fact that a patent application discloses medical uses cannot be taken as an implicit disclosure of methods for preparing the medical compositions.

4.4 Second, the board notes that, while the features of claim 1 may be individually disclosed in the application as filed, these disclosures are in different contexts and the specific combination now claimed involves a selection from several lists, without any pointer leading to the particular selection now in claim 1. Most importantly, there is no teaching in the application as filed that these specific features are to be combined to define one specific method.

4.4.1 The passage on page 36, lines 27 to 34, discloses that the "IMS of the invention may be used alone or may be incorporated in cis or in trans into a recombinant self-vector (plasmid, cosmid, virus or retrovirus) which may in turn code for any self-protein(s), -polypeptide(s), or peptide(s) deliverable by a recombinant expression vector. For the sake of convenience, the IMSs are preferably administered without incorporation into an expression vector." This passage thus discloses incorporation of IMSs (not

further defined) into a self-vector - which can be a plasmid or three other alternatives - wherein the vector may code for any self-proteins, etc., which are also not further defined. Already in this passage, the skilled person would have to select "plasmid vector" from among four alternatives, and would still not know which IMSs and which self-proteins to choose. Admittedly, a plasmid vector is repeatedly mentioned in the application and is also used in the examples, but certainly not one with the features of claim 1.

4.4.2 According to claim 1, the self-proteins / self-polypeptides are to be chosen among insulin, preproinsulin or proinsulin. These are disclosed in the application's Table 2 (pages 13 to 14) among a list of over 50 other self-proteins. Even if the skilled person were already to restrict himself to those self-proteins related to insulin dependent diabetes mellitus (IDDM) - a restriction which is not however present in the disclosure on page 36 and which would mean selecting this disease from among 17 diseases disclosed in Table 2 - he would still have to choose from 14 proteins listed (see also page 17, line 34 to page 18, line 2, and originally filed claim 10). These disclosures are, furthermore, all in the context of methods of treating or preventing a disease by administration of a self-vector, and do not disclose preparing the self-vector at all.

4.4.3 The method according to claim 1 further comprises incorporating into the vector "immune modulatory sequences selected from the group consisting of 5'-Purine-Pyrimidine-[X]-[Y]-Pyrimidine-Pyrimidine-3' and 5'-Purine-Purine-[X]-[Y]-Pyrimidine-Pyrimidine-3' wherein X and Y are any naturally occurring nucleotide, except that X and Y cannot be cytosine-guanine." A

basis for this feature can be found both in original claim 7 and on page 32, lines 19 to 27. Original claim 7 is dependent on claim 6, which refers back to the method of claim 1 (method of treating a disease by administering a self-vector), and further characterises the method of claim 1 as comprising "administration of an immune modulatory sequence or a vector encoding a cytokine, chemokine, immune modulator protein, polypeptide or peptide". There is thus no disclosure here of incorporation of an immune modulatory sequence into a self-vector, but rather said sequences are administered separately, eventually in another vector. Likewise, the passage on page 32 discloses the claimed immune modulatory sequences as "one aspect". After several paragraphs which further define the IMSs, the above-mentioned passage on page 36 then discloses the possibility of incorporating IMSs of the invention into a recombinant self-vector (see above), further stating that this is not the preferred embodiment.

4.5 The skilled person would thus first have to recognise that, although not at all stated in the application, methods for production of vectors were also part of the invention. Then he would have to select the type of vectors from a number of alternatives, select three self-proteins / peptides from an even higher number of alternatives, select one specific group of IMSs from a number of possibilities, and select the least preferred alternative of incorporating the IMSs into the self-vector.

4.6 Thus, while all features may be individually disclosed in the application, the presently claimed combination of these features is not, and is considered to be an artificially created new embodiment.

4.7 The board therefore concludes that the requirements of Article 123(2) EPC are not fulfilled.

5. Request for refund of the appeal fee

In view of the above conclusions regarding Article 123(2) EPC, the question whether the decision of the opposition division was sufficiently reasoned as far as Articles 83 and 84 EPC are concerned is irrelevant and there is no reason to remit the case (Article 11 RPBA). Furthermore, as the appeal is not allowable the appeal fee cannot be reimbursed (Rule 103(1)(a) EPC).

**Order**

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

The appeal is dismissed.

The Registrar: The Chairman:

N. Maslin U. Oswald

Decision electronically authenticated