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**Datasheet for the decision  
of 7 June 2018**

**Case Number:** T 1583/15 - 3.3.07

**Application Number:** 10185522.9

**Publication Number:** 2380594

**IPC:** A61K47/48, C12N15/62

**Language of the proceedings:** EN

**Title of invention:**

Use of serum albumin binding peptides conjugates for the preparation of a medicament

**Applicant:**

Affibody AB

**Headword:**

Peptides conjugates/ AFFIBODY

**Relevant legal provisions:**

EPC Art. 76(1), 123(2), 54(2), 111(1)

**Keyword:**

Divisional application - added subject-matter (no)

Amendments - extension beyond the content of the application  
as filed (no)

Novelty - (yes)

Appeal decision - remittal to the department of first instance  
(yes)



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Case Number: T 1583/15 - 3.3.07

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.07**  
**of 7 June 2018**

**Appellant:** Affibody AB  
(Applicant) Box 20137  
161 02 Bromma (SE)

**Representative:** AWA Sweden AB  
P.O. Box 45086  
104 30 Stockholm (SE)

**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted on 14 January 2015  
refusing European patent application No.  
10185522.9 pursuant to Article 97(2) EPC.

**Composition of the Board:**

**Chairman** J. Riolo  
**Members:** A. Usuelli  
Y. Podbielski

## **Summary of Facts and Submissions**

- I. The appeal of the applicant (appellant) lies from the decision of the examining division to refuse European patent application No.10185522.9 which was filed as a divisional of the European patent application No.05733048.2.
- II. The decision was based on a main request and on an auxiliary request, both filed on 4 September 2014.

The invention defined in claim 1 of the main request related to a method of reducing or eliminating the immunogenicity of a biologically active protein in a mammal which comprised the formation of a conjugate between this protein and a moiety capable of binding to a serum albumin of the mammal. In the auxiliary request it was specified that said moiety was the ABD domain of streptococcal protein G.

The following documents were among those cited in the decision:

D1: US 2004/0001827

D2: WO 01/45746

D3: The Journal of Biological Chemistry, 277(38), 2002, 35035-35043

D4: Nature Biotechnology, 15, 1997, 772-777

D6: Protein Engineering, 8(6), 601-608

The examining division considered that the main request did not comply with the requirements of Articles 83 and 84 EPC and was anticipated by the disclosures of documents D1 to D4. D1 to D4 took away the novelty of claim 1 of the auxiliary request as well.

III. In its statement setting out the grounds of appeal sent on 22 May 2015, the appellant requested to set aside the decision of the examining division and to grant a patent on the basis of a request identical to the auxiliary request forming part of the basis of the decision under appeal. It furthermore filed the following document:

D9: FEBS Letters, 378 (1996), 190-194

IV. By letter of 28 March 2018 the appellant filed two auxiliary requests.

V. In a communication pursuant to Article 15(1) RPBA issued on 18 April 2018, the Board expressed the view that documents D4 and D6 anticipated the subject-matter of the main request whereas auxiliary request 1 appeared to comply with the requirement of novelty. The Board furthermore affirmed that it intended to remit the case to the examining division for further prosecution on the basis of auxiliary request 1.

VI. By letter of 24 April 2018, the appellant filed two new requests replacing all previous requests. The main request was identical to auxiliary request 1 filed on 28 March 2018.

Claim 1 of the main request read as follows:

"1. Use of a moiety capable of binding to a serum albumin of a human or non-human mammal in a molecule including said moiety and a biologically active protein, to reduce or eliminate the immunogenicity in said mammal of said biologically active protein, wherein the moiety capable of binding to a serum

albumin of a mammal is the ABD domain of streptococcal protein G."

- VII. Oral proceedings were held on 7 June 2018 in the absence of the appellant who had informed the Board accordingly.
- VIII. In its written submissions the appellant explained that the ABD domain of streptococcal protein G (hereinafter: ABD-SpG) was a peptide containing 46 amino acids. The amino acid sequence of this peptide was disclosed in Figure 1 of D9. None of documents D1 to D3 disclosed conjugate molecules containing the ABD-SpG. D4 and D6 described such molecules however not in relation to the use recited in claim 1. Hence, the main request complied with the requirement of novelty.
- IX. The appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the main request filed on 24 April 2018 or, in the alternative, on the basis of the first auxiliary request filed on 24 April 2018. It furthermore requested that the case be remitted to the examining division for further prosecution.

## **Reasons for the Decision**

### Main request

1. Articles 76(1) and 123(2) EPC
- 1.1 The description of the present application as filed incorporates the description of the parent application (pages 1 to 63) and the claims of the parent

application in the form of "embodiments" (pages 64 to 75).

Thus, the assessment of Articles 76(1) and 123(2) EPC can be made by comparing the subject-matter claimed with the description of the application as filed.

- 1.2 The use of a moiety capable of binding to a serum albumin of mammal in a molecule including said moiety and a biologically active protein, to reduce or eliminate the immunogenicity of the biologically active protein, can be derived from embodiment 50 of the application as filed.

The indication that the moiety capable of binding to a serum albumin is the ABD-SpG is disclosed for instance in embodiment 62 (page 70) and in the first paragraph of page 14.

- 1.3 It follows from the above that claim 1 of the main request complies with the requirements of Articles 76(1) and 123(2) EPC.

## 2. Novelty

- 2.1 The main request relates to the use of the ABD-SpG, in a molecule containing said peptide linked to a biologically active protein in order to reduce or eliminate the immunogenicity of that protein.

- 2.2 As indicated in the first complete paragraph of page 4 of the description, the ABD-SpG is a peptide of 46 amino acids the sequence of which is described in document D9.

2.3 The Board agrees with the appellant that none of documents D1 to D3 discloses a molecule containing a biologically active protein linked to the ABD-SpG. For this reason alone the main request is novel over D1 to D3.

2.4 Document D4 relates to binding proteins selected from combinatorial libraries that are capable of specific target recognition (page 772, left-hand column, lines 1 to 6). In the last sentence of page 772, D4 explains that these binding proteins are expressed in fusion to the ABD-SpG. Hence, this passage describes a conjugate molecule which corresponds to the molecules referred to in claim 1 of the main request, namely conjugates comprising a biologically active protein coupled to the ABD-SpG.

This passage of D4 also explains that the coupling of the binding protein to the ABD-SpG is made with the purpose of facilitating the purification of the protein. There is no indication in D4 that the ABD-SpG has an effect on the immunogenicity of the protein. Accordingly, document D4 does not disclose that the ABD-SpG can be used to reduce or eliminate the immunogenicity of a biologically active protein.

Hence, the use of the ABD-SpG defined in claim 1 of the main request is not disclosed in D4.

2.5 Document D6 describes proteins, denoted as "Z-variants", which are expressed in fusion with the ABD-SpG (denoted "ABP" in D6; see abstract and chapter "Protein expression and characterization" on page 606). The reason for coupling the Z-variants to the ABD-SpG was apparently for facilitating their recovery. Like document D4, document D6 does not describe the effects



of the ABD-SpG on the immunogenicity of the protein to which it is coupled.

Thus, also D6 does not anticipate the subject-matter of claim 1.

2.6 Therefore, the Board concludes that the main request complies with Article 54 EPC.

3. Remittal

3.1 The primary function of an appeal is to consider whether the decision issued by the first-instance department is correct. Hence, a case is normally remitted if essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the department of first instance.

3.2 These observations fully apply to the present case since important issues such as inventive step have not been considered in the decision under appeal.

Hence the Board exercises its discretion pursuant to Article 111(1) EPC to remit the case to the department of first instance for further prosecution.

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the examining division for further prosecution.

The Registrar:

The Chairman:



S. Fabiani

J. Riolo

Decision electronically authenticated