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Datasheet for the decision of 12 July 2021

Case Number: T 2127/18 - 3.3.01

Application Number: 13791695.3

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IPC: A61K48/00, C12N15/86, A61K38/17, C07K14/71, A61K9/00, A61P27/02, A61K31/7088

Language of the proceedings: EN

Title of invention:
TREATMENT OF AMD USING AAV SFLT-1

Applicant:
Avalanche Australia Pty Ltd.

Headword:
Treatment of AMD/AVALANCHE AUSTRALIA

Relevant legal provisions:
EPC Art. 111(1), 123(2)

Keyword:
Amendments - main request: allowable (yes)
Appeal decision - remittal to the department of first instance (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 2127/18 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 12 July 2021

Appellant: (Applicant)	Avalanche Australia Pty Ltd. c/o MPR Group Pty Ltd. Floor 19, Building HWT Tower 40 City Road Southbank, VIC 3006 (AU)
Representative:	Sharples, Andrew John EIP Fairfax House 15 Fulwood Place London WC1V 6HU (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 15 May 2018 refusing European patent application No. 13791695.3 pursuant to Article 97(2) EPC**

Composition of the Board:

Chairman	A. Lindner
Members:	T. Sommerfeld
	R. Romandini

Summary of Facts and Submissions

I. The appeal lies from the decision of the examining division, in which European patent application 13791695.3, based on an international application published as WO 2013/173129, was refused under Article 97(2) EPC.

II. The decision of the examining division is based on the set of claims of the main request and auxiliary requests 1 to 4 which were filed by letter of 12 March 2018. The examining division decided that none of the claim requests on file fulfilled the requirements of Article 123(2) EPC.

III. The applicant (hereinafter "the appellant") lodged an appeal against the decision of the examining division, requesting that the decision be set aside and that a patent be granted according to the main claim request or, alternatively, according to the claims of auxiliary requests 1 to 5, all filed with the statement of grounds of appeal on 20 September 2018.

IV. The board issued a communication pursuant to Article 17(1) RPBA and Rule 100(2) EPC.

According to the board's preliminary opinion as expressed in said communication, the set of claims corresponding to the main request overcame the objections contained in the appealed decision.

V. With its letter dated 7 April 2021, the appellant filed a main request that the board set aside the appealed decision and remit the case to the examining division

for further prosecution. The previous requests were to be renumbered as auxiliary requests 1 to 6.

Reasons for the Decision

1. The appeal is admissible.

2. Admittance of the new main request

2.1 In the present appeal proceedings the sole ground for refusal of the application was Article 123(2) EPC.

2.1.1 Claim 1 of auxiliary request 4 pursuant to the appealed decision read as follows:

"1. A recombinant adeno-associated virus (rAAV) for use in a method for the treatment of an ocular neovascular disease in a human subject having ocular neovascularization, the method comprising:
i) administering at least one dose of a Vascular Endothelial Growth Factor (VEGF) inhibitor prior to administering the rAAV to the human subject;
ii) administering to the eye of the human subject a unit dose comprising at least 1 x 10^6 and at most 1 x 10^{15} vector genomes of the rAAV and a pharmaceutically acceptable carrier, wherein the rAAV comprises a nucleic acid sequence encoding an anti-VEGF protein, and wherein the anti-VEGF protein comprises a functional fragment of human sFLT1 having at least 90% sequence identity to SEQ ID NO: 121; and
iii) administering one or two doses of a VEGF inhibitor in a 30 day interval following administration of the rAAV."

2.1.2 The examining division objected to the added feature "wherein the anti VEGF protein comprises a functional fragment of human sFLT1 having at last 90% sequence identity to Seq ID No. 121" as it did not have a basis in the application as filed (appealed decision, section 12, on pages 6 and 7). The examining division essentially held that it was "not convinced by the arguments of the Applicant trying to demonstrate that Seq.121 is the preferred embodiment because it rather tends to show that this would be 'obvious for the skilled person in view of the teaching of parts of the application', rather then 'clearly and explicitly disclosed in the application as filed', as is required in the context of Art.123(2) EPC". It also held that there was no basis for a protein having at least 90% sequence identity with the specific fragment of sFLT1 Seq.121. From the minutes of the oral proceedings, it is also apparent that the examining division considered that deletion of the claimed percentage of sequence identity would overcome the objections under Article 123(2) EPC: "The Chairman further suggested to the Applicant to remove the claimed percentage of sequence identity from the claims in order to overcome the objections under Article 123(2) EPC".

2.1.3 With the statement of grounds of appeal, the appellant submitted a new main request, which is based on the previous auxiliary request 4. However, claim 1 differs from claim 1 of the previous auxiliary request 4 in that the following amendments were introduced:

"1. ...
ii) administering to the eye of the human subject a unit dose comprising at least 1 x 10^6 and at most 1 x 10^{15} vector genomes of the rAAV and a pharmaceutically acceptable carrier, wherein the rAAV comprises a

nucleic acid sequence encoding an anti-VEGF protein, and wherein the anti-VEGF protein comprises ~~a functional fragment of~~ human sFLT1 or a functional fragment thereof ~~having at least 90% sequence identity to SEQ ID NO: 121~~; and
..."

2.1.4 Therefore, the board is of the opinion that the amendments introduced successfully overcome the objections of the examining division as put forward in the appealed decision. The replacement of "functional fragment of human sFLT1" by "human sFLT1 or a functional fragment thereof" is based on e.g. paragraphs [0012] and [0174] of the application as filed.

2.2 Since the sole ground for the refusal with respect to the former main and auxiliary requests is considered to be remedied by the new main claim request, and since the amendments cure the deficiency, the new main request is admitted into the proceedings.

3. Remittal to the examining division for further prosecution

3.1 The new main request has overcome the sole ground for refusal. However, the appealed decision only dealt with Article 123(2) EPC, thus leaving all other requirements of the EPC without a decision. The appellant requested a remittal to the department of first instance in the event of the appeal being allowed. No special reasons against such a remittal are apparent to the board in the present case. Therefore, the case is remitted to the department of first instance for further prosecution pursuant to Article 111(1) EPC, based on

the claims of the main request as filed with the statement setting out the grounds of appeal.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated