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Datasheet for the decision of 13 April 2021

Case Number: T 0881/18 - 3.3.04

Application Number: 11769425.7

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Language of the proceedings: EN

Title of invention:
Methods and Compositions for inhibition of Treg Cells

Applicant:
Immunovative Therapies, Ltd.

Headword:
Inhibition of Treg cells/IMMUNOVATIVE THERAPIES

Relevant legal provisions:
EPC Art. 87, 54

Keyword:
Priority - same invention (no)
Novelty - (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 0881/18 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 13 April 2021

Appellant: (Applicant)	Immunovative Therapies, Ltd. POB 974 60850 Shoham (IL)
Representative:	Wilson, Justin Scott Withers & Rogers LLP 4 More London Riverside London SE1 2AU (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 5 October 2017 refusing European patent application No. 11769425.7 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chair	R. Morawetz
Members:	B. Rutz
	R. Romandini

Summary of Facts and Submissions

I. The appeal of the applicant ("appellant") lies from the decision of the examining division refusing European patent application No. 11 769 425.7 (hereinafter: the application) entitled "*Methods and Compositions for inhibition of Treg Cells*". The application was filed on 12 April 2011. It claims priority from US 61/323,557 filed on 13 April 2010.

II. The following documents are cited in this decision:

D5 WO 2011/084451

D7 WO 2009/135199

D12 Janikashvili et al. (2011), Blood, 117(5): 1555-1564

III. In the decision under appeal, the examining division found that the claims of the sole request before them complied with the requirements of Article 123(2) EPC, but that the subject-matter of claims 1 to 6 lacked novelty over the disclosure of document D7 (Article 54 EPC). In an *obiter dictum*, the examining division also found that the subject-matter of claims 1 to 6 lacked inventive step (Article 56 EPC).

IV. With the statement of grounds of appeal, the appellant filed a set of claims (main request) which is identical to the set of claims on which the decision under appeal was based. Furthermore, the appellant filed sets of claims of auxiliary requests 1 to 3.

V. The board notified the appellant of the summons to oral proceedings and issued a communication setting out its preliminary opinion on the case. With regard to auxiliary request 2 the board stated that the claims did not give rise to a right of priority (Article 87 EPC), but that their subject-matter was novel over the prior art cited in the decision under appeal (documents D5 and D7) and over newly cited document D12 (introduced by the board). It stated its intention to set the decision under appeal aside and to refer the case back to the examining division for further prosecution on the basis of the set of claims of auxiliary request 2.

VI. With a letter dated 16 February 2021, the appellant withdrew the main request and auxiliary request 1. The request for oral proceedings was also withdrawn, on condition that the board remitted the case back to the examining division on the basis of the set of claims of auxiliary request 2.

VII. Claim 1 of auxiliary request 2 reads as follows (amendments made to claim 1 of the sole request dealt with in the decision under appeal are indicated):

"1. A therapeutic composition for use in treating a cancerous tumour in a patient, the composition comprising activated allogeneic emTh-1 cells and a chaperone rich cell lysate derived from the tumour~~of disease antigens~~, wherein the composition generates tumour-specific immunity in the patient such that the composition decreases the immunosuppressive activity of tumour-induced Treg cells in the patient while simultaneously promoting a therapeutic effect in the patient, and wherein, in use, the emTh-1 cells and the tumour-derived chaperone rich cell lysate~~disease~~

~~antigens~~ are administered 3-6 times and at intervals of about 3-10 days by intradermal injections at the same location, followed then by an intravenous infusion of the emTh-1 cells."

Claims 2 to 5 depend on claim 1.

VIII. With a letter dated 22 February 2021, the board cancelled the oral proceedings.

IX. The appellant's arguments, which were submitted in writing, may be summarised as follows.

The examining division did not assess the novelty of claim 1 correctly, as document D7 did not clearly disclose the combination of all the features of claim 1. The features of the present claim 1 that were in fact disclosed were described in a number of different locations across document D7, not all in a single embodiment in a single location. Further, there was no teaching or suggestion in document D7 that all the features of the present claim 1 should be combined into a single embodiment.

Claims 39 and 40 of document D7 were dependent on claim 30, which related to a general method involving the administration of T-cells and one or more antigens to stimulate an immune response in the host. Therefore, claims 39 and 40 did not teach an intravenous infusion of emTh-1 cells following administration of a combination of CRCL of disease antigen and activated allogeneic memory Th1 cells.

X. The appellant requested that the decision under appeal be set aside and that the case be remitted to the examining division for further prosecution based on

auxiliary request 2, which had been filed with the statement of grounds of appeal.

Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 99 EPC and is admissible.

Auxiliary request 2 (highest-ranking request)

Admittance (Article 12(4) RPBA 2007)

2. Auxiliary request 2 aims to address the finding in the decision under appeal that there was a lack of novelty. As the reasoning for lack of novelty was already given in the annex to the summons to oral proceedings before the examining division, this request could have been filed earlier. However, the board sets aside the decision under appeal (see points 9. to 20. below) and, in a communication under Article 15(1) RPBA, has raised new objections under Articles 123(2) and 84 EPC with regard to the main request and auxiliary request 1. Auxiliary request 2 overcomes those objections (see points 7. and 8. below), and the board thus considers it appropriate to admit that request.

Effective date and relevant state of the art

3. The requirement for claiming priority of "the same invention", referred to in Article 87(1) EPC, means that priority of a previous application in respect of a claim in a European patent application in accordance with Article 88 EPC is to be acknowledged only if the skilled person can derive the subject-matter of the claim directly and unambiguously, using common general

knowledge, from the previous application as a whole (see opinion G 2/98, OJ EPO 2001, 413, Conclusion).

4. The priority date claimed (13 April 2010) is not valid, because neither "intradermal injections at the same location" nor the "intravenous infusion" referred to in claim 1 are disclosed in the priority document. The effective date for the present set of claims is thus the filing date (12 April 2011).

5. Document D5 was published on 14 July 2011 and filed on 15 December 2010 and is therefore state of the art according to Article 54(3) EPC.

6. Document D12 was published on 3 February 2011 and is therefore state of the art according to Article 54(2) EPC.

Amendments (Article 123(2) EPC)

7. The board is satisfied that the subject-matter of claim 1 finds a basis in claims 37, 38 and 40 to 42 and in paragraphs [0042], [0054], [0057] to [0061], [0088] and [0091] to [0093] of the application as filed. A basis for the subject-matter of claims 2 to 5 can be found *inter alia* in claims 2 to 4 and 39, respectively, and in paragraph [0060] of the application as filed.

Clarity (Article 84 EPC)

8. The indication of the source of the "chaperone rich cell lysate" (CRCL) in claim 1 as "derived from the tumour" allows the skilled person to distinguish CRCLs falling within the scope of claim 1 from those that do not. For this reason the board considers claim 1 to be clear.

Novelty (Article 54 EPC)

9. The examining division held that document D7 disclosed "*a booster i.v. injection of allogeneic memory Th1 cells after the administration of a combination of CRCL* [chaperone rich cell lysate] *+ allogeneic memory Th1 cells, see claims 39-40, page 10 l.18-25 and page 11 l.8-10*" and also that "*both CRCL and the cells are preferably administered intradermally, and most preferably intradermally at the same location (see examples 1-2 of D7)*" (see decision under appeal, point 2. of the Reasons).

10. The appellant submits that the examining division combined different parts of document D7, despite the fact that document D7 does not disclose the claimed features in combination.

11. The point at issue is thus whether or not document D7 directly and unambiguously discloses an intradermal injection of activated allogeneic effector/memory Th1 (emTh-1) cells and a CRCL at the same location followed by an intravenous infusion of emTh-1 cells.

12. While a booster injection of activated T-cells is mentioned in claims 39 and 40 of document D7, those claims depend only on claim 30, which reads as follows:

"*30. A method of reducing antigens related to or causing a disease in a host comprising: administering a pharmaceutical composition comprising an adjuvant and one or more antigens, the adjuvant comprising living immune cells wherein the immune cells comprise at least a portion of T-cells, and wherein the*

pharmaceutical composition, upon administration to the host, stimulates an immune response in the host."

Claim 30 thus relates to a general method of reducing antigens comprising administering T-cells and one or more antigens. The claim does not mention a combination of CRCL and activated allogeneic emTh-1 cells.

13. Thus, claims 39 and 40 of document D7 do not disclose an intravenous infusion of emTh-1 cells after administration of a combination of CRCL and activated allogeneic emTh-1 cells.

14. The passage on page 10, referred to by the examining division, reads as follows:

"*immune cells alone can be administered intravenously at the same time or anytime after the vaccine composition is administered*" (see page 10, lines 23 to 25).

15. However, this passage does not name the disease or the specific vaccine. The further passages referred to ("*Additional booster injections may be administered as needed on a monthly or yearly basis.* [...] *Subsequent injections of allogeneic cells can activate the pool of anti-alloantigen cells that can release the inflammatory cytokines necessary for disabling immune avoidance mechanisms.*", see page 11, lines 1 and 2, and lines 8 to 10) do not disclose the administration route.

16. Thus, the passages on pages 10 and 11 relied on by the examining division do not disclose directly and unambiguously intravenous infusion of emTh-1 cells after the administration of a combination of CRCL and

activated allogeneic emTh-1 cells either.

17. In view of the above findings, the issue of whether or not document D7 discloses that "*both CRCL and the cells are preferably administered intradermally, and most preferably intradermally at the same location (see examples 1-2 of D7)*", see point 9. above, can be left undecided.

18. The board concludes that the subject-matter of claim 1 and of dependent claims 2 to 5 is novel over the disclosure of document D7.

19. The subject-matter of claims 1 to 5 is also novel over document D5, because a CRCL is not disclosed in document D5.

20. The subject-matter of claims 1 to 5 is novel over the disclosure of document D12, because this document does not disclose an intravenous infusion of emTh-1 cells.

Remittal (Article 111(1) EPC)

21. Pursuant to Article 111(1) EPC the board may either exercise any power within the competence of the department which was responsible for the decision appealed or remit the case to that department for further prosecution.

22. The primary function of the appeal proceedings is to review the decision under appeal (see Case Law of the Boards of Appeal, 9th edition 2019, section V.A.1.1, second paragraph and decisions referred to there).

23. As explained in section III. above, the sole reason for refusing the application was that the subject-matter of

claims 1 to 6 of the sole request was not novel in view of document D7; the board sets aside this decision (see points 9. to 20. above).

24. In view of the fact that (i) the examining division did not yet decide on inventive step, (ii) the claims of auxiliary request 2, which were submitted only at the appeal stage, differ substantially from the claims dealt with in the decision under appeal, and (iii) document D12 was introduced by the board, the board considers that special reasons present themselves which justify a remittal of the case to the examining division (Article 11 RPBA 2020).

25. Accordingly, in line with the appellant's request, the board decides to remit the case to the examining division 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 with the order to continue prosecution on the basis of the set of claims of auxiliary request 2, filed with the statement of grounds of appeal.

The Registrar: The Chair:

I. Aperribay R. Morawetz

Decision electronically authenticated