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Datasheet for the decision of 30 January 2024

Case Number: T 1006/21 - 3.3.08

Application Number: 05808659.6

Publication Number: 1810026

IPC: A61K39/395, G01N33/574

Language of the proceedings: EN

Title of invention:
B7-H1 and PD-1 in treatment of renal cell carcinoma

Patent Proprietor:
Mayo Foundation for Medical Education and Research

Opponents:
Merck Sharp & Dohme LLC
Janssen Biotech, Inc.

Headword:
B7-H1 in RCC/MAYO FOUNDATION

Relevant legal provisions:
EPC Art. 56, 87(1), 111(1)
RPBA 2020 Art. 11

Keyword:
Inventive step - (no)
Priority - same invention (no)
Remittal - (no)

Decisions cited:
G 0002/98, T 1805/14, T 0078/17, T 1919/17, T 1913/19

Catchword:

1. The discretionary decision under Article 111(1) EPC to remit a case or not is to be taken *ex officio*, at any time during the appeal proceedings. It is not dependent on any request by a party. A request for remittal made by a party is therefore not subject to the provisions of Articles 12 and 13 RPBA 2020 (points 23 and 24 of the Reasons).

2. Articles 12 and 13 RPBA 2020 serve to take account of changes in the facts or the subject-matter of the appeal proceedings ("amendments" within the meaning of Articles 12(4) and 13(1) and (2) RPBA), within narrow limits (point 25 of the Reasons).

3. Procedural requests are not amendments within the meaning of Articles 12(4) and 13(1) and (2) RPBA. They can therefore be made at any time during the appeal proceedings and must be considered by the board, regardless of when they are made (points 26 to 29 of the Reasons).

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Case Number: T 1006/21 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 30 January 2024

Appellant: (Patent Proprietor)	Mayo Foundation for Medical Education and Research 200 First Street S.W. Rochester, MN 55905 (US)
Representative:	Fish & Richardson P.C. Highlight Business Towers Mies-van-der-Rohe-Straße 8 80807 München (DE)
Respondent I: (Opponent 1)	Merck Sharp & Dohme LLC 126 East Lincoln Avenue P.O. Box 2000 Rahway, NJ 07065 (US)
Respondent II: (Opponent 2)	Janssen Biotech, Inc. 800/850 Ridgeview Drive Horsham PA 19044 (US)
Representative:	Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 19 May 2021 revoking European patent No. 1810026 pursuant to Article 101(3)(b) EPC**

Composition of the Board:

Chair	T. Sommerfeld
Members:	A. Schmitt
	R. Winkelhofer

Summary of Facts and Submissions

I. The appeal of the patent proprietor (appellant) lies from the opposition division's decision to revoke European patent No. 1 810 026 (the patent).

II. The patent was granted on the basis of European patent application No. 05 808 659.6, which had been filed as an international application published as WO 2006/042237 (the application) and claiming priority from, *inter alia*, US provisional application number 60/616,590 (the priority application P1).

III. Two oppositions were filed against the patent.

IV. In the decision under appeal, the opposition division found, *inter alia*, that the invention defined in claim 1 of the main request did not enjoy the right to priority from P1 as P1 and the application had not been filed by the same applicant. Document D16 was therefore part of the state of the art under Article 54(2) EPC, and the subject-matter of claim 1 of the main request and auxiliary requests 1 to 7 did not involve an inventive step in view of the disclosure in documents D20 and D16.

V. With the statement of grounds of appeal, the appellant maintained the main request and auxiliary requests 1 to 7 submitted during the opposition proceedings.

Claim 1 of the main request reads as follows:

"1. An agent which is an antibody or an antigen-binding antibody fragment that interferes with an interaction between B7-H1 and a receptor for B7-H1,

for use in the treatment of an immunosuppression characterized by an impaired function and survival of activated tumor-specific T-cells in a subject with cancer,
wherein some or all cells of the cancer express B7-H1,
wherein said subject is a human and said B7-H1 is human B7-H1 (hB7-Hl),
wherein the agent binds to said receptor for hB7-Hl,
wherein the receptor is the PD-1 receptor,
wherein the cancer is a renal cell carcinoma."

Claim 1 of each of auxiliary requests 1 to 7 differs from claim 1 of the main request on account of one or more of the following additional features, as indicated in brackets.

The cancer is a "clear cell" renal cell carcinoma (RCC) (auxiliary requests 1, 3, 5 and 7), "at least 10%" or all cells of the cancer express B7-H1 (auxiliary requests 2 and 3), "at least 10%" or all cells of the cancer express B7-H1 "according to the percentages of cancer cells that stained positive for B7-H1" (auxiliary requests 4 and 5), "at least 10%" or all cells of the cancer express B7-H1 "according to the percentages of cancer cells that stained positive for B7-H1 as quantified by a urologic pathologist without prior knowledge of patient outcome" (auxiliary requests 6 and 7).

VI. Opponents 1 and 2 (respondents I and II) both replied to the appeal.

VII. The board summoned the parties to oral proceedings in accordance with their requests and, in a communication pursuant to Article 15(1) RPBA, expressed its preliminary opinion, *inter alia*, that P1 did not

disclose the same invention as defined in claim 1 of the main request and could therefore not give rise to a right of priority.

VIII. Oral proceedings were held as scheduled. Respondent II did not attend the oral proceedings, as announced previously.

IX. The following documents are referred to in this decision:

D1 L. Chen, Nature Reviews Immunology, 4, 2004, 336-47

D8 Y. Y. Zha et al., Critical Reviews™ in Immunology, 24(4), 2004, 229-37

D16 R. H. Thompson et al., PNAS, 101 (49), 2004, 17174-9

D20 EP 1 537 878 A1

X. The appellant's arguments relevant to the decision are summarised as follows.

Main request
Priority (Article 87 EPC) - claim 1

The priority application P1 disclosed the same invention as defined in the claim when the disclosure in P1 was reasonably assessed as a whole. The priority had therefore been validly claimed.

Inventive step (Article 56 EPC) - claim 1

The appellant did not challenge the opposition division's decision on inventive step when document D16 was part of the state of the art under Article 54(2) EPC (see section IV.).

Auxiliary requests 1 to 7
Priority (Article 87(1) EPC) and inventive step (Article 56 EPC) - claim 1

The appellant did not submit any arguments on the validity of the right to priority from P1 of the invention defined in claim 1 of auxiliary requests 1 to 7 or on the inventive step of the claimed subject-matter when document D16 was part of the state of the art under Article 54(2) EPC (see section IV.).

Request for remittal (Article 111 EPC, Article 11 RPBA)

The opposition division erred in its finding on the validity of the claim to priority from P1. This changed the factual situation and thus the basis of the opposition division's decision, and therefore qualified as exceptional circumstances that warranted a remittal to the opposition division. Whether P1 disclosed the same invention as defined in the claim was critical for the assessment of inventive step and therefore for the outcome of the appeal case, but this had not been decided upon by the opposition division. It would therefore be fair that this issue be assessed at two instances.

XI. The respondents' arguments relevant to the decision are summarised as follows.

Main request
Priority (Article 87 EPC)

The claim combined two features, an antibody against PD-1 and the treatment of an immunosuppression characterised by an impaired function and survival of

activated tumour-specific T cells in a subject with cancer (RCC). These features were disclosed separately in P1 without any link between them or pointer that the separate teaching could be combined. P1 did not disclose the same invention as defined in the claim.

Inventive step (Article 56 EPC) - claim 1

As the claim to priority from P1 was not valid for the subject-matter of claim 1, document D16 was part of the state of the art under Article 54(2) EPC. The claimed subject-matter lacked an inventive step in view of the disclosure in documents D16 and D20 for the same reasons as indicated in points 3.1, 3.2 and 3.3 of the decision under appeal.

Auxiliary requests 1 to 7
Priority (Article 87(1) EPC) and inventive step (Article 56 EPC) - claim 1

The same considerations on priority and inventive step as for claim 1 of the main request applied to claim 1 of each of auxiliary requests 1 to 7. The subject-matter of claim 1 of each of auxiliary requests 1 to 7 therefore lacked an inventive step in view of the disclosure in documents D16 and D20.

Request for remittal (Article 111 EPC, Article 11 RPBA)

The appellant's request for remittal had been submitted very late without any justification and should not be admitted into the appeal proceedings under Article 13(2) RPBA. No special circumstances could justify this request as the appellant had dealt with whether P1 disclosed the same invention as defined in claim 1 in the statement of grounds of appeal, so the

request contradicted previous requests of the appellant and should not be deemed allowable under Article 11 RPBA.

The opposition division had already given a preliminary opinion on this aspect of the right to priority from P1. There was no absolute right to have an issue decided on by two instances. Since all parties had submitted arguments on this issue in writing, they were prepared to discuss this matter, and a remittal was not appropriate.

However, if priority was held to be valid, there should be a remittal so novelty, inventive step and sufficiency of disclosure as of the priority date could be assessed at two instances.

XII. The parties' requests relevant for the decision are as follows.

The appellant requests that the decision under appeal be set aside and amended such that the patent be maintained on the basis of the claims of the main request or auxiliary requests 1 to 7, all requests as submitted in the opposition proceedings and re-submitted with the grounds of appeal.

The respondents request that the appeal be dismissed.

In the alternative, both sides request remittal to the opposition division, if under different conditions (see above).

Reasons for the Decision

Main request
Priority (Article 87 EPC) - claim 1

1. The claim concerns an agent characterised, *inter alia*, by the two features that it is an antibody or antigen-binding antibody fragment that binds to PD-1 and interferes with the interaction between B7-H1 and PD-1 and that it is "for use in the treatment of an immunosuppression characterized by an impaired function and survival of activated tumor-specific T-cells" in a subject with renal cell carcinoma (RCC) (see section V. for the full wording of the claim).

2. The treatment recited in the claim is therefore not the treatment of RCC but the treatment of a type of immunosuppression in subjects suffering from RCC. This type of immunosuppression is described in P1 only in lines 7 to 13 of page 16, which disclose that "*based on its recognized ability to impair the function and survival of activated tumor-specific T cells, we infer that B7-Hl, expressed by either RCC tumor cells or infiltrating lymphocytes, may contribute to the profile of immunosuppression that is observed in patients with RCC. We suggest that intratumoral B7-Hl functions as a critical host determinant of treatment responses in patients who receive immunotherapy for management of advanced RCC (i.e., IL-2, INF-α, vaccination or T cell adoptive therapy)*".

3. This passage of P1 describes that B7-H1 expression in RCC may contribute to that type of immunosuppression in RCC patients and identifies B7-Hl as a determinant of responses to immunotherapy in these patients. The described immunotherapy is not directed to B7-H1 or any

molecules interacting with B7-H1, and no treatment with an anti-PD-1 antibody is disclosed in this passage.

4. The subsequent paragraph on page 16 of P1 discloses that "[a]*ntibody-mediated blockade of B7-Hl may prove useful, either alone or in combination with other immune-based manipulations, to improve the effectiveness of RCC treatment*" (see lines 21 to 23 of page 16).

5. This passage hence suggests an antibody-mediated blockade of B7-H1 in RCC treatment. In view of the disclosure in the previous paragraph cited in point 2. above, it could be understood that the suggested improvement of treatment effectiveness by antibody-mediated blockade of B7-H1 may be achieved by treating the B7-H1-mediated immunosuppression described in this section. However, even if this were understood from this section in P1, it would not disclose the treatment with an anti-PD-1 antibody.

6. The expression "antibody-mediated blockade of B7-Hl" does not implicitly include an antibody binding to PD-1 either. It only encompasses antibodies that bind to H7-B1. This understanding is supported, for example, by documents D1 and D8, which separately refer to B7-H1 blockade and PD1 blockade to describe the blockade of the respective proteins (see Table 4 of D1; first paragraph of the left-hand column on page 231 and paragraph bridging the left- and right-hand columns on page 232 of D8) and was, in general, not disputed by the appellant.

7. However, the appellant argued that this expression would have been understood by the skilled person as encompassing PD-1 antibodies in the context of the

teaching of P1 as a whole. This was because the entire disclosure of P1 concerned the expression of B7-H1 in RCC and diagnosis and treatment of RCC based on this analysis. The second paragraph on page 3 and claims 43 to 46 of P1 that disclosed, *inter alia*, the use of a PFD-1 antibody for the treatment of subjects afflicted with a cancer in which cancer cells or tumour-infiltrating lymphocytes expressed B7-H1 should therefore be understood in the context of RCC and the "antibody-mediated blockade of B7-Hl" and would thus have been understood by the skilled person as encompassing both the only two alternatives of therapeutic antibodies disclosed on page 3 and in claims 43 to 46.

8. This is not persuasive. In opinion G 2/98 (OJ EPO 2001, 413), the Enlarged Board of Appeal ruled that the requirement for claiming priority of "the same invention", referred to in Article 87(1) EPC, means that priority of a previous application 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 (Headnote). Hence, the same requirements as for Article 123(2) EPC apply.

9. The passage on page 3 of P1 reads as follows: "*Yet another aspect of the invention is a method of treatment. The method involves: (a) identifying a subject with cancer, wherein some or all cells of the cancer or some or all tumor-infiltrating lymphocytes of the cancer express B7-H1; and (b) delivering to the subject an agent that interferes with an interaction between B7-H1 and a receptor for B7-H1. The agent can be an antibody, or an antibody fragment, that binds B7-H1; soluble B7-H1 or a soluble functional fragment of*

B7-H1; a soluble receptor for B7-H1 or a soluble functional fragment thereof; an antibody, or an antibody fragment, that binds to a receptor for B7-H1, e.g., the PD-1 receptor". Claim 43 relates to the same method of treatment comprising steps (a) and (b) as described on page 3, and claim 46 defines that the agent comprises an antibody, or a fragment of it, that binds to the PD-1 receptor.

10. These two passages of P1 therefore concern the treatment of cancer in general and define neither that the cancer is RCC nor that an immunosuppression characterised by an impaired function and survival of activated tumour-specific T cells is to be treated. They therefore relate to an embodiment different from that disclosed on page 16 of P1 and cannot be combined with the disclosure on page 16 without creating a new teaching. The combination of features recited in the claim is therefore not directly and unambiguously disclosed in the priority application P1, which hence does not concern the same invention as defined in the claim (G 2/98, *supra*).

11. The appellant asserted that since P1 disclosed, as a single inventive concept, the role of B7-H1 in RCC and methods of RCC treatment based on this role, as was clear from the disclosure on pages 7, 8, 9, 10, 15 and 16; Figures 1 and 2; and Tables IA, IB, II and III, the teaching on page 3 and in claims 43 to 46 of P1 also had to be understood as referring to RCC. Moreover, as only two aspects of treatment (with an antibody against B7-H1 and with an antibody against a receptor of B7-H1, e.g. PD-1) were disclosed in P1, the skilled person would have linked the disclosure on page 16 of P1, which was part of the "DISCUSSION" section of P1 and hence reflected the results of the

disclosed study, with the method of treatment on page 3 and in claims 43 to 46, including the treatment with an agent that binds to the PD-1 receptor.

12. This line of argument cannot be accepted, either. The section on page 3 of P1 starts with "[y]*et another aspect of the invention*". This aspect is, *inter alia,* described as the treatment of a cancer with a PD-1 antibody, not the treatment of an immunosuppression in a subject afflicted with RCC as defined in the claim. As assessed above (see point 2.), the only passage in P1 that describes this immunosuppression (page 16) does not disclose treatment with a PD-1 antibody. P1 therefore lacks a direct and unambiguous disclosure of these two features in combination.

13. The appellant's considerations might imply that it was obvious to the skilled person that the immunosuppression described on page 16 of P1 might also be treated with a PD-1 antibody as described on page 3 and in claim 46 for a different treatment. However, obviousness is not the decisive criterion for the assessment of whether a claimed invention is directly and unambiguously disclosed in a priority application (see point 8. above).

14. With the invention as defined in the claim not being entitled to priority from P1, document D16 forms part of the state of the art under Article 54(2) EPC, and its disclosure is relevant for the assessment of inventive step of the claim.

Inventive step (Article 56 EPC) - claim 1

15. The opposition division found that the claimed subject-matter lacked an inventive step in view of the

disclosure in documents D20 and D16 (see section IV. above).

16. This finding of the opposition division was not challenged by the appellant in the appeal proceedings and is therefore not reviewed by the board. The subject-matter of claim 1 does not involve an inventive step (Article 56 EPC).

Auxiliary requests 1 to 7

Priority (Article 87(1) EPC) and inventive step (Article 56 EPC) - claim 1

17. No arguments were submitted by the appellant on the claim to priority from P1 or on inventive step for the subject-matter of claim 1 of any of auxiliary requests 1 to 7. Hence, the same considerations as for claim 1 of the main request on these issues apply to claim 1 of each of auxiliary requests 1 to 7 (see points 1. to 16. above).

18. The subject-matter of claim 1 of each of auxiliary requests 1 to 7 also lacks an inventive step in view of the disclosure in documents D16 and D20 (Article 56 EPC).

Admittance and consideration of auxiliary requests 2 to 7

19. Given the above (points 17. and 18.), the question of admittance and consideration of auxiliary requests 2 to 7 is moot.

Requests for remittal (Article 111 EPC, Article 11 RPBA)

20. Both parties request remittal of the case to the opposition division, albeit under different conditions, as formulated in their requests for remittal (see above, sections X., XI. and XII.). The respondents also request that the appellant's request for remittal not be considered for being late filed.

21. Without there being any need to go into the substance of these conditions, the following general principles apply to requests for remittal.

22. Under Article 111(1) EPC, the board may either exercise any power of the department having handed down the appealed decision or remit the case to that department for further prosecution. Whether to remit is a discretionary decision of the board which is subject to the limitations of Article 11 RPBA that remittal also requires "special reasons".

23. The discretionary decision to remit or not is to be taken *ex officio*, at any time during the appeal proceedings (see, *inter alia*, T 1805/14, Reasons 2.4; T 78/17, Reasons 2.5; Case Law of the Boards of Appeal of the EPO, 10th edn., 2022 (CLBA), V.A.9.5).

24. Thus, a decision on remittal is not dependent on any request by the parties and must be taken even in the absence of such a request. Any request for remittal made by a party is therefore not subject to the provisions of Articles 12 and 13 RPBA 2020.

25. Rather, Articles 12 and 13 RPBA 2020 serve to take account of changes in the facts or the subject-matter of the appeal proceedings ("amendments" within the

meaning of Articles 12(4) and 13(1) and (2) RPBA), within narrow limits (see T 1919/17, Reasons 25; T 1913/19, Reasons 10 and 16). These provisions are thus directed at (claim) requests or (allegations of) facts and evidence, i.e. at substantive issues, objections and related arguments (see Article 12(2) and (4) and Article 13(1) and (2) RPBA 2020).

26. In contrast, procedural requests are not amendments within the meaning of Articles 12(4) and 13(1) and (2) RPBA.

27. Procedural requests on questions that have to be taken up *ex officio* may relate to remittal, as in this case, or to referral to the Enlarged Board of Appeal (Article 112(1)(a) EPC), the admissibility of the appeal (Article 110 EPC), (non-)admission and consideration of claim requests, allegations of facts or evidence (Article 114, Rule 116(1) EPC), interruption of proceedings (Rule 142 EPC), exclusion of board members (Article 24(1) and (2) EPC), or the appointment of oral proceedings if expedient (Article 116(1) EPC).

28. The same applies to other procedural requests on questions that do not have to be taken up *ex officio* but only upon request, such as for a change of date of oral proceedings (Article 15(2) RPBA), acceleration of proceedings (Article 10(3) RPBA), objections against board members (Article 24(3) EPC) or according to Rule 106 EPC, or requests for stay of proceedings (Rule 14 EPC).

29. None of these procedural requests are subject to the provisions of Articles 12 and 13 RPBA 2020. They can therefore be made at any time during the appeal

proceedings and must be considered by the board, regardless of when they are made.

30. Consequently, the question of the late filing of the appellant's request for remittal, as raised by the respondents, cannot arise in this case or in other circumstances. Rather, the board must decide *ex officio* whether the case should be remitted, irrespective of any request of the parties.

31. In the exercise of its *ex officio* discretion in these appeal proceedings, the board does not see any reasons, let alone any "special reasons", in favour of a remittal. The only issues to be dealt with in these appeal proceedings were priority ("same invention") and inventive step (see points 1. to 18. above), i.e. the same issues that were dealt with in the appealed decision, and these could be answered directly by the board, in the interest of procedural economy, without prejudice to the rights of the parties to be heard (CLBA, V.A.9.2.1).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

L. Malécot-Grob T. Sommerfeld

Decision electronically authenticated