

Internal distribution code:

- (A) [-] Publication in OJ
- (B) [-] To Chairmen and Members
- (C) [-] To Chairmen
- (D) [X] No distribution

**Datasheet for the decision
of 27 October 2022**

Case Number: T 3002/19 - 3.3.04

Application Number: 12168565.5

Publication Number: 2559440

IPC: A61K39/395, C07K16/18,
G01N33/574, C07K16/30,
A61K49/00, G01N33/68, C07K16/28

Language of the proceedings: EN

Title of invention:

A microvesicle membrane protein and application thereof

Applicant:

Jiang, Ming-Chung

Headword:

Microvesicle membrane protein/JIANG

Relevant legal provisions:

RPBA 2020 Art. 13(1), 13(2)

Keyword:

Amendment after summons - exceptional circumstances (no) -
cogent reasons (no) - taken into account (no)
Amendment to appeal case - amendment gives rise to new
objections (yes)

Decisions cited:

T 0910/02, T 0663/10, T 1459/11, T 2486/16, T 2703/16



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 3002/19 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 27 October 2022

Appellant: Jiang, Ming-Chung
(Applicant) 2F., No. 5, Alley 31, Lane 61, Sec. 1
Guangfu Road
Sanzhong District
New Taipei City 241, Taiwan (TW)

Representative: Games, Robert Harland
Albright IP Limited
County House
Bayshill Road
Cheltenham, Glos. GL50 3BA (GB)

Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 12 August 2019
refusing European patent application
No. 12168565.5 pursuant to Article 97(2) EPC**

Composition of the Board:

Chair M. Pregetter
Members: A. Schmitt
M. Blasi

Summary of Facts and Submissions

- I. The applicant's (appellant's) appeal lies from the decision of the examining division to refuse European patent application No. 12 168 565.5 (application as filed), which was published as EP 2 559 440 A2. The title of the application is "*A microvesicle membrane protein and application thereof*".
- II. The examining division decided that the subject-matter of claim 1 of the sole claim request did not involve an inventive step (Article 56 EPC), and that the same applied to dependent claims 2 to 5.

Independent claim 1 of the claim request underlying the decision under appeal reads as follows:

"1. An *in vitro* method of determining the level of phosphorylated form of CSE1L but not non-phosphorylated CSE1L in biological fluid sample obtained from a subject, characterized in that, [*sic*] the method comprises a step of contacting the sample with an antibody capable of specifically binding a peptide defined by SEQ ID NO 3 [*sic*] or antibody capable of specifically binding phosphorylated CSE1L but not non-phosphorylated CSE1L defined by SEQ ID NO: 2".

- III. With letter dated 10 October 2019, comprising the notice and the statement of grounds of appeal, the appellant submitted sets of claims of a main request and auxiliary requests 1 to 3, and arguments *inter alia* to the effect that the claimed subject-matter involved an inventive step.

Independent claim 1 of the main request and each of auxiliary requests 1, 2 and 3 submitted with the statement of grounds of appeal read as follows:

"1. An *in vitro* method of assaying the level of phosphorylated form of CSE1L defined by SEQ ID NO: 2 but not non-phosphorylated CSE1L in biological fluid sample obtained from a subject, characterized in that, [*sic*] the method comprises a step of contacting the sample with an antibody capable of specifically binding phosphorylated CSE1L containing a sequence LTpEYpLKKTLDPDPA, where Tp denotes phosphothreonine and Yp denotes phosphotyrosine, or an antibody capable of specifically binding phosphorylated CSE1L but not non-phosphorylated CSE1L."

- IV. On 20 May 2021, the board summoned the appellant to oral proceedings as requested, and subsequently, on 7 February 2022, issued a communication pursuant to Article 15(1) RPBA 2020 ("the board's communication"), in which it, *inter alia*, expressed its view that the main request and auxiliary request 1 should be held inadmissible, that no basis was present in the application as filed for the assaying method of claim 1 of auxiliary request 2 using an antibody as defined in this claim, that the subject-matter of claim 1 of auxiliary request 2 lacked inventive step and that the same considerations on inventive step as for claim 1 of auxiliary request 2 applied to claim 1 of auxiliary request 3.
- V. Thereafter, the appellant, with a letter dated 18 May 2022, submitted sets of claims of a new main request and auxiliary requests 1 to 3, which replaced all previous claim requests on file; the appellant also submitted five documents and arguments on admittance

and allowability of the new claim requests. In the same letter, the board was informed that the appellant would not attend the oral proceedings scheduled for 2 June 2022.

Independent claim 1 of the main request submitted on 18 May 2022 reads as follows:

"1. An *in vitro* method of diagnosing the presence or progression of cancer by assaying the level of phosphorylated form of CSE1L defined by SEQ ID NO: 2 but not non-phosphorylated CSE1L in biological fluid sample obtained from a subject, characterized in that, [*sic*] the method comprises a step of contacting the sample with an antibody capable of specifically binding threonine phosphorylated CSE1L but not non-phosphorylated CSE1L."

Independent claim 1 of auxiliary request 1 submitted on 18 May 2022 is identical to claim 1 of the main request (see above).

Independent claim 1 of auxiliary request 2 submitted on 18 May 2022 reads as follows:

"1. An *in vitro* method of diagnosing the presence or progression of cancer by assaying the level of phosphorylated form of CSE1L defined by SEQ ID NO: 2 but not non-phosphorylated CSE1L (a) on the membrane of a microvesicle and free phosphorylated CSE1L in biological fluid sample obtained from a subject or (b) on the membrane of a microvesicle that is isolated from biological fluid sample obtained from a subject or (c) in free phosphorylated CSE1L in biological fluid sample obtained from a subject, characterized in that, [*sic*] the method comprises a step of contacting the

sample with an antibody capable of specifically binding threonine phosphorylated CSE1L but not non-phosphorylated CSE1L."

Independent claim 1 of auxiliary request 3 submitted on 18 May 2022 reads as follows:

"1. An *in vitro* method of diagnosing the presence or progression of cancer by assaying the level of phosphorylated form of CSE1L defined by SEQ ID NO: 2 but not non-phosphorylated CSE1L (a) on the membrane of a microvesicle and free phosphorylated CSE1L in biological fluid sample obtained from a subject or (b) on the membrane of a microvesicle that is isolated from biological fluid sample obtained from a subject, characterized in that, [*sic*] the method comprises a step of contacting the sample with an antibody capable of specifically binding threonine phosphorylated CSE1L but not non-phosphorylated CSE1L."

VI. The board cancelled the oral proceedings.

VII. The appellant's arguments relevant to the present decision are summarised as follows:

Admittance (Article 13(2) RPBA 2020)

The board should exercise its discretion to admit the new main request and auxiliary requests 1 to 3 into the appeal proceedings under Article 13 RPBA in view of Case Law of the Boards of Appeal ["Case Law"], 9th edition, 2019, points V.A.4.2, 4.3 and 4.5.1(a), 4.12.1, 4.12.2, 4.12.3 and 4.12.6, and because admitting these requests would streamline the appeal proceedings.

Moreover, the claim requests were submitted in response to the board's communication under Article 15(1) RPBA 2020 dated 7 February 2022. In particular, the main request and auxiliary request 1 were submitted in response to points 43 to 46 of the board's communication, which suggested that a limitation to a diagnostic method was relevant to inventive step of the claimed subject-matter. Auxiliary requests 2 and 3 were submitted in response to points 52 and 53 of the board's communication, which suggested that a limitation to detecting phosphorylated CSE1L on a microvesicle membrane was relevant to inventive step of the claimed subject-matter.

VIII. The appellant's requests relevant to the present decision, as understood by the board from the written submissions, were that the decision under appeal be set aside, that the sets of claims of the new main request and auxiliary requests 1 to 3, all submitted on 18 May 2022, be admitted into the appeal proceedings, and that a patent be granted on the basis of the set of claims of the new main request or one of the sets of claims of new auxiliary requests 1 to 3.

Reasons for the Decision

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

Procedural matters

2. By letter dated 18 May 2022, the board was informed that the appellant would not be attending the oral proceedings. If a party informs the board that it does not intend to attend the oral proceedings, the board is

not obliged to hold oral proceedings in the absence of that party. Rather, under these circumstances, it is within the discretion of the board to decide whether the scheduled oral proceedings are maintained or cancelled (see e.g. decision T 663/10, Reasons 1.3 and decision T 910/02, Reasons 6).

3. In deciding not to attend the oral proceedings, the appellant chose not to make use of the opportunity to make oral submissions in these proceedings, but instead chose to rely on the arguments submitted in writing. Under such circumstances, it is not appropriate to hold oral proceedings since the board is in a position to reach a decision, including a decision on admittance of amended claim requests, which respects the party's right to be heard (Article 113(1) EPC) based only on the party's written submissions. The board therefore decided to cancel the oral proceedings. In accordance with Article 15(3) RPBA 2020, the appellant was treated as relying on its written case.

Admittance (Article 13(1) and (2) RPBA 2020)

4. In the case at hand, the summons to oral proceedings was notified after 1 January 2020, and the sets of claims of the main request and auxiliary requests 1 to 3 were submitted after notification of said summons. Pursuant to Article 24 and Article 25(1), (3) RPBA 2020, admittance of these claim requests is therefore subject to the provisions set out in Article 13(2) RPBA 2020.
5. Consequently, the sections of Case Law cited by the appellant in support of the arguments that the board should exercise its discretion to admit the new claim requests into the proceedings (see section VII.) are not relevant to the case at hand since they concern

Article 13 RPBA 2007. Moreover, the appellant only generally referred to these sections in the Case Law without pointing out why they were cited, i.e. did not submit any specific arguments in this respect to which the board could respond.

6. Under Article 13(2) RPBA 2020, in cases where a communication under Rule 100(2) EPC is not issued, any amendment to a party's appeal case made after notification of a summons to oral proceedings shall, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

Amendment to the party's appeal case

7. Independent claim 1 of the set of claims considered by the examining division related to a method of determining the level of the phosphorylated form of CSE1L but not non-phosphorylated CSE1L in biological fluid sample obtained from a subject (see section II.). The same was true for independent claim 1 of each of the sets of claims of the main request and auxiliary requests 1 to 3 submitted with the statement of grounds of appeal (see section V.). In contrast, independent claim 1 of the main request and each of auxiliary requests 1 to 3 submitted on 18 May 2022 relate to a method of diagnosing the presence or progression of cancer, i.e. relate to different subject-matter. Therefore these claim requests amount to an amendment of the appeal case and are therefore only to be taken into account, i.e. admitted into the proceedings, if there are exceptional circumstances justified with cogent reasons by the party concerned (see point 6. above).

Exceptional circumstances

8. It has been established in the case law of the boards of appeal that "exceptional circumstances" within the meaning of Article 13(2) RPBA 2020 concern new or unforeseen developments in the appeal proceedings, such as, for example, new objections raised by the board in its communication under Article 15(1) RPBA 2020 (see Case Law, 10th edition, 2022, V.A.4.5.4 a), second paragraph and the decisions cited there).
9. In the case at hand, the board cannot recognise any new or unforeseen developments in the appeal proceedings which might justify the new main request and auxiliary requests 1 to 3 being filed this late in the appeal proceedings. The appellant argued that the submission of the new sets of claims was justified by the board's communication dated 7 February 2022, which, according to the appellant, in points 43 to 46 and 52 to 53, expressed limitations of the claimed subject-matter relevant to inventive step.
10. However, in line with the primary object of appeal proceedings to review the decision under appeal in a judicial manner (Article 12(2) RPBA 2020), a board's communication under Article 15(1) RPBA 2020 is not an invitation to file additional submissions (see e.g. T 1459/11, Reasons 3.2 and T 2703/16, Reasons 3.5). Moreover, even if a board disagrees in its communication with the assessment of the examining division on some aspects of the decision, a disagreement as such does not qualify as exceptional circumstances which would justify amendments of a case being accepted under Article 13(2) RPBA 2020, in particular if the board reaches the same conclusion as

the examining division (see e.g. T 2486/16, Reasons 6.6.3).

11. In points 43 to 46 of its communication, the board responded to the appellant's argument that the gist of the invention was that the presence of phosphorylated CSE1L in cancer sera but not in sera from healthy subjects could increase the sensitivity and specificity of cancer diagnosis (summarised in point 42 of the board's communication). The board acknowledged that Examples 5 and 14 of the application as filed did indeed disclose that the levels of threonine phosphorylated CSE1L in the sera of cancer patients could be used as a cancer biomarker (point 43 of the board's communication). However, as explained in points 44 to 46 of the communication, this argument was not considered relevant to the claims under consideration since they did not concern diagnostic methods.
12. The board hence agreed with the examining division's finding that the claims under consideration concerned detection methods without being limited to the purpose of detecting cancer (see point 32 of the decision under appeal) and that no inventive step could be acknowledged for mere detection methods (see points 47 to 51 of the board's communication). Consequently, in points 43 to 46 of said communication, the board neither raised new objections nor disagreed with the examining division's decision on inventive step of the independent claim.
13. In point 53 of the board's communication, the board responded to a further argument submitted in the statement of grounds of appeal. As summarised in point 52 of the board's communication, the appellant

argued that it could not have been expected that phosphorylated CSE1L could be detected on the membrane of microvesicles. In response to this argument, the board indicated that while the appellant's argument might have some merit, this feature was only present in a dependent claim and therefore had no bearing on the finding of lack of inventive step of the independent claim (see point 53 of the board's communication). Therefore, in this part of its communication too, the board neither raised new objections nor disagreed with the examining division's decision on inventive step of the independent claim.

14. Consequently, the board's communication issued on 7 February 2022 did not contain any information which could have been interpreted as a new or unforeseen development in the appeal proceedings that might have justified the submission of amended claims. The board therefore could not identify any cogent reasons for submitting the new main request and auxiliary requests 1 to 3 only once it had issued the communication under Article 15(1) RPBA 2020 and shortly before the scheduled oral proceedings. Hence no exceptional circumstances pursuant to Article 13(2) RPBA 2020 presented themselves which might justify the admission of the new main request and auxiliary requests 1 to 3 into the appeal proceedings.

Additional consideration

15. Additionally, the board considered aspects set out in Article 13(1) RPBA 2020. According to this provision, the board shall exercise its discretion, in the case of an amendment to a patent application, in view of *inter alia* whether the party demonstrated that any such amendment did not give rise to new objections. This is

however not the case for the main request and auxiliary requests 1 to 3 submitted on 18 May 2022 because, in the board's opinion, at least claim 1 of each of these claim requests contains subject-matter that extends beyond the content of the application as filed within the meaning of Article 123(2) EPC.

16. In the letter dated 18 May 2022, the appellant indicated that "[s]upport for Main Request claims 1-5 may be found throughout the Original specification, including in paragraphs [0098] Example 5, [0070], [0087], [0104]-[0105] Example 7, [0108] Example 9, [0092] Example 4, [0093] Figure 4, [0110]-[0111] Example 10, [0112]-[0123] Examples 11-14, Table 2, and [0116] Figure 11" and that "[s]upport for all Auxiliary Request claims may be found throughout the Original specification, including in paragraphs [0098] Example 5, [0070], [0087], [0104]-[0105] Example 7, [0108] Example 9, [0092] Example 4, [0093] Figure 4, [0110]-[0111] Example 10, [0112]-[0123], Examples 11-14, Table 2, and [0116] Figure 11." (see page 5, second and third full paragraphs from the bottom).
17. The board was however unable to identify a basis in the application as filed for all the features of the claims of the main request and auxiliary requests 1 to 3. In particular, the board was unable to identify in these passages a basis for (a method using) "an antibody capable of specifically binding threonine phosphorylated CSE1L but not non-phosphorylated CSE1L" recited in claim 1 of the main request and each of auxiliary requests 1 to 3.
18. The appellant referred to, *inter alia*, Examples 4, 5, 7 and 9 to 14, Table 2 and Figures 4 and 11 of the application as filed. However, in Examples 4, 5, 7, 9,

10 and Figure 4, anti-phosphoserine/threonine antibodies, anti-phosphothreonine antibodies, anti-phosphotyrosine antibodies and/or an anti-CSE1L antibody are disclosed, but not "an antibody capable of specifically binding threonine phosphorylated CSE1L". In Examples 11 to 14, Table 2 and Figure 11, phosphorylated CSE1L is detected with an antibody raised against a peptide phosphorylated at a specific threonine and a specific tyrosine (see SEQ ID NO: 3 and paragraph [0066] of the application as filed). The disclosure of this specific antibody does however not provide a basis for any antibody "capable of specifically binding threonine phosphorylated CSE1L but not non-phosphorylated CSE1L". Furthermore, the board could not identify any disclosure of such an antibody, let alone a method for diagnosing the presence or progression of cancer using such an antibody, in any passage cited by the appellant (see point 16. above).

19. Consequently, claim 1 of the main request and each of auxiliary requests 1 to 3 contain subject-matter that extends beyond the content of the application as filed within the meaning of Article 123(2) EPC. Each of these claim requests therefore gives rise to new objections and is therefore *prima facie* not allowable.

Conclusion

20. In view of the above considerations the board decided not to admit the main request and auxiliary requests 1 to 3 into the proceedings, pursuant to Article 13(2) RPBA 2020.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chair:



I. Aperribay

M. Pregetter

Decision electronically authenticated