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**Datasheet for the decision  
of 9 October 2024**

**Case Number:** T 2276/22 - 3.3.07

**Application Number:** 17712274.4

**Publication Number:** 3419636

**IPC:** A61K35/50, A61L27/14, A61P17/02

**Language of the proceedings:** EN

**Title of invention:**  
DECELLULARIZED HUMAN AMNIOTIC FLUID PREPARATION HAVING LONG-  
TERM STABILITY

**Applicant:**  
MAM Holdings of West Florida, L.L.C.

**Headword:**  
DECELLULARIZED HUMAN AMNIOTIC FLUID PREPARATION HAVING LONG-  
TERM STABILITY/MAM Holdings of West Florida L.L.C.

**Relevant legal provisions:**  
EPC Art. 113(1), 111(1)  
EPC R. 103(1)(a)  
RPBA 2020 Art. 11

**Keyword:**

Substantial violation of procedure  
Reimbursement of the appeal fees  
Case remitted to the examining division

**Decisions cited:**

T 0186/02, T 0405/12, T 0305/14

**Catchword:**



**Beschwerdekammern**  
**Boards of Appeal**  
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Case Number: T 2276/22 - 3.3.07

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.07**  
**of 9 October 2024**

**Appellant:** MAM Holdings of West Florida, L.L.C.  
(Applicant) 1972 MacGregor Road  
Tarpon Springs, FL 34689 (US)

**Representative:** Potter Clarkson  
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**Decision under appeal:** **Decision of the Examining Division of the  
European Patent Office posted on 24 March 2022  
refusing European patent application No.  
17712274.4 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

**Chairman** E. Duval  
**Members:** D. Boulois  
S. Ruhwinkel

## **Summary of Facts and Submissions**

- I. The appeal lies from the decision of the examining division to refuse European patent application n° 17 712 274.4. The decision was based on:
- the new main request, new auxiliary request 1 and new auxiliary request 2, each filed during the oral proceedings before the examining division on 10 February 2022,
  - the new auxiliary request AR3A filed during the oral proceedings,
  - auxiliary requests 3-9 (corresponding to the main request and auxiliary requests 1, 2 and 4-7 filed on 20 December 2021),
  - the new auxiliary request 7 filed with the letter of 8 February 2022.
- II. The documents cited during the examination proceedings included the following:
- D1: US 2015/025366 A1  
D2: Naci Karaçal M.D. et al: "Effect of Amniotic Fluid on Peri-implant Capsular Formation", Aesthetic Plastic Surgery, Springer-Verlag, NE, Vol. 29, no. 3, 1 June 2005, pages 174-180, XP019364356  
D3: WO 2015/195506 A1  
D4: WO 2006/091546 A2
- III. According to the decision under appeal, the main request filed during oral proceedings did not comply with the requirements of Article 123(2) EPC.
- Auxiliary request 1 filed during oral proceedings was considered to meet the requirements of Article 123(2) EPC and was novel over D1, D3 and D4. Auxiliary request

1 was however not inventive over D4 as the closest prior art.

Auxiliary request 2 filed during oral proceedings was also found to be not inventive over D4.

Auxiliary requests 3 to 5 (submitted as main request and auxiliary requests 1, 2 on the 20 December 2021) did not meet the requirements of Article 123(2) EPC.

Auxiliary requests 3-9 (submitted as main request and auxiliary requests 1, 2, 4-7 on the 20 December 2021) did not meet the requirements of Article 56 EPC.

Neither the auxiliary request AR3A filed during the oral proceedings nor the new auxiliary request 7 filed on 8 February 2022 were admitted into the proceedings.

- IV. The patent applicant (hereinafter the appellant), filed an appeal against the decision. It filed the following requests with its statement of grounds of appeal:
- the main request, corresponding to auxiliary request 1 filed during the oral proceedings;
  - auxiliary requests 1-29.

- V. The appellant's written arguments can be summarised as follows:

The appellant disagreed with the selection of D4 as the closest prior art and considered that it was D1.

Moreover, the appellant mentioned *inter alia* that, prior to the oral proceedings, the examining division's (ED's) comments on inventive step had been rather brief, and at no point had D4 been identified by the ED as the closest prior art. Prior to the oral

proceedings, the applicant had not been made aware of the particular technical issues upon which the ED's finding of lack of inventive step was predicated, in particular when starting from D4 as the closest prior art.

At the oral proceedings, the claims of auxiliary request 1 (corresponding to the main request in appeal) were admitted, and found to satisfy the requirements of Articles 123(2) and 54 EPC. However, the claims were considered to lack an inventive step, taking D4 as the closest prior art. Up to that point in proceedings, the ED had not previously acknowledged the novelty of the claimed subject matter, and issues of novelty had been the primary focus. Moreover, the specific technical issues upon which the ED's decision was based, in deciding at the oral proceedings to refuse auxiliary request 1 for lack of an inventive step when taking D4 as the closest prior art, had not been fully articulated to the applicant at an earlier stage.

Following the refusal of auxiliary request 1 at the oral proceedings, the ED was explicit that the applicant was to be given only a single further opportunity to present a subsequent auxiliary request. This was presented as auxiliary request 2 during the proceedings. The enclosed auxiliary requests were a legitimate attempt to address the issues of lack of inventive step upon which the ED's decision was based.

VI. A communication expressing the Board's preliminary opinion dated 2 August 2024 was sent to the applicant. In this communication, the Board considered *inter alia* that the decision under appeal was based on grounds on which the applicant had no opportunity to comment and that the decision was partially not

motivated. The Board envisaged to remit the case to the ED (Article 111(1), second sentence, EPC and Article 11 RPBA) and to reimburse the appeal fee (Rule 103(1)(a) EPC). The Board invited the appellant to react to this point, and, in case of agreement with the Board, informed the appellant that a decision on the case can be issued without holding an oral proceedings.

VII. With its letter dated 8 August 2024, the appellant agreed with the Board's proposal to remit the case to the ED and to reimburse the appeal fee.

VIII. Requests

The appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the sets of claims filed as main request or alternatively auxiliary requests 1-29 with letter of 1 August 2022.

## **Reasons for the Decision**

1. Overview of the examination proceedings

1.1 In the international preliminary report on patentability (IPRP) dated 30 May 2018 and 6 September 2018, documents D1-D4 were identified, while in the context of inventive step, only D1 was specifically mentioned.

1.2 The communication of the examining division (ED) under Article 94(3) EPC, dated 6 April 2020, raised issues solely under Article 54 EPC over D1-D3 and Article 84 EPC. The communication did not mention D4 at all.

1.3 The applicant's response, dated 14 July 2020, addressed issues under Article 54 EPC over documents D1-D3, as well as under Article 84 EPC.

1.4 A summons to oral proceedings before the ED was issued on 9 July 2021, focussing primarily on an objection of lack of novelty pursuant to Art 54 EPC over D1, dealing only very briefly and generally with inventive step in Section 1.3 thereof: *"It is finally noted, in case the composition of claim 1 is rendered novel by showing that the product of the present invention differs from the ones of the prior art, an inventive step is presently not acknowledged. Even when considering the storage at 2-8°C it is at present not seen which advantages could be derived from the product obtained. The two examples given by the invention concern the process for preparing sterile filtered amniotic fluid but do not show any advantage for the product per se or in terms of its medical applications."*

Only D1 was mentioned in the summons and D4 was not mentioned.

1.5 The patent applicant replied to the summons on 20 December 2012 in particular by filing new auxiliary requests, and addressing the issues raised on novelty and inventive step.

1.6 During a telephone consultation between the primary examiner and the patent applicant on 2 February 2022 (as reported in the EPO communication of 4 February 2022), issues of Articles 123(2) EPC and 54 EPC were primarily discussed, and those issues maintained. D1 remained as the primary reference and was the only document discussed in the context of novelty. Inventive



step was also discussed as reported: *"All objections raised during the summons and concerning inventive step are not overcome (Art. 56 EPC). In particular D1 ([041]-[042]), D3 (page 8 [021]) and D4 (page 10 l. 11-15) were shortly discussed as well as figure 1 of the originally filed application was briefly discussed"*.

1.7 With a letter dated 8 February 2022, the patent applicant filed auxiliary requests 3-7. The letter addressed issues pursuant Article 123(2) EPC as well as novelty and inventive step over D1.

1.8 During a second telephone consultation between the primary examiner and the patent applicant on 9 February 2022 (as reported in the EPO communication of 16 February 2022), the day before the appointed oral proceedings, the applicant's representative was informed that *"none of the requests on file appeared to comply with the EPC"*.

1.9 At the oral proceedings, the claims of auxiliary request 1, corresponding to the main request on file in the appeal proceedings, were admitted, and found to satisfy the requirements of Articles 123(2) and 54 EPC over D1, D3 and D4. However, the claims were considered to lack an inventive step. The new auxiliary request 2 was also found to lack inventive step, while the chair announced also that the ED was of the opinion that auxiliary requests 3 to 9 also did not fulfil the requirements of Articles 123(2) and 56 EPC.

In the minutes of the oral proceedings, only document D1 has been mentioned as having been discussed as closest prior art in combination with D4 (see points 9.1 and 9.2 of the minutes).

1.10 The decision of the ED mentioned that the patent applicant used D1 as closest prior art with regard to the assessment of inventive step of the auxiliary request 1 (corresponding to the main request in the appeal proceedings), but that the ED considered that D4 was more appropriate as closest state of the art; hence, the ED made a problem-solution approach starting from D4 in its decision (see point 15.3 of the decision). The ED concluded that the claimed subject-matter was not inventive over D4 combined with D1.

The same conclusion applied to auxiliary request 2 filed during the oral proceedings when starting from D4 which was preferred over D1 as closest state of the art (cf. point 16 of the decision).

Auxiliary requests 3 to 9 were neither considered to meet the requirements of Article 56 EPC. The ED argued that same reasons discussed above apply *mutatis mutandis* but did not add any further argument or comment (see point 18.1 of the decision).

## 2. Substantial procedural violation

2.1 In the present case, the Board notes that D4 had never been cited as possible closest prior art for the assessment of inventive step by the ED in the written proceedings. There is no further trace of a possible discussion on this point during the telephonic consultations or during the oral proceedings before the ED, even less on a complete problem-solution approach based on D4 as closest state of the art.

There is neither any trace of a problem-solution approach over any document in any of the communication

dated 6 April 2020 or 9 July 2021, even less in the minutes of the telephonic consultations.

Consequently, an assessment on inventive step on the subject-matter of auxiliary request 1, corresponding to the main request on file in the appeal proceedings, over D4 and accompanied by a problem-solution approach appears for the first time in the decision of the ED. The same conclusion applies for auxiliary requests 2-9.

Moreover, with regard to auxiliary requests 3-9, the decision of the ED simply mentions the following:

*"These request are considered not to meet the requirements of Art. 56 EPC. The same reasons discussed above under item 14.3 and 15 apply mutatis mutandis".*

The decision does however not explain why the amendments carried out in these auxiliary requests should have no incidence with regard to the assessment of inventive step.

2.2 Even though the appellant has not challenged the ED's decision on the grounds of a substantial procedural violation, the Board is entitled to examine whether or not any such violation occurred during the examination proceedings (see for instance decision T 405/12, point 3 of the Reasons; CLB, *ibid.*, III.B.2.1.). The Board considers in particular it inappropriate to start an examination on facts and requests which have never been discussed during the examination phase and which constitute a new case in the appeal proceedings, in particular in view of the large number of requests.

2.3 Under Article 113(1) EPC the decisions of the European Patent Office may only be based on grounds or evidence on which the parties concerned have had an opportunity to present their comments.

In the context of the examining procedure, Article 113(1) EPC is intended to ensure that before a decision refusing the application is issued, the applicant has been clearly informed of the essential legal and factual reasons on which the finding of non-compliance with the requirements of the EPC is based, so that he knows in advance the reasons as to why the application may be refused and has the opportunity to comment on this reasoning. According to the established case law of the Boards of Appeal, the term "grounds or evidence" in Article 113(1) EPC should not be narrowly interpreted, so that the word "grounds" does not refer merely to a ground of objection to the application in the narrow sense of a requirement of the EPC, but refers to the essential reasoning, both legal and factual, which leads to the refusal of the application (see for instance T 186/02, point 2.5 of the Reasons; T 305/14, point 2.3 of the Reasons; Case Law of the Boards of Appeal (CLB), 10th edition, July 2022, III.B. 2.3.2.). Although it is not required to provide the parties in advance with all foreseeable arguments in favour of or against a request (see CLB, *ibid.*, III.B. 2.3.1.), in the present case the assessment of inventive step starting from D4 as closest prior art constitutes a fundamental reason for the decision under appeal and represents therefore a "ground" under Article 113(1) EPC.

Since an assessment on inventive step over D4 accompanied by a problem-solution approach appears as an essential point of the decision that was presented for the first time in the decision of the ED, and since that has never been mentioned or discussed in any step of the examination proceedings, it results that the

applicant's right to be heard enshrined in Article 113(1) EPC has been infringed.

- 2.4 The Board also considers that the decision under appeal was insufficiently reasoned in the sense of Rule 111(2) EPC, which constitutes a further fundamental procedural deficiency (see CLB, *ibid.*, V.A.9.4.4.b)). Pursuant to Rule 111(2), first sentence, EPC, decisions which may be appealed must be reasoned. According to established case law, a decision must set out the essential factual and legal considerations justifying the decision taken in a logical chain of reasoning. Furthermore, the conclusions drawn from the facts and evidence must be clearly set out. The reasoning should enable the parties and, in the case of an appeal the Board, to understand whether the decision is justified or not (see CLB, *ibid.*, III.K.3.4.1).

This is not the case here, as explained above, since the decision does not explain why the substantial amendments carried out in auxiliary requests 3-9 should have no incidence with regard to the assessment of inventive step.

- 2.5 For the reimbursement of the appeal fee to be equitable (see Rule 103(1)(a) EPC), there has to be not only a substantial procedural violation but also a causal link between this procedural violation and the necessity to file the appeal. In this case, there is such causal link since the appeal is based on a request which was refused for lack of inventive step.

Consequently, the Board decides to remit the case to the ED (Article 111(1), second sentence, EPC and Article 11 RPBA) and to reimburse the appeal fee (Rule 103(1)(a) EPC).

## 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.
3. The appeal fee is reimbursed.

The Registrar:

The Chairman:



A. Vottner

E. Duval

Decision electronically authenticated