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**Datasheet for the decision  
of 18 January 2016**

**Case Number:** T 1743/11 - 3.3.02

**Application Number:** 03711758.7

**Publication Number:** 1495108

**IPC:** C12M3/04

**Language of the proceedings:** EN

**Title of invention:**

AUTOMATED TISSUE ENGINEERING SYSTEM

**Applicant:**

Octane Biotech Inc.

**Headword:**

Automated tissue engineering system/OCTANE

**Relevant legal provisions:**

EPC Art. 123(2)

RPBA Art. 13

**Keyword:**

Amendments - added subject-matter (yes)

Late-filed auxiliary requests - admitted (no)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**  
**Boards of Appeal**  
**Chambres de recours**

European Patent  
Office  
D-80298 MUNICH  
GERMANY  
Tel. +49 (0) 89 2399-0  
Fax +49 (0) 89  
2399-4465

Case Number: T 1743/11 - 3.3.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.02**  
**of 18 January 2016**

**Appellant:** Octane Biotech Inc.  
(Applicant) 640 Cataragui Woods Drive  
Kingston, ON K7P 2Y5 (CA)

**Representative:** Brady, Paul Andrew  
Abel & Imray  
20 Red Lion Street  
London WC1R 4PQ (GB)

**Decision under appeal:** **Decision of the Examining Division of the  
European Patent Office posted on 23 February  
2011 refusing European patent application No.  
03711758.7 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

**Chairman** U. Oswald  
**Members:** K. Giebeler  
L. Bühler

## Summary of Facts and Submissions

- I. European patent application No. 03 711 758.7, entitled "Automated Tissue Engineering System" and published as WO 03/087292 (hereafter referred to as "the application as filed"), was filed with 137 claims.

Claims 1 and 26 of the application as filed read as follows:

"1. An automated tissue engineering system comprising; - a housing;  
- at least one bioreactor supported by said housing, said bioreactor facilitating physiological cellular functions and/or the generation of one or more tissue constructs from cell and/or tissue sources;  
- a fluid containment system supported by said housing and in fluid communication with said bioreactor,  
- one or more sensors associated with one or more of said housing, bioreactor or fluid containment system for monitoring parameters related to said physiological cellular functions and/or generation of tissue constructs; and  
- a microprocessor linked to one or more of said sensors."

"26. An automated tissue engineering system comprising;  
- a housing;  
- at least one tissue engineering module removably accommodated within said housing, said tissue engineering module comprising a support structure that holds at least one bioreactor, said bioreactor facilitating cell culture and/or tissue engineering functions, a fluid containment system in fluid communication with said bioreactor, and one or more

sensors for monitoring parameters related to said cell culture and/or tissue engineering functions; and  
- a microprocessor disposed in said housing and linked to said tissue engineering module, said microprocessor controlling the operation of said tissue engineering module."

- II. The examining division refused the application under Article 97(2) EPC and held that the claims of the main and first auxiliary requests did not comply with Articles 123(2) EPC, and that the second and third auxiliary requests were not allowable under Articles 54 and 56 EPC.

During the examination proceedings, objections under Article 123(2) EPC had been raised by the examining division in a communication dated 30 November 2006, the record of a telephone conversation dated 8 May 2008, and in the summons to oral proceedings dated 24 September 2010. The applicant had filed amended claims with letters dated 26 September 2007, 1 December 2008 and 8 November 2010, and during the oral proceedings before the examining division on 8 December 2010.

- III. The applicant (appellant) filed an appeal against this decision. With the statement of grounds of appeal of 5 July 2011, the appellant filed a new main request and a new first auxiliary request.

Claim 1 of the **main request** reads:

"An automated tissue engineering system (100) which enables cell proliferation, cell differentiation and tissue formation, comprising;  
- a housing (102);

- at least one bioreactor (202) supported by said housing, said bioreactor facilitating physiological cellular functions and/or the generation of one or more tissue constructs from cell and/or tissue sources;
  - a fluid containment system (206) supported by said housing and in fluid communication with said bioreactor,
  - one or more sensors (132, 134) associated with said bioreactor for monitoring parameters related to said physiological cellular functions and/or generation of tissue constructs including changes in environmental conditions and the status of cell proliferation by detection of metabolic turnover as a function of time;
- and
- a microprocessor (128) which controls and customises the internal environment of the bioreactor and which is linked to one or more of said sensors, said sensors providing feedback to said microprocessor."

Claim 1 of the **first auxiliary request** reads:

"An automated tissue engineering system (100) which enables cell proliferation, cell differentiation and tissue formation, comprising;

- a housing (102);
- at least one bioreactor (202) supported by said housing, said bioreactor facilitating physiological cellular functions and/or the generation of one or more tissue constructs from cell and/or tissue sources;
- a fluid containment system (206) supported by said housing and in fluid communication with said bioreactor,
- one or more sensors (132, 134) associated with said bioreactor for monitoring physiological cellular functions; and
- a microprocessor (128) which controls and customises the internal environment of the bioreactor and which is

linked to one or more of said sensors, said sensors providing feedback to said microprocessor."

- IV. On 25 August 2015, the board summoned the appellant to oral proceedings. In an annex accompanying the summons pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) and expressing its preliminary opinion, the board explained in detail why neither of the sets of claims on file met the requirements of Article 123(2) EPC.
- V. With letter dated 16 December 2015, the appellant responded to the board's communication and filed a second auxiliary request.

Claim 1 of the **second auxiliary request** reads:

"An automated tissue engineering system (100) which enables cell proliferation, cell differentiation and tissue formation, comprising;

- a housing (102);
- at least one bioreactor (202) supported by said housing, said bioreactor facilitating physiological cellular functions and/or the generation of one or more tissue constructs from cell and/or tissue sources;
- a fluid containment system (206) supported by said housing and in fluid communication with said bioreactor,
- one or more sensors (132, 134) associated with said bioreactor for monitoring parameters related to said physiological cellular functions and/or generation of tissue constructs; and
- a microprocessor (128) which controls and customises the internal environment of the bioreactor and which is linked to one or more of said sensors, said sensors providing feedback to said microprocessor."

VI. During the oral proceedings before the board held on 18 January 2016, the appellant filed an amended claim 1 as a third auxiliary request and an amended claim 1 as a fourth auxiliary request.

Claim 1 of the **third auxiliary request** reads:

"An automated tissue engineering system (100) which enables cell proliferation, cell differentiation and tissue formation, comprising;

- a portable sterile tissue engineering module (118) having one or more bioreactors (202) facilitating physiological cellular functions and/or the generation of one or more tissue constructs from cell and/or tissue sources;
- said one or more bioreactors operatively connected with a media flow and reservoir system (206) in fluid communication with said one or more bioreactors;
- sensors (132, 134) within or on said one or more bioreactors for monitoring parameters related to said physiological cellular functions and/or generation of tissue constructs including changes in environmental conditions and the status of cell proliferation by detection of metabolic turnover as a function of time;

and

- a microprocessor (128) which controls and customises the internal environment of the bioreactor and which is linked to one or more of said sensors, said sensors providing feedback to said microprocessor."

Claim 1 of the **fourth auxiliary request** reads:

"An automated tissue engineering system (100) comprising;

- a housing (102);



- at least one tissue engineering module (118) removably accommodated within said housing, said tissue engineering module comprising a support structure that holds at least one bioreactor, said bioreactor facilitating cell culture and/or tissue engineering functions, a fluid containment system (206) in fluid communication with said bioreactor, and one or more sensors (132, 134) for monitoring parameters related to said cell culture and/or tissue engineering functions; and

- a microprocessor (128) disposed in said housing and linked to said tissue engineering module, said microprocessor controlling the operation of said tissue engineering module,

wherein said microprocessor controls and customises the internal environment of the bioreactor and which is linked to one or more of said sensors, said sensors providing feedback to said microprocessor."

VII. The appellant's arguments, as far as they are relevant for the present decision, can be summarised as follows:

The claims of the main request and the first and second auxiliary requests met the requirements of Article 123(2) EPC, because the combination of features stated therein was directly and unambiguously derivable from the application as filed. In particular, the features in claim 1 concerning the microprocessor were disclosed on page 23, lines 3-8 of the application as filed. It had no significance that said passage referred to sensors "within" the bioreactor, since page 5, lines 1-6 of the application as filed referred to sensors "associated" with the bioreactor, as in claim 1. Both options were thus disclosed in the application as filed and could be used interchangeably. Additionally, page 27, line 11 and page 28, line 15 referred to sensors present "on" the

bioreactor. In the automated tissue engineering system according to the invention, it was the inherent purpose of the sensor(s), within or associated with the bioreactor, to feed information to the microprocessor, allowing the microprocessor to customise and control the functioning of the bioreactor.

The third and fourth auxiliary requests, although late-filed, should be admitted into the proceedings because they addressed the board's objections under Article 123(2) EPC. These requests had not been filed prior to the oral proceedings in order to avoid unnecessary requests, as indicated in the letter of 16 December 2015. Claim 1 of the third auxiliary request was an attempt to avoid any undisclosed combination of features and was based on the passages from page 5, line 7 to page 6, line 4 and page 23, lines 3-8 of the application as filed, both passages concerning the same embodiment. Furthermore, page 27, line 11 and page 28, line 15 of the application as filed also concerned the modular embodiment and provided a basis for sensors being present "on" the bioreactor. The amendments were thus not complex, did not raise any new issues or extend the discussion. Claim 1 of the fourth auxiliary request was based on original claim 26 and on page 23, lines 3-8 of the application as filed. It was thus clearly allowable under Article 123(2) EPC and did not raise any new issues.

#### VIII. Final requests

The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 to 29 of the main request or, alternatively, of the first auxiliary request, both filed with the statement of the grounds of appeal, or, alternatively,

on the basis of claim 1 of the second auxiliary request, filed with letter of 16 December 2015, and claims 2 to 29 filed with the statement of the grounds of appeal, or, alternatively, on the basis of the third or fourth auxiliary request filed during the oral proceedings of 18 January 2016.

## **Reasons for the Decision**

1. The appeal is admissible.

### **2. *Main request - Article 123(2) EPC***

2.1 Article 123(2) EPC stipulates that a European patent may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed.

In accordance with established case law of the boards of appeal, the relevant question to be decided in assessing Article 123(2) EPC is whether the skilled person would derive the subject-matter as amended directly and unambiguously from the application as filed, meaning that the amendments must not result in the introduction of technical information which a skilled person would not have objectively derived from the application as filed. Moreover, the content of a document as originally filed may not be seen as a reservoir of features from which features pertaining to separate embodiments can be combined in order to artificially create a particular embodiment.

2.2 Claim 1 of the application as filed concerns an automated tissue engineering system comprising a

housing, at least one bioreactor, a fluid containment system, one or more sensors, and a microprocessor. The "one or more sensors" are "associated with one or more of said housing, bioreactor or fluid containment system for monitoring parameters related to said physiological cellular functions and/or generation of tissue constructs", and the microprocessor is "linked to one or more of said sensors."

Claim 1 of the main request differs from claim 1 as filed *inter alia* in that it refers to a microprocessor "which controls and customises the internal environment of the bioreactor and which is linked to one or more of said sensors, said sensors providing feedback to said microprocessor".

- 2.3 The appellant submitted that said amendment was based on page 23, lines 3-8 of the application as filed. Said passage is part of a larger passage starting on page 22, line 26 relating to the tissue engineering system as illustrated in Figure 1, which comprises a tissue engineering module. It is stated that a "microprocessor is present within the tissue engineering system and controls and customizes the internal environment of the bioreactor" and that "sensors **within** the bioreactor provide feedback to the microprocessor" (emphasis added by the board).

Said passage thus relates to an embodiment in which the automated tissue engineering system has sensors **within** the bioreactor, which sensors provide feedback to the microprocessor; it does not disclose an automated tissue engineering system wherein sensors **associated** with the bioreactor provide feedback to the microprocessor, as required by claim 1 of the main request.

2.4 The appellant further submitted that page 5, lines 1-6 of the application as filed disclosed sensors associated with the bioreactor. Said passage states that "Associated with the housing and/or the bioreactor are sensors that monitor physiological **parameters of fluid provided in the fluid containment system**" (emphasis added by the board). Thus the sensors referred to in said passage, which are associated with the housing and/or the bioreactor, are not required to monitor **parameters related to the physiological cellular functions and/or generation of tissue constructs**, as required by claim 1 of the main request, but instead monitor parameters of fluid provided in the fluid containment system.

2.5 The board thus considers that it cannot be directly and unambiguously derived from said passages cited by the appellant, taken alone or in combination, that sensors which are not within the bioreactor, but merely associated therewith, and which monitor parameters related to the physiological cellular functions and/or generation of tissue constructs, provide feedback to a microprocessor. Therefore, the board cannot follow the appellant's argument that the terms "within" and "associated" could be used interchangeably with respect to the claimed system.

Moreover, the passages on page 27, line 11 and page 28, line 15 of the application as filed refer to sensors present **"on"** the bioreactor, which cannot thus provide a basis for the more general term **"associated"** used in claim 1.

2.6 The appellant has furthermore submitted that the claimed subject-matter was disclosed in the application as filed, because it made no difference for the

microprocessor where the sensors were located with respect to the bioreactor, and the inherent purpose of the sensors of the automated tissue engineering system as disclosed in the application as filed was to feed information to the microprocessor.

The board cannot follow this line of argument either, since the question to be considered in the context of Article 123(2) EPC is not what may be rendered obvious by the disclosure of the application as filed, but what is directly and unambiguously derivable therefrom. In the present case, the board is convinced that the claimed combination of features from separate embodiments of the application as filed is not directly and unambiguously derivable therefrom.

2.7 The board concludes that claim 1 of the main request does not meet the requirements of Article 123(2) EPC.

**3. *First auxiliary request - Article 123(2) EPC***

Claim 1 of this request concerns an automated tissue engineering system comprising *inter alia* one or more sensors associated with a bioreactor for monitoring physiological cellular functions, and a microprocessor which controls and customises the internal environment of the bioreactor and which is linked to one or more of said sensors, said sensors providing feedback to said microprocessor.

The reasons given above as to why claim 1 of the main request does not comply with Article 123(2) EPC apply *mutatis mutandis* to claim 1 of the first auxiliary request. Consequently, the first auxiliary request does not meet the requirements of Article 123(2) EPC.

**4. Second auxiliary request - Article 123(2) EPC**

Claim 1 of this request concerns an automated tissue engineering system comprising *inter alia* one or more sensors associated with a bioreactor for monitoring parameters related to physiological cellular functions and/or generation of tissue constructs, and a microprocessor which controls and customises the internal environment of the bioreactor and which is linked to one or more of said sensors, said sensors providing feedback to said microprocessor.

Claim 1 of the second auxiliary request does not meet the requirements of Article 123(2) EPC for the same reasons as set out in detail above for claim 1 of the main request.

**5. Third and fourth auxiliary requests - Admission**

- 5.1 These requests were filed only at the oral proceedings before the board as attempts to overcome the board's objections under Article 123(2) EPC.
- 5.2 Under Article 13(1) RPBA, such late-filed requests are considered amendments to a party's case and admissible only at the board's discretion. Said discretion is to be exercised in view of *inter alia* the complexity of the new subject matter submitted, the current state of the proceedings and the need for procedural economy.
- 5.3 The board notes that the objections that the third and fourth auxiliary requests attempt to overcome were raised by the board in its communication accompanying the summons to oral proceedings, which was issued already in August 2015. Thus, said requests could and should have been filed with the reply to the board's

communication raising these objections for the first time. With letter of 16 December 2015, the appellant filed the second auxiliary request and stated that it "requested that the Board should engage in a dialogue with the Appellant at the Oral Proceedings, and exercise its discretion to allow the Appellant to propose additional Auxiliary Requests should the Board maintain any of its objections under Art. 123(2) EPC." Hence, in spite of being aware of the board's objections under Article 123(2) EPC more than four months before the oral proceedings, the appellant chose not to file amended claims attempting to overcome these objections in order to set out its case and determine the framework for discussion at the oral proceedings in good time.

Therefore, the board holds that there was no procedural justification for filing these requests at such a late stage of the proceedings.

- 5.4 Claim 1 of the third auxiliary request concerns an automated tissue engineering system which differs from that of claims 1 of the main and first and second auxiliary requests *inter alia* in that it does not comprise a housing and a fluid containment system supported by said housing, in that it comprises a portable, sterile tissue engineering module having one or more bioreactors, and in that it comprises sensors within or on said one or more bioreactors.

In comparison to claim 1 of the higher-ranking requests, claim 1 of the third auxiliary request thus entails considerable amendments, including deletions of features and insertions of features based exclusively on the description (page 5, lines 7-30; page 27, line 11; page 28, line 15). The claim thus recites only part of the features of claim 1 of the higher-ranking requests



and is shifted to a different group of features, resulting in diverging subject-matter.

Moreover, the amendments raise new issues with respect to Article 123(2) EPC, in particular whether the combination of the features of the embodiment on page 5, lines 7-30 of the application as filed with the feature of positioning the sensors **on** the bioreactor from page 27, line 11 and page 28, line 15, and the deletion of features from original claim 1, are directly and unambiguously derivable from the application as filed.

- 5.5 Claim 1 of the fourth auxiliary request is not based on original claim 1, but represents a combination of original independent claim 26 with features from page 23, lines 3-8 of the application as filed. This claim thus concerns subject-matter which diverges from that of the main and first and second auxiliary requests even more than the subject-matter of the third auxiliary request does.

Moreover, the claim raises a new issue with respect to Article 123(2) EPC, i.e. the question whether the combination of the features of the embodiment of original claim 26 with those from page 23, lines 3-8 is directly and unambiguously derivable from the application as filed.

- 5.6 For the above reasons, the board made use of its discretionary power under Article 13 RPBA and decided not to admit the third and fourth auxiliary requests into the proceedings.

**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:



N. Maslin

U. Oswald

Decision electronically authenticated