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**Datasheet for the decision  
of 28 November 2008**

**Case Number:** W 0030/08 - 3.3.08

**Application Number:** PCT/DK 2007/000291

**Publication Number:** WO 2007/144001

**IPC:** C12N 5/06

**Language of the proceedings:** EN

**Title of invention:**

Embryo quality assessment based on blastomere division and movement

**Applicant:**

UNISENSE FERTILITECH A/S

**Opponent:**

-

**Headword:**

Embryo quality/UNISENSE FERTILITECH

**Relevant legal provisions:**

PCT Art. 17(3) (a)  
PCT R. 13.1, 13.2, 13.3  
PCT R. 40.1, 40.2(c)

**Relevant legal provisions (EPC 1973):**

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**Keyword:**

"Protest partially admissible"

**Decisions cited:**

W 0006/90, G 0001/89, W 0037/04, W 0016/08

**Catchword:**

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**Case Number:** W 0030/08 - 3.3.08

**International Application No.** PCT/DK 2007/000291

**D E C I S I O N**  
**of the Technical Board of Appeal 3.3.08**  
**of 28 November 2008**

**Applicant:** Unisense Fertilitech A/S  
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**Decision under appeal:** Protest according to Rule 40.2(c) of the Patent Cooperation Treaty made by the applicants against the invitation (payment of additional fees) of the European Patent Office (International Searching Authority) dated 11 December 2007.

**Composition of the Board:**

**Chairman:** L. Galligani  
**Members:** F. Davison-Brunel  
T. Bokor

## Summary of Facts and Submissions

I. International patent application PCT/DK2007/000291 (published as WO 2007/144001) was filed on 15 June 2007 with 14 claims of which claims 1, 6 and 13 read as follows:

"1. A method for determining embryo quality comprising monitoring the embryo for a time period, said time period having a length sufficient to comprise at least one cell division period and at least a part of an inter-division period, and determining the length of the at least one cell division period; and/or ii) determining the extent and/or spatial distribution of cellular or organelle movement during the cell division period; and/or iii) determining duration of an inter-division period; and/or iv) determining the extent and/or spacial distribution of cellular or organelle movement during the inter-division period thereby obtaining an embryo quality measure.

6. The method according to any of the preceding claims, wherein the period of cellular movement in at least two inter-division periods is determined.

13. A system for determining embryo quality comprising means for monitoring the embryo for a time period, said time period having a length sufficient to comprise at least one cell division period and at least a part of an inter-division period, said system further having means for determining the length of the at least one cell division period and/or determining the cellular movement during the inter-division period and/or determining length of time period of cellular movement

during an inter-division period and having means for determining an embryo quality measure based on the determinations in the cell-division period(s) and the inter-division period(s)."

Dependent claims 2 to 5, 7 to 12 defined further features of the methods in accordance with the preceding claims. Dependent claim 14 defined further features of the system of claim 13.

II. On 11 December 2007, the EPO acting in its capacity as the International Searching Authority (ISA) issued a reasoned invitation under Article 17(3) (a) PCT and Rule 40.1) PCT to pay two additional search fees, considering that the application contained three groups of different inventions.

III. In the invitation to pay additional fees, the ISA identified the three groups of inventions as follows:

1. Claims 1-3, 9-14 (all in part), 4-5 (entirely)  
Method for determining embryo quality by monitoring the length (time) of a cell cycle, cytokinesis or an inter-division period of the developing embryo.

2. Claims 1-3, 8-9, 11-14 (all in part), 7 (entirely)  
Method of determining embryo quality by monitoring the extent or spatial distribution of cellular or organelle movement during the cell cycle.

3. Claims 8, 10-14 (all in part), 6 (entirely)  
Method of determining embryo quality by monitoring the time period of cellular movement during an inter-division period for determining embryo quality.

IV. The reasons for the findings of non-unity were as follows:

"The alleged inventive concept of, and the problem to be solved by, the present application is the provision of a method and a system to facilitate the selection of optimal embryos to be implanted for in vitro fertilisation (IVF) based on the evaluation of kinetic cell biological parameters of embryonic development (p.2 ll.19-22 in the description). The concept is known from the prior art : Documents D1 to D4 (cf. abstracts) all disclose the monitoring of the length of cell cycles or the length of inter-division periods for the assessment of the developmental potential of embryos. No other technical features could be identified that form a technical relationship among each of the separate inventions claimed and which could be considered as a special technical feature within the meaning of Rule 13.2 PCT. Thus, the present application lacks unity a posteriori."

Documents D1 to D4 were thereafter identified as:

D1: Holm, P. et al., *Theriogenology*, Vol. 50, pages 1285 to 1299, 1998;

D2: Lequarre, A.S. et al., *Biology of Reproduction*, Vol. 69, pages 1707 to 1713, 2003;

D3: Grizart, B. et al., *J. of Reproduction and Fertility*, Vol. 101, pages 257 to 264, 1994;

D4: Gonzales, D.S. et al., J. of Reproduction and Fertility, Vol. 105, pages 1 to 8, 1995;

V. On 9 January 2008, the appellant (applicant) paid two additional search fees under protest according to Rule 40.2(c) PCT as well as the protest fee. It was requested that "the ISA withdraws the objection against lack of unity because of lack of sufficient reasoning since lack of unity a posteriori should be substantiated logically by taking note of all common features, and since the main invention as clearly put forth in the independent claims has neither been defined or been searched yet." The arguments presented in favour of unity of invention were as follows:

- No system claims had been included in the defined three groups of inventions.
- No reasoning had been provided as to why the claims had been divided in these three specific groups of inventions nor as to why group 1 of inventions had been chosen as the first group.
- The grouping of the inventions had no basis in the claim set but rather related to elements found in the description.
- It was not even clear whether the lack of unity objection had been raised on an a posteriori analysis of the novelty situation. If it was indeed so, then the case law was clear that the ISA should exercise restraint and in borderline cases preferably refrain from considering an application as not complying with the requirements

of unity of invention on the grounds of lack of novelty or inventive step.

- There was a common feature to all groups of inventions, namely that the monitoring should be carried out for a time period having a length sufficient to comprise at least one cell division period and at least a part of an interdivision period. This feature had not been taken into consideration in any of the three groups of inventions.

VI. On 17 April 2008, the ISA search report and its written opinion were sent to the appellant. On that same date, the Review Panel of the ISA confirmed the finding of lack of unity. The reasons given for justifying the invitation to pay additional fees were essentially the same as that given by the ISA. In answer to the appellant's arguments accompanying the payment under protest, the Review Panel remarked that the first group of inventions simply corresponded to the first invention mentioned in the claim request, that the claims relating to a system rather than a method had been properly allocated to the various groups of inventions and, furthermore, that the feature regarding the minimum time of monitoring (claim 1) had been duly considered as being a common feature to all groups of invention, yet not decisive for unity. The Review Panel also pointed out that the appellant itself had failed to identify special technical features which could justify unity between the different groups.

VII. No specific reply was submitted in respect of said finding by the Review Panel. In its letter dated

9 January 2008, the appellant had already requested "reimbursement of the additional search fee paid with the present protest."

## **Reasons for the decision**

### *Competence and admissibility*

1. The application in suit was filed on 15 June 2007. Therefore, the protest is subject to the provisions of the PCT as in force from 1 April 2006. The Boards of Appeal are responsible for deciding on protests relating to PCT applications pending at the time of entry into force of the EPC 2000. Details of the procedure are guided by the Decision of the President of the EPO dated 24 June 2007, Article 3 (OJ EPO 2007, Special edition No. 3, 140); see also W 16/08, points 1.1-1.5 of the reasons.
2. The protest against the invitation by the ISA to pay two additional search fees is admissible.

### *Substantive matters*

3. According to the PCT regulations (cf. Rule 13.1 PCT), the international patent application shall relate to one invention only or to a group of inventions so linked as to form a single inventive concept. If the ISA considers that the claims lack this unity, it is empowered under Article 17(3)(a) PCT to invite the applicant to pay additional fees.



4. According to Rule 13.2 PCT, the requirement of unity of invention shall be fulfilled only when there is technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.
5. According to Rule 13.3 PCT, the determination of whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternative within a single claim.
6. Lack of unity may be directly evident **a priori**, ie before the examination of the merits of the claims in comparison with the state of the art revealed by the search (cf., for example, decision W 6/90, OJ EPO 1991, 436). Alternatively, having regard to decision G 1/89 of the Enlarged Board of Appeal (OJ EPO 1991, 155), the ISA is also empowered to raise an objection **a posteriori**, ie after having taken the prior art revealed by the search into closer consideration. This practice is laid down in the PCT International Search Guidelines (Chapter 10, pages 75 to 100), which are the basis for a uniform practice of all international searching authorities. The Enlarged Board of Appeal indicated that such consideration represents only a provisional opinion on novelty and inventive step which is in no way binding upon the authority subsequently responsible for the substantive examination (point 8.1 of the Reasons for the decision).

7. In the present case, claim 1 comprises different independent embodiments and the ISA correctly identified the **first** group of inventions as comprising, in particular, the **first** independent embodiment mentioned in the claim. The ISA then raised a lack of unity a posteriori objection based on prior art documents D1 to D4 (see section IV, supra). As a consequence of this objection, the ISA considered that the claim request in fact comprised three groups of inventions.
  
8. It is observed that, although all three groups relate to a method for determining embryo quality, the first is based on monitoring the length of a cell division or inter-division, while the other two are based on monitoring either the extent of cellular movement (group 2) or the duration of a cellular movement during an inter-division period (group 3).
  
9. The question to be answered is whether these three groups of inventions are so linked as to form a single general inventive concept, in particular whether there is a technical relationship among them involving one or more of the same "special technical features" (cf. point 4 supra).
  
10. As said above, the first group of inventions relates to "a method for determining embryo quality comprising monitoring the embryo for a time period, said period of time having a length sufficient to comprise at least one cell division period and at least a part of an interdivision period and determining the length of the at least one cell division period". It is based on the

- concept that the timing of embryo development reflects its future viability. If this concept was known in prior art, it cannot be seen as providing a possible link with the other inventions.
11. Prior art document D3 is concerned with determining the duration of the cell cycles during development of bovine embryos. It is found to be 35 hours, 14 hours and 11-62 hours for the three first cell cycles respectively, with the possibility of a developmental arrest at different stages. Furthermore, those embryos arrested at the eight-cell stage were described as developing into morula-blastocysts at a higher rate than did those arrested at earlier stages. The observation was also made that the faster the embryos cleaved into early stages, the higher the probability they developed into morula-blastocysts. On page 263, it is mentioned that " A clear relationship between the kinetics of early cleavage and further development was observed, allowing the selection of a more homogeneous embryo population in terms of its further developmental capacity."
  12. Thus, the concept that the earlier behaviour of the embryo - assessed through measuring cell division and inter-division periods - reflects its future developmental capacities had undoubtedly already been disclosed in the prior art.
  13. In the board's judgment, there is no other technical feature characterising this group of inventions which could be considered as a "special technical feature" common to all claims within the meaning of Rule 13.3 PCT. In particular, the fact that the minimum time for

monitoring is defined as of a length sufficient to comprise at least one cell division period and a part of at least one cell inter-division period does not correspond to an inventive concept. Indeed, if one is to study embryo development, manifestly, the study should be carried for long enough as to be meaningful. Evidence thereto is clearly derivable from eg. document D3 where many cell cycles comprising division periods as well as lag phases are investigated.

14. The second and third groups of inventions as defined by the ISA share the technical feature that the monitoring is done by measuring parameters relating to cell or organelle movement, namely, its extent or spatial distribution and its period of occurrence. Documents D1 to D4 cited by the ISA do not deal in any way with cellular or organelle movement nor do they suggest that this characteristic could reflect embryo quality. Accordingly, the two groups of inventions have in common "a special technical feature which defines the contribution which each of the claimed groups of inventions makes over the cited prior art. Therefore, the requirement of unity of invention is fulfilled by groups of inventions 2 and 3.
  
15. For sake of completeness, the board will shortly review the arguments in favour of unity presented in the appellant's protest. It was argued for example that claims 13 and 14 directed to systems for monitoring had not been included in the defined three groups of inventions. This is clearly wrong as each of them (in part) is indeed mentioned in each of the groups (see section III). The appellant also mentions the decision W 37/04 of 12 May 2005 as establishing that restraint

should be exercised when concluding lack of unity on an a posteriori basis. While undoubtedly true, this is not relevant to the present case - group 1 of inventions versus groups 2 and 3 - inasmuch as, as above mentioned, document D3 at least discloses the concept on which the first group of inventions is based. Finally, contrary to the appellant, the board finds that the elements taken into account by the ISA to reach the conclusion of lack of unity are elements which are parts of the claims even if the ISA chose a wording different from that of the claims - such as cytokinesis - which is in any case equivalent.

## **Order**

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

1. The protest is partially justified.
2. One additional search fee is reimbursed.

The Registrar

The Chairman

C. Eickhoff

L. Galligani