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**Datasheet for the decision
of 3 May 2012**

Case Number: T 1199/08 - 3.3.08
Application Number: 00980267.9
Publication Number: 1257168
IPC: A01N 1/02, C12N 5/06,
A61D 19/02
Language of the proceedings: EN

Title of invention:

Method of cryopreserving selected sperm cells

Patentee:

XY, LLC

Opponent:

Greenpeace e.V.
Monsanto Company
Breyer, Hiltrud

Headword:

Selected sperm/XY

Relevant legal provisions:

EPC Art. 53(b), 56, 84, 123(2)

Keyword:

"Main request: compliance with Art. 53(b) yes"
"Inventive step (no)"
"Auxiliary request: added matter (yes)"
"Lack of clarity (yes)"

Decisions cited:

G 0005/83, G 0002/06, G 0002/07, G 0001/08
Decision D-34-10 of the CJEU

Catchword:

-



Case Number: T 1199/08 - 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 3 May 2012

Appellant I:
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
18 April 2008 concerning maintenance of
European patent No. 1257168 in amended form.

Composition of the Board:

Chairman: M. Wieser
Members: T. J. H. Mennessier
C. Heath

Summary of Facts and Submissions

- I. The patent proprietor (appellant I) and opponent 03 (appellant II) each lodged an appeal against the interlocutory decision of the opposition division dated 18 April 2008, whereby European patent No. 1 257 168, which had been granted on European patent application No. 00 980 267.9 (published as the international application WO 01/37655 with the title "*Method of cryopreserving selected sperm cells*"), was maintained on the basis of auxiliary request 2 filed at the oral proceedings held on 30 January 2008.
- II. The main request as filed on 24 January 2008 and auxiliary request 1 as filed on 30 January 2008 had been refused for reasons of lack of clarity (Article 84 EPC).
- III. In addition to opponent 03, two other parties had filed an opposition, namely opponents 01 and 02 which are respondents (I and II, respectively) to the appellant I's appeal. Respondent II withdrew its opposition with a letter dated 16 September 2008.
- IV. The oppositions were filed on the grounds that:
- a) the claimed subject-matter was not patentable under Article 52(4) EPC 1973, and Articles 53(a), 54(2), 56 and 57 EPC (see Article 100(a) EPC);
 - b) the invention was not disclosed in a manner sufficiently clear and complete (see Articles 83 and 100(b) EPC);

- c) the subject-matter of the patent extended beyond the content of the application as filed (Articles 123(2) and 100(c) EPC).
- V. Opponent 03 (appellant II) further argued in the course of the opposition (see the letter of 29 November 2007) that the main request then on file did not comply with Article 53(b) EPC.
- VI. On 18 August 2008, appellant II filed her statement of grounds. It was argued that the request on which the patent had been maintained did not comply with Articles 53(a), 53(b), 53(c), 56, 57 and 83 EPC.
- VII. Together with its statement of grounds dated 28 August 2008, appellant I filed a main request and ten auxiliary requests. The main request corresponded to the main request of 24 January 2008, on which the decision under appeal was based.
- VIII. Each appellant replied to the other appellant's statement of grounds.
- IX. The Board issued a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) containing Board's preliminary and non-binding views. Both parties replied thereto. Appellant I's reply dated 21 October 2011 was accompanied by a new main request and eight auxiliary requests to replace the previous requests.
- X. On 21 November 2011, the Board issued a communication by which it informed the parties that it had become aware of a publication of appellant I, co-authored by

the inventor of the patent in suit and published on 1 January 1999. This publication will be referred to in the decision as document D30 (see Section XIX, *infra*).

- XI. Oral proceedings took place as scheduled on 24 November 2011. They were attended by the two appellants. Respondent I was not represented. In the light of the new prior art document D30, appellant I requested that the case be remitted to the first instance, or else that the case be adjourned. The Board refused these requests and decided to continue the procedure under consideration of document D30. A new main request and twelve new auxiliary requests were filed by appellant I to replace all the previous requests. In the course of the proceedings, the main request and the first and second auxiliary requests were withdrawn and the third auxiliary request became the main request while the subsequent nine auxiliary requests were re-numbered (1 to 9) and re-filed. Appellant II declared that her request to submit questions to the Enlarged Board of Appeal, formulated in the written procedure, was withdrawn. After the final deliberation, the Board decided that the subject-matter of the new main request met the requirements of Articles 123(2), 123(3), 83, 84, 53(b) and 54 EPC, and that oral proceedings would be continued on 3 May 2012 with the possibility of making further submissions until one month before the oral proceedings.

- XII. The minutes of the oral proceedings were sent to the parties. They contained in particular the following sentence "*Appellant II declares that her request to submit questions to the Enlarged Board of Appeal, formulated in the written procedure, is withdrawn*" (see

page 3/4). The minutes were not contested by the parties.

- XIII. On 2 December 2011, the Board issued a further communication pursuant to Article 15(1) RPBA which was attached to the summons to oral proceedings scheduled on 3 May 2012. It was made clear that the main issue to be discussed would be inventive step as regards the main request filed on 24 November 2011 in view of document D30.
- XIV. Each of appellants I and II, with letters of 3 April 2012 and 31 March 2012 respectively, replied to the Board's communication. Additional documents were filed, one by appellant I and nine by appellant II. Appellant II contested the admissibility of the claim requests on file by the end of the oral proceedings of 24 November 2011 and commented not only on the issue of inventive step but also on the issues of Articles 53(b) and 123(2) EPC, already decided by the Board at the previous oral proceedings. At point 3.2 on page 5 of her letter, appellant II argued that she had not withdrawn her request to refer questions of law to the Enlarged Board of Appeal regarding the issue of exceptions to patentability as governed by Article 53(b) EPC.
- XV. On 3 April 2012, third party observations were filed in accordance with Article 115 EPC. Five additional documents were attached thereto, including a document to be referred to in the present decision as document D31 (see Section XIX, *infra*).

XVI. Second oral proceedings took place on 3 May 2012. They were attended by the two appellants. Respondent I was not represented. Appellant II requested that additional new documents (seven pages) be introduced into the proceedings. Appellant I withdrew previous auxiliary requests 2 to 9 and filed new auxiliary requests 1a, and 2 to 6. Appellant II did not further comment on the issue whether or not she has withdrawn her request to refer questions of law to the Enlarged Board of Appeal.

XVII. The main request, originally filed as third auxiliary request at the first oral proceedings on 24 November 2011, consisted of 17 claims of which claims 1 and 14 read as follows:

"1. A method for the cryopreservation of sex-selected bovine sperm comprising:

- (a) obtaining a bovine sperm sample;
- (b) adding an initial extender and sex-selecting sperm by flow cytometry;
- (c) cooling said selected sperm sample;
- (d) isolating by centrifugation sperm from said selected cool sperm to produce isolated cool sperm;
- (e) adding final extender to said cool isolated sperm to produce a cool suspension of sperm, wherein the final extender comprises a cryoprotectant and Tris[hydroxymethyl]aminomethane; and
- (f) freezing said suspension of sperm."

"14. A frozen sex-selected bovine sperm sample comprising a portion of the sperm present in a source sample and an extender, said portion of sperm being stained with a fluorescent dye and sex-selected by flow cytometry, and said extender comprising a

cryoprotectant and Tris[hydroxymethyl]aminomethane, wherein thawing yields sperm that can be used in artificial insemination and achieves pregnancy."

Claims 2 to 13 were dependent on claim 1 and claim 15 on claim 14. Claim 16 was directed to the use of the sperm sample of claim 14 or 15 for the manufacture of a formulation for artificial insemination. Claim 17 was dependent on claim 16.

XVIII. Claim 14 of the first auxiliary request, originally filed as fourth auxiliary request at the onset of the first oral proceedings on 24 November 2011, read as follows:

"14. A frozen sex-selected bovine sperm sample comprising a portion of the sperm present in a source sample and an extender, said portion of sperm being stained with a fluorescent dye and sex-selected by flow cytometry, and said extender comprising a cryoprotectant and Tris[hydroxymethyl]aminomethane, wherein thawing yields sex-selected sperm that achieves a pregnancy rate that is 90% or more of the rate with unsexed control sperm having 7 to 20 times more sperm than said sex-selected sperm."

XIX. The following documents are cited in the present decision:

(D5) 'Physiology of Reproduction and Artificial Insemination of Cattle', Salisbury et al., Second Edition, W. H. Freeman and Company, 1978, pages 442 to 554

(D22)E. Kommissrud et al., *Theriogenology*, Vol. 45, 1996,
pages 1515 to 1521

(D30)G.E. Seidel, Jr. et al., *Theriogenology*, Vol. 51,
No. 1, 1 January 1999, page 400

(D31)A.J. Dhami and K.L. Sahni, *Theriogenology*, Vol. 40,
1993, pages 1269 to 1280

XX. The submissions made by appellant I, insofar as they are relevant to the present decision, may be summarised as follows:

Procedural issues

Admissibility of document D31

Document D31 had been submitted by a third party on 3 April 2012, i.e. one month before the date on which oral proceedings took place. It dealt with cryopreservation of bovine semen and, therefore, was relevant for the discussion of the issue of inventive step. Consequently, it should be admitted into the proceedings.

Admissibility of the set of seven pages submitted at the oral proceedings of 3 May 2012

These seven pages were late filed, lacked relevance and consisted of single pages of incorrectly identified journal articles. Therefore, it should not be admitted into the proceedings.

Admissibility of auxiliary requests 1a, and 2 to 6 (all filed at the oral proceedings held on 3 May 2012)

Auxiliary requests 1a and 2 to 6 were filed at the oral proceedings as reaction to the negative conclusion reached by the Board regarding the main and the first auxiliary requests. Therefore, they should be admitted into the proceedings.

Main request

Requirements of Article 53(b) EPC

The method of claim 1 was entirely non-biological because its steps, including the step of sex-selecting sperm by flow cytometry, relied entirely on "the hand of the man" and did not occur in biological systems. Claim 14 referred to a bovine sperm sample, i.e. to a product and not to a process. The only products excluded from patentability pursuant to Article 53(b) EPC were plant and animal varieties. The use of the frozen sperm sample for the manufacture of a formulation for artificial insemination according to claim 16 could also not be considered to be an essential biological process.

The frozen sperm sample specified in the claims was intended to be used ultimately in a method for the production of an animal, but such a method was not claimed.

A parallel should be made with the provision of Article 53(c) EPC which excluded methods for treatment of the animal body, whereas it did not apply to

products for use in any of these methods (see decision G 5/83 - OJ EPO 1985, 64). By the same principle, it had to be considered that the provision of Article 53(b) EPC excluding from patenting essentially biological products for the production of plants or animals did not apply to (i) products to be used in such methods (such as the frozen sperm of claims 14 to 15), (ii) methods for producing such products (such as the method for the cryopreservation of sex-selected bovine sperm of claims 1 to 13) and (iii) methods of using such products in the manufacture of veterinary formulations (such as the use of claims 16 to 17).

Requirements of Article 56 EPC (claim 14)

The technical problem to be solved was to provide an alternative product compared to the one disclosed in closest prior art document D30. This was achieved by replacing the egg yolk / citrate sodium extender of document D30 in a non obvious way.

Egg yolk / citrate sodium was recognised in the art as being the preferred extender for freezing of sperm samples and was in fact the most widely used extender. It was, moreover, known to be a valuable constituent in preserving fertility of frozen sperm samples (see document D5, page 499, first and second full paragraphs).

Furthermore, in addition to egg yolk / citrate sodium, various other extenders were at the skilled person's disposition and had been tested for producing frozen bovine sperm. There was no suggestion in the prior art that Tris extenders would have worked better. This was

illustrated in document D22 in which no significant difference was found in a comparative test between semen samples comprising either a skim milk-yolk extender or a commercial Tris-citrate extender (see D22, bottom of page 1520).

Thus, there were no obvious reasons for a skilled person to substitute the egg yolk / citrate sodium extender used in the experiment reported in document D30 with any other extender, let alone with a Tris extender.

First auxiliary request

Requirements of Article 84 and 123(2) EPC

The conditions for obtaining the frozen sex-selected bovine sperm sample of claim 14 were clearly defined. The claim did not require success under every possible condition and reflected a perfectly reasonable description of the product.

Support for claim 14 was found on page 49, lines 30 to 31 of the application as originally filed. The product did not necessarily have to include the features of the process for obtaining it.

XXI. The submissions made by appellant II, insofar as they are relevant to the present decision, may be summarised as follows:

Procedural issues

Admissibility of document D31

Document D31 had been submitted late. Furthermore, while dealing with an evaluation of different cooling rates, equilibration periods and diluents and their effects on deep-freezing, enzyme leakage and fertility of taurine bull spermatozoa, it was *prima facie* no more relevant than the documents already on file at the onset of the appeal proceedings. Therefore, it should not be admitted into the proceedings.

Admissibility of the set of seven pages submitted at the oral proceedings of 3 May 2012

The set of seven pages was merely filed for the purpose of illustrating facts already discussed in writing.

Admissibility of auxiliary requests 1a, and 2 to 6 (all filed at the oral proceedings held on 3 May 2012)

Auxiliary requests 1a, and 2 to 6 were filed in the course of the second oral proceedings, i.e. at a very late stage of the appeal proceedings. They could have been submitted earlier. Therefore, they should not be admitted into the appeal proceedings.

Main request

Requirements of Article 53(b) EPC

All claims contravened Article 53(b) EPC. The step of 'sex-selecting sperm by flow cytometry' amounted to a

step of selection which was decisive for the ultimate and inescapable result of the method according to claim 1, namely the production of an animal. The other steps were assisting steps of technical nature which only served the purpose of performing what was nothing else than a breeding process. This was in line with decision G 1/08 (OJ EPO 2012, 206) regarding the patentability of plant breeding processes. A correct application of the provisions of Article 53(b) EPC implied that not just the wording of the claims but the whole teaching of the application on which the patent was granted be taken into account. This was in agreement with the "whole content approach" referred to in decision G 2/06 (OJ EPO 2009, 306; see point 22 of the Reasons) and decision C-34-10 of the CJEU (see paragraph 50 thereof). Appellant I had recognised in paragraph 27 of its statement of grounds that the claims, whatever their subject-matter (method for the preparation of sex-selected bovine sperm - see present claim 1; frozen sex-selected bovine sperm sample - see present claim 14; and use of frozen sex-selected bovine sperm sample - see present claim 16), had been carefully drafted to avoid claiming methods for the production of an animal. As explained in the decisions referred to, this should not be permitted and, thus, the main request as a whole should be considered to contravene Article 53(b) EPC.

Requirements of Article 56 EPC (claim 14)

It was clear from Table 6 of the patent (see page 16) that the use of a Tris extender was not associated with any improvement. Therefore, a skilled person looking for just an alternative freezing extender to the egg

yolk / citrate sodium extender of document D30, taken as the closest prior art, would have regarded it as obvious to follow up the recommendation of using Tris as an universal freezing extender made in document D5 (see page 499, first full paragraph).

First auxiliary request

Requirements of Articles 84 and 123(2) EPC

Claim 14 looked like a patchwork of features taken out from different parts of the patent. It was not clear and had no support in the application as filed.

- XXII. Respondent I did no make any submissions in the present appeal proceedings.

- XXIII. Appellant I (patent proprietor) requests that the decision under appeal be set aside and the patent maintained according to the main request, or according to the auxiliary request 1, both filed during the oral proceedings held on 24 November 2011, or according to any of the auxiliary requests 1a, 2 to 6 filed during the second oral proceedings on 3 May 2012.

- XXIV. Appellant II (opponent 03) requests that the patent be revoked.

Reasons for the decision

Procedural issues

Admissibility of late filed documents

1. In the course of the oral proceedings on 3 May 2012, the Board had to decide on the admissibility of late filed documents which the appellants wished to use in their pleadings in support of their views regarding the issue of inventive step.
2. A set of seven pages representing four different "documents" were submitted by appellant II. These "documents" are referred to hereinafter as documents A to D.
3. Document A consists of one page and shows the abstract, some lines of the text and parts of the references of a journal article dealing with an optical method of qualitative assessment of sperm mobility. Document B consists of one page and shows the title of a journal article dealing with a semen analysis system in combination with parts of the content of an unidentified page of this article. Document C consists of one page and gives some information derived from the internet referring to a journal article dealing with the motility of spermatozoa in combination with a kind of summary. Document D consists of 4 pages derived from a WHO laboratory manual dealing with human ejaculates.
4. The Board takes notice of the objection to the introduction of documents A to D raised by appellant I arguing that it was taken by surprise at such a late

stage of the appeal proceedings and that it would be deprived of an opportunity to present appropriate comments, which is contrary to the requirements of Article 113(1) EPC.

5. Documents A, B and C represent patchworks of information picked from different parts of journal articles (A and B) or from different internet sites (C). They do not meet the usual standard requirements for a document to qualify as a reliable source of information before the Boards of Appeal. As regards document D, from which only a very limited number of pages has been submitted, and which deals with **human** ejaculates, the Board is not *prima facie* convinced that it is relevant for the assessment of any of the claim requests on file which all refer to **bovine** sperm.
6. In view of the above comments, the Board exercising its discretion according to Article 13(1) (RPBA), decides not to admit documents A to D.
7. Appellant I have relied on document D31, a document which was attached to third party observations filed on 3 April 2012.
8. Document D31 is a journal article concerned with investigations carried out on Friesian bull spermatozoa which led to conclusion that Tris- and milk-based diluents were equally efficacious in the cryopreservation of cattle sperm. The Board is not *prima facie* convinced that D31 qualifies as a more relevant document than those documents which were on file at the onset of the appeal proceedings of 3 May 2012.

9. In view of the above comments, the Board exercising its discretion according to Article 13(1) RPBA decides not to admit document D31.

Introduction of document D30 into the appeal proceedings

10. In its communication faxed on 21 November 2011, the Board informed the parties that, in the course of its final preparation for the first oral proceedings to be held on 24 November 2011, it had become aware of a scientific article **published on behalf of appellant I and co-authored by the inventor of the patent**. The document (D30) had been published on 1 January 1999, thus almost a year before the earliest priority date claimed for the patent and disclosed field trial 3 of example 8 of the patent. The Board indicated that it intended to hold oral proceedings as scheduled and to introduce the document into the proceedings.
11. The admissibility of document D30 was discussed at the onset of the oral proceedings of 24 November 2011. Appellant I neither contested that the content of document D30 corresponded to the description of field trial 3 of Example 8 as reported and commented in particular in paragraphs [0086] to [0092] and [0101] on pages 20, 21 and 23 of the patent specification nor objected to its introduction into the proceedings.
12. In the light of appellant I's reaction and being aware that document D30 is of high relevance for the issue of inventive step, the Board considers that it is exceptionally empowered by Article 114(1) EPC to introduce it into the proceedings.

Admissibility of the main request and the first auxiliary request

13. As both requests were filed at the oral proceedings held on 24 November 2011 as a reaction to the introduction on the same day of document D30, the Board admits them into the proceedings

Admissibility of auxiliary requests 1a, and 2 to 6 (all filed at the oral proceedings held on 3 May 2012)

14. Second oral proceedings were held on 3 May 2012, thus more than five months after the first oral proceedings, which had been adjourned to give the parties the possibility of making further submissions with regard to the issue of inventive step (Article 56 EPC) in the light of newly introduced document D30. The time limit to make such further observations was set at one month before said second oral proceedings. Document D30 has been published on behalf of appellant I and co-authored by the inventor of the present patent. It is not credible that its content was unknown to appellant I. The Board is therefore of the opinion that appellant I has been allowed sufficient time to consider its position in the light of this prior art document and, if necessary to file amended claims, at the latest within the time limit given at the end of the first oral proceedings. Therefore, the Board, exercising its discretion pursuant to Article 13(1) RPBA, does not admit auxiliary requests 1a, and 2 to 6 filed at the second oral proceedings.

Substantial issues

Main request

15. At the oral proceedings held on 24 November 2011, the main request was found to meet the requirements of Articles 123(2), 123(3), 83, 84, 53(b) and 54 EPC. Furthermore, the objections raised under Article 52(4) EPC 1973 (now Article 53(c) EPC) and Article 53(a) EPC have not been pursued in view of the amendments made to the case. At the oral proceedings held on 3 May 2012, the main request was found not to meet the requirements of Article 56 EPC. Although, the Board in the present decision could restrict itself with regard to the main request to the issue of inventive step, it will also provide below a full reasoning regarding the sensitive issue of exceptions to patentability (Article 53(b) EPC).

Article 53(b) EPC

16. Article 53(b) EPC provides that:
"European patents shall not be granted in respect of:
(a) [...]
(b) plant or animal varieties or **essentially biological processes for the production of plants or animals**; this provision shall not apply to microbiological processes or the products thereof." (emphasis added by the Board).
17. Appellant II considers that claim 1 contravenes this provision, insofar as the prohibition applies to essentially biological processes for the production of animals and argues that this objection extends to the other claims, including the product claims 14 to 15 and the use claims 16 to 17. In support of her objection,

appellant II has referred to decisions G 2/06 (OJ EPO 2009, 306) and G 1/08 (OJ EPO 2012, 206), the proceedings of which were consolidated with those of decision G 2/07 (OJ EPO 2012, 130), as well as the *Oliver Brüstle v. Greenpeace* decision of 18 October 2011 of the Court of Justice of the European Union (CJEU decision C-34-10). As only an abridged version of decision G 1/08 was published, reference will be made hereinafter to decision G 2/07 which was published in its entirety.

18. Appellant II argues that, in accordance with the "whole content approach" developed by the Enlarged Board of Appeal in decision G 2/06 (see point 22 of the Reasons), not the explicit wording of claim 1 but the technical teaching of the patent as a whole should be taken into consideration for a correct assessment of whether claim 1 falls under the prohibition of Article 53(b) EPC. Appellant II contends that, following this approach which is reflected by the CJEU decision C-34-10, it becomes obvious that the only purpose of the claimed method is the production of an animal.

19. Appellant II considers further that, in the method of claim 1, the step of sex-selecting sperm by flow cytometry is a selection step which, together with the other technical steps, serves the only purpose of assisting in the crossing step and leads subsequently and inevitably to the breeding of an animal. Consequently, drawing a parallel with the reasoning made in decision G 1/08 regarding a process for the production of plants, the claimed method should be regarded as an essentially biological process for the production of animals.

20. In decision G 2/06, the Enlarged Board of Appeal has answered *inter alia* the question of whether Rule 28(c) EPC forbids the patenting of claims directed to products (in the referring decision: **human embryonic stem cell cultures**) which - as described in the application - at the filing date could be prepared exclusively by a method which necessarily involved **the destruction of the human embryos** from which the said products were derived, if the said method is not part of the claims. Regarding Rule 28(c) EPC which provides that, under Article 53(a) EPC, European patents should not be granted in respect of biotechnological inventions which, in particular, concern uses of embryos for industrial or commercial purposes, the Enlarged Board has noted that said rule does not mention claims, but refers to "invention" in the context of its exploitation and has indicated that "**[W]hat needs to be looked at is not just the explicit wording of the claims but the technical teaching of the application as a whole as to how the invention is to be performed**" (emphasis added by the Board). This defines the "whole content approach" as referred to by appellant II. The Enlarged Board of Appeal has noted further that "[T]o restrict the application of Rule 28(c) (formerly 23d(c)) EPC to what an applicant chooses explicitly to put in his claim would have the undesirable consequence of making avoidance of the patenting prohibition merely a matter of clever and skilful drafting of such claims" (see point 22 of the Reasons).
21. The present Board does not see any reason to apply this approach of decision G 2/06 to the situation underlying present claim 1. Said approach has been developed in the context of a particular exception to patentability governed by Article 53(a) EPC in view of Rule 28(c) EPC

which focuses on the patentability of inventions related specifically to the ethical concerns associated with **the destruction of a human embryo**, whereas for present claim 1 the context to be considered is the one of another exception to patentability which is governed by Article 53(b) EPC. Present claim 1 is indeed directed to a method for the preparation of sex-selected **bovine** sperm resulting in a product with properties allowing its long term storage.

22. In the case underlying the CJEU decision C-34-10, the invention was concerned with neural precursor cells obtainable from **human embryonic stem cells**. The Court had to answer *inter alia* the question of whether technical teaching is to be considered unpatentable pursuant to Article 6(2)(c) of the Directive 98/44/EC (Rule 28(c) EPC) even if the use of **human embryos** does not form part of the technical teaching claimed by the patent, but is a necessary precondition for the application of that teaching. In paragraph 50 of the Decision, the Court noted that "*Not to include in the scope of the exclusion from patentability set out in Article 6(2)(c) of the Directive technical teaching claimed, on the ground that if does not refer to the use, **implying their prior destruction, of human embryos** would make the provision concerned redundant by allowing a patent applicant to avoid its application by skilful drafting of the claim*" (emphasis added by the Board). Thus, for the very same reason given at point 21 *supra*, the Board sees no reason to apply the approach of CJEU decision C-34-10 to the situation underlying present claim 1.

23. In the case underlying decision G 2/07, the referring Board had to decide on the patentability of a process for

the production of *Brassica oleracea*, which as claimed comprised in succession steps of a) crossing wild *Brassica oleracea* species with broccoli double haploid breeding lines, b) selecting hybrids, c) backcrossing and selecting plants with a the genetic combination encoding the expression of elevated levels of given compounds and d) selecting a broccoli line with elevated levels of said compounds. This was a non-microbiological process for the production of plants which contained a step of sexually crossing the whole genome of plants and of subsequently selecting plants, i.e. a traditional method of breeding new plant varieties

24. The Enlarged Board of Appeal came to the conclusion that "*[S]uch a process does not escape the exclusion of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, a step of a technical nature which serves to enable or assist the performance of the steps of sexually crossing the whole genomes or plants or of subsequently selecting plants*" (see decision G 2/07, point 2 of the Order).
25. Regarding additional technical steps performed either **before** or **after** the process of crossing and selection *per se* decision G 2/07 indicates: "*For the previous or subsequent steps per se patent protection is available*" (G 2/07, page 70, lines 4 to 5) and "*[H]owever, in such case the claims should not, explicitly or implicitly, include the sexual crossing and selection process.*" (G 2/07, page 70, lines 10 to 12).
26. The process of claim 1 does not comprise a step of breeding an animal and none of its steps involves any

crossing. Furthermore, it is an obvious fact, in an attempt to draw a parallel between a method for the production of plants and a method for the production of animals, that a selection step equivalent to a selection step in a traditional method of breeding new plant varieties which takes place after a crossing step between pre-existing varieties is not present in claim 1.

27. Therefore, appellant II's argument that it was only skilful claim drafting that avoided in the present case the application of the prohibition of Article 53(b) EPC, regarding processes for the production of animals, is not convincing.
28. From the analysis made at points 20 to 27 *supra*, the Board concludes that claim 1 is directed to a method which allows for the long term preservation of sex-selected sperm. This method does not qualify as an essentially biological process for the production of animals, and, therefore, in line with the parallel reasoning developed in decision G 2/07 regarding processes for the production of plants, it does not fall under the prohibition of Article 53(b) EPC. Thus, claim 1 meets the requirements of Article 53(b) EPC. The same conclusion applies to dependent claims 2 to 13.
29. Claim 14 and dependent claim 15 are directed to a frozen sex-selected bovine sperm sample, a product which is not mentioned in Article 53(b) EPC. In view of the fact that, according to established case law, any exception to patentability must be construed narrowly, Article 53(b) EPC provides an exhaustive list of possible exclusions from patentability. Therefore, the frozen sex-selected

bovine sperm sample according to claim 14 or claim 15 does not fall under the prohibition of Article 53(b) EPC.

30. Claim 16 and dependent claim 17 are directed to the use of a sperm sample according to claim 14 or claim 15 for the manufacture of a formulation for artificial insemination. Such a use is also not mentioned in Article 53(b) EPC. Therefore, the use of frozen sex-selected bovine sperm sample according to claim 16 or claim 17 does not fall under the prohibition of Article 53(b) EPC.
31. In view of these remarks, the Board concludes that the main request as a whole complies with the requirements of Article 53(b) EPC. The Board regards it as relevant to note that, in the course of the oral proceedings of 24 November 2011, as clearly reflected in the minutes thereof which were not contested by the parties, appellant II withdrew her request to refer questions of law with respect to this issue. Therefore, the attempt made by appellant II in her letter of 31 March 2012 to re-open the debates in this respect was unsuccessful. When formulating her final requests, appellant II did not include such a request.

Article 56 EPC

32. Claim 14 is directed to a frozen sex-selected bovine sperm sample comprising a portion of the sperm present in a source sample and an extender (see Section XVII *supra*). The sperm sample is stained with a fluorescent dye and sex-selected by flow cytometry. The extender comprises a cryoprotectant and Tris[hydroxymethyl]aminomethane.

Thawing yields sperm that can be used in artificial insemination and achieves pregnancy.

33. In order to assess inventive step in an objective and predictable manner, the so-called "problem-and-solution approach" has to be applied, which in its first step requires the determination of the document representing the closest prior art.
34. The Board considers document D30, which is concerned with the evaluation of the fertility of frozen bovine sperm that has been sex-selected by flow cytometry, to represent the closest state of the art. It contains the data of field trial 3 disclosed in example 8 of the patent in suit (see point 11 *supra*).
35. In view of appellant I's declaration made at the second oral proceedings, saying that the invention does not provide any improvement over the prior art, the technical problem underlying the invention is defined as the provision of an alternative frozen sex-selected bovine sperm sample.
36. As solution to this technical problem the patent proposes the bovine sperm sample of claim 14 which contains an extender comprising a cryoprotectant and Tris[hydroxymethyl]aminomethane (hereinafter also referred to as Tris). The experimental results reported in Example 8 regarding field trials 4 to 11 in which sex-sorted, frozen bovine sperm comprising a Tris-based extender and glycerol (see paragraphs [0086] to [0092]) were used for artificial insemination, show that the problem has been actually solved.

37. The question to be answered is whether it would have been obvious for a skilled person trying to solve the problem to amend the teaching of document D30 in such a way as to arrive at the subject-matter of claim 14.
38. The only difference between the sperm sample of claim 14 and the one of document D30 lies in the use of an extender comprising Tris, whereas in document D30 the extender consists of a combination of egg yolk and citrate sodium.
39. Document D5 is a basic textbook published in 1978 dealing with artificial insemination of cattle. In section 17-3.1 on page 498, it refers to extenders for freezing bovine sperm and lists the basic components of such extenders. The listed components include "*dissolved ionic and nonionic substances to maintain osmolality and to buffer the pH of the medium*". In the next paragraph on page 499, document D5 gives a short list (eight substances or groups of substances) of buffers and nonionic substances that have been used in extenders for freezing bovine sperm. Tris[hydroxymethyl]amino methane is mentioned on position two of this short list.
40. Appellant I argued that a skilled would have been discouraged to replace the egg yolk / citrate sodium extender of document D30 by a Tris-based extender and it referred in this context to document D22, which reports on a comparison of two bull semen processing systems based on either a skim milk-yolk extender or the Biladyl[®] Tris-based extender. The Tris-based extender is found to be inferior with regard to post-thaw mobility and nonreturn rates. However, a closer look to the data of document D22 shows that the two extenders compared

differed in several aspects, including their antibiotic components, that they were diluted at different temperatures (the milk-yolk extender at 5°C, the Biladyl[®] extender at room temperature) and that most of the differences found between the extenders were not significant (page 1520, first paragraph).

41. Thus, the skilled person looking for an alternative for the egg yolk / citrate sodium extender used in document D30, which is also mentioned in the short list on page 499 of document D5, would have had no reason to ignore the teaching in document D5. By exchanging the extender disclosed in the closest prior art by one of the extenders disclosed in document D5 as being known to be useful for freezing of bovine sperm he/she would have arrived at the subject-matter of claim 14 in an obvious manner.
42. Thus, the Board decides that the subject-matter of claim 14 does not involve an inventive step and that the main request does not comply with the requirements of Article 56 EPC.

Auxiliary request 1

Articles 123(2) and 84 EPC

43. Claim 14 of auxiliary request 1 differs from claim 1 of the main request in that it contains the additional technical feature that "*thawing yields sex-selected sperm that achieves a pregnancy rate that is 90% or more of the rate of unsexed control sperm having 7 to 20 times more sperm than said sex-selected sperm*".

44. The added technical feature has no support within the meaning of Article 123(2) EPC in the description as filed. The sentence on page 49, lines 29 to 30, which reads "*Pregnancy rates with sexed sperm were generally 70-90 % of unsexed controls within experiments with 7 to 20 times more sperm*", cannot be a basis for a pregnancy rate above 90%. The pregnancy rates achieved in the field trials of example 8 with sex-selected sperm according to the invention in comparison to pregnancy rates achieved with unsexed control sperm are shown in tables 13 to 16 and 18 to 20 on pages 45 to 49. Pregnancy rates that are 90% or more of the rate of unsexed control sperm samples are reported with regard to control sperm samples having (i) **6,6 times** (20/3) more sperm (see Table 14, fourth line; Table 18, second and fourth lines; Table 19, second line; Table 20, second and fourth lines), (ii) **13 times** (20/1,5) more sperm (see Table 16, second line), and **20 times** (20/1) more sperm (see Table 19, first line; Table 20, first and third lines). This cannot serve as basis for the broad range of "7 to 20 times more sperm" as contained in claim 14.
45. Therefore, claim 14 does not comply with the requirements of Article 123(2) EPC.
46. The added technical feature is defined in terms of a result to be achieved by a complex process involving biological material, i.e. artificial insemination of cattle, which result depends on a plethora of conditions and parameters. These conditions and parameters include, amongst others, the thawing of the frozen sperm samples, the heifer management and the various parameters that have to be considered at the actual insemination process itself. Several of these parameters are discussed in the

patent (see paragraphs [0093] to [0098] of the patent specification) and their influence on the outcome of the fertility tests is acknowledged, however none of them is referred to in claim 14. Therefore, claim 14 does not define clearly the matter for which protection is sought.

47. This leads to the conclusion that auxiliary request 1 does not comply with the requirements of both Articles 123(2) and 84 EPC.

Conclusion

48. As neither the main request nor auxiliary request 1 may serve as a basis to maintain the patent, in the absence of any further claim request on file, the patent must be revoked.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked

The Registrar

The Chairman

L. Fernández Gómez

M. Wieser