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Datasheet for the decision of 18 September 2025

Case Number: T 1941/23 - 3.3.04

Application Number: 16856306.2

Publication Number: 3362578

IPC: A01K67/027, C12N5/073, C12Q1/6876, C12N15/877, C12Q1/68

Language of the proceedings: EN

Title of invention:
Methods of Genomic Evaluation in Livestock

Patent Proprietor:
Inguran, LLC

Opponent:
James Poole Limited

Headword:
Genomic Evaluation Methods/INGURAN

Relevant legal provisions:
EPC Art. 56, 84

Keyword:
Inventive step - main request (no)
Claims - clarity - auxiliary requests (no)

Decisions cited:
G 0001/24, T 0936/22

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Case Number: T 1941/23 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 18 September 2025

Appellant: (Patent Proprietor)	Inguran, LLC 22575 State Highway 6 South Navasota, TX 77868 (US)
Representative:	Jacob, Reuben Ellis Maucher Jenkins Seventh Floor Offices Artillery House 11-19 Artillery Row London SW1P 1RT (GB)
Respondent: (Opponent)	James Poole Limited One Southampton Row London WC1B 5HA (GB)
Representative:	Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 26 September 2023 revoking European patent No. 3362578 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairwoman	M. Pregetter
Members:	A. Chakravarty
	A. Bacchin

Summary of Facts and Submissions

I. The patent proprietor (appellant) filed an appeal against the decision of the opposition division to revoke the patent. The opponent is respondent to this appeal.

II. The opposition was filed invoking grounds for opposition under Article 100(a) EPC, lack of inventive step (Article 56 EPC), and under Article 100(b) EPC.

III. The opposition division considered a main request (claims as granted) and a set of claims of an auxiliary request. It held that the main request did not comply with the requirements of Article 56 EPC and the auxiliary request did not comply with the requirements of Article 84 EPC. It decided to not admit novelty as a ground for opposition. Document D16 was admitted into the proceedings.

IV. With the statement setting out the grounds of appeal, the appellant re-filed the sets of claims of the main request and as auxiliary request 1, the set of claims of the auxiliary request considered by the opposition division. They also filed a set of claims of an auxiliary request 2.

V. The respondent submitted a reply to the statement setting out the grounds of appeal.

VI. Claim 1 as granted reads:

"1. A method of determining a genomic estimated breeding value (GEBV) or a genomic predicted

transmitting ability (GPTA) of a non-human mammalian fetus comprising:
extracting DNA from one or more fetal amniocytes;

genotyping the DNA to obtain a genotype for the fetus; and

determining a GEBV or a GPTA of the fetus based on the genotype".

Claim 1 of auxiliary request 1 reads:

"1. A method of increasing genetic progress in a population of non-human mammals comprising:

extracting DNA from one or more amniocytes derived from a fetus from the population;

genotyping the DNA to obtain a genotype for the fetus; and

determining a GEBV or a GPTA of the fetus based on the genotype;

selecting the fetus as a parent for the population based on the genotype; and cloning the fetus to produce a clone".

Claim 1 of auxiliary request 2 reads:

"1. A method of increasing genetic progress in a population of non-human mammals comprising:

extracting DNA from one or more fetal amniocytes;

genotyping the DNA to obtain a genotype for the fetus; and

determining a GEBV or a GPTA of the fetus based on the genotype;

selecting the fetus as a parent for the population based on the genotype; and

cloning the fetus to produce a clone".

VII. The following documents are referred to in this decision.

D1: P. Kasinathan *et al.*, Acceleration of genetic gain in cattle by reduction of generation interval, Scientific Reports, vol. 5:8674, published 2nd March 2015

D16: US 7 910 308 B1

VIII. The appellant's submissions relevant to the decision are summarised as follows.

Admittance of document D16

Document D16 should not be admitted into the appeal proceedings because it was filed late during the oral proceedings before the opposition division. D16 concerned genetic markers in fatty acid synthase for identification of meat product fatty acid content in cattle (see title). Thus, its content was not *prima facie* relevant to the patentability of the present claims within the context set out in the Guidelines for Examination, E-VI, 2.1.

During the oral proceedings before the opposition division, the opponent mentioned that D16 was cited in the prosecution of another of the patent proprietor's patents. Since the opponent in the present case was the same as in that other case (concerning EP 3 385 394) it was aware of D16 at the time of filing the present opposition. Thus, D16 should have been submitted with the Notice of Opposition.

Main Request (patent as granted)- claim 1

Inventive step (Article 56 EPC)

Document D1 was the closest prior art. It disclosed a cost-effective approach combining genomic selection with reproductive technologies to reduce generation intervals. However, D1 did not teach the feature of extracting DNA from foetal amniocytes and determining a GEBV or GPTA based on the genotype.

The technical effect of this difference was an increase in the rate of pregnancy of high genetic merit foetuses, leading to greater genetic progress. This was due to the ability to abort foetuses with low genomic scores and recycle recipient females sooner, as well as by cloning superior females to increase selection intensity.

The objective technical problem was to increase the rate of pregnancy of high genetic merit foetuses and therefore increase genetic progress.

The skilled person would not have modified the method disclosed in D1 to include amniocentesis because:

- D1 emphasized cost efficiency and taught that genomic evaluation from early-stage embryos was advantageous.
- Amniocentesis was invasive, costly, and associated with risks such as spontaneous abortion. The livestock industry had not adopted amniocentesis for genetic evaluation due to these drawbacks.

Furthermore, D1 taught away from the present invention because it stated that collection of early stage embryos and establishment of cell lines from the embryos was a highly cost effective means for increasing genetic gain in a cattle breeding program (page 3, second full paragraph). The skilled person would not have looked beyond the teaching of D1.

Combining the teaching in D1 with that in D16 would not have been obvious to the skilled person because:

- D16 related to genetic markers for fatty acid content and did not address genetic progress.
- using amniotic fluid would reduce DNA quality and quantity, undermining D1's objectives.
- there was no indication in D16 that the use of amniocytes would be a suitable method for use in the context of improving genetic progress. Indeed, the skilled person knew about risks associated with amniocentesis such as a high risk of abortion, mixing up the cells of the foetus and mother and the result of a low yield. There was therefore no motivation for the skilled person to combine the teaching in D1 with that in D16.

Auxiliary request 1 - claim 1

Clarity (Article 84 EPC)

Claim 1 of auxiliary request 1 was clear and met the requirements of Article 84 EPC. There was no doubt that the skilled person with a mind willing to understand the claimed method in its technical context would consider that claim 1 referred to a method of increasing genetic progress. The opposition division had considered that the GEBV or GPTA were not used in the subsequent steps of the claim and that their relationship to the purpose of increasing genetic progress remained unclear. However, the paragraph bridging pages 4 and 5 of the application as filed referred to the features of claim 1 of auxiliary request 1 and stated that the method could further comprise the step of determining a GEBV or GPTA of the foetus based on the phenotype.

The reference to amniocytes derived from a foetus was also clear and would have been understood to have the same meaning as foetal amniocytes.

IX. The respondent's submissions relevant to the decision are summarised as follows.

Admittance of document D16

There was no legal basis in the EPC for excluding documents correctly admitted by the first instance, especially when the decision was based on them. The appellant had not claimed that the opposition division exercised its discretion using the wrong principles, but had only argued that the opposition division had reached the wrong conclusion.

Case law (e.g. T 2603/18 and T 487/16) confirmed that the Boards of Appeal should only overturn such discretion if exercised arbitrarily or on wrong principles, which was not the case here.

Main Request (patent as granted)- claim 1

Inventive step (Article 56 EPC)

D1 disclosed a method of determining a genomic estimated breeding value (GEBV) or a genomic predicted transmitting ability (GPTA) of a non-human mammalian foetus comprising: extracting DNA from one or more foetal amniocytes, genotyping the DNA to obtain a genotype for the fetus and determining a GEBV or a GPTA of the foetus based on the genotype. It did not disclose that the DNA was extracted "from one or more fetal amniocytes". Instead, in D1 DNA was extracted from foetal fibroblasts. The opposition division was therefore right to find that D1 disclosed all features of the claimed except the step of extracting DNA from fetal amniocytes.

The appellant alleged that this difference resulted in the technical effect of increasing the rate of pregnancy of high genetic merit fetuses. However, this effect was not inevitably achieved by the claimed method because the claim did not require e.g. abortion of low-merit fetuses or cloning of high-merit ones. In fact, the claim merely required that GEBV or GPTA of the foetus be determined and required no downstream steps of any kind. Any subsequent actions to the determination of the GEBV or GPTA were not inherent in the claimed method either as they were entirely optional.

Since none of the advantages alleged by the appellant were either a feature of the claim or inherent to the claimed method, the objective technical problem was the provision of an alternative method for post-implantation foetal genotyping.

In seeking to solve this problem, the skilled person would have combined the teaching in document D1 with that in D16 which taught DNA extraction from amniocytes and genotyping for breeding traits. D1 encouraged early genomic analysis and did not teach away from amniocentesis. Combining these teachings would have been obvious and involved no technical difficulty.

In more detail and contrary to the appellant's submission, D1 did not teach away from the use of amniocytes for genomic selection. Instead, D1 emphasised the importance of 'genomic analyses at early an embryonic stage' (see page 1, second paragraph), thereby encouraging the skilled person to seek further opportunities for early analyses. D1 contained no indication that cells from amniocentesis could not be employed for its genomic analysis.

The appellant asserted that it would have been surprising to the skilled person that amniocentesis could be used to obtain enough cells to perform genotype analysis. However, the amniocentesis methods used in the claimed invention were known ones and there was no surprise involved. Ultimately, the skilled person starting from D1 and seeking to provide an alternative method for post-implantation foetal genotyping would look to D16 and employ its teaching that genomic analysis can be performed on DNA extracted from amniocytes.

The appellant's arguments about cost and technical barriers were also not convincing because these were speculative and unsupported by evidence.

Auxiliary requests 1 and 2

Clarity (Article 84 EPC)

The opposition division's finding of lack of clarity was correct. It was not apparent how the GEBV or GPTA were employed for the purposes of "increasing genetic progress" because selection of the foetus as a parent was not based on either of these.

The parties' requests

X. The appellant requests that the decision under appeal be set aside and the patent be maintained on the basis of the claims of the main request (claims as granted) or, alternatively, on the basis of the sets of claims of auxiliary requests 1 or 2. Further, it requests that document D16 be not admitted into the appeal proceedings.

The respondent requests that the appeal be dismissed.

Reasons for the Decision

Admittance of document D16

1. The appellant requests that document D16 not be admitted into the appeal proceedings on the grounds that it was late filed and that it is not *prima facie* relevant to the patentability of the claims on file.

2. D16 was submitted by the respondent before the date set under Rule 116(1) EPC. It was admitted into the proceedings by the opposition division as evidence relating to inventive step.

3. The opposition division's decision to admit document D16 can be reviewed by the board, but such a review must be conducted in accordance with the principles established for reviewing decisions taken by opposition divisions in exercise of their discretion, namely limited to considering whether the opposition division exercised its discretion according to the correct principles and in a reasonable way (see the principles in decision G 7/93 and, in general, Case Law of the Boards of Appeal of the EPO, 11th ed. 2025, V.A.3.4.1). In the present case, there is no legal basis which would allow said document, which was admitted by the opposition division and considered in the decision under appeal, to be retroactively excluded from the appeal proceedings. In this context, the board notes that the opposition division has far-reaching powers to consider facts and evidence of its own motion under Article 114(1). The rights of the patent proprietor in this situation are safeguarded via Article 113 EPC (see T 936/22, points 1 to 4 of the reasons).

4. The appellant has not argued that the opposition division did not exercise its discretion according to the correct principles in an unreasonable way (see the principles in decision G 7/93 and, in general, Case Law of the Boards of Appeal of the EPO, 11th ed. 2025, *ibid*) and the Board can see no evidence to this effect. There is therefore no reason to remit the case to the opposition division.

5. Accordingly, document D16 is part of the appeal proceedings under Article 12(2) RPBA.

Patent as granted - claim 1

Claim construction

6. The subject-matter of claim 1 is a method for determining of two parameters of a non-human mammalian foetus, its genomic estimated breeding value (GEBV) and genomic predicted transmitting ability (GPTA). The claim does not require the use of the GEBV or GPTA in any additional steps, e.g. for selecting an embryo. This subject-matter is introduced in claim 3 which relates to a method for cloning a foetus.

7. The parties disagree about how the skilled person would understand the expressions "genomic estimated breeding value (GEBV)" and "genomic predicted transmitting ability (GPTA)". The appellant considers that they refer to parameters related to "genetic merit" (see paragraph [0001] of the patent). The respondent considers that the terms encompass any determination of a breeding value based upon genomic data.

8. Interpreting the claims in the context of the description (cf. G 1/24, OJ EPO 2025, 60, Order), the skilled person would understand that the expressions "genomic estimated breeding value" and "genomic predicted breeding value" relate to parameters derived from measurements done on the animal's genome. However, neither GEBV or GPTA is defined in the patent and there is no evidence on file that there was a common understanding of them in the art. It is also apparent that "breeding value" and "genetic merit" are subjective terms, the meaning of which is not fixed and

depends on the subjective requirements of the skilled person (the breeder) at a certain point in time. Thus, "breeding value" in the parameter GEBV is understood as relating to **any** subjectively desirable trait.

9. The description of the patent reinforces this view. It makes reference to two publications, Meuwissen *et al.* and VanRaden (see paragraphs [0045] and [0046]) for examples of calculating GEBV and GPTA. These references however neither impart any specific information to the skilled person nor address the problem of the subjective nature of the breeding value. Moreover, the heading "*Determining GEBVs from SNP Data*" (see paragraph [0045] of the patent) makes it clear that this section relates to one particular way of determining GEBVs, namely from SNP data, but does not deal with ways of determining GEBVs based on genomic data that is not SNP data.

10. No different conclusion can be reached in relation to the term GPTA since the term "transmitting ability" according to the paragraph [0047] may be determined based on the GEBV. Thus both GEBV and GPTA are subjective and undefined parameters, relating to **any** genomic measurement correlated to **any** subjectively desirable trait.

11. The claimed method is therefore understood as comprising the steps of (i) extracting DNA from one or more foetal amniocytes, (ii) genotyping the DNA to obtain a genotype for the foetus, and (iii) from this determining any parameter that reflects any subjectively desirable trait (phenotype). No steps after step iii) are required by the claim.

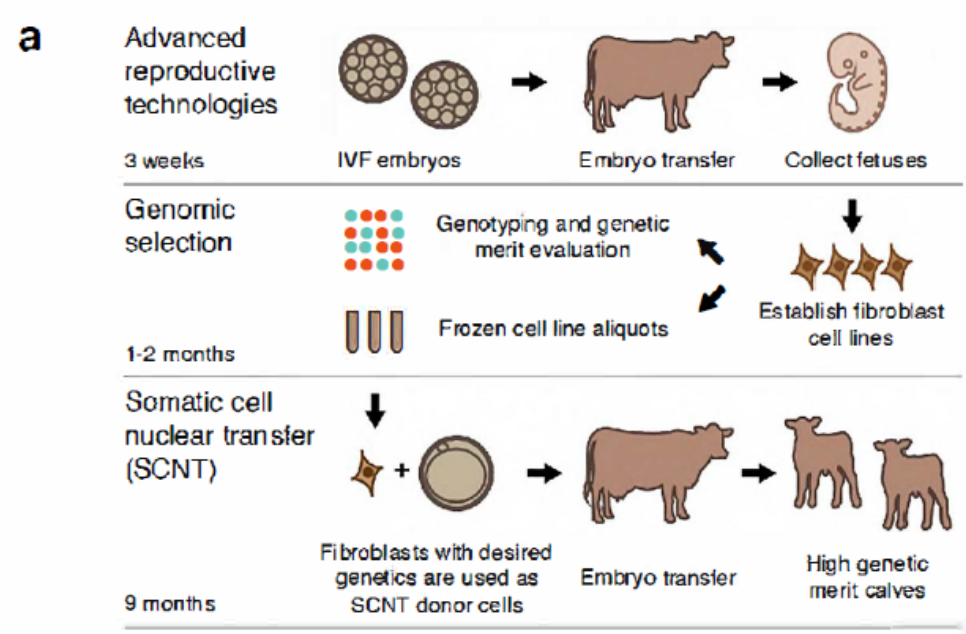
Inventive step (Article 56 EPC)

Closest prior art

12. In the decision under appeal, document D1 was taken to represent the closest prior for the claimed method. Both parties agree with this.

13. Document D1 discloses methods for genomic selection in breeding programs in livestock species, particularly in cattle with the aim of using genomic readouts to provide estimates of breeding value incorporating reproductive technologies to reduce generation interval by rapidly producing high genetic merit calves. The disclosed method involves steps for estimating desirable traits based on genetic testing of foetal cells (see abstract). The method disclosed in D1 comprises the collection of foetuses derived from IVF embryos, the establishment of fibroblast cell lines from foetal cells, followed by their genotyping and genetic merit evaluation (which corresponds to determining a GEBV or a GPTA according to the present claim). Selected fibroblasts are then used in somatic cell nuclear transfer (SCNT) to create embryos for embryo transfer leading to "High genetic merit calves" (see Figure 1a).

Figure 1a of D1 is reproduced below and shows a schematic representation of reproductive process employed.



14. The claimed method differs from that disclosed in D1 in the cell type used for genotyping. In the claimed method, DNA is extracted from one or more foetal amniocytes, whereas in D1 it is extracted from fibroblast cell lines derived from collected foetuses. The claimed method ends with the provision of genotype derived information (the so-called GEBV or GPTA). As noted above, steps carried out using the information are not a feature of claim 1. From consulting Example 1 of the patent it is furthermore apparent that the claimed invention includes embodiments where the amniocytes are cultured and the genotyping is done on cultured fibroblasts derived from said amniocytes (see Example 1, steps 2 to 4). Thus, both the claimed method and that disclosed in the prior art include genotyping of cultured fibroblasts. In D1 these are directly derived from an embryo (a collected foetus) whereas in the claimed method they are obtained by amniocentesis without having to collect the foetus.

15. The technical effect of these differences is the provision of genome-derived data without the need to collect a foetus.

The objective technical problem

16. The objective technical problem formulated on the basis of these differences may be seen as either the provision of an alternative method for post-implantation foetal genotyping (as suggested by the respondent and adopted in the decision under appeal) or more precisely, the provision of a method for post-implantation foetal genotyping that avoids the need to collect a foetus.

17. The appellant is of the view that the technical effect of the difference between the claimed method and that of D1 is an increase in the rate of pregnancy of high genetic merit foetuses and that therefore the objective technical problem was to increase the rate of pregnancy of high genetic merit foetuses and therefore increase genetic progress.

18. However, rate of pregnancy of high genetic merit foetuses is not a feature of the claimed method, which merely results in the determination of a genomic estimated breeding value (GEBV) or a genomic predicted transmitting ability (GPTA). Indeed, there is no requirement in the claim that these values are used in a method of animal breeding or reproduction at all. The rate of pregnancy of high genetic merit foetuses is not an implicit or inherent feature of the claimed method either. Such embodiments are also technically meaningful: for example, granted claim 10 (which refers to claim 1) comprises the further step of "verifying parentage of the fetus using the genotype". Confirming

the parentage of a foetus cannot by itself increase the rate of pregnancy. Thus, the technical problem suggested by the appellant cannot be adopted.

Obviousness

19. The question to be answered in assessing obviousness is whether or not the skilled person starting from the disclosure in D1 and seeking to provide a method for post-implantation foetal genotyping which avoids the need to collect foetuses would have arrived at the claimed method. In particular, it is asked whether the skilled person would have carried out the genotyping step described in D1 on DNA from amniocytes. Amniocytes are not mentioned in D1 at all. Thus, D1 alone did not provide a pointer to the claimed solution. However, as noted in the decision under appeal, the skilled person was aware of D16 which comes from the same field as the claimed invention (marker-assisted breeding methods in cattle; see abstract, column 2, lines 57 to 59, column 13, lines 11 to 13 and column 14, lines 51 to 67). D16 discloses methods for genotyping DNA from cattle foetuses and thus determining a parameter that reflects a desirable trait. In D16 this parameter is a genetic marker - SNPs located in the 3' end of the fatty acid synthase gene and encoded with exons 39-42 - associated with difference in fatty acid composition of meat products derived from those animals (see column 2, lines 40 to 59). In one embodiment, amniocytes are used as a source of DNA for genotyping, (see column 6, lines 40 to 47).

20. The skilled person starting from the method for post-implantation foetal genotyping disclosed in D1 and seeking a method which avoids the need to collect foetuses, having consulted D16, would have realised

that carrying out post-implantation genotyping on DNA from foetal amniocytes represented a solution to this technical problem. It is concluded that the claimed subject-matter was obvious to the skilled person and therefore does not involve an inventive step.

21. The board is not persuaded by the appellant's submission that D1 teaches away from adapting its method because it states that collection of early stage embryos and establishment of cell lines from the embryos is a highly cost effective means for increasing genetic gain in a cattle breeding program that the skilled person would not depart from.

22. The board can see no disclosure in D1 to the effect that cost effectiveness of the method disclosed therein would deter a skilled person from seeking an alternative post-implantation foetal genotyping method. D1 does not disclose any technical or practical obstacles which would prevent the skilled person from looking beyond its teaching. More importantly, the claim does not relate to a breeding program, only to a method for providing genomic data. The cost effectiveness of the breeding program disclosed in D1, is not relevant to the assessment of inventive step of the claimed method.

23. The appellant further submitted that combining the teaching in D1 with that in D16 would not have been obvious to the skilled person because:

i) D16 related to genetic markers for fatty acid content and did not address genetic progress.
ii) using amniotic fluid would reduce DNA quality and quantity, undermining D1's objectives.

iii) there was no indication in D16 that the use of amniocytes would be a suitable method for use in the context of improving genetic progress.

24. The board was not persuaded by these arguments either.

Re. i): as noted in the section on claim construction (see points 6. to 11. above), GEBV and GPTA as referred to in the claim are understood as relating to any parameter that reflects any subjectively desirable trait, and therefore also include genetic markers for fatty acid content or fatty acid content as such.

Re. ii): the appellant suggests that D1 teaches away from the claimed invention because the skilled person considered that DNA derived from cells from amniotic fluid had poorer quality and quantity, undermining D1's objectives. However, no such teaching is explicitly present in D1 (which does not mention cells from amniotic fluid). Also if a teaching away is to be considered as a technical obstacle sufficient to dissuade the skilled person from a certain path, it must be substantiated by verifiable facts, which it is not.

Re. iii): it is correct that D1 does not mention the use of amniocytes as a source of DNA for genotyping. Under the problem and solution approach, the motivation needed by a skilled person to modify or depart from the prior art starting point does not have to come from said starting point itself, but may come from considering what the skilled person at the relevant date would have done when seeking a solution to the objective technical problem "*having regard to the state of the art*" (Article 56 EPC).

Auxiliary request 1 - claim 1

Clarity (Article 84 EPC)

25. The opposition division held that this claim was not clear, *inter alia*, because the GEBV or a GPTA of the fetus based on the genotype was not used in the subsequent steps which referred to the genotype determined in a previous step. One of the reasons that the claim lacked clarity was that, in the opposition division's view, the reason from determining the GEBV or GPTA was not apparent nor was how these values were to be used to achieve the aim of increasing genetic progress.

26. The appellant has submitted that consulting the description would lead the skilled person to understand that "*the method can further comprise the step of determining a GEBV or GPTA of the fetus based on the phenotype*" (see point 4.1 of the statement of grounds of appeal). This submission seems to be beside the point and rather confirms the opposition division's concern that the GEBV and GPTA need not play a role in the claimed method, also confirming its concern that the claim including the step of determining these values, lacks clarity.

27. The board agrees with the opposition division that claim 1 lacks clarity for the reasons indicated above. Therefore claim 1 does not fulfil the requirements of Article 84 EPC.

Auxiliary request 2 - claim 1

28. Claim 1 of auxiliary request 2 suffers from the same lack of clarity as claim 1 of auxiliary request 1.

29. Since no claim request is allowable, the appeal must be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairwoman:

I. Aperribay M. Pregetter

Decision electronically authenticated