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Datasheet for the decision
of 7 August 2019

Case Number: T 1785/14 - 3.3.01
Application Number: 03787739.6
Publication Number: 1540336

IPC: G01N33/04, G01N21/35, A01J5/013, G05B13/04, G05B17/02, G05B23/02

Language of the proceedings: EN

Title of invention:
A SYSTEM AND A METHOD FOR OBSERVING AND PREDICTING PHYSIOLOGICAL STATE OF AN ANIMAL

Patent Proprietor:
Lattec I/S

Opponent:
Octrooibureau Van der Lely N.V.

Headword:
System and method for predicting physiological state of animal/LATTEC I/S

Relevant legal provisions:
EPC Art. 54(2), 56
Keyword:
Novelty - (yes)
Inventive step - (yes)

Decisions cited:

Catchword:
DECISION
of Technical Board of Appeal 3.3.01
of 7 August 2019

Appellant: Octrooibureau Van der Lely N.V.
(Opponent) Weverskade 110
3147 PA MAASSLUIS (NL)

Respondent: Lattec I/S
(Patent Proprietor) Slangerupgade 69
3400 Hillerød (DK)

Representative: Zacco GmbH
Bayerstrasse 83
80335 München (DE)

Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted on 4 July 2014 concerning maintenance of the
European Patent No. 1540336 in amended form

Composition of the Board:
Chairman A. Lindner
Members: T. Sommerfeld
P. de Heij
Summary of Facts and Submissions

I. European patent 1540336 is based on application 0378739.6, which was filed as an international application and published as WO 2004/017066. The patent is entitled "A system and a method for observing and predicting physiological state of an animal" and was granted with 40 claims.

II. Opposition was filed against the granted patent, the opponent requesting revocation of the patent in its entirety on the grounds of lack of novelty and inventive step (Articles 54(2) and 56 EPC and Article 100(a) EPC). Additionally, the opponent challenged the validity of the priority claim.

III. During the proceedings before the opposition division, the patent proprietor requested that the patent be maintained according to the main request filed during oral proceedings.

Claim 1 of the main request differs from claim 1 as granted essentially by insertion of the features of granted dependent claims 2 and 3. It reads:

"1. A system for observing and predicting a physiological state of an animal, the system comprising:
- a computer comprising a processor and being operatively connected to a database,
- at least one sample providing device for repetitively providing at least one sample of a body fluid of the animal,
- an analysis apparatus for analysing the at least one sample, so as to obtain at least one sample value of at least one parameter of the body fluid,"
- a data interface for repetitively entering the sample value of the at least one parameter in the database, wherein the database is adapted to store multiple database entries representing the sample value of the at least one parameter at various points in time, and wherein the processor is programmed to:
- perform at least one mathematical analysis of the at least one sample value, the mathematical analysis is a statistical analysis and the statistical analysis is a univariate analysis of the database entries to obtain a first set of data representing expected sample values of at least one of the parameters at future points in time, and
- selecting, on the basis of the at least one mathematical analysis, the point in time for providing a subsequent sample and performing a subsequent analysis of said subsequent sample for at least one of the parameters."

Likewise, independent claim 15 of the main request is based on granted claim 17, to which features of granted claims 18 and 19 were added:

"15. A method for observing and predicting a physiological state of an animal, the method comprising:
- repetitively providing at least one sample of a body fluid of the animal,
- analysing the at least one sample, so as to obtain at least one sample value of at least one parameter of the body fluid,
- entering the sample value of the at least one parameter in a database of a computer system, whereby the database is loaded with multiple database entries representing the sample value of the at least one parameter at various points in time, and
performing at least one mathematical analysis of the at least one sample value, the mathematical analysis is a statistical analysis and the statistical analysis is a univariate analysis of the database entries to obtain a first set of data representing expected sample values of at least one of the parameters at future points in time and selecting, on the basis of the at least one mathematical analysis, the point in time for providing a subsequent sample and performing a subsequent analysis of said subsequent sample for at least one of the parameters."

IV. By an interlocutory decision announced at oral proceedings, the opposition division decided that the patent could be maintained in amended form on the basis of the main request filed during oral proceedings (Articles 101(3)(a) and 106(2) EPC).

V. The opponent (appellant) lodged an appeal against the decision of the opposition division. With the statement of the grounds of appeal, the appellant requested that the decision be set aside and that the patent be revoked in its entirety.

VI. With its letter of reply to the statement of grounds of appeal, the patent proprietor (respondent) requested that the appeal be dismissed and that the patent be maintained in the form upheld by the appealed decision (main request) or, alternatively, that the patent be maintained according to the first or second auxiliary requests, both filed with the letter of reply.

VII. Oral proceedings before the board took place on 7 August 2019. At the end of oral proceedings, the chairman announced the board's decision.
VIII. The documents cited during the proceedings before the opposition division and the board of appeal include the following:

D1  WO 01/14887
D2  WO 02/069697
D8  WO 97/47187

IX. The appellant's submissions, in so far as they are relevant to the present decision, may be summarised as follows:

Novelty

The subject-matter of claims 1 and 15 of the main request was not novel over documents D1, D2 and D8.

It was apparent from Figure 4 of document D1 that the decision on when to take future samples depended on the values measured in the samples taken. As soon as the values reached a minimum, it was assumed that at least during the next 14 days there would be no need to sample because it was predicted that the values would remain high. This was further clear from page 6, lines 1 to 4 and lines 7 to 11, and from claim 8. Determining the minimum was in fact an univariate analysis since the set of data of one variable (in this case, progesterone) was used. Even if this prediction was not exclusively based on mathematical analysis but also on previous experience, it was still the determination of the minimum that triggered the selection of the next sampling time point, and the predicted high sample values within the next 14 days constituted a set of data representing expected sample values of the concentration at future points in time, which was used
to select when the next sampling should take place. All features were thus unambiguously disclosed in D1.

Document D2 also disclosed all features of the claimed subject-matter. The progesterone measurements were used to predict periods of expected oestrus, which constituted a set of data representing expected future sample values of the progesterone concentration, and the time points for sampling were adjusted depending on these data (page 14, second paragraph; page 17, lines 11 and following).

Document D8 also disclosed all features of the claimed subject-matter. If sampling was stopped, then it was obvious that it would have to be resumed at some time. There was no requirement in the claim that the next sampling time would have to be actively selected. The mere decision to continue sampling would correspond to deciding that the next point in time would be the next milking.

**Inventive step**

The subject-matter of claims 1 and 15 of the main request lacked an inventive step, starting from either D1, D2 or D8 as closest prior art and taking into account common general knowledge.

When starting from D1 as the closest prior art, the problem to be solved was the improvement of D1's system in terms of efficiency (sample economy) without jeopardising accuracy. It would have been immediately obvious to improve the system by getting rid of the inaccurate curve of D1's Figure 4 and replace it with a realistic curve based on the measured data. Page 3, line 28 and following, provided an incentive for
further processing the data. In the literal wording of the claims, there was no link between the set of predicted data and the selection of the sampling time point. But even if there were, D1 already provided the suggestion (page 5, line 20 to page 6, line 7). By using the measured data, a more accurate curve, with better approximation, could be extrapolated, thus leading to a more efficient system.

Likewise, when starting from document D2, the skilled person would have been prompted to use the progesterone concentration measurements for determining expected oestrus periods, thus generating expected future sample values, upon which the sample frequency would be based in accordance with the disclosure of page 17.

When starting from document D8, the alleged distinguishing feature of selecting a next point in time for sampling would have been incorporated by the skilled person without an inventive effort.

X. The respondent's arguments, in so far as they are relevant to the present decision, may be summarised as follows:

Novelty

Document D1 did not disclose using a mathematical analysis to obtain a set of predicted future values. Rather, D1's system selected the sampling time point based on experience, represented by the idealised oestrus cycle of Figure 4.

The same was true for document D2, which did not disclose the generation of a data set of predicted future values either.
In document D8, the samples were taken at every single milking, so there was no selection of a sampling time point. If sampling was stopped and then re-started, a new set of data was used because the previous model was no longer reliable. Not stopping the sampling was not equivalent to selecting a new point in time for sampling and analysis.

**Inventive step**

Starting from D1, the technical problem was to make sampling more efficient. There was nothing in D1 suggesting that the data could be processed further to obtain a set of expected sample values, given that what was meant by further processing on page 3, line 28 and following, of D1, was to determine the fertility status of the animal. Even if the claim did not explicitly state it, the only interpretation that made technical sense was that the predicted data set obtained by the mathematical analysis was used to select the sampling time point. D1 did not allow making such a prediction because this would require a statistical analysis of measurement data from several cycles and not from only one cycle as disclosed in D1. The solution was not suggested in D1, and it was too specific to be derived from common general knowledge. The same reasoning applied when starting from document D2.

As to document D8, it described a system for monitoring the animal's health status. It would thus not make any sense to restrict sampling times since illness could befall an animal at any time.

**XI.** The appellant requested that the decision under appeal be set aside and that the patent be revoked.
The respondent requested that the appeal be dismissed and that the patent be maintained in the form upheld in the appealed decision (main request) or, alternatively, that the patent be maintained on the basis of the set of claims of the first or second auxiliary requests, filed with the reply to the grounds of appeal.

**Reasons for the Decision**

1. The appeal is admissible.

**Main request**

2. **Novelty (Article 54(2) EPC)**

2.1 In the appealed decision, the opposition division decided that none of the documents D1, D2 and D8 was novelty-destroying for the subject-matter of the independent claims 1 and 15 of the main request. The board concurs with this conclusion for the following reasons.

2.2 **Document D1**

2.2.1 Document D1 discloses automated methods and systems for determining progesterone in raw milk of dairy animals. The method comprises multiple measurements of progesterone concentration of individual cows by using a biosensor connected to a computer. In this way, the course of the concentration of progesterone in raw milk, spread in time, can be determined per animal, stored and further processed. On the basis of the time-dependent concentration curve, it can be accurately determined when the cow is in heat, whether the cow is
in-calf, or whether the cow possibly has a defect of its reproductive apparatus (page 3, line 15, to page 4, line 4). A general representation of the course of the milk progesterone concentration in time is shown in Figure 4. By signalling the time at which the concentration sharply decreases, the time of oestrus can be accurately determined. When the concentration does not decrease again around the twenty-sixth day, the animal is either gestating or possibly has a defect of its reproductive apparatus. Since it is known that the progesterone concentration will remain high for about two weeks after a change in the determined amount of progesterone in time has reached a minimum, the progesterone content of the milk of the cow is not determined during this time. As shown in Figure 4, in general only after the fourteenth day, when the animal is not gestating and/or does not have a defect of its reproductive apparatus, will the concentration decrease again. Only after 14 days, therefore, is it again of interest to start monitoring the change over time of the amount of progesterone in the milk (page 5, line 20, to page 6, line 11).

2.2.2 It is thus undisputed that D1 discloses "a system for observing and predicting a physiological state of an animal" (oestrus in D1), which comprises "a computer comprising a processor and being operatively connected to a database, at least one sample providing device for repetitively providing at least one sample of a body fluid of the animal, an analysis apparatus for analysing the at least one sample, so as to obtain at least one sample value of at least one parameter of the body fluid, a data interface for repetitively entering the sample value of the at least one parameter in the database, wherein the database is adapted to store multiple database entries representing the sample value
of the at least one parameter at various points in
time". Moreover, D1 also discloses that "the processor
is programmed to perform at least one mathematical
analysis of the at least one sample value, the
mathematical analysis being a statistical analysis
which is a univariate analysis of the database
entries" (e.g. the determination of a minimum of the
progesterone concentration) and that "on the basis of
the at least one mathematical analysis, the point in
time for providing a subsequent sample and performing a
subsequent analysis of said subsequent sample for at
least one of the parameters" is selected (namely 14
days after the minimum is measured). However, D1 does
not disclose that "a first set of data representing
expected sample values of at least one of the
parameters at future points in time" is obtained by
mathematical analysis. The appellant failed to indicate
any passage in D1 where such a feature is disclosed,
and the board disagrees that such a disclosure may be
considered implicit. While, as argued by the appellant,
the system of D1 is based on the prediction that, after
a concentration dip, the progesterone concentration
will remain high for at least the next 14 days, this
prediction is not equivalent to creating a data set of
predicted values.

2.2.3 Hence, the subject-matter of claims 1 and 15 of the
main request is novel over D1 (Article 54(2) EPC).

2.3 Document D2

2.3.1 Document D2 is an international patent application
published after the priority dates of the present
patent but before its filing date. During the
proceedings before the opposition division, it was
concluded that the priority was not valid for the
subject-matter of claims 1 and 15 of the main request, and this finding was not contested during appeal. Hence, document D2 is considered prior art citable under Article 54(2) EPC.

2.3.2 Document D2 discloses an automated system for optimising the production performance of a milk producing animal herd, which comprises "an apparatus for analysing a plurality of compounds or parameters in a milk sample of an individual member of a milk producing animal herd, said apparatus comprising: (i) separate means for analysing individual compounds or parameters in the milk sample, each of said separate means being capable of generating a detectable signal in the presence of an individual sample compound or parameter, (ii) means for directing a part of the milk sample to each separate analysing means, said directing means being controlled by means for storing data for the physiological and nutritional state of each individual herd member, including data indicating point in time in the reproduction and lactation cycles of said herd member, such that the directing means is only activated at pre-selected points in time or at pre-selected time intervals in the production or lactation cycles of the individual herd member" (page 8, lines 19 to 33).

2.3.3 Similarly to D1, document D2 thus discloses all features of claims 1 and 15 of the main request, with the exception of the feature that "a first set of data representing expected sample values of at least one of the parameters at future points in time" is obtained by the mathematical analysis. Again, while the sampling time is under control of the processor and depends on the values obtained for the measured parameters, there is no disclosure in D2 that a data set of predicted
values is created, on the basis of which the sampling time is decided upon. The passages on pages 14 (second paragraph) and 17 (second paragraph) teach that the progesterone measurements are used to predict periods of expected oestrus, but this is not equivalent to creating a set of data representing expected future sample values of the progesterone concentration.

2.3.4 Hence, the subject-matter of claims 1 and 15 of the main request is novel over D2 (Article 54(2) EPC).

2.4 Document D8

2.4.1 Document D8 discloses a system and method for monitoring the physical condition of a herd of livestock, that comprise using errors between values predicted in accordance with a time-series model and corresponding measured values to determine a confidence interval for each animal individually. Figure 2 depicts a flow chart showing how the system is implemented, the algorithm according to the flow chart being preferably repeated at each milking (page 7, lines 7 to 10). Measurements of different parameters are taken at each milking and for each individual, identified animal, and the measured values are read by the data processing structure. On the basis of earlier measurements and predictions, or at the first milking of a lactation as an initial set of values and parameters, status data which determine the prediction for each next value to be measured and characterise the distribution of errors in previous predictions are stored in a memory of the data processing structure for each individual, identified cow (page 7, lines 24 to 30). If at least one of the measured values is outside the confidence interval or if a combination of errors symptomatic of a particular condition of an animal occurs, an attention
signal is generated (page 9, lines 2 to 6). After an
attention signal has been generated, the model on the
basis of which the predictions are being made is not
reliable anymore for the respective cow, in particular
if the attention signal indicates that a value outside
one of the wider confidence intervals has been
measured. Therefore, in step 30 of Figure 2, the
monitoring of a cow on the basis of the collected data
is as a rule stopped in response to an attention signal
regarding the respective animal, or at least in
response to an attention signal above a certain
confidence level regarding the respective animal. If it
is decided that no attention signal or no attention
signal above a predetermined confidence level is to be
generated, the status data for the respective
individual cow are updated using two of the following
three sets of data: the latest measured values, the
latest predictions and the latest errors between the
predictions and the corresponding measured values (step
31 of the flow chart). If after an attention signal has
been generated verification by the farmer or by a
veterinarian reveals that the attention signal was
unjustified, the measured values are preferably
replaced by the predicted values, so the monitoring of
the checked animal can be continued on the basis of the
previously collected data and the data entered instead
of the latest set of measured values (page 10, lines 2
to 31).

2.4.2 Document D8 thus discloses "a system for observing and
predicting a physiological state of an animal" (health
status in D8), which comprises "a computer comprising a
processor and being operatively connected to a
database, at least one sample providing device for
repetitively providing at least one sample of a body
fluid of the animal, an analysis apparatus for
analysing the at least one sample, so as to obtain at least one sample value of at least one parameter of the body fluid, a data interface for repetitively entering the sample value of the at least one parameter in the database, wherein the database is adapted to store multiple database entries representing the sample value of the at least one parameter at various points in time. Moreover, D8 also discloses that "the processor is programmed to perform at least one mathematical analysis of the at least one sample value, the mathematical analysis being a statistical analysis which is a univariate analysis of the database entries to obtain a first set of data representing expected sample values of at least one of the parameters at future points in time" (e.g. the calculation of predicted values and confidence intervals). The system of D8 thus comprises all features of the system of claim 1 of the main request, with the exception that there is no selection of a next time point for sampling on the basis of the predicted data set. In fact, D8's system is programmed for continuous sampling at each milking, and this sampling is only interrupted if there is an error falling outside the confidence interval. Should the error be still within the confidence interval, sampling is continued normally. There is thus no selection of a time point for further sampling but merely a decision to stop or to continue sampling. Contrary to appellant's arguments, this is not equivalent to deciding on a specific time point for the next sampling to take place.

2.4.3 Hence, document D8 does not disclose all the technical features of claim 1 and claim 15 of the main request. Claims 1 and 15 of the main request are thus novel over D8 (Article 54(2) EPC).
3. **Inventive step (Article 56 EPC)**

3.1 Documents D1 or D2 as closest prior art

3.1.1 The present patent is directed to a system and a method for observing and predicting the physiological state of an animal, as defined by the features of claims 1 and 15 (for the exact wording, see section III).

3.1.2 Document D1, which also discloses a system and method for observing and measuring the physiological state of an animal (in this case, the fertility status of a dairy animal), is the closest prior art. As discussed above under novelty, the distinguishing feature between the system and method of D1 and those of the claimed invention is that D1 does not disclose that a first set of data representing expected sample values of at least one of the parameters at future points in time is obtained by mathematical analysis, on the basis of which the point in time for a subsequent sampling is selected. The technical effect associated with this feature is that the system can be adapted to each individual animal. The technical problem can thus be formulated as the provision of a system and method which are improved in terms of being more individualised and therefore allowing better accuracy in determining the sampling time. The solution is the subject-matter as claimed and the board is satisfied that it plausibly solves the technical problem.

3.1.3 With the aim of solving the technical problem, the skilled person would have considered modifying the system and method of D1 to render it more individualised. For this purpose, they would have used the data collected for each individual animal to define its particular oestrus cycle, thereby being able to
decide, for each animal, what the best point in time for a subsequent sampling would be. Hence, the skilled person would have arrived at a solution to the technical problem, however, not necessarily at the claimed solution, which requires that a data set of predicted values be produced. The board fails to see any incentive or suggestion in D1 or in the remaining prior art to produce a set of predicted values in the context of the present invention or that the common general knowledge would have prompted the skilled person to do so. The passage of page 3, lines 28 to 30, cited by the appellant, only suggests further processing of the data, without teaching how. It is true that the skilled person would have considered the curve of Figure 4 as an over-simplistic model and would thus have been motivated to use the data actually measured for each cow to define a more realistic, individualised curve, but they would not necessarily have been motivated to create a data set of predicted values. Hence the claimed subject-matter is inventive over D1 (Article 56 EPC).

3.1.4 The same reasoning applies also when starting from document D2 as the closest prior art. As determined above under novelty, the distinguishing feature between the system and method of D2 and those of the claimed invention is the same as in relation to document D1 and, again, D2 does not provide any suggestion or incentive, alone or combined with common general knowledge, pointing to the claimed invention. Hence, the claimed subject-matter is also inventive over D2 (Article 56 EPC).

3.1.5 A further issue which was discussed in the context of the distinguishing feature over the systems of D1 and D2 was whether there was indeed an associated technical
effect. As the claims do not state explicitly that the selection of the time point for subsequent sampling is on the basis of the data set of predicted values but rather that it is on the basis of mathematical analysis, it could be interpreted that the system did not necessarily require the use of the obtained data set, in which case this feature did not have a technical effect. However, the board agrees with the respondent's arguments that this interpretation would not make technical sense in the context of the claim. The mathematical analysis clearly results in the creation of the data set of predicted values and thus the use of the mathematical analysis implicitly means that the created data set is used.

3.2 Document D8 as closest prior art

3.2.1 Document D8 is further away from the presently claimed invention because it is concerned with monitoring the animal's health status rather than determining physiological states. Starting from document D8, the distinguishing feature between the system and method of D8 and those claimed is that, although there is generation of predicted data values, there is no selection of a time point for subsequent sampling based on these predicted data values. Rather, the predicted data values are used to define confidence intervals which allow determining whether a given measured value falls within the intervals and, accordingly, whether the measurement model is still reliable or has to be reset. The technical effect associated with the distinguishing feature is that a more accurate, animal-tailored sampling scheme, which is particularly useful for measuring parameters which change with the different physiological states of the animal, is provided. The technical problem can thus be formulated
as the provision of an improved system and method for assessment of the animal's physiological state. There is no suggestion or incentive in D8 or in the remaining prior art that would have prompted the skilled person, taking their common general knowledge into account, to change the system and method of D8 in this way for solving the technical problem. Hence, the claimed subject-matter is also inventive over document D8 (Article 56 EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated