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**Datasheet for the decision
of 12 March 2019**

Case Number: T 0662/14 - 3.3.08

Application Number: 05783958.1

Publication Number: 1786920

IPC: C12Q1/04

Language of the proceedings: EN

Title of invention:

MODULAR COMPOSITING-MULTIPLE LOT SCREENING PROTOCOLS FOR
DETECTION OF PATHOGENS, MICROBIAL CONTAMINANTS AND/OR
CONSTITUENTS

Patent Proprietor:

Institute for Environmental Health, Inc.

Opponent:

bioMérieux Inc.

Headword:

Test lot screening/INSTITUTE FOR ENVIROMENTAL HEALTH

Relevant legal provisions:

EPC Art. 54, 111(1), 123(2)
RPBA Art. 13(1)

Keyword:

Consideration of late-filed evidence (no)
Main request - added matter (no)
Novelty (yes)
Remittal for examination of inventive step

Decisions cited:

G 0009/91, T 1002/92

Catchword:



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Case Number: T 0662/14 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 12 March 2019

Appellant: Institute for Environmental Health, Inc.
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 14 February
2014 revoking European patent No. 1786920
pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman B. Stolz
Members: M. R. Vega Laso
R. Winkelhofer

Summary of Facts and Submissions

- I. The appeal of the patent proprietor lies from a decision of an opposition division under Article 101(3) (b) EPC posted on 14 February 2014, revoking the European patent No. 1 786 920 (application No. 05783958.1) with the title "Modular compositing-multiple lot screening protocols for detection of pathogens, microbial contaminants and/or constituents". The application had been filed as an international application under the Patent Cooperation Treaty and published as WO 2006/017832 (in the following "the application as filed").
- II. The patent, which was granted with 16 claims, had been opposed on the grounds for opposition of Article 100(a) in conjunction with Articles 54 and 56; 100(b) and 100(c) EPC.
- III. In the decision under appeal, the opposition division found that none of the requests then on file (main request and first and second auxiliary requests) fulfilled the requirements of the EPC. In particular, the subject-matter according to the main request filed at the oral proceedings was considered to lack novelty over document (3) (see section XII below).
- IV. Claim 1 of the main request reads:
- "1. A method of sampling, testing and validating test lots, comprising:
- a) collecting a plurality of portions from each of a plurality of test lots, the test lots each comprising an assemblage of one or more specimens, wherein each test lot is separately sampled by taking said plurality of portions thereof;

b) combining the collected portions corresponding to each of the separate test lots to provide a corresponding set of separate test lot samples, wherein each separate test lot sample is attributed to a particular corresponding separate test lot;

c) incubating the set of separate test lot samples under conditions suitable to allow levels of a target agent or organism that is present in one or more of the separate test lot samples to reach detectable levels and become uniform, or substantially uniform, throughout the respective one or more separate test lot samples, to provide a set of separate enriched test lot samples;

d) removing, aseptically, equal portions of each enriched separate test lot sample, and combining the removed portions to provide a modular composite sample; and

e) testing of the modular composite sample, using a suitable detection assay, for the target agent or organism, wherein where such testing is negative all of said separate test lot samples are validated, and wherein where such testing is positive, individual test lots are validated by further testing of a portion of the respective enriched separate test lot sample using the same or a more sensitive protocol and obtaining a negative test result."

Dependent claims 2 to 16 are directed to various embodiments of the method of claim 1.

V. Together with its statement of grounds of appeal, the appellant submitted eight sets of claims as main request and first to seventh auxiliary requests which replaced the requests underlying the decision under appeal.

- VI. The opponent (respondent) replied to statement of the grounds of appeal and contested the new requests.
- VII. On 27 October 2015, the appellant re-submitted the set of claims according to the main request underlying the decision under appeal (see section IV above) and filed seven new sets of claims that replaced the sets of claims filed together with the statement of grounds of appeal. Moreover, the appellant filed additional evidence.
- VIII. The parties were summoned to oral proceedings. On 18 January 2019, the respondent submitted a new line of argument relying on new documentary evidence (document (16); see section XII below). The appellant replied and requested that the new submissions and evidence not be admitted into the proceedings.
- IX. In a communication sent in preparation of the oral proceedings, the board provided some observations on procedural issues and expressed a provisional opinion on novelty in view of documents (1) to (3) (see section XII below).
- X. In reply to the board's communication, the appellant withdrew its fourth to seventh auxiliary requests.
- XI. Oral proceedings were held on 12 March 2019.
- XII. The following documents are referred to in this decision:
- (1): R.J. Thomas et al., Australian Veterinary Journal, February 1981, Vol. 57, pages 69 to 71;

- (2): R.H. Davies et al., Journal of Applied Microbiology, 2003, Vol. 95, pages 1016 to 1025;
- (3): W.R. Price et al., Applied Microbiology, April 1972, Vol. 23, No. 4, pages 679 to 682;
- (4): US 2004/0241773, published on 2 December 2004; and
- (16): D.E. Gombas et al., Journal of Food Protection, 2003, Vol. 66, No. 4, pages 559 to 569.

XIII. The submissions made by the appellant concerning issues relevant to this decision, were essentially as follows:

Admission and consideration of document (16)

The new cited document (16) should not be admitted into the proceedings and considered by the board. The introduction, at a very late stage of the appeal proceedings, of evidence which could have been filed much earlier, was an abuse of proceedings and should be rejected independently of the possible relevance of the evidence.

Article 54 EPC - novelty

Document (3)

The opposition division erred in finding that the subject-matter of the main request lacked novelty over document (3). Document (3) related to a model of a practical situation, rather than to the situation itself, and did not describe a method comprising the two combination steps b) and d) specified in claim 1. Contrary to the opposition division's view, the

artificially constructed "samples" in Figure 1 of document (3) were not "test lots" as defined in paragraph [0014] of the patent. Even if the opposition division's unduly broad interpretation of "test lot" were correct, the content of document (3) did not destroy the novelty of claim 1 because a person skilled in the art could not derive from this document either the step of collecting a plurality of portions from each of those test lots, or the step of combining those collected portions to provide a corresponding set of separate test lot samples (steps a) and b) of the method of claim 1).

Document (3) did not teach step c), either. In the method of document (3), the "samples" were incubated in pre-enrichment media, before being combined for enrichment and subsequent testing. Pre-enrichment was, however, not the same as enrichment because it did not allow the target organism to reach detectable levels, otherwise a subsequent enrichment step would not have been necessary. In sum, the main request was novel over document (3).

Document (1)

Also document (1) did not describe the two combination steps b) and d) of the method of claim 1. Moreover, the pre-enrichment step described in document (1) was not equivalent to step c) of the method of claim 1, because during pre-enrichment little or no growth took place. Consequently, the method of claim 1 was novel over document (1).

Document (2)

The method described in document (2) was aimed at monitoring *Salmonella* in slaughter pigs by taking different kinds of samples. As for blood samples, the method described in document (2) did not involve either step a) or step b) as defined in claim 1, let alone steps c) and d). While faecal samples were in fact pooled and incubated in order to allow *Salmonella* to grow sufficiently to be detected, as required by steps b) and c) in claim 1, the test lot samples taken from separate farms/herds were not combined to form a modular composite sample representative of the plurality of test lots, but rather tested individually. Hence, the method described in document (2) did not destroy the novelty of the method of claim 1.

- XIV. The submissions by the respondent, insofar as they are relevant to the present decision, may be summarised as follows:

Admission and consideration of document (16)

Although document (16) had been submitted late in the proceedings, it should be admitted and considered by the board because its content was clearly highly prejudicial to the novelty of the claimed subject-matter. The new evidence could not have been submitted earlier because the respondent had become aware of it only recently. The content of document (16) should be well known to the appellant from related US litigation proceedings.

Article 54 EPC - novelty

Document (3)

The opposition division's finding that the method of claim 1 lacked novelty over document (3) was correct. The term "test lot" as used in step a) and defined in paragraph [0014] of the patent was not restricted to very large units of production, but could be arbitrarily defined according to the want of the user to cover any particular assemblage of specimens, the only limitation being that the specimens are "operationally linked". Figure 1 of document (3) showed three samples (test lots), with a portion of the sample having been separated from the main sample. Step b) of the method of claim 1 should not be interpreted as defining an active step. The act of scooping a powder (as in document (3)) inherently followed a temporal order of first collecting a plurality of portions from the specimens of the test lot and subsequently combining them, as required in steps a) and b) of claim 1.

There was no limitation in the claims that could distinguish between a pre-enrichment phase and an enrichment phase. As apparent from paragraph [0022] of the patent, test lot samples could be enriched without the addition of a distinct "enrichment medium". In view of the statements on page 681, column 1, lines 22 to 27 of document (3), it was clear that even in the pre-enrichment step there was active growth of *Salmonella*. The wording "detectable levels" of target organism as used in step c) of claim 1 was largely meaningless, especially in view of the fact that extremely small quantities of microorganisms could be detected with modern detection methods.

Document (1)

Document (1) destroyed the novelty of the method of claim 1. In the method described in this document, 10 x 25 g samples from a single stock feed were each (i.e. individually) added to 225 ml volumes of buffered peptone water to produce 10 pre-enrichment samples per stock feed. The opposition division correctly found that one could designate each of the 25 g samples of the primary stock feed as a "test lot" which contained a plurality of "portions" (i.e. particles, as the stock feed was a particulate aggregate). When transferring the 25 g of the stock feed into the receptacle, the collected portions were necessarily combined. Nothing in the patent required a lengthy temporal and physical break between collecting the portions and combining them.

Claim 1, step e) did not require that the retesting of the enriched test lot samples was conducted only on condition that a positive result was obtained when testing the modular composite samples. There was no absolute requirement that one could not be testing enriched test lot samples in parallel with testing the modular sample.

Document (2)

Two alternative scenarios were taught in document (2). In a first scenario, individual pigs in a farm could be considered as a test lot because a pig comprised an assemblage of "operationally linked" specimens (e.g. aliquots of blood). In paragraph [0016] of the patent, a "product portion" was defined as a piece, aliquot or weight of a product. There was neither a limitation of

any required size of volume of a product portion, nor a limitation that the aliquots or weights had to be collected from separate parts of the test lot, or at separate times. Each blood sample as described in document (2) necessarily comprised a plurality of portions, since it inevitably comprised numerous aliquots of blood. Allowing the blood samples to stand at room temperature as described on page 1017, 4th full paragraph of document (2) fell within the terms of step c) in claim 1. In any case, the frozen blood samples had to be incubated to restore them to a working temperature in order that the tests could be performed. The opposition division was mistaken in its finding that there was a conditional requirement in the patent that testing of an enriched test lot sample was only carried out on the finding of a positive result whilst testing the modular composite sample.

In a second scenario of document (2), one could designate groups of pigs within the herd of a single farm as each being a test lot. Thus, taking a single farm, there was a plurality of test lots, each of which had a plurality of portions (blood samples) separately collected from, and allocated to, them. As regards steps c) to e), the same applied as for the first scenario. Consequently, claim 1 lacked novelty over document (2).

XV. The appellant requests that the decision under appeal be set aside and the case be remitted to the opposition division for the examination of inventive step of the main request.

XVI. The respondent requests that the appeal be dismissed.

Reasons for the Decision

Admission and consideration of document (16) and the respondent's new line of argument based on this document

1. More than five months after receiving the summons to oral proceedings and only few weeks before the date for which the oral proceedings had been scheduled, the respondent put forward a new line of attack to the novelty of the claimed subject-matter based on a new document (16). The respondent admitted that the new evidence was filed late, but argued that document (16) could not have been submitted earlier because the respondent had been unaware of it until shortly before the oral proceedings.

2. This circumstance does not justify the late filing of the new evidence. Document (16) is a scientific publication dealing with the results of a survey of the microbial pathogen *Listeria monocytogenes* in different categories of ready-to-eat foods (e.g. deli salads, luncheon meats or soft cheeses) carried out in the United States with the aim of assessing the risk posed by the pathogen to consumers. Hence, the document belongs to the same technical field as the present invention, namely sampling and detecting environmental contaminants, in particular microbial food contaminants. Moreover, document (16) was published in 2003, i.e. about a year before the priority date claimed in the patent in suit.

3. There is no apparent reason why document (16) could not have been retrieved by a search for the relevant state of the art carried out when preparing the opposition or the response to the appellant's statement of grounds of appeal, at the latest. It should be noted that claim 1

according to the present main request is identical to claim 1 of the main request underlying the decision under appeal and, except for a minor amendment introduced into step e), also essentially identical to the corresponding claim of the patent as granted. Hence, the legal and factual framework of the proceedings has not changed. Under these circumstances, there is no **objective** reason that justifies the submission of document (16) only few weeks before the oral proceedings before the board.

4. Pursuant to Article 13(1) of the Rules of Procedure of the Boards of Appeal (RPBA), any amendment to a party's case after it has filed its grounds of appeal or reply may be admitted and considered at the board's discretion. When deciding to exercise its discretion not to admit the new line of argument and the new document (16), the board has taken into account not only the very late stage of the proceedings at which both were submitted and the need for procedural economy (see Article 13(1), second sentence RPBA), but also the fact that the appellant objected to the admission and consideration of the late-filed evidence. As regards the alleged high relevance of the content of document (16), the board considers this to be a factor which only in exceptional cases justifies the admission of new evidence and related arguments in appeal proceedings, in line with the primary purpose of the appeal proceedings which is to give a judicial decision upon the correctness of a separate earlier decision taken by a department of the European Patent Office (see decision of the Enlarged Board of Appeal G 9/91, OJ EPO 1993, 408 and decision T 1002/92, OJ EPO 1995, 605). In the present case there are no exceptional circumstances that justify admitting document (16) and the new line of argument based on this document.

5. Despite not being relevant to the present decision, the board remarks that it appears doubtful whether document (16) can be regarded as highly relevant to the issue of novelty, in the sense that it can reasonably be expected to change the eventual result on novelty and is thus highly likely to prejudice maintenance of the patent. In the board's view, the method described therein does not seem to be aimed at the validation of food test lots, as required by claim 1.
6. Hence, new document (16) and the respondent's arguments based on this document are not admitted into the proceedings.

Article 123(2) EPC - added matter

7. In the decision under appeal, the opposition division found that the claimed subject-matter does not extend beyond the content of the application as filed (see section 2 of the decision under appeal). This finding has not been contested in appeal proceedings and the board sees no reason to raise any objection under Article 123(2) EPC on its own motion.

Article 54 EPC - novelty

Document (3)

8. In the decision under appeal, the subject-matter of claim 1 was found to lack novelty over document (3). In particular, the opposition division held that document (3) described a method in which a plurality of samples are taken and then incubated (see section 6.3 of the decision). This finding was contested by the appellant arguing that document (3) does not describe a

method comprising two compositing steps, in particular does not teach the compositing step defined in steps a) and b) of the method of claim 1.

9. The board shares the appellant's view. Document (3) describes a method for testing multiple food samples for *Salmonella* by pooling pre-enrichment broth cultures. The authors found that up to 25 pre-enrichment broth cultures can be pooled without apparent loss in the sensitivity of *Salmonella* detection as compared to individual sample analysis (see abstract).
10. For the experiments, *Salmonella*-inoculated test samples were prepared by blending the dry test food, specifically dried egg albumen, cocoa, non-fat dry milk, wheat flour, coconut or cottonseed flour with one of three different dry inocula, at levels ranging from 6 salmonellae per 100 g to 3,000 salmonellae per g (see page 679, right-hand column, second full paragraph and the paragraph bridging pages 679 and 680). *Salmonella*-inoculated samples and uninoculated samples were "... individually pre-enriched followed by transfer from multiple pre-enrichments to single selenite and tetrathionate broths at the enrichment stage" (see page 679, second sentence of the paragraph bridging the left- and right-hand column). Prior to pooling, a portion of each pre-enrichment culture was transferred to a sterile culture tube and retained at 4°C for later reference to the individual samples when the *Salmonella* test of the pooled samples turned out to be positive (see page 679, second sentence of the paragraph bridging the left- and right-hand column).
11. The method is illustrated in Figure 1 of document (3) as follows:

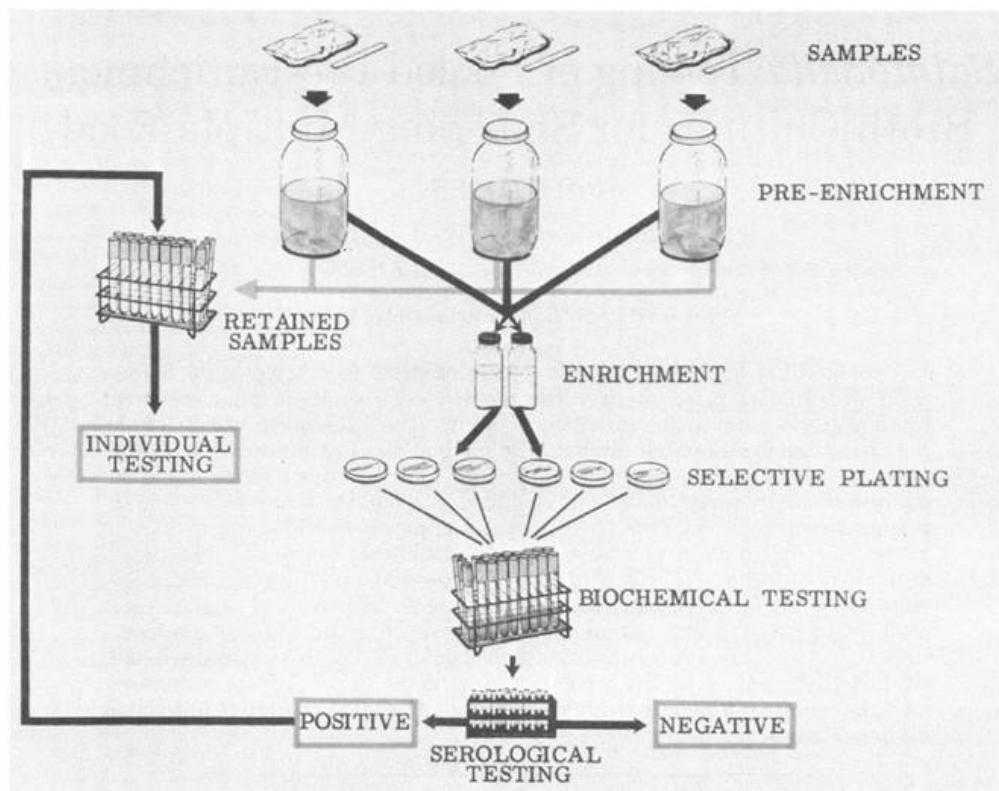


FIG. 1. *Salmonella* testing of pooled pre-enrichment broths.

- 12. As stated by the opposition division in the decision under appeal, it is apparent from Figure 1 that a plurality of samples are incubated in pre-enrichment broth for *Salmonella*; however, the question arises whether it is also apparent from the figure or can be derived from the statements in document (3) that each of these samples is obtained by combining a plurality of portions collected from a test lot to be validated (see steps a) and b) in claim 1).

- 13. In the appeal proceedings, the interpretation of the terms "test lot" and "portion" used in steps a) and b) gave rise to much controversy between the parties. The term "test lot" is defined in paragraph [0014] of the patent as referring to "... an assemblage of one or more specimens of a medium or process (e.g., assemblage

of specimens of air, water, solids, or of products of a production process, etc.), where such assemblage can be sampled by taking portions of the one or more specimens thereof, and where the one or more specimens of the assemblage are operationally linked in a manner (e.g., proximity, time, process step, etc.) whereby information derived about sampled portions is operationally applicable to all specimens of the assemblage, and thus to the test lot". A similar definition is found in paragraph [0030] ("... one or more operationally-linked specimens of a medium or process"). The term "portion" used in claim 1 is defined in paragraph [0016] of the patent as "... a product piece (e.g., a piece of solid beef trim, etc.), aliquot of product (e.g., a volume of liquid juice) or weight of product (e.g., a weight of semi-solid pudding)."

14. The term "test lot" is defined in paragraphs [0014] and [0030] of the patent quite generally in order to cover different situations in specific production technologies. However, as the appellant asserted, this term has a clear technical meaning to a skilled person in the field of testing industrially manufactured products, in particular food products and pharmaceuticals, for microbiological safety and quality. In the relevant art, a "test lot" is understood as a unit of production that is being tested in order to assess its microbiological safety and quality. Contrary to the respondent's view, the mere fact that, as apparent from the statements in paragraphs [0055] and [0060] of the patent relating to specific applications of the claimed method, what constitutes a "test lot" may vary depending on, *inter alia*, the product being tested, the production process and the specific test required, does not mean that the

definition in paragraph [0014] of the patent is arbitrary or ambiguous, and that the term "test lot" in claim 1 must be interpreted broadly so that it covers also samples as illustrated on top of Figure 1 of document (3).

15. The respondent argued that Figure 1 shows three samples (test lots), with a portion of the sample having been separated from the main sample, this indicating that there has been collection of a plurality of portions (particulate matter) from the main sample (test lot). In a further line of argument, the respondent contended that each of the objects on top of Figure 1 represented a portion of a test lot, and that two of the portions were combined by adding them to the pre-enrichment medium. In the board's view, both interpretations are highly speculative. In the light of the statements in the second full paragraph on the right-hand column of page 679, it appears that the two objects might represent the dry test food and the inoculum being blended to prepare a sample "artificially" inoculated with *Salmonella* (see paragraph 10 above).

16. Even if, for the sake of argument, it is assumed that the "SAMPLES" in Figure 1 are "test lots", a person skilled in the art cannot derive directly and unambiguously from Figure 1 of document (3) that portions of each of those "test lots" are collected **and** combined to provide a set of test lot samples, as specified in steps a) and b) of claim 1. The board cannot accept the respondent's argument that, when taking a sample from a package of a dry test food, e.g. cocoa as described in document (3), inevitably a plurality of portions is taken and combined. Since the purpose of steps a) and b) is "*to form a typical or average sample that is representative of the test*

lot ... being sampled" (see page 4, lines 52 and 53 of the patent), they require action to be taken, i.e. first collecting a plurality of different portions and then combining them to form a representative sample.

17. As regards the respondent's further line of argument that the content of the large bottles marked as "PRE-ENRICHMENT" in Figure 1 of document (3) may be considered to be the "test lot", similar considerations apply. Moreover, if this interpretation were accepted, the question would arise whether a person skilled in the art can derive from Figure 1 a second compositing step as defined by step d) of claim 1, i.e. removing equal portions of each enriched separate test lot sample and combining the portions to provide a modular composite sample for testing. This is clearly not the case.

18. Summarising the above, a person skilled in the art cannot derive from Figure 1 of document (3) a method comprising the steps a) and b) specified in claim 1, i.e. the steps of collecting a plurality of portions from each of a plurality of test lots, and combining the collected portions corresponding to each of the separate test lots to provide a set of separate test lot samples. Hence, already for this reason the method of claim 1 is novel over document (3).

Document (1)

19. In this document, three different techniques, the Most Probable Number technique, the 10 x 25 g samples technique and a pooled pre-enrichment technique for the examination of stock feeds for *Salmonella* are compared (see page 69, left-hand column, last paragraph under the heading "Introduction" and Table I). The authors

found that the results obtained using the pooled pre-enrichment technique were not significantly different from the results obtained by examining the 10 x 25 g samples individually.

20. In the decision under appeal, the opposition division held that document (1) does not describe re-testing the separate enriched test lot samples **after** the modular composite sample has been tested positive (see section 4.4 of the decision under appeal). In fact, in the experiment described in document (1) the composite sample and the individual 10 x 25 g samples are tested at the same time, i.e. a positive testing of the modular composite sample is not a pre-condition for re-testing the individual test lot samples, contrary to what claim 1 specifies.
21. The board disagrees with the respondent's view that step e) in claim 1 does not require that the testing of the individual enriched test lot samples is conducted only on condition that a positive result is obtained when testing the modular composite sample. This interpretation is at odds with the wording of step e) and one of the purposes of the invention, namely to allow for cost savings associated with testing (see paragraph [0001] of the patent).
22. For these reasons, the content of document (1) is not prejudicial to the novelty of the method of claim 1.

Document (2)

23. The experiments described in document (2) were designed to evaluate the use of pooled serum and meat juice samples in comparison with i) the conventional ELISA test carried out on individual samples and

ii) bacteriological results for samples taken at the farm of origin of the batches of pigs tested. The objective was to determine whether pooled serum or meat juice could act as an effective indicator of *Salmonella* infection status for the purpose of monitoring pig herds (see last paragraph under the heading "Introduction").

24. For comparison, individual samples and pooled samples (pools of 5, 10 or 20 samples) were tested in the same experiment (see Table 1 for pig serum and Table 2 for pig meat juice). The authors found that testing one pooled sample per farm gave results which compared well with testing 20 individual samples, and concluded that pooled serum or meat juice samples could be used as a cheaper substitute for surveillance of farms for *Salmonella* (see page 1023, right-hand column, first two sentences of the second full paragraph, and abstract).
25. The opposition division found that, as in document (1) "... *there is no teaching [in document (2)] of the Step e) insofar as individual validation of samples occurs only upon the receipt of a positive pooled/composite result*". Moreover, the opposition division stated that "... *the leaving of the blood clot to form is not the same as a deliberate step of incubation for the target agent or organism to become uniform ...*", as required in step c) of claim 1 (see section 5.2 of the decision under appeal).
26. These findings are correct. Irrespective of the possible "scenarios" put forward by the respondent with regard to what could represent a "test lot" in document (2) (individual pigs vs. groups of pigs), neither step c) nor step e) of the method of claim 1

can be derived directly and unambiguously from this document.

27. Hence, document (2) does not destroy the novelty of the method of claim 1.

Remittal to the opposition division

28. Since in the decision under appeal the opposition division found that the subject-matter of claim 1 of the main request lacked novelty, inventive step was not assessed in respect of this request. The issue was discussed only in connection with the first auxiliary request then on file, starting from document (4), which was published after the priority date, as the closest state of the art.
29. It has not been disputed in appeal proceedings that the subject-matter of claim 1 of the main request is entitled to the priority right, and the parties have not put forward any arguments on inventive step during the written proceedings. Under these circumstances, the board grant the appellant's request to remit the case to the opposition division (Article 111(1) EPC), should any of the requests on file be found to meet the requirement of Article 54 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division for examination of inventive step on the basis of the main request.

The Registrar:

The Chairman:



M. Kiehl

B. Stolz

Decision electronically authenticated