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Datasheet for the decision of 23 January 2008

Case Number: T 1335/05 - 3.3.04

Application Number: 98910425.2

Publication Number: 0925369

IPC: C12Q 1/00

Language of the proceedings: EN

Title of invention:
Universal test systems and methods of use thereof for identifying multiple families of microorganisms

Patentee:
DADE BEHRING INC.

Opponent:
BioMérieux

Headword:
Universal test system/DADE BEHRING

Relevant legal provisions (EPC 2000):
EPC Art. 54(2), 84, 114(2), 123(2),(3)
RPBA Art. 10b (OJ EPO 2004, 541), 13 (OJ EPO 2007, 536)

Keyword:
"Admission of appellant's submissions into proceedings (yes)"
"Clarity (yes); added subject-matter (no); broadening of scope of protection (no)"
"Admission into proceedings of new evidence (yes)"
"Novelty (yes)"
"Remittal (yes)"

Decisions cited:
T 0381/87, T 0729/91, T 0472/92, T 0782/92, T 0296/93, T 0097/94, T 0750/94, T 0848/94, T 0936/02, T 0503/03, T 0313/05

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Case Number: T 1335/05 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 23 January 2008

Appellant: (Patent Proprietor)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 12 July 2005 revoking European patent No. 0925369 pursuant to Article 102(1) EPC 1973.

Composition of the Board:

Chair: U. Kinkeldey
Members: B. Claes
D. S. Rogers

Summary of Facts and Submissions

I. European patent No. 0 925 369 was granted with 28 claims on the basis of European patent application 98910425.2 (published as WO 98/045469, referred to as the application as filed) and was opposed on the grounds of Article 100(a) EPC, for lack of novelty and inventive step (Articles 54 and 56 EPC).

Claims 1, 2, 27 and 28 of the patent as granted read:

"1. A test system for identifying a microorganism in a sample, wherein the test system is capable of identifying that microorganism from groups of widely divergent microorganisms, comprising yeast and at least one of:

i) anaerobic bacteria,
ii) enteric bacteria,
iii) gram positive group of bacteria,
iv) neisseria and Haemophilus or
v) fastidious bacteria,

which may be present in such a sample and wherein the test system comprises:
a predetermined combination of non-redundant biochemical tests disposed in a predetermined number of reaction chambers, wherein each biochemical test comprises a substrate for an enzyme or a group of enzymes, and further wherein the substrate, if acted on by the enzyme or group of enzymes, results in the formation of a detectable product in the reaction chamber; and wherein the detectable products from the combination of biochemical tests are used to identify the microorganism in the sample by using a probability matrix."

"2. A test system according to claim 1, wherein identifying a microorganism comprises classifying the microorganism to a genus or a species of microorganism or both."

"27. A method for identifying a microorganism in a sample from among at least two groups of widely divergent microorganisms comprising yeast and at least one of:
i) anaerobic bacteria,
ii) enteric bacteria,
iii) gram positive group of bacteria,
iv) neisseria and Haemophilus or
v) fastidious bacteria,
which may be present in such a sample by use of a test system according to claim 1, wherein the method comprises:
a) adding the sample to each reaction chamber comprising a substrate;
b) allowing the enzyme, if present, to react with the substrate;
c) determining the presence of the enzyme in the sample by detecting the detectable product in a test; and
d) comparing the results of the combination of predetermined tests with at least one predetermined standard to identify the microorganism in the sample."

"28. A test according to claim 1 for detecting carbon source utilization by a microorganism comprising yeast and at least one of:
i) anaerobic bacteria,
ii) enteric bacteria,
iii) gram positive group of bacteria,

iv) neisseria and Haemophilus,

v) fastidious bacteria,

wherein the test comprises at least one carbon source and at least one fluorometric indicator, wherein the microorganism acts on the carbon source to produce a pH change which causes a change in fluorescence of the indicator, the change in fluorescence being indicative of carbon source utilization by the microorganism."

II. The appellant (patent proprietor) lodged an appeal against the decision of the opposition division revoking the patent. With the statement of the grounds of appeal the appellant filed a main and first auxiliary request.

III. The respondent (opponent) responded with letter dated 7 April 2006, including a declaration by Ms Picon (including two annexes) and four further new documents.

IV. With letter dated 28 December 2006 the appellant made further submissions concerning its appeal and reacted to the respondent's submissions.

V. With letter dated 8 February 2007 the respondent requested to disregard the last submissions of the appellant by virtue of Article 10b of the Rules of Procedure of the Boards of Appeal (OJ EPO 2004, 541).

VI. In reaction to the summons to oral proceedings, the appellant filed a second auxiliary request.

VII. Oral proceedings took place on 23 January 2008 during which the appellant filed a new main request consisting of 19 claims.

VIII. Claims 1, 18 and 19 of the new main request read

"1. A test system for identifying a microorganism in a sample, wherein the test system is capable of identifying that microorganism from groups of widely divergent microorganisms, comprising yeast and **all** of:

i) anaerobic bacteria,

ii) enteric bacteria,

iii) gram positive group of bacteria,

iv) neisseria and Haemophilus,

v) fastidious bacteria,

which may be present in such a sample and wherein the test system comprises:

a predetermined combination of non-redundant biochemical tests disposed in a predetermined number of reaction chambers, wherein each biochemical test comprises a substrate for an enzyme or a group of enzymes, and further wherein the substrate, if acted on by the enzyme or group of enzymes, results in the formation of a detectable product in the reaction chamber; and wherein the detectable products from the combination of biochemical tests are used to identify the microorganism in the sample **to the species** by using a probability matrix." (emphasis added)

"18. A method for identifying a microorganism in a sample from **among groups** of widely divergent microorganisms comprising yeast and **all** of:

i) anaerobic bacteria,

ii) enteric bacteria,

iii) gram positive group of bacteria,

iv) neisseria and Haemophilus,

v) fastidious bacteria,

which may be present in such a sample by use of a test system according to claim 1, wherein the method comprises:
a) adding the sample to each reaction chamber comprising a substrate;
b) allowing the enzyme, if present, to react with the substrate;
c) determining the presence of the enzyme in the sample by detecting the detectable product in a test; and
d) comparing the results of the combination of predetermined tests with at least one predetermined standard to identify the microorganism in the sample **to the species.**" (emphasis added)

"19. A test according to claim 1 for detecting carbon source utilization by a microorganism comprising yeast and **all** of:

i) anaerobic bacteria,
ii) enteric bacteria,
iii) gram positive group of bacteria,
iv) neisseria and Haemophilus,
v) fastidious bacteria,

wherein the test comprises at least one carbon source and at least one fluorometric indicator, wherein the microorganism acts on the carbon source to produce a pH change which causes a change in fluorescence of the indicator, the change in fluorescence being indicative of carbon source utilization by **the species of** the microorganism." (emphasis added)

Dependent claims 2 to 17 were identical (other than the references to preceding claims) to claims 3 to 15 and 24 to 26 of the patent as granted.

IX. The following documents are referred to in this decision:

D1: RAPIDEC ur, Instruction manual, version A, 1986

D2: API 20 E, Instruction manual, version E, 1989

D4: API 20 B, 1982

D6: Declaration by Ms Picon, comprising annexes I and II.

D7: von Graevenitz *et al.* (1988), J. Clin. Microbiology, Vol. 26 (1), pages 151-152.

D8: Anderson *et al.* (1983), Am. J. Medical Technology, Vol. 49 (12), pages 879-881.

D9: Tomita *et al.* (1987), Applied and Environmental Microbiology, Vol. 53 (7), pages 1541-1547.

D10: Hofherr & Lund (1979), Am. J. Medical Technology, Vol. 45 (2), pages 127-129.

X. The appellant's arguments which are relevant for the present decision can be summarised as follows:

Interpretation of claim 1 of the new main request

– Amended claim 1 requires that the claimed test system is capable of identifying a (any) microorganism from groups of microorganisms comprising yeast and anaerobic bacteria, enteric bacteria, the gram positive group of bacteria,

neisseria and Haemophilus and fastidious bacteria. This is neither a restriction of the test system to these and only these groups of microoorganisms nor does it mean that a test sample has to include at least one microorganism from each groups. The claimed test system has the desired universal capability of not being restricted to any group or groups of microorganisms. It can identify any microorganism whatever indicated group it may belong to.

Articles 84, 123(2) and 123(3) EPC

– The amended claims were clear and were supported by the description within the meaning of Article 84 EPC and they complied with the requirements of Articles 123(2) and (3) EPC.

– The amendment in the preamble of the independent claims was a selection of the possible combinations of groups of widely divergent microorganisms as indicated in the independent claims of the patent in suit. This subject-matter was therefore already provided for in the patent as granted.

– The amendment in the independent claims that the identification is "to the species" finds a basis in claim 2 as granted and page 19, lines 17 to 20 of the application as filed.

Admission into the proceedings of documents D6 to D10

– No objection was raised to the introduction of documents D6 to D10 into the proceedings.

Article 54(2) EPC, state of the art

– The opposition division was wrong in finding that D1, D2 and D4 were instruction manuals for the test systems mentioned therein, that these documents were freely available on the market within the period of their printing dates, and that they therefore constituted prior art within the meaning of Article 54(2) EPC.

– An instruction manual could only be said to constitute prior art if it was shown that a test system including this manual had been sold, or otherwise had reached the public. The respondent's evidence (documents D7 to D10) did not contribute any additional information over what was already on file.

– the numbers on the last page of each document were the respective printing dates of the documents, which was however no proof that the document could also be assumed to have been published.

Novelty

– None of the document cited disclosed a test system or related method which, as the test system and related method as subject-matter of claims 1 and 18, was capable of identifying a microorganism

from groups of widely divergent microorganisms, comprising yeast and all of anaerobic bacteria, enteric bacteria, the gram positive group of bacteria, neisseria and Haemophilus and fastidious bacteria, i.e. which can identify microorganisms whatever indicated group they may belong to.

Remittal to the first instance for further prosecution

– The case should be remitted to the first instance department in order to enable the parties two instances for the issue of inventive step of subject-matter of the claims of the request.

XI. The respondent's arguments which are relevant for the present decision can be summarised as follows:

Interpretation of claim 1 of the new main request

– The feature "predetermined" in the expression "a predetermined combination of non-redundant biochemical tests disposed in a predetermined number of reaction chambers" has no technical meaning in the context of product claim 1. Similarly, the feature "wherein the detectable products from the combination of biochemical tests are used to identify the microorganism in the sample to the species by using a probability matrix" has no limiting effect on the subject-matter of product claim 1.

– The claim therefore needs to be interpreted as to require the test system to be capable to identify to the species at least one microorganism.

Articles 84, 123(2) and 123(3) EPC

– The independent claims of appellant's request lacked clarity and support in the description within the meaning of Article 84 EPC and their subject-matter went beyond the disclosure of the application as filed, thereby infringing the requirements of Article 123(2) EPC.

– In view of paragraph [0040] of the patent in suit, the amendment concerning the extension of the group of widely divergent microorganisms to all of the six groups and the identification to the species inevitably lead to a change of the number (increase) of predetermined combination of non-redundant biochemical tests in the test system. Accordingly, the protection by claim 1 as amended was extended as compared to the protection provided by the patent in suit. The claim therefore infringed the requirements of Article 123(3) EPC.

Admission into the proceedings of documents D6 to D10

– Document D6 should be admitted into the proceedings as it proves that the technical notices 30188 and 30105 had actually been part of the products produced and sold by company API SYSTEM, under the name RAPIDEC ur and API 20 E, respectively. In the light of document D6, the decision of the opposition division to refuse the introduction of one of the annexes to the

declaration (referred to as "D6" in the opposition decision) was wrong.

– Documents D7 to D10 should be admitted into the proceedings as they are indisputably contained in the prior art and have at least the same relevance as documents D1, D2 and D4.

Article 54(2) EPC, state of the art

– There was no *prima facie* reason to doubt that the numbers printed at the bottom of the last pages of documents D1, D2 and D4 were the respective printing dates. It was reasonable to assume that these documents had been made available to the public before the priority date by being distributed with the corresponding test systems. In addition there was no question that the API test systems had been put on the market before the priority date, then it followed that these systems were sold with documents D1, D2 and D4,their respective instruction manuals.

– Documents D7 to D10 were undoubtedly part of the state of the art and referred to the usage of various API test systems identical to those disclosed in documents D1, D2 and D4. This indicated that documents D1, D2 and D4 were in fact the instruction manuals that were enclosed with the API test systems that were available before the priority date.

– The declaration by Mrs Picon, document D6, stated that she was involved in preparing API test

systems for sale and that this involved including an instruction manual in the packaging.

Novelty

– As claim 1 needed to be interpreted as to require the test system to be capable to identify to the species at least one microorganism, at least document D7 had to be detrimental for novelty, e.g. in view of the identification of Staphylococcus saprophyticus (see table 2, penultimate line in the table).

Remittal to the first instance for further prosecution

– In view of the desire for a speedy conclusion of the opposition/appeal proceedings the case should not be remitted to the first instance department for further prosecution.

XII. The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained on the basis of claims 1 to 19 of the main request filed at the oral proceedings on 23 January 2008; or claims 1 to 19 of auxiliary request I filed with the grounds of appeal dated 21 November 2005; or claims 1 to 19 of auxiliary request II filed with a letter dated 13 December 2007; and to continue the proceedings in appeal.

The respondent (opponent) requested that the appeal be dismissed. The respondent further requested the introduction of documents D6 to D10 into the proceedings, that the board remit the case to the

department of first instance for a consideration of inventive step and that the board disregards the appellant's submission dated 28 December 2006.

Reasons for the Decision

1. The appeal is admissible.

Admission of the appellant's submissions dated 28 December 2006 into the proceedings

2. The submissions filed by the appellant with letter of 28 December 2006 constitute a mere response of the appellant to the reply of the respondent to the statement of the grounds of appeal. The response is not complex and does not complicate the proceedings, it was filed before the board summoned the oral proceedings, does not request the introduction of new evidence into the procedure and is considered to contribute, rather than hamper, the procedural economy of the case. Accordingly, the board applies its discretion to admit this submission into the proceedings pursuant to Article 13 of the Rules of Procedure of the Boards of Appeal (OJ EPO 2007, 536).

Interpretation of claim 1 of the new main request

3. In accordance with established principles, the skilled person, when considering a claim, should rule out interpretations which are illogical or which do not make technical sense. He should try, to arrive at an interpretation of the claim which is technically sensible and takes into account the whole disclosure of

the patent (see Case Law of the Boards of Appeal of the European Patent Office, 5th edition, 2006, page 205).

4. Amended claim 1 requires that the claimed test system is capable of identifying a microorganism in a sample, wherein the test system is capable of identifying that microorganism from groups of widely divergent microorganisms, comprising yeast and all of anaerobic bacteria, enteric bacteria, the gram positive group of bacteria, neisseria and Haemophilus and fastidious bacteria.

5. The respondent has argued that claim 1 needs to be interpreted as merely requiring the test system to be capable to identify at least one microorganism (to the species).

6. The board considers, however, that the skilled person commonly understands the feature "capable of identifying that microorganism from groups of widely divergent microorganisms, comprising yeast and all of anaerobic bacteria, enteric bacteria, the gram positive group of bacteria, neisseria and Haemophilus and fastidious bacteria" as requiring the test system to identify a microorganism from each of the referred to groups of microorganisms, i.e. the claimed test system has the desired universal capability of not being restricted to any group or groups of microorganisms. It can identify microorganisms whatever group they may belong to.

7. The board notes that the claim construction of the board finds confirmation in paragraph [0040] of the patent in suit which states that "[t]he number of tests

disposed on a universal test panel of the present invention is sufficient to identify a single microorganism in a sample **belonging to any one of a number of widely divergent groups**" (emphasis added).

8. The board therefore concludes that, in the light of the description, the skilled person would **not** interpret claim 1 in the manner as advocated by the respondents.

Articles 84, 123(2) and 123(3) EPC

9. Since the requirements of Article 84 EPC are not a ground of opposition and the ground of opposition under Article 100(c) EPC has not been invoked within the framework of the present opposition proceedings, the examination of the requirements of Articles 84 and 123(2) EPC of the claims of the appellant's request is restricted to amendments made over the patent in its granted form (see also T 503/03 of 29 November 2005, point 11 and T 936/02 of 21 December 2006, point 3). Also in the context of Article 123(3) EPC, the claims of the requests need comparison to the claims as granted.

10. Independent claims 1 and 18 and dependent claim 19 of the appellant's request differ from the two independent claims 1 and 27 and dependent claim 28 as granted in two aspects.

Firstly in the preamble of the claims the feature that the test system (or a method) is capable of identifying the microorganism from (among) groups of widely divergent microorganisms, comprising *yeast and* ***at least one*** *of* the five specifically cited groups of

microorganisms is amended to the extent that the test system is now capable of identifying that microorganism from (among) groups of widely divergent microorganisms, comprising *yeast and* ***all*** *of* the same five specifically cited groups of microorganisms. The board judges that the subject-matter as now defined is clearly and unambiguously derivable from claims 1 and 27 and dependent claim 28 as granted seeing that the amended feature relates to one of the possible groups of widely divergent microorganisms enumerated in these claims, i.e. *at least one* also discloses *all*.

Secondly, the amendment in the independent claims that the identification is "to the species" finds a basis in claim 2 as granted and page 19, lines 17 to 20 of the application as filed.

11. From the finding above it follows that the amendments to the preamble of the claims and the amendments that the identification is "to the species" restrict the protection provided by the claims as amended as compared to the protection provided by the patent in suit.

12. The respondent has argued that in view of paragraph [0040] of the patent in suit, the amendment concerning the extension of the group of widely divergent microorganisms to all of the six groups and the identification to the species inevitably lead to a change of the number (increase) of predetermined combination of non-redundant biochemical tests in the test system. However, rather than providing an indication that the protection provided by claims as amended was extended as compared to the protection

provided by the patent in suit, the board considers this argument in fact to support the restriction of the provided protection.

13. In view of the above considerations the claims of the appellant's request comply with the requirements of Articles 84, 123(2) and 123(3) EPC.

Admission into the proceedings of documents D6 to D10

14. The respondent filed documents D6 to D10 with letter dated 7 April 2006 in response to the statement of the grounds of appeal. At the oral proceedings, the appellant consented to the introduction of these documents into the proceedings.

15. According to the case law of the Boards of Appeal late filed evidence may only be introduced into the proceedings if particular conditions are met. The later in the procedure the new evidence is filed the stricter it is scrutinised for its relevance. In principle the new material must be *prima facie* "highly" relevant in the sense that it is likely to prejudice maintenance of the European patent.

16. For the reasons given below the Board considers documents D1, D2 and D4 not to belong to the state of the art pursuant to Article 54(2) EPC. Document D6 is highly relevant in the sense of the case law of the boards of appeal for the assessment thereof (see point 28 below). Furthermore, documents D7 to D10 refer to the same subject-matter as documents D1, D2 and D4 and it is undisputed that they are contained in the prior art. The documents are furthermore highly

relevant in the sense of the case law of the boards of appeal. Therefore, the board exercises its discretion provided by Article 114(2) EPC and admits these documents D6 to D10 into the proceedings.

Article 54(2) EPC, state of the art

17. The disclosures in documents D1, D2 and D4 are undisputedly highly relevant for the question of patentability of the claimed subject-matter. Therefore it has to be considered whether they were made available to the public before the priority date of the patent in suit.

18. The respondent asserts that these documents were made available to the public by being inserted in the packaging of the respective API test systems. The appellant contests this and argues that there is no evidence on file that this was so. Both parties accept that such API test systems were on sale before the priority date of the patent in suit.

The opposition division decided that documents D1, D2 and D4 were made available to the public before the priority date. Points 12 and 12.1 of the opposition division's decision state:

"*12. The OD considers that there is prima facie no founded reason to doubt that the numbers printed at the bottom of the last pages of D1, D2 and D4, i.e. respectively 86, 89 and 1982 correspond to their date of printing.*

12.1 It appears that the test systems relating to D1, D2 and D4 were well known in the art, a fact that has not been denied by P. Moreover, the OD considers that booklets containing the operating instructions of a test system (Instruction Manual) are indeed addressed to the users that had purchased said test system. In addition, other documents, the granted patent in particular [0006], give indications that the test systems disclosed in the booklets were freely available on the market. In the absence of proof of the contrary, the OD considered it reasonable to assume that D1, D2 and D4 which have been printed well before the priority date, have been made available to the public within this period and are therefore comprised in the state of the art in the sense of Article 54(2) EPC".

19. According to the established case law of the boards of appeal, when lack of novelty is alleged the burden of proof lies with the party claiming that the information in question was made available to the public, in this case with the respondent.

The case law of the boards of appeal has developed certain principles on the standard of proof necessary to establish the facts on which a decision is to be based.

In some decisions the boards of appeal have applied the standard of "the balance of probabilities", which means that in relation to, for example, the question of when a document was first made available to the public, the board must decide what is more likely than not to have happened (see for example decisions T 381/87, OJ EPO

1990, 213, T 296/93, OJ EPO 1995, 627, and T 729/91 of 21 November 1994).

In other decisions the boards judged that a fact on which a case against novelty was made had to be proved "beyond reasonable doubt" or "up to the hilt" (see for example decisions T 313/05 of 6 July 2006, T 782/92 of 22 June 1994, T 97/94, OJ EPO 1998, 467, T 848/94 of 3 June 1997, T 472/92, OJ EPO 1998, 161 and, in particular, T 750/94, OJ EPO 1998, 32).

20. Here a case of revocation of a granted European patent is at issue. To base a revocation decision on the mere balancing of probabilities of what **might** have occurred would be difficult to reconcile with the need for reliability in the decision-making procedures of the EPO, which is of utmost importance for users of the patent system as well as the general public. Thus, the public availability of documents D1, D2 or D4 before the priority date of the patent in suit can only be regarded as established if, in view of the evidence, the board has no reasonable doubt in this respect.

Some doubts may be permitted as to whether the opposition division applied this approach. The opposition division stated in paragraph 13 of its decision: "*In the absence of proof of the contrary, the OD considered it reasonable to assume that D1, D2 and D4 which have been printed well before the priority date, have been made available to the public...*". The opposition's approach of shifting the evidential burden to the proprietor could only apply had further hard evidence been on file to support the public availability of these documents. However there is no

such evidence before the board, neither was such evidence before the opposition division. Accordingly, there is no shift of the burden of proof on this issue.

21. The evidence on the public availability of documents D1, D2 and D4 is as follows:

- the numbers printed at the bottom of the last pages of each of documents D1, D2 and D4;

- the reference to various API test systems at paragraph [0006] of the patent in suit;

- the references to various API test systems in documents D7 to D10; and

- the declaration of Mrs Picon, including two annexes.

22. For the evaluation of the evidence it is at this point useful to recall that document D1 is the instruction manual for a "RAPIDEC ur" test system, D2 is the instruction manual for an "API 20E" test system, and D4 is the instruction manual for an "API 20B" test system. All of these test systems were manufactured by API System of France.

23. The respondent argued, and the opposition division accepted, that the numbers printed at the bottom of the last pages of each of documents D1, D2 and D4 were the dates of printing of these documents. These dates were all before the priority date. However, the actual date of printing of these documents is not material to the board reaching a decision on their public availability.

What has to be proven is whether the printed documents ever reached the public domain.

24. Paragraph [0006] of the patent in suit refers to the fact that since the 1960s commercial bacterial identification kits have been available and lists the family specific kits sold by the IDS company, apparently under the reference "RapID" plus a suffix indicating the relevant bacterial family, and the family specific kits sold by the API System company, apparently under the reference "API 20" plus a letter indicating the relevant bacterial family. Paragraph [0006] specifically refers to the "API 20 E" test system that is the subject of document D2, that is referred to in document D8, and that is mentioned in Mrs Picon's declaration.

25. Document D7 refers to the use of a RAPIDEC ur test system produced by API System of France. Document D8 refers to the use of an API 20E system. Document D9 refers to the use of the API ZYM system, the API 20 B system and the API 20 NE system, all produced by API System S.A. of France. Document D10 refers to the use of an API 20 E system.

26. The declaration of Mrs Picon (document D6 in the appeal proceedings) states that she works for the subsidiary of the respondent that at one time was known as API System. Mrs Picon started working for API System in 1973. Mrs Picon states that she took part in the production and preparation of the "RAPIDEC ur" and "API 20 E" test systems. She states that the instruction manuals were included in the packages of the test systems that were to be sold. The annexes to the

declaration appear to be check lists for enclosures for the packaging of a RAPIDEC ur and API 20 E test system. These check lists indicate that instruction manuals were included in such packaging, however, these check lists are not evidence that the particular systems to which they refer were in fact sold.

27. The above evidence suggests, and the appellant has not contested, that test systems bearing the names "RAPIDEC ur", "API 20 E" and "API 20 B" were on sale before the priority date of the patent in suit. What the respondent needs to prove beyond reasonable doubt is, however, that such a test system was accompanied by a document with the same contents as documents D1, D2 or D4. On this point the evidence put forward by the respondent is circumstantial and does not meet the high standard of proof required by the case law of the boards of appeal.

28. In the oral proceeding before the board the respondent argued that there was an overlap between the tests disclosed in document D7 and those disclosed in document D1, the inference being that document D1 was the instruction manual to which the authors of document D7 referred in order to carry out the tests that formed the subject of their article. Again this overlap between document D1 and document D7 does not provide a basis for concluding beyond reasonable doubt that a document with the same contents as document D1 was in the possession of the authors of document D7.

29. Hence, from the evidence on file it cannot be established with the necessary certainty that all or any of documents D1, D2 or D4 were made available to

the public before the priority date of the patent in suit.

Novelty

30. In view of the findings above the documents cited contained in the state of the art pursuant to Article 54(2) EPC are documents D3, D5 and D7 to D10.

31. It has not been disputed by the respondent that none of these documents disclose a test system or related method which, as the test system and related method as subject-matter of claims 1 and 18, is capable of identifying a microorganism from groups of widely divergent microorganisms, comprising yeast and **all** of anaerobic bacteria, enteric bacteria, the gram positive group of bacteria, neisseria and Haemophilus and fastidious bacteria, i.e. which can identify microorganisms whatever indicated group it may belong to. In particular, by way of example it is noted that none of the above referred to documents disclose a test system and related method which is capable of identifying a microorganism from the group of fastidious bacteria.

32. In view of the above considerations the subject matter of the claims of the appellant's request are novel.

Remittal to the first instance for further prosecution

33. The patent is suit had been revoked by the opposition division on grounds of lack of compliance with the requirements of Articles 54 and 123 EPC, no examination having been made as to whether or not the claimed

subject-matter, before the opposition division or as now formulated in the request before the board, involves an inventive step. In order to ensure that the parties have the opportunity of having the question of inventive step of the amended claims decided by the opposition division, with the possibility of a further appeal remaining open, the board considers it appropriate to make use of the power granted to it under Article 111(1) EPC to remit the case to the first instance for further examination.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution upon the basis of claims 1 - 19 of the Main Request.

The registrar The Chair

P. Cremona U. Kinkeldey