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**Datasheet for the decision  
of 8 November 2013**

**Case Number:** T 0304/10 - 3.3.08

**Application Number:** 98910425.2

**Publication Number:** 925369

**IPC:** C12Q1/00

**Language of the proceedings:** EN

**Title of invention:**

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

**Patent Proprietor:**

Dade Behring Inc.

**Opponent:**

BioMérieux

**Headword:**

Test systems/DADE

**Relevant legal provisions:**

EPC Art. 56  
RPBA Art. 12(4)

**Keyword:**

Admissibility of two documents filed at the onset of second  
appeal (no)  
Inventive step - (yes)

**Decisions cited:**

G 0009/91, T 1335/05

**Catchword:**



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Case Number: T 0304/10 - 3.3.08

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.08**  
**of 8 November 2013**

**Appellant:** BioMérieux  
(Opponent) Chemin de l'Orme  
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**Representative:** Guerre, Dominique  
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**Respondent:** Dade Behring Inc.  
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**Representative:** Schweitzer, Klaus  
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**Decision under appeal:** **Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
22 December 2009 concerning maintenance of the  
European Patent No. 925369 in amended form.**

**Composition of the Board:**

**Chairman:** M. Wieser  
**Members:** T.J.H. Mennessier  
D. Rogers

## **Summary of Facts and Submissions**

- I. European patent No. 0 925 369 was based on European application No. 98910425.2, published under the international publication No. WO 98/45469.
- II. An opposition was filed on the grounds that the subject-matter of the patent was neither new nor inventive (see Articles 54, 56 and 100(a) EPC). By its decision of 12 July 2005, the opposition division revoked the patent.
- III. The patent proprietor filed an appeal (case T 1335/05) which was terminated by a decision given by a Board of appeal at the oral proceedings of 23 January 2008. The case was remitted to the opposition division for further prosecution on the basis of claims 1 to 19 of the main request filed at the oral proceedings. These claims had been found to meet the requirements of Articles 54, 84 and 123 EPC. The Board had, moreover, decided that documents D1 and D2 did not belong to the state of the art. After remittal, in the written procedure before the opposition division, the opponent exclusively referred to document D3 in support of its argument concerning lack of inventive step.
- IV. At a further oral proceedings held on 29 September 2009, the opposition division came to the conclusion that the main request of 23 January 2008 met the requirements of Article 56 EPC and decided to maintain the patent on the basis of that request.
- V. The opponent (appellant) filed the present appeal against this second decision of the opposition division. Its statement of grounds was accompanied by two new documents, to be referred to as documents D11

- and D12. It argued that the claimed subject-matter was not inventive either in view of the disclosure in document D3 alone, or in view of document D11, possibly supplemented by document D12. Oral proceedings were requested.
- VI. In its reply, the patent proprietor (respondent) responded to the appellant's arguments and requested the Board not to admit documents D11 and D12 into the proceedings.
- VII. On 4 July 2013, the Board issued, as an annex to a summons to oral proceedings, a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA), expressing its preliminary and non-binding views. The Board informed the parties that it was inclined not to admit documents D11 and D12 into the appeal proceedings and that it was of the opinion that the appellant's inventive step argument, relying on document D3, as already developed before the opposition division, was not convincing.
- VIII. In reply to the Board's communication, the appellant sent a letter dated 23 September 2013, by which it informed the Board that it would neither be represented at, nor attend the scheduled oral proceedings.
- IX. On 30 September 2013, the Board issued a communication pursuant to Article 17(1) RPBA in which it informed the parties that it considered claim 19 of the main request of 23 January 2008 not to satisfy the requirements of the EPC.
- X. In reply to the Board's communication, the respondent on 18 October 2013 filed an amended set of claims to replace the main request of 23 January 2008. This new

main request was identical to the replaced main request except that claim 19 had been deleted.

XI. With a communication dated 29 October 2013 the parties were informed that the scheduled oral proceedings were cancelled.

XII. The request of 18 October 2013 consists of 18 claims of which claim 1 reads:

"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."

Claims 2 to 17 are dependent on claim 1.

Claim 18 is directed to a method for identifying a microorganism in a sample by using a test system according to claim 1.

XIII. The following documents are referred to in the present decision:

(D1) 'RAPIDEC ur' instruction manual (version A) of API System S.A. (undated)

(D2) 'API 20 E' instruction manual (version E) of API System S.A. (undated)

(D3) M. Manafi et al., Microbiological Reviews, Vol. 55, No. 3, September 1991, pages 335 to 348"

(D11) C. E. Stager and J. R. Davis, Clinical Microbiology Reviews, Vol. 5, No. 3, July 1992, pages 302 to 327

(D12) B. Bochner, Am. Clin. Lab., Vol. 12, No. 4, April 1993, page 6

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

Admissibility of documents D11 and D12

Documents D11 and D12 illustrated the general knowledge of the skilled person at the priority date. They supplemented the information contained in the patent and, moreover were 'implicitly' referred to in the patent at issue for the reason that the same 'MicroScan' test systems were referred to in the patent and in document D11 and that the same 'Biolog' test

systems were referred to in both documents D11 and D12. Therefore, both documents should be admitted into the proceedings.

Article 56 EPC (inventive step)

The test system of claim 1 was not inventive in view of document D3 alone as explained in the submissions of 10 July 2009 filed in preparation for the oral proceedings held on 29 September 2009 before the opposition division.

Furthermore, the skilled person by combining the teaching of document D3 with common general knowledge would have arrived at the test system of claim 1 in an obvious way.

Description

The description had not been sufficiently adapted to the main request of 23 January 2008.

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

Admissibility of documents D11 and D12

Documents D11 and D12 were late filed. They disclosed nothing more than the prevailing belief at the priority date that the known batteries of biochemical tests had to be run separately from one another and, therefore, did not add anything beyond what was already disclosed in document D3.



Article 56 EPC (inventive step)

Document D3 represented the closest state of the art. It was a review article discussing a number of fluorogenic and chromogenic substrates used in bacterial diagnostics. It provided the skilled person with a list of enzymatic assays useful to detect bacteria (in particular, *Salmonella* spp., *Shigella*, *Legionella* and *Neisseria*), referred to some assays for the detection of fungi such as *Candida* and taught how to conduct individual batteries of tests.

The technical problem underlying the patent in the light of the disclosure in document D3 was the provision of an assay having the universal capability of detecting any microorganism belonging to groups of widely divergent microorganisms as indicated in claim 1.

The solution to this problem was the method according to claim 1.

Document D3 did not provide any indication or suggestion for a universal test. The only indications given therein referred to test systems for the detection of a gram-negative bacteria only or the detection of gram-negative bacteria on one hand and gram-positive bacteria on the other hand. Document D3 did not provide any hint to a possible broader test. Therefore, the skilled person would not have found therein any incentive that would have led him/her to the test system of claim 1. The gap between the disclosure in document D3 and the method of claim 1 was not filled by any other prior art document and, indeed, no such documents had been cited by the appellant in combination with document D3.

#### Description

No comments were made by the respondent in this respect.

- XVI. The appellant (opponent) requests that documents D11 and D12 be admitted into the proceedings, the decision under appeal be set aside and the patent be revoked.
- XVII. The respondent (patent proprietor) requests that documents D11 and D12 not be admitted into the proceedings, the decision under appeal be set aside and the patent be maintained on the basis of claims 1 to 18 filed under cover of the letter of 18 October 2013.

#### **Reasons for the Decision**

##### Admissibility of documents D11 and D12

1. Documents D11 and D12 were filed with the statement setting out the grounds of appeal in order, as argued by the appellant, to supplement the information contained in the patent.
2. Document D11 is a review article, dated July 1992, discussing automated systems for identification of microorganisms. D12 is a one-page article from a journal aiming to provide the clinical diagnostic community with the latest developments in technology for clinical diagnostics. It discusses advances in the identification of bacteria and yeast as at its publication date, April 1993. Neither D11 nor D12 are referred to in the patent at issue.

3. The appellant contends that it has the right to have these two documents admitted into the proceedings. Such a right does not exist.
4. Decision T 1335/05 of 23 January 2008, ordered the remittal of the case to the department of first instance for further prosecution so that inventive step could be assessed at two levels of jurisdiction and the patent proprietor would not be deprived of the possibility of a subsequent review.
5. As a consequence of the remittal, the present appellant was offered the opportunity to provide again a complete argument in support of its objection of lack of inventive step. The appellant could not rely on its previous case, which was based on a combination of document D1 with either document D2 or document D3, as documents D1 and D2 had not been admitted into the proceedings by the Board. The appellant deliberately chose to rely on document D3 alone. However, its inventive step argument based on document D3 failed to convince the opposition division.
6. The function of the appeal procedure before the Boards of Appeal is to give a judicial decision upon the correctness of a separate earlier decision taken by an administrative department of first instance (see decision G 9/91, OJ EPO, 408). As a consequence, it is the legal and factual framework on which the contested decision was based which determines the extent of scrutiny by the Board. This is the reason why the Board has the power to hold inadmissible facts, evidence and requests which could have been presented in the first instance proceedings (see Article 12(4) RPBA).

7. In the present case, the Board considers that the appellant, being aware of documents D11 and D12, which were published four and five years respectively before the priority date of the patent in suit, could have presented these documents at the latest in the second opposition proceedings after remittal by the Board of appeal. Under these circumstances, in order not to be confronted with a fresh case, the Board exercising the discretionary power conferred to it by Article 12(4) RPBA, does not admit documents D11 and D12 into the proceedings.

Articles 84 and 123 EPC

8. The present request differs from the request of 23 January 2008 only in that independent claim 19 has been deleted. In view of this amendment, the Board abides by the conclusion of the opposition division made with respect to that previous request regarding the formal requirements of the EPC. Therefore, the present request meets the requirements of Articles 84, 123(2) and 123(3) EPC.

Article 56 EPC (inventive step)

9. Document D3 is considered to represent the closest prior art. It is a review article dealing with fluorogenic and chromogenic substrates useful for the detection of activities of specific enzymes in microbial diagnostics. While D3 focuses on bacterial diagnostics with particular emphasis to the specific detection of *Escherichia coli*, it also refers to the detection of yeast enzymes by using 4-methylumbelliferyl (4-MU) substrates. This is illustrated in detail in a paragraph on page 342

referring to the identification of yeast species belonging to the genus *Candida*.

10. The incorporation of enzyme tests using fluorogenic and chromogenic substrates in complex testing systems is briefly mentioned on page 343 in the last paragraph of document D3, but no detailed information is given. In this paragraph two abstracts are mentioned, having been presented at different meetings (see the bibliographic data given with respect of references 118 and 221 on pages 345 and 348 of D3), which are said on page 343 to report on a test system allowing the identification of both gram-positive and gram-negative bacteria or of gram-negative bacteria only.
11. The technical problem underlying the patent in suit in the light of the disclosure in document D3 is seen in the provision of a test system which permits the identification, at species level, of a microorganism present in a (clinical) sample, whether it be a yeast or a bacterium.
12. As a solution to this problem, the patent proposes a test system according to claim 1. This test system is capable of identifying a microorganism present in a sample as a member of a yeast species or of a bacterial species of five defined groups of bacteria. The system relies on a predetermined combination of non-redundant biochemical tests disposed in a predetermined number of reaction chambers, each biochemical test comprising a substrate for an enzyme or a group of enzymes. The identification is obtained upon comparison of the results of the biochemical tests to a probability matrix used as a predetermined standard.

13. In view of the experiments reported in the description of the patent, the technical problem is considered to be credibly solved.
14. Apart from documents D11 and D12, which have not been admitted into the proceedings, document D3 is the only document which has been referred to by the appellant in support of its objection of lack of inventive step.
15. The question to be answered is whether a skilled person relying on the teaching of document D3 alone would at the priority date have been in a position to devise in without the exercise of inventive skill the test system according to claim 1.
16. The test system of claim 1 is based on the concept of permitting several biochemical reactions, each being specific for a microorganism or a group of microorganisms, to be examined simultaneously. Document D3 is not concerned with such a test system. The mere mention in document D3 of two undisclosed test systems which, moreover, obviously do not relate to the identification of yeasts, in the very last paragraph of the document, did not provide any guidance to the skilled person facing the objective technical problem defined at point 11 above.
17. The appellant in these appeal proceedings has not referred to any specific prior art document which reflects the alleged common general knowledge and which could be combined with the teaching of document D3 to arrive in an obvious way at the test system of claim 1. Therefore, the appellant's argument based on such a combination is not convincing.

18. The Board comes to the conclusion that the skilled person facing the objective technical problem to be solved, when starting from the disclosure of document D3, would not have arrived in an obvious way at the solution provided by claim 1.
  
19. Therefore, the test system according to claim 1 involves an inventive step. The same applies to the subject-matter of claims 2 to 18 (see Section XII, *supra*).

#### Description

20. The appellant has argued that the description was not in agreement with the main request of 23 January 2008. By ordering the department of first instance to adapt the description to the present claim request, this issue can be re-assessed.

**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 with the order to maintain the patent on the basis of claims 1 to 18 of the request filed under cover of the letter of 18 October 2013 and a description to be adapted thereto.

The Registrar:

The Chairman:



A. Wolinski

M. Wieser

Decision electronically authenticated