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Datasheet for the decision of 22 February 2007

Case Number: T 1053/05 - 3.3.04

Application Number: 90902964.7

Publication Number: 0454784

IPC: C12Q 1/18

Language of the proceedings: EN

Title of invention:
Apparatus and methods for antimicrobial susceptibility testing of microorganisms

Patentee:
ALAMAR BIOSCIENCES LABORATORY INC.

Opponent:
BioMérieux

Headword:
Antimicrobial susceptibility/ALAMAR

Relevant legal provisions:
EPC Art. 56, 84, 123(2)

Keyword:
"Admissibility of fresh ground for opposition (no)"
"Added subject-matter (no)"
"Clarity, inventive step (yes)"

Decisions cited:
G 0009/91, T 0023/86, T 0532/88, T 0172/89, T 0623/93, T 0594/00, T 1288/01

Catchword:
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Case Number: T 1053/05 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 22 February 2007

Appellant: (Opponent)
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Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 28 June 2005 concerning maintenance of European patent No. 0454784 in amended form.

Composition of the Board:

Chair: U. Kinkeldey
Members: M. Wieser
D. S. Rogers

Summary of Facts and Submissions

I. This decision concerns the second appeal proceedings relating to the opposition against European patent No. 0 454 784.

II. The patent had been opposed under Article 100(a) EPC on the ground of lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC).

In the opposition procedure the Patent Proprietor (Respondent) filed amended claims.

Lack of sufficient disclosure (Article 100(b) and Article 83 EPC) was introduced by the Opponent (Appellant) as new ground of opposition after the expiry of the nine month opposition period (Article 99(1) EPC).

III. This Board in a different composition had set aside, with its decision T 594/00 posted on 24 June 2004, the interlocutory decision of the Opposition Division posted on 17 April 2000 maintaining the patent in amended form and had remitted the case to the first instance with the order for further prosecution. The basis for the Board's first decision was that the Opponent (Appellant) had not had the opportunity to present his comments during the oral proceedings before the Opposition Division on whether or not the fresh ground of opposition under Article 100(b) EPC could be admitted into the proceedings. This constituted an essential procedural violation.

IV. After remittal the Opposition Division issued the decision now under appeal, i.e. the further interlocutory decision posted on 28 June 2005 according to which the patent in amended form met the requirements of the EPC.

In the decision the Opposition Division gave reasons why the ground of opposition under Article 100(b) EPC in conjunction with Article 83 EPC was not permitted as a fresh ground for opposition. Moreover, they decided that the subject-matter of claims 1 to 36 of the main request before them met the requirements of Articles 123(2), 123(3), 84 and 56 EPC.

Claim 1 read as follows:

"A method for testing the susceptibility of a microorganism to growth inhibition by a preselected concentration of an antimicrobial product comprising the steps of:

(a) disposing in each of a negative growth control recepticle and a positive growth control recepticle a prearranged concentration of a growth medium for microorganisms and a prearranged concentration of resazurin predetermined to be in a concentration range characterized by low toxicity to microorganisms and substantial sensitivity to reduction to resorufin by metabolic products of microorganism growth, and a pre-selected redox stabiliser characterised by substantial lowering of the reduction of resazurin by said growth medium during step (g);

(b) disposing in said positive growth control recepticle a prearranged concentration of said microorganism;

(c) disposing in a test recepticle said preselected concentration of said antimicrobial product;

(d) disposing in said test recepticle said prearranged concentration of resazurin, and a pre-selected redox stabiliser characterised by substantial lowering of the reduction of resazurin by said growth medium during step (g);

(e) disposing in said test recepticle said prearranged concentration of growth medium;

(f) disposing in said test recepticle said prearranged concentration of said microorganism;

(g) incubating all of said recepticles together for an incubating time period associated with a preselected reading protocol comprising one of a visible light reading protocol and a fluorescence excitation reading protocol; and

(h) after said incubating time period, reading said recepticles in accordance with said preselected reading protocol to determine the presence or absence of growth of said microorganism in said test recepticle on the basis of the relative concentrations of resazurin and resorufin therein, said visible light reading protocol including a decision algorithm based on at least one predetermined functional combination of the visible light reflectance color detected in each of said

recepticles, said fluorescence excitation reading protocol including a decision algorithm based on at least one predetermined functional combination of the values of the fluorescence emission signal produced by the reduction product resorufin in each of said recepticles."

Claims 2 to 15 referred to preferred embodiments of the method of claim 1, claims 16 to 20 referred to an apparatus and claims 21 to 36 to a kit for carrying out the method.

V. The Opponent (Appellant) lodged an appeal against this decision. He requested to set aside the decision under appeal, to permit the ground of opposition under Article 100(b) EPC in conjunction with Article 83 EPC as a fresh ground for opposition and to remit the case to the department of first instance for further prosecution. In case the Board should decide not to remit the case he requested to revoke the patent.

The Patent Proprietor (Respondent) requested to dismiss the appeal and to hold oral proceedings in case his request was not allowed (Article 116(1) EPC).

VI. The Board expressed its preliminary opinion in a communication dated 16 August 2006.

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

(1) CA 1 112 140

(9) Zbl. Bakt. Hyg.; 1984, pages 217 to 224

(10) Am. Rev. Pulm. Dis.; vol.78, 1958, pages 111 to 116

(12) J. of Antibiotics, vol.XIX, no.5, 1966, pages 229 to 232

(15) Nature, vol.155, 1945, pages 401 to 402

(17) US-A-4 385 115

(18) US-A-5 501 959

VIII. The submissions made by the Appellant as far as they are relevant for the present decision may be summarised as follows:

The Opposition Division's decision, not to permit the ground for opposition under Article 100(b) EPC in conjunction with Article 83 EPC as a fresh ground for opposition, was wrong as this ground prima facie prejudiced the maintenance of the patent in suit.

In order to meet the requirements of Article 83 EPC the patent had to disclose methods and means allowing a skilled person to find redox stabilisers, a term not generally used in the here relevant technical field, which were able to perform the claimed function, namely to lower the reduction of resazurin by a growth medium, under any circumstances. The sole example on page 15 showed that this specific effect was achieved for one specific substance, potassium ferrocyanide, in one specific set-up. The description did not contain any information that allowed a person skilled in the art,

using his common general knowledge, to find other redox stabilisers useful in different set-ups. Without such information it amounted to undue burden to perform the invention over the whole area claimed.

Document (18) a continuation-in-part of the present priority application, contrary to the patent in suit, contained a number of examples describing concentrations of resazurin, pH buffers and specific redox stabilizers. Thus, this document provided the information necessary to perform the claimed invention. It was not obvious why the criteria for sufficiency of disclosure or for deciding on the general knowledge of a person skilled in the art should be different in Europe and in the USA.

Lack of sufficient disclosure was introduced as new ground of opposition in response to substantial amendments to the claims by the Respondents.

The new ground was introduced and substantiated immediately after the filing of said amended claims.

The amendments had the effect that the invention claimed, the problem to be solved and the technical contribution to the art had changed, which according to the case law of the Boards of Appeal justified the introduction of a fresh ground of opposition.

The introduction of an additional feature, i.e. a redox stabiliser, into independent claims 1, 16, 17, 21 and 22 had no basis in the application as filed and contravened the requirements of Article 123(2) EPC. The newly introduced feature was a generalisation of what

was disclosed on page 20, lines 20 to 23 of the original application, which therefore was no basis for the amendment. Original claim 3 referred to a redox stabiliser but additionally requested the presence of a pH buffer. The omission of this buffer from the amended independent claims resulted in a violation of Article 123(2) EPC.

The term "a pre-selected redox stabiliser characterised by substantial lowering of the reduction of resazurin" was open to interpretation and not clear within the meaning of Article 84 EPC. The only substance disclosed for which it was clear that it had the technical property required was potassium ferrocyanide.

Document (1) was considered to represent the closest sate of the art. The problem to be solved by the patent in suit was to prevent that, during incubation, the growth medium itself reduced resazurin. Once this problem was realized the solution to it according to the claims of the patent in suit was immediately obvious for a skilled person. According to established case law of the Boards of Appeal, the statement of a hitherto unrecognized problem does not constitute inventiveness.

IX. The submissions made by the Respondent as far as they are relevant for the present decision may be summarised as follows:

The Appellant has not discharged his burden of proof and not convincingly shown that the fresh ground of opposition under Article 100(b) EPC in conjunction with Article 83 EPC prima facie prejudiced the maintenance

of the patent. Moreover, the introduction of a feature into the independent claims during opposition procedure, which feature was already contained in the claims as granted (claim 3), did not constitute a modification of the legal framework legitimating the admittance of a fresh ground of opposition. Thus, the Opposition Division correctly did not permit this fresh ground.

The amendments of the claims with regard to the claims as granted were based on the application as originally filed.

All terms and expressions in the claims to which the Appellant objects under Article 84 EPC, lack of clarity, were already present in the claims as granted and cannot now be the subject of an attack under Article 84, EPC which is not a ground of opposition.

It was the patent in suit that disclosed for the first time that methods and devices according to the claims might suffer from inaccuracy due to the autoreduction of a growth medium even in the absence of microorganisms. In the light of the disclosure in document (1), which represented the closest state of the art, the problem underlying the patent in suit was the provision of a more accurate assay. Considering that none of the prior art documents on file was concerned with the influence of the growth-medium on the accuracy of the assays disclosed, the solution to this problem could not be considered to have been obvious.

Reasons for the Decision

Admissibility of objections under Article 100(b) EPC in conjunction with Article 83 EPC as fresh ground of opposition

1. The ground of opposition under Article 100(b) EPC in conjunction with Article 83 EPC was raised by the Appellant after expiry of the time limit laid down in Article 99(1) EPC. The Opposition Division, in the decision under appeal, has decided not to admit this ground for opposition into the proceedings.

2. The Enlarged Board of Appeal in decision G 9/91 (OJ EPO 1993, 408) decided that an Opposition Division may, in application of Article 114(1) EPC, of its own motion raise a ground for opposition not covered by the statement pursuant to Rule 55(c) EPC or consider such a ground raised by the Opponent (or referred to by a third party under Article 115 EPC) after the expiry of the time limit laid down in Article 99(1) EPC. The Enlarged Board emphasised that the consideration of grounds not properly covered by the statement pursuant to Rule 55(c) EPC, should only take place before the Opposition Division in cases where, prima facie, there are clear reasons to believe that such grounds are relevant and would in whole or in part prejudice the maintenance of the European patent.

3. Thus, in order to decide if the Opposition Division in the present case, when deciding not to admit the fresh ground for opposition, has exercised its discretion correctly, the Board has to investigate if there are clear reasons that the ground for opposition under

Article 100(b) EPC in conjunction with Article 83 EPC would prejudice the maintenance of the patent in suit.

4. The patent contains on page 15, lines 54 to 58 an example describing a specific embodiment of the claimed subject-matter. Said example discloses the use of a specific growth medium for microorganisms (Mueller-Hinton broth), of a specific concentration of resazurin (0.02 grams per litre) and of a specific concentration of a defined redox stabilizer, namely potassium ferrocyanide (0.004 molar). The Board is convinced that this example provides an enabling disclosure of a preferred embodiment of the invention claimed. The Appellant has not questioned this.

5. The Appellant, however, argues that the example does not enable a skilled person to put into practice the invention over the whole scope claimed, as it does not provide the information that the person skilled in the art would need in order to find other redox stabilisers for assays using the same or other growth media and/or working at the same or a different pH value. This is all the more so as the purely functional definition "redox stabiliser" is not used in the here relevant technical field and the patent does not provide the necessary information to reliably identify a reagent of this type. Therefore, the Appellant by referring to decisions T 172/99 of 7 March 2002 and T 1288/01 of 26 March 2004, concludes that the requirements of Article 83 EPC are not met as the execution of the invention over the whole scope claimed amounted to undue burden.

6. In January 1989, the priority date of the patent in suit, a skilled person with a basic knowledge in chemistry is considered to have been aware of the following:

Bacterial growth media, like all other chemical species, have their own intrinsic redox potential, which is the tendency of a chemical species to acquire electrons and thereby be reduced. The more positive the potential, the greater is the species' affinity for electrons and tendency to be reduced.

The redox potential can be measured by standard electrometric methods which were known long before the relevant date of the patent in suit (see for instance document (15), published in 1945). Redox indicators, like resazurin *(7-Hydroxy-3H-phenoxazin-3-on-10-oxid)*, which also have their own intrinsic redox potential, change their color upon reduction. Resazurin has been used as a redox indicator in antibiotic sensitivity testing assays where oxidation (that is where electrons are donated) took place by metabolic processes of living microorganisms (see document (1)).

7. The inventors of the patent in suit have discovered that the reduction of resazurin in absence of microorganisms by a growth medium with a lower redox potential than resazurin negatively effects the accuracy of assays testing antibiotic sensitivity. As a solution to this drawback it discloses the addition of a redox stabiliser.

8. The Appellant argues that the term "redox stabiliser" was not known in the here relevant technical field at

the priority date of the patent in suit and thus was meaningless for a person skilled in the art.

9. The term "stabilizer" in its ordinary meaning describes a substance or device which prevents a certain parameter from variation and maintains it at a particular value. From a reading of the patent in suit it is clear that the parameter to be stabilised in the above sense is the redox potential of resazurin which should be prevented from changing its colour by the reductive activity of the growth medium, which means that the flow of electrons from the growth medium to resazurin should be prevented. According to the example on page 15 of the patent this is achieved by adding potassium ferrocyanide, another chemical species, which also has its own intrinsic redox potential. In fact the redox potential of potassium ferrocyanide is similar to that of resazurin (see Respondent's letter of 10 May 2006, page 3, second paragraph). Thus, by adding a component of similar redox potential to resazurin, the flow of electrons from the growth medium to resazurin is prevented until the point where the reducing power of bacterial growth overcomes the holding power of the stabilizer. Thereby the influence of the growth medium on the test result is prevented and the assay accuracy is improved.

10. In the light of his/her general knowledge (see point (6) above) in combination with the disclosure of the patent in suit (see point (7) above) the skilled person, in order to find redox stabilisers other than potassium ferrocyanide for other assay compositions and thus to carry out the claimed invention over the whole scope claimed, has to look for non-toxic substances having a redox potential similar to that of resazurin. The problem of the correct concentration of the added stabilizer in dependency of the concentrations of growth medium and resazurin used in the respective assay can be solved by standard titration elements. These tasks can be performed by a skilled person without undue burden.

11. This situation is different from the one underlying decisions T 172/99 and T 1288/01 (supra), which both refer to cases where a claim referred to a parameter which was newly defined by the respective Patent Proprietor and for which parameter no method of determination was described in the art. These decisions are not considered to be relevant for the present case.

12. According to another line of argumentation the Appellant took the view that the legal framework of the present case has been modified as a result of the amendments introduced into independent claims 1, 16, 17, 21 and 22. He considers such modification to justify the admittance of grounds for opposition not properly covered by the statement pursuant to Rule 55(c) EPC and refers in this respect to point (19) of the decision of the Enlarged Board of Appeal G 9/91 (supra) and to decision T 623/93 of 19 October 1995.

13. The feature introduced into the independent claims, namely the presence of " a pre-selected redox stabiliser characterised by substantial lowering of the reduction of resazurin by said growth medium" was contained in claim 3 as granted, corresponding to claim 3 of the application as originally filed, published as WO 90/08 196.

Moreover it was disclosed in the description of the patent as granted (see page 8, lines 23 to 26; corresponding to page 20, lines 20 to 23 of the WO publication).

14. Point (19) of decision G 9/91 reads as follows:

"In order to avoid any misunderstanding, it should finally be confirmed that in case of amendments of the claims or other parts of a patent in the course of opposition or appeal proceedings, such amendments are to be fully examined as to their compatibility with the requirements of the EPC (e.g. with regard to the provisions of Article 123(2) and (3) EPC)."

The introduction of a feature into an independent claim, which feature was present in the claims and in the description as granted, cannot be considered as an amendment which legitimates the admittance of Article 100(b) EPC as fresh ground of opposition, which requires that a European patent as a whole must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

15. Decision T 623/93 (supra) is not concerned with sufficiency of disclosure at all but with the question if an Opponent who had substantiated his opposition solely with regard to novelty of claim 1, upon filing of amended claims by the Patent Proprietor is legitimated to file new citations and arguments with regard to other claims and to inventive step of claim 1.

The decision is not considered to be relevant for the present case.

16. Finally the Appellant argued that lack of sufficiency of disclosure of the patent in suit is prima facie evident upon comparison of its disclosure with the disclosure in document (18), a US patent which is a continuation-in-part application of the present priority application.

The Board stresses the following:

Document (18), being a continuation-in-part application, is not identical to the present priority application as it extends beyond the principles described therein.

There are a whole host of reasons why the claims of a US patent may be different from a corresponding European patent, for instance by containing additional limitations which are not required or even not applicable in the European proceedings. Thus, before applying any conclusions drawn from something that has happened in proceedings before the USPTO to the proceedings before the EPO one has to have exact information about the procedural situation before the

USPTO. Even when having this information care should be taken, because the law, case law and granting practice in the USA may be different than in Europe. In the present case there is no convincing evidence on file that allows the drawing of a parallel between the USPTO and the EPO proceedings in a way that lends support to the Appellant's lack of sufficiency of disclosure argument.

17. To summarise, the Board arrives at the decision that the Opposition Division has correctly exercised its discretion not to allow into the proceedings the ground for opposition under Article 100(b) EPC in conjunction with Article 83 EPC.

Amendments - Article 123(2) and 123(3) EPC

18. Claims 1 to 36 contain the following amendments compared to claims 1 to 36 as granted:

Claim 1 contains the additional feature that "a pre-selected redox stabiliser characterized by substantial lowering of the reduction of resazurin by said growth medium during step (g)" is disposed in each of the negative growth control-, the positive growth control- and the test receptacle.

In claim 6, which contains an explicit reference to claim 1, the above characterization of the redox stabiliser has been removed.

Claims 16, 17, 21 and 22 contain the additional feature that the set of test chemicals includes "a pre-selected

redox stabiliser characterized by substantial lowering of the reduction of resazurin by said growth medium".

Moreover, a clerical mistake in claim 22 has been corrected.

In addition page 5 of the description has been amended to recite claim 1 (pages 5a to 5b). Pages 6-8 have been adapted to the wording of the claims.

The amendment to claim 1 is based on page 20, lines 20 to 23 of the application as filed, published as WO 90/08 196, which read:

"In addition, it has been discovered that, during incubation, the growth medium itself tends to reduce resazurin and for that reason it is preferable to include a redox stabilizer such as potassium ferrocyanide in the set of test chemicals disposed in the three wells."

Claims 16, 17, 21 and 22 all refer to test modules carried in each of the three wells, wherein each of said test modules comprises a dry solid volume of a subset of the constituents of a set of test chemicals.

The amendments contained in these claims are based on page 13, lines 21 to 23 and page 29, lines 7 to 10 of the published WO application.

19. The Appellant argues that claim 3 as originally filed (the WO application), which refers to a redox stabilizer, explicitly requires the presence of a pH buffer. The omission of this pH buffer from the

independent claims is considered to contravene the requirements of Article 123(2) EPC.

As all amendments have been found to be based on the passages of the published WO application indicated in point (18) above, from which it cannot be deduced that the presence of an pH buffer is an obligatory feature, the Appellant's argument is not convincing.

20. Claims 1, 16, 17, 21 and 22 differ from the corresponding claims as granted by the insertion of an additional feature, with the effect that the extent of protection conferred had been reduced.

21. Accordingly, the Board decides that the requirements of Articles 123(2) and 123(3) EPC are met.

Clarity - Article 84 EPC

22. The Appellant argued that the meaning of the following terms was open to interpretation and that the claims containing them did not meet the requirements of Article 84 EPC:

- "pre-selected redox stabiliser characterised by substantial lowering of the reduction of resazurin",

- "decision algorithm based on at least one predetermined functional combination",

- "low toxicity", and

- "substantial sensitivity".

Moreover, the Appellant argued that claim 1, which did not require the presence of a pH buffer, lacked clarity by omitting an essential feature.

23. The first of the four terms in question was contained in claim 3 as granted; the other three were contained in claim 1 as granted.

In decision T 23/86 (OJ EPO 1987, 316) the competent Board was confronted with the allegation of an Opponent that an unamended claim was unclear. The Board held that Article 84 EPC was an EPC requirement concerning patent applications which, although it had to be taken into account in opposition proceedings whenever the patent proprietor made any amendments, was not itself a ground for opposition under Article 100 EPC.

24. In the present case, although the claims have been amended in opposition proceedings by introducing an additional feature into the independent claims, the Opponent's objections are directed to terms which are identical to those contained in the claims as granted. Thus, the alleged lack of clarity cannot be produced by the amendments.

Therefore, the Board will not consider the Appellant's objections.

Novelty - Article 54 EPC

25. The Appellant has not argued that the claims lack novelty.

The subject-matter of claims 1 to 36 is not disclosed in the documents on file. It is therefore novel and meets the requirements of Article 54 EPC.

Inventive step - Article 56 EPC

26. The claims refer to a method and to apparatuses and kits for testing the susceptibility of a microorganism to growth inhibition by a preselected concentration of an antimicrobial product.

The closest state of the art is represented by the disclosure in document (1), which also refers to such a method and devices (see claims).

The problem underlying the present invention was the provision of a more accurate and thus improved assay.

27. The Board is convinced that this problem has been solved by the claimed subject-matter, which is distinguished from the disclosure in document (1) by the addition of a pre-selected redox stabiliser which substantially lowers the reduction of resazurin by the growth medium (see independent claims 1, 16, 17, 21 and 22).

28. The Appellant argues that claim 1 covers embodiments which do not solve the posed problem, as it does not require the presence of a pH buffer which is considered to be an essential feature of the claimed method.

Moreover, he takes the view that, once it is evident to a skilled person that the accuracy of the assay is negatively affected by the reduction of the redox

indicator by the growth medium, the solution to this problem is immediately evident to him/her in the light of his/her common general knowledge and of the disclosure either in the closest prior art itself (document (1)) or in combination with documents (9), (15) or (17). He draws the Board's attention to decision T 532/88 of 16 May 1990, wherein the competent Board held that the addressing of a problem simply by looking for ways of overcoming difficulties arising in the course of routine work did not constitute inventiveness.

29. Appellant's argument that claim 1, by not referring to a pH buffer, covers embodiments not solving the posed problem, has been disputed by the Respondent. According to the Respondent the use of a pH buffer is required only if the used growth medium does not have sufficient buffer capacity. Thus, rather than being an essential feature of the claimed method it is a preferred embodiment which may become necessary under specific circumstances only. The general knowledge of a skilled person allows him/her to immediately realize such specific circumstances and to react with the addition of a pH buffer.

30. According to an established principle of law the burden of proof lies with the party who alleges something. The Board notes that Appellant has merely asserted that the claimed method inevitably depends on the presence of a pH buffer but that he has not submitted any evidence for substantiating this.

Therefore, and in the light of the arguments presented by the Respondent, the Board does not agree that claim 1

covers embodiments not solving the problem underlying the present invention.

31. With regard to the question whether or not the claimed subject-matter was obvious for a skilled person, the Appellant, who agreed that document (1) represented the closest state of the art, defined the problem differently than this was done by the Board in point (26) above.

Rather than the provision of a more accurate, improved assay, the Appellant considered it to be the problem of the present invention to inhibit the reduction of resazurin by the growth medium. By referring to decision T 532/88 (supra) he concluded that the solution to this problem, which simply overcame a difficulty arising in the course of routine work, did not constitute inventiveness.

32. In identifying the problem underlying an invention it is not permissible to draw on knowledge acquired only after the date of filing or priority (see Case Law of the Boards of Appeal, Chapter I.D.4.1, pages 106 to 107, 4th Ed., English version).

The invention underlying decision T 532/88 was concerned with a lavatory cleansing block comprising a surface active agent and a bleaching agent. The subject-matter of claim 1 was distinguished from the disclosure in the closest state of the art (document (2)) in so far as the bleaching agent was embedded in or adhered to a shaped body formed of a slow-dissolving cleaning composition containing a surface active agent. Document (2) itself contained a clear hint that the

preparation of lavatory cleansing blocks of the claimed composition could be difficult because the interaction of their components (see points (2.1) to (3.1) of the reasons). As this problem was known at the relevant date of the patent, it was permissible to define the problem as being the provision of a lavatory cleansing block which overcomes difficulties resulting from interaction of its components. The competent Board came to the decision that once this problem was known, its solution according to claim 1 of the patent was obvious and denied an inventive step.

Thus, should the above decision's gist be applicable in the present case it has to be examined whether or not the prior art documents on file contain information from which a skilled person could have concluded that the accuracy of an assay according to document (1) could suffer from the reduction of resazurin by the growth medium.

33. Document (1) does not mention the problem of autoreduction of resazurin by the growth medium but, to the contrary, describes on page 12, second paragraph that it is not expected that there will be any colour change (and thus no reduction of resazurin) in the control wells not containing microorganisms to be tested. The same is reported in document (12).

Document (9) relates to tests for measuring bacterial contamination of meat carcasses wherein the amount of bacterial growth is assessed in a liquid growth medium on the basis of the reduction of resazurin. On page 220, lines 3 to 5 it is disclosed that the used medium, trypticase soy broth, is slightly reductive.

However, in the discussion section on page 223, second full paragraph, it is stated that only the use of media which are slightly reductive per se would allow the detection of poorly reducing Bacteria such as Pseudomonas and Lactobacilli. Thus, far from recognizing that a reducing growth medium could be a problem and could negatively affect the accuracy of an assay as claimed in the patent in suit, document (9) promotes the use of such media for its own assays under certain circumstances.

Document (10) considers the influence of a microorganism growth medium on the reduction of resazurin. However, when incubating cell-free filtrates and the used growth medium, namely Dubos broth, in the presence of resazurin, no colour change was observed. The conclusion drawn by the authors of document (10) that the growth medium did not possess any reducing activity (sentence bridging pages 113 and 114) directly teaches away from the present invention.

Document (15) describes the autoreduction of resazurin in acid medium but does not mention any microorganism growth medium, which is not an acid medium, let alone the reducing activity thereof.

Document (17), describing diagnostic testing devices and processes like the ones presently claimed, mentions in column 20, lines 52 to 55 the addition of "...adjunct materials, such as substances to adjust pH and osmotic pressure, buffers and the like". It discloses neither the addition of a redox stabiliser nor does it refer to reduction of resazurin by a growth medium.

34. Accordingly, in the light of the disclosure in the prior art documents on file, a skilled person at the priority date of the patent in suit was not aware of the problem that the accuracy of an assay as disclosed in document (1) could be disturbed by the reduction of resazurin by the growth medium.

The Appellant's definition of the problem underlying the patent in suit (see point (31) above) draws on knowledge acquired only after the priority date, which is not permissible according to the established case law of the Boards of Appeal (cf point (32) above). As shown above, the present situation is different from the one underlying decision T 532/88 (supra) which is therefore not applicable in the present case.

35. The problem underlying the patent in suit in the light of the disclosure in document (1), representing the closest state of the art, is rather the provision of a more accurate and thus improved assay. Neither document (1) itself nor the other relevant documents on file (see point (34) above) contain information that would prompt a skilled person to amend the disclosure of document (1) and to arrive at the solution to this problem according to independent claims 1, 16, 17, 21 and 22 in an obvious way.

The subject-matter of claims 1 to 36 thus involves an inventive step and meets the requirements of Article 56 EPC.

Order

For these reasons it is decided:

The appeal is dismissed.

Registrar: Chair:

P. Cremona U. Kinkeldey