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Datasheet for the decision of 9 December 2022

Case Number: T 0490/19 - 3.3.08

Application Number: 10754882.8

Publication Number: 2480682

IPC: C12Q1/18

Language of the proceedings: EN

Title of invention:
Paper strip for determining minimum inhibitory concentrations of antibiotics

Patent Proprietor:
Liofilchem S.r.l.

Opponent:
Himedia Laboratories Pvt. Ltd.

Headword:
Paper strip/LIOFILCHEM

Relevant legal provisions:
EPC Art. 56, 54
RPBA Art. 12(4)

Keyword:
Main request, auxiliary requests 1 and 2 - Inventive step - (no)

Decisions cited:
G 0007/93, T 0444/88, T 1742/12

Catchword:

Europäisches Patentamt
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Beschwerdekammern

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Case Number: T 0490/19 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 9 December 2022

Appellant: (Patent Proprietor)	Liofilchem S.r.l. Via Scozia- Zona Industriale 64026 Roseto Degli Abruzzi (TE) (IT)
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Respondent: (Opponent)	Himedia Laboratories Pvt. Ltd. 23, Vadhani Industrial Estate L.B.S. Marg, Ghatkopar West 400086 Mumbai, Maharashtra (IN)
Representative:	Kaminsky, Michael Cohausz & Florack Patent- & Rechtsanwälte Partnerschaftsgesellschaft mbB Bleichstraße 14 40211 Düsseldorf (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 14 December 2018 revoking European patent No. 2480682 pursuant to Article 101(3)(b) EPC**

Composition of the Board:

Chairman	T. Sommerfeld
Members:	M. Montrone
	R. Winkelhofer

Summary of Facts and Submissions

I. The appeal is against the decision of an opposition division to revoke European patent No. 2 480 682. This patent is based on European patent application No. 10754882.8 which has been filed as International patent application published as WO 2011/032683 with a priority date of 21 September 2009.

II. The opposition division held that the subject-matter of claim 1 of the main request and of auxiliary requests 1 and 2 lacked an inventive step (Article 56 EPC). Moreover, the opposition division decided not to admit document D21 into the proceedings.

III. With their statement of grounds of appeal, the patent proprietor ("appellant") submitted auxiliary requests 1 and 2 which were identical to those dealt with in the decision under appeal. In addition the appellant re-submitted document D21, which had been already filed during the oral proceedings before the opposition division, and new documents D22 and D23.

IV. In reply, the opponent ("respondent") submitted further documents (D24 and D25) and requested that document D21 not be admitted.

V. In a communication pursuant to Article 15(1) RPBA, the parties were informed of the board's provisional, non-binding opinion.

VI. Oral proceedings before the board were held on 9 December 2022.

VII. Claim 1 of the main request (claims as granted) reads:

"1. Paper strip (1) for determining Minimum Inhibitory Concentration of antibiotics, characterized by the fact that,

it is made from paper being permeable to air, it prevents air bubbles from forming at the point of contact with the microbial culture medium (3) that could invalidate the test or render it inaccurate and that it has a predetermined concentration gradient of antibacterial agent graded on a scale of fifteen dilution intervals."

VIII. Claim 1 of the auxiliary request 1 reads:

"1. Paper strip (1) for determining Minimum Inhibitory Concentration of antibiotics, characterized by the fact that,

it is made from paper being permeable to air, it prevents air bubbles from forming at the point of contact with the microbial culture medium (3) that could invalidate the test or render it inaccurate and that it has a predetermined concentration gradient of antibacterial agent graded on a scale of fifteen dilution intervals, wherein the aforementioned paper strip (1) on initial contact with the microbial culture medium (3) begins to release the antibiotics with which it is impregnated very slowly and gradually facilitating the user should the strip require repositioning on the microbial culture medium (3)."

IX. Claim 1 of the auxiliary request 2 reads:

"1. Paper strip (1) for determining Minimum Inhibitory Concentration of antibiotics, characterized by the fact that,

it is made from paper being permeable to air, it prevents air bubbles from forming at the point of contact with the microbial culture medium (3) that could invalidate the test or render it inaccurate and that it has a predetermined concentration gradient of antibacterial agent graded on a scale of fifteen dilution intervals, wherein the paper strip (1) comprises a colour scale and the fifteen dilution intervals are expressed in µg/mL."

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

D4: EP-A-0157071

D8: Indian Patent application No. 1013/MUM/2007

D8a: Extract from the Indian Patent Office journal regarding D8

D9: Merriam-Webster dictionary entry of the term "porous"

D10: PrintWiki entry of the term "Porosity"

D11: E Test: A Novel Technique for Antimicrobial Susceptibility Testing, Sader H.S. and Campos Pignatari A.C., São Paulo Medical Journal, 1994, Vol. 112(4), 635-638

D12: EP-A-0444390

D14: "M.I.C. Evaluators (M.I.C.E.) Simple, Convenient Method for Accurate MIC Values", 30 May 2008, 1-6, in www.rapidmicrobiology.com

D20: Affidavit from Narain Ramchandani, dated 29 August 2018

D21: Experimental data: Time of antibiotic release from MTS Liofilchem® to agar versus time of antibiotic release from Etest® Biomerieux®

D22: "Paper and Paperboard Characteristics, Nomenclature and Significance of Tests", Third Edition, 1963, 61, 62

D23: Macmillan dictionary entry: "on either side"

D24: The Wockhardt office copy of the Indian application 1013/MUM/2007 filed 30 May 2007, including the provisional specification

D25: The stamped and returned submission letter of Wockhardt Research Centre with the duplicate of the complete specification of the Indian application 1013/MUM/2007 (dated 28 May 2008, stamp dated 29 May 2008)

XI. The appellant's submissions, insofar as relevant to the present decision, may be summarised as follows:

Admission and consideration of documents D21, D24 and D25 in the appeal proceedings

The data of document D21 had already been filed during the examination proceedings and were therefore "*known to the parties*". Furthermore, document D21 was "*prima*

facie relevant and should have been admitted to the proceedings" because the data in this document provided experimental evidence of a technical effect which was not observed in document D11, which was, in the appellant's view, the closest prior art document.

Documents D24 and D25 were late filed by the respondent and should not be considered in the proceedings.

Main request

Public availability of document D8

Document D8 was not publicly available before the relevant filing date of the patent in suit. In accordance with the provisions of the Indian Patent Act, the publication of document D8 on 27 February 2009 in the Indian patent office journal, i.e. seven months before the priority date of the present application (21 September 2009), included basic information on this patent application only. Although the public could have filed a request for file inspection to access the complete application documents in this seven-month period, the records on file showed that the earliest request for inspection was filed on 20 February 2017, while the complete text of the application was available online since 15 October 2011 (affidavit D20). Thus since the opposition division's conclusion on the public availability of document D8 was in contrast with affidavit D20, the "*balance of probabilities standard*" was wrongly applied. Furthermore, D8 was not the application that had been published on 27 February 2009 as referred to in document D8a, because there were differences between documents D8 and D8a as regards the filing date, the applicant's address, the exact wording of the abstract, and the number of pages of the

complete application. Document D8 thus had to be disregarded because the publication date of D8 was unknown and so D8 did not form part of the prior art.

Novelty

The claimed paper strip was *inter alia* characterised by the feature in that the concentration gradient of an antibacterial agent was "*graded on a scale of fifteen dilution intervals*" (feature "M6"). This feature was lacking from documents D4 and D8, and thus at least for this reason the claimed paper strip was novel.

Inventive step

Document D11 represented the closest prior art, not document D8. Document D8 was directed to a different purpose because it provided a solution for a different technical problem compared to the claimed paper strip, i.e. the improvement of assay handling instead of improving the assay's accuracy. Moreover, document D8 disclosed a confusing and contradictory teaching. The reason for using a porous carrier material in document D8 remained elusive to the skilled person and the only Figure of document D8 showed an inaccurate MIC test.

The porous carrier of the test device disclosed in document D8 (e.g. claim 1) differed from the paper strip in claim 1 in at least two, if not three of the following technical features:
"*it is made from paper being permeable to air*" (feature "M3"),
"*it prevents air bubbles from forming at the point of contact with the microbial culture medium (3) that could invalidate the test or render it inaccurate*" (feature "M4"), and

in that the concentration gradient was "*graded on a scale of fifteen dilution intervals*" (feature "M6").

Features M3 and M4 were functionally connected. The skilled person would construe claim 1 in the sense that the air permeability of the paper was responsible for the prevention of air bubbles. Moreover, the prevention of air bubbles at the point of contact with the medium as defined in feature M4 required that no air bubbles formed under the paper when placed on the medium, i.e. in the off-plane direction of the paper strip.

Document D8 did not disclose that the exemplary porous chromatography paper cited therein was air permeable. The standards for an implicit disclosure according to the case law were not fulfilled, since it had to be immediately apparent to the skilled person that the disclosure must show that nothing other than the contentious feature formed part of the subject-matter disclosed or could be unequivocally gathered from the disclosure of the document as a whole. It was, however, doubtful that every chromatography paper was air permeable, since these papers were different and porosity was not equivalent to air permeability (document D22). Moreover, chromatography paper was neither necessarily thin nor transparent. For example, nitrocellulose chromatography paper was white. Document D8 did not disclose that the active substance was transported in an off-plane direction to the other side of the carrier by capillary forces. The document disclosed on page 5, third paragraph that the active substance was found "*on either side*" of the porous carrier. This implied that either one side of the carrier was coated with the agent, or both sides. Furthermore, while chromatography paper as mentioned in document D8 was commonly used to separate compounds in

liquids in the plane direction of the paper, chromatography paper did not necessarily do so in the off-plane direction. For example, the formation of air bubbles was a well known problem in Western blotting. Here proteins were transferred from an SDS gel to a nitrocellulose chromatography paper in an off-plane direction which often suffered from the presence of air bubbles that prevented the transfer. This showed that liquid permeability was not equal to air permeability. Thus the prevention of air bubbles was an additional functional feature of the claimed paper strip which was not implicitly disclosed by any chromatography paper.

Auxiliary request 1

Inventive step

The data of document D21 showed that the antibiotic was slowly released compared to a commercial Etest strip. This effect was not mentioned in document D8, nor in any of the other prior art documents. The subject-matter of claim 1 was thus inventive (Article 56 EPC).

Auxiliary request 2

Inventive step

The colour scale feature of claim 1 allowed the user to identify the MIC on the sample plate more easily and faster compared to the use of Arabic numbers. The information content of colours versus numbers was higher. The use of colours was thus advantageous, in particular, if many plates had to be screened. Furthermore, since the colour scale was printed in parallel to the different concentrations of the antibiotic on the strip, the determination of MIC was

more accurate. This effect was independent of any user preferences. The subject-matter of claim 1 was therefore inventive (Article 56 EPC).

XII. The respondent's submissions, insofar as relevant to the present decision, may be summarised as follows:

Admission and consideration of documents D21, D24 and D25 in the appeal proceedings

Document D21 had not been admitted by the opposition division because it was filed at the oral proceedings only. At this very late stage of the proceedings the respondent (opponent) was unable to analyse the data, let alone to disprove them by comparative tests. Therefore, the discretionary decision of the opposition division not to consider document D21 in the proceedings was taken according to the right principles.

The appellant submitted for the first time in their statement of grounds of appeal that differences existed in the bibliographic information between documents D8 and D8a. According to the appellant these differences were a further indication that document D8 was not published prior to the relevant filing date of the patent in suit. Since this assertion was new in the proceedings, documents D24 and D25 were submitted in reply to provide evidence that the bibliographic differences between documents D8 and D8a were due to the filing of a provisional specification and the complete specification a year later.

Main request

Public availability of document D8

Document D8 was publicly available before the relevant filing date of the patent, as derivable from documents D8a, D24 and D25.

Novelty

The feature "*graded on a scale of fifteen dilution intervals*" in claim 1 had no technical effect, was a mere presentation of information, and was moreover implicitly disclosed in documents D4 and D8.

Inventive step

Document D8 represented the closest prior art for the paper strip of claim 1.

Document D8 disclosed a porous chromatography paper as sole example of a porous carrier to be used for MIC determination (see page 5, third paragraph, page 6, fifth paragraph). The mentioning of a porous chromatography paper implicitly disclosed to the skilled person that the paper was "*permeable to air*" (see documents D9, D10 and D22). Although document D22 stated explicitly that "*air permeability depends on porosity but is not a measure of it*" (see page 61, left-hand column, last paragraph), this passage did not state that a porous paper was not air permeable. On the contrary, the passage stated that air permeability depended on porosity, i.e. pores in paper were the prerequisite of air permeability. This was likewise derivable from the statement in document D22 which summarised that papers with different pore sizes "*could have very different air-permeability values*" (see page 61, right-hand column, lines 1 and 2). In other words,

the air permeability range of porous paper was between low and high, which excluded any non permeability. Document D8 disclosed implicitly that the antimicrobial agent was transported in an off-plane direction through the porous paper. The third paragraph on page 5 reported that the porous carrier of the device contained on its surface a biological agent, wherein substantially all of the substance was present on either side of the carrier. This was likewise derivable from page 6, fourth paragraph. The application of an antimicrobial solution on the surface of a porous paper strip necessarily implied that the agent was transported in an off-plane direction from the coated side of the porous carrier to the other side due to capillary forces. Consequently, document D8 did not disclose that both sides were coated with the agent. Furthermore, since the porous paper was permeable to liquids in an off-plane direction, the same applied to air, since otherwise chromatography would not work. This finding was likewise supported by page 6, fourth paragraph of document D8, which disclosed that the test strip was used from both sides for the intended purpose. This was possible only because the paper strip allowed the passage of fluids, i.e. air and liquids from both sides. Feature M3 of claim 1 relied on the same physical principle, i.e. air permeability necessarily implied fluid permeability. Since the porous paper strip of document D8 was permeable to fluids it was necessarily also permeable to air.

The patent neither defined a minimum pore size nor a minimum air permeability of the paper for preventing air bubble formation. Thus no specific paper properties were required to achieve this effect except that the paper had to be air permeable. Consequently, according to the patent any air permeable paper irrespective of

whether it had a low or high permeability prevented air bubble formation. Features M3 and M4 of claim were therefore functionally linked.

Since the porous chromatography paper of document D8 was liquid and air permeable, it necessarily also prevented the formation of air bubbles.

The use of a scale of fifteen dilution intervals (feature M6) in claim 1 remained thus the sole distinguishing feature vis-a-vis the porous chromatography paper disclosed in document D8. This difference was not associated with a technical effect since it represented an arbitrary design choice of the gradient scale mentioned in document D8.
The technical problem to be solved was therefore the provision of an alternative paper strip for determining MIC. The solution of this problem as defined by claim 1 was obvious to the skilled person, since any dilution scale was suitable for the determination of MIC. Moreover, the use of a fifteen dilution scale was known from the prior art, for example, from document D11.

Auxiliary request 1

Inventive step

Claim 1 of auxiliary request 1 differed from claim 1 of the main request in that it further functionally defined that the antibiotics were released "*very slowly and gradually*" to facilitate any repositioning of the strip on the culture medium if found necessary. Claim 1 was silent on any paper properties that caused this effect. The appellant had submitted during the first instance proceedings that this effect was caused by the capillary actions of the paper strip (see appellant's

(patent proprietor's) reply to the notice of opposition, page 13, third paragraph). In other words, the effect relied on an inherent property of the paper strip. Document D8 disclosed likewise a porous chromatography paper strip for the determination of MIC. Consequently, this paper strip had the same inherent properties as the paper strip of claim 1. Thus, the same objections raised under lack of inventive step against the paper strip of claim 1 of the main request applied to claim 1 of auxiliary request 1.

Auxiliary request 2

Inventive step

Claim 1 of auxiliary request 2 differed from claim 1 of the main request in that a colour scale was used and in that the dilution intervals were expressed in µg/mL. A colour scale was a mere presentation of information that was exclusively addressed to the human mind. The same applied to the use of the concentration unit as indicated in claim 1. These features were non-technical. According to established jurisprudence such features did not contribute to the solution of the technical problem and, hence, were not considered in the assessment of an inventive step. The paper strip of claim 1 thus lacked an inventive step for the same reasons advanced for claim 1 of the main request.

XIII. The appellant requests that the decision under appeal be set aside and amended such that the opposition be rejected (main request), or that the patent be maintained on the basis of auxiliary requests 1 or 2. Further it is requested that document D21 be admitted

and considered in the proceedings, and documents D24 and D25 not be admitted and considered.

XIV. The respondent requests that the appeal be dismissed, and that document D21 not be admitted and considered in the proceedings.

Reasons for the Decision

Admission and consideration of documents D21, D24 and D25 in the appeal proceedings

1. Document D21 had already been submitted during the opposition proceedings. In exercising their discretion according to Article 114(2) EPC, the opposition division disregarded it. Such discretionary decision should only be overruled if it exceeds the proper limits of discretion, as applying the wrong principles, or without taking into account the right principles, or if it was done in an unreasonable way (see Case Law of the Boards of Appeal 10th ed., 2022 ("Case Law"), IV.C. 4.5.2).

2. There are no indications that the opposition division exceeded the limits of their discretion. To the contrary, the opposition division in their decision (see points 6.11 to 6.14) provided a sound reasoning why document D21 lacked *prima facie* relevance. While the appellant disagrees with the conclusions of the opposition division and argues that document D21 is indeed *prima facie* relevant, the board notes that "*it is not the function of a Board of Appeal to review all the facts and circumstances of the case as if it were in the place of the first instance department, in order to decide whether or not it would have exercised such discretion in the same way as the first instance*

department" (see G 7/93, point 2.6). Moreover, as argued by the respondent, document D21, which comprises comparative experimental data, was filed only at the oral proceedings and thus the respondent would not have been able to analyse the data, let alone to disprove them by comparative tests at the oral proceedings.

3. Already against this background, there is no reason to depart from the opposition division's decision and to consider document D21 in the appeal proceedings. The board moreover notes that there are no arguments from the appellant that this document should be admitted into the appeal proceedings as a new document, filed in reaction to the decision of the opposition division. The board thus exercises its discretion pursuant to Article 12(4) RPBA 2007 and does not admit document D21 into the appeal proceedings.

4. Documents D24 and D25 have been filed by the respondent in reply to a line of arguments against the public availability of document D8 that has been raised by the appellant for the first time in their grounds of appeal (see page 6, point 3.2, and respondent's reply, page 3, second and third paragraphs). As outlined below, the appellant's new line of arguments is not persuasive, even without taking documents D24 and D25 into account. The question of their consideration in these proceedings does therefore not arise.

Main request

Claim construction - claim 1

5. Claim 1 refers to a paper strip for determining Minimum Inhibitory Concentration (MIC) of antibiotics. Since claim 1 concerns a product claim, the MIC determination

of antibiotics is limiting for the paper strip only in so far as that the paper strip is suitable for this purpose.

6. The paper strip is further characterised by the functional features that the strip "*is made from paper being permeable to air*", and that "*it prevents air bubbles from forming at the point of contact with the microbial culture medium (3) that could invalidate the test or render it inaccurate*". Structural features that achieve these results are not mentioned in the claim. Likewise the description of the patent is silent on properties that allow a paper to be air permeable.

6.1 The term "*permeable to air*" in claim 1 is relative since it is not further defined. Thus claim 1 encompasses paper strips with any degree of air permeability, i.e. low or high. Furthermore, the term "*prevents air bubbles from forming at the point of contact*" in claim 1 defines a result to be achieved. Claim 1 leaves the time point open as to when this has to be achieved, i.e. immediately or over time.

6.2 In the context of claim 1 the terms "*permeable to air*" and "*prevents air bubbles from forming at the point of contact*" are functionally linked in the sense that the air permeability of the paper strip is responsible for preventing air bubble formation. In the absence of any further criteria, the skilled person construes claim 1 such as that the effect of air bubble prevention must be achieved by any paper having any degree of air permeability and irrespective of the time it takes.

6.3 The appellant argued that the functional requirement that air bubble formation was prevented "*at the point of contact*" necessarily implied that this occurred in

an off-plane direction relative to the paper strip. The board does not agree. This functional feature requires that air bubbles should not be formed at the contact site, irrespective of how this is achieved. Thus, to achieve this effect air could pass through the filter in any direction, not necessarily solely in an off-plane direction.

7. Furthermore claim 1 requires that the paper strip has a "*predetermined concentration gradient of antibacterial agent graded on a scale of fifteen dilution intervals*". This structural feature refers to a paper strip that contains an antibiotic concentration in 15 dilution steps (areas) arranged in a gradient that are, moreover, graded on a scale. The location of the dilution areas on the paper strip is not defined. Accordingly, the areas might be located on the surface of the strip, or within the strip, for example, in a multilayer paper strip. Since the "*fifteen dilution intervals*" is a limiting feature of claim 1, paper strips with less or more than 15 dilution intervals are not considered to fall within the claimed subject-matter.

Public availability of document D8

8. In the decision under appeal (see point 3 starting on page 5) the opposition division held that document D8 was publicly available as from 27 February 2009 and thus before the priority date of the patent in suit (21 September 2009), and therefore formed prior art under Article 54(2) EPC. For the reasons given there, the board agrees with the opposition division's findings (Article 15(8) RPBA 2020).

9. According to the Indian Patens Act, 1970, Section 11A(5), the publication of every patent application shall include the particulars of the date of application, number of application, name and address of the applicant identifying the application and an abstract. Any additional details about a published patent application may be inspected upon written request, and copies thereof may be obtained (see document D20, in part referring to the previous, but insofar corresponding rules of the Indian Patents Act 1940).

10. Indian patent applications were not fully digitised in 2009. The complete application was thus obtainable, as also acknowledged by the appellant, through a request for file inspection or the ordering of a paper copy of the application without a "*definite time line*" (see document D20, points 7 and 8).

10.1 According to the jurisprudence of the Boards of Appeal, the theoretical possibility of having access to information renders it available to the public (see Case Law, I.C.3.1, e.g. T444/88, reasons 3.1). As a consequence, the possibility to request access to the full file upon inspection renders the content of document D8 publicly available as from 27 February 2009. Within a period of seven months between the publication of document D8 and the earliest filing date of the patent, any member of the public requesting a file inspection could have also obtained a paper copy of this document. The appellant did not argue that there had been physical or other obstacles for a file inspection in this period.

10.2 In view thereof, any questions concerning the standard of proof as applied by the opposition division are not

relevant. It is also immaterial if and when a request for file inspection was actually made.

10.3 The appellant's further argument as to alleged contradictions in the bibliographic data between documents D8 and D8a is likewise not persuasive. In particular, it is clear from these documents, taken together, that a provisional application pursuant to Section 9 of the Indian Patents Act, 1970, has been filed on 30 May 2007, which has been completed on 29 May 2008, and was then published on 27 February 2009. The application number is identical, as is the applicant, the title and the abstract in its core. Document D8a thus fully corresponds to D8.

Novelty

11. The board agrees with the opposition division's finding in the decision under appeal (see points 5.1.4.9 and 5.1.5.8) that documents D4 and D8 do not mention that the antimicrobial agent is "*graded on a scale of fifteen dilution intervals*" (so-called feature "M6" of claim 1). At least for this reason the claimed paper strip is novel over documents D4 and D8 (Article 54 EPC).

12. The respondent submitted that this feature had no technical effect, was a mere presentation of information, and was moreover implicitly disclosed in documents D4 and D8. In support of the latter argument, the respondent submitted that 15 dilution levels were the "*standard scale of choice*" (see e.g. document D11, page 636, left column, last paragraph; document D12, page 3, line 1; and document D14, page 1, third paragraph).

12.1 These arguments are not persuasive. A scale of 15 dilutions of an antibacterial agent on the claimed paper strip allows the skilled person to determine the MIC of that agent for a particular bacterial species. Consequently, this feature has a technical effect.

12.2 Furthermore this feature relates not to the presentation of information, because it concerns not only a printed scale but refers to a scale which contains 15 different concentrations of an antibacterial agent.

12.3 Lastly, a scale of 15 dilutions of the antibacterial agent is not implicitly disclosed in documents D4 and D8. It is established case law that an alleged disclosure can only be considered implicit if it is immediately apparent to the skilled person that nothing other than the alleged implicit feature forms part of the subject-matter disclosed. In other words, the implicit disclosure means no more than the clear and unambiguous consequence of what is explicitly mentioned in a document (see Case Law, I.C.4.3).

12.4 Even if 15 intervals might be a "*standard scale of choice*" in the art, the term "*standard*" does not necessarily imply that MIC test strips must exclusively use 15 dilution intervals. Document D12 states "*When setting up the checkerboard with for example 15 dilutions*" (see page 3, line 1, emphasis added). The term "*for example*" in this statement implies that 15 dilutions do not define a necessary requirement.

13. Thus the main request complies with the requirements of Article 54 EPC.

Inventive step

Closest prior art

14. The respondent and the opposition division considered document D8 as closest prior art for the paper strip as defined in claim 1. The appellant argued that document D11 is the closest prior art instead.

15. In essence the appellant argued that document D8 did not represent the closest prior art because it concerned an invention that provided a solution for a different technical problem compared to the claimed paper strip, i.e. an improvement of assay handling instead of improving the assay's accuracy. Moreover, document D8 disclosed a confusing and contradictory teaching.

15.1 This is not convincing. The case law has established that the "closest prior art" for assessing inventive step is normally a prior art document disclosing subject-matter conceived for the same purpose or aiming at the same objective as the claimed invention and having the most relevant technical features in common, i.e. requiring the minimum of structural modifications. A further criterion is the similarity of the technical problem (see Case Law, I.D.3.2. and I.D.3.3.). In addition, the case law further sets out that if the skilled person has a choice of several workable routes, i.e. routes starting from different documents which might lead to the invention, the invention must be assessed relative to all these possible routes before an inventive step is to be acknowledged (see Case Law, I.D.3.1, e.g. T 1742/12, reasons 6.6).

15.2 Document D8 mentions the need of getting MIC "*results rapid and accurate*". Moreover, document D8 states that the paper strip provides "*accurate MIC values due to a continuous concentration gradient of the antimicrobial agent on the test strips*" (see page 2, first paragraph, last sentence; page 6, fifth paragraph). In other words, document D8 belongs to the same technical field and aims at the same objective as the claimed paper strip. Thus, document D8 is a valid starting point for an inventive step assessment.

16. As regards the relevant technical features in common, it is uncontested that document D8 discloses the following features of claim 1:
"*Paper strip*" (so-called "M1" feature), "*for determining Minimum Inhibitory Concentration of antibiotics*" (so-called "M2" feature), and "*that it has a predetermined concentration gradient of antibacterial agent*" (so-called "M5" feature).

17. It is however contested whether or not a porous paper such as the chromatography paper mentioned in document D8 (see page 6, fifth paragraph) implicitly discloses that the claimed strip "*is made from paper being permeable to air*" and that the claimed strip "*prevents air bubbles from forming at the point of contact with the microbial culture medium (3) that could invalidate the test or render it inaccurate*", i.e. so-called features "M3" and "M4", respectively of claim 1.

17.1 Document D8 does not explicitly disclose that the porous chromatography paper is permeable to air. Therefore, the question poses if this term implicitly discloses that this material is air permeable, in other words whether a porous chromatography paper is necessarily air permeable. During the first instance

proceedings documents D9 and D10 have been discussed between the parties which provide a definition of the terms "*porous*" and "*porosity*". The appellant contested the validity of these two documents because they were either an excerpt from a non-technical dictionary, or were derived from a document that was not prior art at the relevant filing date of the patent.

17.2 In view thereof, the appellant submitted document D22 which is an excerpt from a prior art text book on paper. This document states that paper porosity is not a synonym for air permeability, since the latter "*depends on porosity but is not a measure of it. Two materials having the same porosity, one having many small pores and the other having fewer but larger pores, could have very different air permeability values*" (see page 61, last two sentences in the left column, last paragraph). The appellant further provided three figures which showed that a porous material was not implicitly air permeable since this required that pores "*form a continuous channel from one side of the material to the other*" (see statement of grounds of appeal, page 11, last paragraph).

17.3 Document D8 states on page 5, third paragraph as follows: "*It is another object of the present invention to provide a test device, comprising a porous carrier, containing on the surface thereof a biologically active substance for example an antimicrobial agent, wherein substantially all of the active substances are on either side of the carrier in a continuous concentration gradient manner, so that when carrier is applied to the surface of a antimicrobial growth supporting medium, a concentration pattern is transferred to the surface of the same medium completely, which on further processing gives MIC*

values. The test device has calibrated values printed on one side of the test device." (emphasis added)

17.4 Furthermore, page 6, fourth paragraph of document D8 states: "*Another embodiment of the present invention is the use of the test strips from both sides. The porous nature of one side printed carrier allows one to apply the test strip keeping printed one side facing downwards or upwards to the agar media in a Petri-dish. This enables to interpret results without opening the lid of a petri-dish as one can read results from the transparent bottom side of the Petri dish. However, for a non porous strip material where the calibration is done on one side, one needs to open the lid to read the results as condensed water on the inner side of the lid would obstruct the view to the reading scale. This is a dangerous situation as pathogenic organisms get exposed to open atmosphere.*" (emphasis added)

17.5 The skilled person would interpret these two passages in the sense that the porous character of the carrier is responsible for the antimicrobial agent's presence on both sides of the carrier in substantially equal amounts. This is derivable from the consistent mentioning of a "*porous*" carrier or a carrier with a "*porous nature*". These pores in the carrier make the carrier permeable for liquid antimicrobial solutions (see document D8, paragraph bridging pages 6 and 7). Furthermore, since the pores allow the passage of the liquid antimicrobial agent to the other side of the carrier, the pores must form a continuous channel from one side of the paper strip to the other. The skilled person would moreover derive from these two passages of document D8 that only one side of the paper carrier is coated with the solution, and not both sides, as submitted by the appellant.

17.6 The appellant further submitted that the skilled person would have interpreted the term "*porous*" in document D8 to refer to cavities on the surface of the carrier, and not necessarily to pore channels so that each side of the carrier had to be coated with the agent separately.

For the reasons set out above, this is not convincing.

17.7 In summary, document D8 implicitly discloses in the two passages cited above a liquid permeable porous chromatography paper strip, which due to the porous nature of the carrier has substantially equal amounts of an antibiotic on both sides of the carrier. Moreover, since the antibiotic is applied to the surface of the porous chromatographic paper strip in a liquid solution, the capillary forces within the pores transport the agent in an off-plane direction to the other side of the carrier. These forces have likewise the effect that any air present in the paper strip is displaced by the liquid containing the antimicrobial agent. Furthermore, as soon as the antibacterial solution dries on the paper strip, air must enter the porous paper structure again.

17.8 The appellant lastly submitted that even if the chromatographic paper of document D8 was liquid permeable this did not necessarily imply that the paper was air permeable. Reference was made to personal Western blot experiences.

17.9 The board does not agree. As set out above, the ability of a porous chromatography paper to be liquid permeable implies that this paper is air permeable too, since liquids displace air/gases due to the capillary forces (see point 17.7). These properties cannot be separated

from each other. Furthermore, as set out above under claim construction, the paper strip of claim 1 is not limited by a minimum air permeability. Nor does claim 1 require a minimum air permeability to prevent the formation of air bubbles. The patent is also silent on any other requirement of the claimed paper strip than air permeability for achieving this effect. Therefore claim 1 defines that any air permeable paper strip prevents the formation of air bubbles. Consequently, since the paper strip of document D8 is liquid permeable which necessarily includes air permeability, the paper strip of document D8 must also prevent the formation of air bubbles at the contact point with the medium in the Petri dish plate.

18. In light of these considerations and in line with the opposition division's findings, the sole distinguishing feature between the paper strip of claim 1 and that of document D8 is an antibiotic that is "*graded on a scale of fifteen dilution intervals*" (i.e. so-called feature "M6").

19. Since no particular technical effect can be ascribed to this distinguishing feature, the technical problem to be solved resides in the provision of an alternative paper strip for determining MIC.

20. The paper strip as defined in claim 1 provides a solution to this problem.

Obviousness

21. It remains to be assessed whether or not the skilled person, starting from the paper strip of document D8 and facing the problem defined above, would have

arrived at the paper strip of claim 1 in an obvious manner.

22. Starting from the paper strip of document D8 and looking for an alternative paper strip, the skilled person would have consulted other commercial test strips for determining MIC. In this context the skilled person would have considered all features of these test strips, for example, their antibiotic dilution scales. Document D11 discloses, for example, the use of a plastic test strip for determining MIC that is characterised by the so-called "M6" feature (see page 636, left column, last paragraph, and point 18 above).

23. By combining the paper strip of document D8 with this teaching in document D11, the skilled person would have arrived at the claimed paper strip in an obvious manner. Therefore the paper strip of claim 1, and hence the main request, does not comply with the requirements of Article 56 EPC.

Auxiliary request 1

24. Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that the feature "*wherein the aforementioned paper strip (1) on initial contact with the microbial culture medium (3) begins to release the antibiotics with which it is impregnated very slowly and gradually facilitating the user should the strip require repositioning on the microbial culture medium (3)*" has been added.

Inventive step

25. The appellant's arguments with regard to the claimed paper strip under inventive step are exclusively based

on an advantageous effect as demonstrated by the data of document D21. However, for the reasons set out above, document D21 can not be considered in these appeal proceedings. In the absence of any other argument, let alone evidence of an advantageous effect, there is no reason to depart from the finding of the opposition division (see decision under appeal, points 6.15 and 6.16) that the subject-matter of claim 1 lacks an inventive step (Article 56 EPC).

Auxiliary request 2

26. Claim 1 of auxiliary request 2 differs from claim 1 of the main request in that the feature "*wherein the paper strip (1) comprises a colour scale and the fifteen dilution intervals are expressed in µg/mL*" has been added.

Inventive step

27. The appellant argued that the "*colour scale*" feature of claim 1 was not a mere presentation of information because it allowed the skilled person to identify the MIC on the sample plates more easily and faster compared to Arabic numbers, in particular if many test plates were analysed. This effect was independent from any user preferences and facilitated the identification of the correct MIC, i.e. provided an improved paper strip for determining MIC.

28. The board agrees with the findings of the opposition division (see decision under appeal, points 7.5.1 to 7.5.4) also insofar as the colour scale feature of claim 1 is a presentation of information which cannot contribute to an inventive step.

28.1 As stated by the opposition division, the preference of colours over numbers depends entirely on subjective interests of the user. Moreover, colours in the form of a scale as used in the paper strip of claim 1 are an information that is solely directed to the human mind. While a colour scale may support a first user to identify the correct MIC on the plate more easily and faster compared to numbers, the opposite may be true for a second user, who for example, suffers from a red-green blindness, or for other reasons prefers numbers over colours. The board does therefore not agree with the appellant that the use of a coloured scale compared to Arabic number necessarily improves the claimed paper strip.

28.2 Further, the board does not agree with the appellant that the higher information content of a colour code compared to Arabic numbers necessarily improves the claimed paper strip. While it might be true that a colour scale has a higher information content than numbers, an increased information content as such can not be equated with an improvement, because this depends on the circumstances of the case. Already for this reason the argument must fail. Moreover, as set out above, while the provision of more information might be beneficial for a first user, an increased information content might be confusing and distracting for a second user.

29. Likewise, the scaling of 15 dilution intervals in "*µg/mL*" as mentioned in claim 1 is a presentation of information, since - as correctly held by the opposition division - the indication of a mere concentration unit is meaningless without a defined amount, for example, a range of concentrations.

30. In light of these considerations, the features added to claim 1 lack a technical character and cannot therefore be taken into account for the assessment of inventive step.

31. Consequently, the arguments set out above for the paper strip of claim 1 of the main request under lack of inventive step (Article 56 EPC) apply likewise to the paper strip of claim 1 of auxiliary request 2.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairwoman:

L. Malécot-Grob T. Sommerfeld

Decision electronically authenticated