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Datasheet for the decision of 14 January 2016

Case Number: T 2056/12 - 3.3.08

04751790.9 Application Number:

Publication Number: 1620572

IPC: C12Q1/68, C12P19/34

Language of the proceedings: EN

Title of invention:

SYSTEMS AND METHODS FOR FLUORESCENCE DETECTION WITH A MOVABLE DETECTION MODULE

Patent Proprietor:

BIO-RAD LABORATORIES, INC.

Opponent:

Pfau, Anton Konrad

Headword:

Movable detection module/BIO-RAD LABORATORIES

Relevant legal provisions:

EPC Art. 54, 56, 114(2) RPBA Art. 12(4), 13(1), 13(3)

Keyword:

Main request - requirements of the EPC met (yes)

Decisions cited:

T 0724/08

Catchword:



Beschwerdekammern Boards of Appeal Chambres de recours

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Case Number: T 2056/12 - 3.3.08

DECISION of Technical Board of Appeal 3.3.08 of 14 January 2016

Appellant: Pfau, Anton Konrad
(Opponent) Grünecker, Kinkeldey,
Stockmair & Schwanhäusser

Anwaltssozietät Leopoldstrasse 4 D-80802 München (DE)

Respondent: BIO-RAD LABORATORIES, INC. (Patent Proprietor) 1000 Alfred Nobel Drive

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Representative: Kazi, Ilya

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Decision under appeal: Decision of the Opposition Division of the

European Patent Office posted on 13 July 2012 rejecting the opposition filed against European patent No. 1620572 pursuant to Article 101(2)

EPC.

Composition of the Board:

Chairman M. Wieser Members: B. Stolz

J. Geschwind

- 1 - T 2056/12

Summary of Facts and Submissions

- I. An appeal was filed against the decision of the opposition division whereby the opposition against European patent No. 1620572 was rejected.
- II. The opposition was based on the grounds of Article 100(a) EPC in conjunction with Articles 54 and 56 EPC. Documents D1 to D13 were considered by the opposition division.
- III. With the statement setting out the grounds of appeal, the opponent (appellant) submitted a new document, D14, on which a new novelty objection was based.
- IV. With its response the patent proprietor (respondent) filed auxiliary requests 1 to 11.
- V. The parties were summoned to oral proceedings. A communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA), annexed to the summons, informed them of the preliminary non-binding opinion of the board on some of the issues of the appeal proceedings.
- VI. In a further submission, the appellant commented on auxiliary requests 1 to 11.
- VII. The respondent filed further comments, new auxiliary requests 1 to 15, and expert declaration D15.
- VIII. Oral proceedings were held on 14 January 2016.
- IX. Independent claims 1 and 13 of the main request read:

- 2 - T 2056/12

- "1. A fluorescence detection apparatus for analyzing samples located in a plurality of wells in a thermal cycler, the apparatus comprising:
 - a support structure attachable to the thermal cycler; and a detection module movably mountable on the support structure, the detection module including:
 - an excitation light generator disposed within the
 detection module; and an emission light
 detector disposed within the detection
 module;
 - wherein, when the support structure is attached to the thermal cycler and the detection module is mounted on the support structure, the detection module is movable so as to be positioned in optical communication with different ones of the plurality of wells.
- 13. A method for detecting the presence of a target molecule in a solution, the method comprising:
 - preparing a plurality of samples, each containing
 a fluorescent probe adapted to bind to a
 target molecule;
 - placing each sample in a respective one of a
 plurality of sample wells of a thermal
 cycler instrument, the thermal cycler
 instrument having a detection module movably
 mounted therein, the detection module
 including an excitation/detection channel,
 the excitation/detection channel including
 an excitation light generator disposed

- 3 - T 2056/12

within the detection module and an emission light detector disposed within the detection module;

stimulating a reaction using the thermal cycler instrument; and

scanning the plurality of sample wells to detect a fluorescent response by moving the detection module and activating the excitation/ detection channel,

wherein during the step of scanning, the detection module is moved such that the excitation/ detection channel is sequentially positioned in optical communication with each of the plurality of sample wells."

Dependent claims 2 to 12 define specific embodiments of the fluorescence detection apparatus of claim 1. Dependent claims 14 to 20 define specific embodiments of the method of claim 13.

X. The following documents are cited in this decision:

D1: US 5,585,242

D2: US 5,578,818

XI. The arguments of the appellant can be summarized as follows:

Admissibility of documents D14 and D15

Documents D1 and D2 filed in the opposition procedure were considered to anticipate the claimed subject

matter. The opponent/appellant was surprised that the opposition division came to a different conclusion. Therefore, document D14 was submitted at the earliest possible moment after the decision under appeal had been delivered. The content of this document was prima facie highly relevant, not complex and the relevant paragraph, column 4, lines 10 to 18, described a fluorescence detection system with all the features of claim 1. Document D15 should not be admitted because it would convolute the procedure and contained unproven allegations drafted by an employee of the inventor who was not familiar with European patent law.

Article 54 EPC

Document D1 disclosed a method for the detection of nucleic acids using a fluorescence excitation source and optics, and fluorescence detection optics.

According to column 16, lines 9 to 13, such optics could be located on a movable platform. The movable platform was inevitably connected to a support structure and inevitably attachable to a thermal cycler in order to perform its function. Since the excitation/detection optics could be located on a moving platform, they were in functional relationship and physically combined on the platform. Figure 2 clearly showed the excitation optics associated with the excitation source and the detection optics associated with the detection optics. Hence they were located within a detection module.

The main request also lacked novelty over the fluorescence detection apparatus disclosed in document D2.

Article 56 EPC

Document D1 represented the closest prior art. The fluorescence detection apparatus located on a movable platform as proposed in column 16 differed from the apparatus of claim 1 only in the location of the excitation/light source. Having the light source on the movable platform made the apparatus more versatile. Consequently, the technical problem was the provision of a more versatile apparatus. Document D2, belonging to the same technical field, disclosed a fluorescence detection apparatus used for the same technical purpose as described in the patent, (see column 1, lines 4 to 6 and lines 42 to 45). It proposed to use an LED as a compact and inexpensive light source as described in column 1, lines 50 to 55 and in column 3, lines 10 to 22, and as shown in Figures 2 and 5. Moreover, document D2 also disclosed that a small light weight detector could be directly placed on a scan head. The skilled person was aware that a support structure providing a connection to the thermal cycler was needed. The solution to the technical problem was thus obvious.

XII. The arguments of the respondent can be summarized as follows:

Admissibility of documents D14 and D15

A decision unfavourable to an opponent was not a reason for admitting a new document (D14). The patent was maintained unamended and the situation of the opponent was the same as at the beginning of the opposition procedure. Document D14 should and could have been submitted during the opposition procedure. Document D15 was submitted in response to a comment in the board's communication.

- 6 - T 2056/12

Article 54 EPC

Document D1 drew a distinction between the excitation source and the excitation optics as could be seen from column 14, line 42. The location of the excitation source was not mentioned in column 16, lines 9 to 12. Novelty had to be assessed on the basis of facts, not on the basis of probabilities. Moreover, the optical communication system of document D1 was different from the communication system disclosed in Figure 6 of the patent.

Article 56 EPC

The optical system disclosed in document D2 was completely different from the optical system of document D1. For this reason alone, the skilled person would not have turned to document D2. Moreover, the excitation system of document D1 did not excite a sample in a well and the communication between the surface of the light transmitting element and the sample in the well was not optical in the sense of the patent. The set-up of document D1 was very specific, requiring particular arrangements for coupling the light beam to the quartz rods representing the TIR elements. The optics of the fluorescence detection apparatus of document D2 would have to be re-engineered to properly illuminate the TIR elements of document D1. Simply attaching the apparatus of document D2 to the thermal cycler of document D1 would not work.

- XIII. The appellant requested that the decision under appeal be set aside and the patent be revoked.
- XIV. The respondent requested that the appeal be dismissed.

- 7 - T 2056/12

Reasons for the Decision

Admissibility of documents D14 and D15

- 1. With its grounds of appeal, appellant II submitted document D14 and based a new novelty objection on it. The respondent objected to its introduction into the proceedings.
- 2. The appellant stated that document D14 had not been filed earlier because it had assumed that document D1 would convince the opposition division of the lack of novelty of the claimed subject-matter. Under these circumstances, document D14 was filed as soon as possible, i.e. with the grounds of appeal, when the appellant became aware that its assumption was not correct. The document was highly relevant and its content could be easily understood.
- 3. The purpose of appeal proceedings is primarily to give a judicial decision upon the correctness of an appealed decision (cf. Case Law of the Boards of Appeal, 7th edition, IV.E.1, page 934). Its purpose is not to give a losing party a new opportunity to try to attack a patent on the basis of new evidence and arguments.
- 4. Article 114(2) EPC gives the board the discretion to disregard facts or evidence which are not submitted in due time. The exercise of discretion is governed by the principles laid down in Articles 12(4) and 13(1) RPBA.
- 5. The technical relevance of a document is only one of the factors the board has to take into account. It is however not the only one and also not the decisive factor. If this were not so, this would open a door to

- 8 - T 2056/12

an appellant to submit a document at any point of the appeal proceedings and to rely on its admission on the basis of its relevance (cf. point 3.4 of decision T 724/08 of 16 November 2012). Other factors taken into consideration are whether the evidence could have been presented in the first instance proceedings (Article 12(4) RPBA), the complexity of the new subject matter submitted, the current state of the proceedings and the need for procedural economy (Article 13(1) RPBA).

- 6. In view of the circumstances of the present case and in the light of appellant's arguments, the board is of the opinion that document D14 could have been presented in opposition proceedings and decides not to admit it.
- 7. The respondent submitted expert declaration D15 in response to a comment made by the board in its communication attached to the summons to oral proceedings. The appellant objected to its admission.
- 8. This document was filed one month before the oral proceedings. It contains comments provided by respondent's own technical expert in relation to an inventive step argument already on file but does not introduce additional arguments or experimental evidence. Therefore, document D15 is also not admitted into the procedure.

Article 54 EPC

- 9. Claim 1 comprises the following features:
 - 1.1 A fluorescence detection apparatus for analyzing samples located in a plurality of wells in a thermal cycler, the apparatus comprising:

- 9 - T 2056/12

- 1.3 a detection module movably mountable on the support structure, the detection module including:
 - 1.3.1 an excitation light generator disposed
 within the detection module; and
 - 1.3.2 an emission light detector disposed within the detection module;
- 1.4 wherein, when the support structure is attached to the thermal cycler and the detection module is mounted on the support structure, the detection module is movable so as to be positioned in optical communication with different ones of the plurality of wells.
- 10. Document D1 discloses a method and an apparatus for the detection of nucleic acids using total internal reflection. The apparatus detects fluorescence from a sample located in a well and comprises elements of a thermal cycler (column 4, lines 16-24).

A first embodiment of the apparatus comprises fixed excitation source and optics and detection optics, and the reaction vessels are brought into alignment (i.e. by moving them) with the excitation and detection optics (column 16, lines 1-5). Alternatively, the excitation and detection optics can be located on a moving platform which aligns with each individual reaction vessel kept in stationary position (column 16, lines 9-12).

- 10 - T 2056/12

- 11. The appellant argued that the alternative embodiment, comprising excitation and detection optics on a movable platform, inherently comprised a support structure holding the movable platform in place, and that the movable platform should be regarded as the detection module according to feature 1.3 of claim 1. The appellant then argued that the movable platform also comprised the excitation source according to feature 1.3.1 of claim 1.
- 12. The board disagrees. In the alternative embodiment disclosed in column 16, lines 9-12, of document D1 "the excitation and detection optics can be located on a moving platform". There is however no mention of an excitation source that could be mounted on the moving platform. Throughout part D of document D1, which discloses the set up of the apparatus, a distinction is made between the (fluorescence) excitation source (the "lamp") and the excitation optics (lenses, mirrors and the like) (cf. column 14, lines 35, 42, 49, 52, 59, 63; column 15, line 56; column 16, lines 1 and 9). Only the excitation optics are directly and unambiguously disclosed as being mounted on the movable platform. Furthermore, "the light source 40 may be a direct current driven tungsten-halogen lamp, a phosphor-coated mercury lamp, a pulsed Xenon flash lamp or laser" (cf. column 14, lines 52-54). These types of light sources are rather bulky, which makes it unlikely that the term excitation optics used in connection with the disclosure of a movable platform (column 16, line 9) has to be understood as including an excitation source. As to figures 1 and 2 of document D1, the configurations shown leave the position of the excitation source completely open or undefined.

- 11 - T 2056/12

Thus, even if the movable platform were regarded as a detection module according to feature 1.3 it lacked the excitation light generator disposed within the detection module (feature 1.3.1).

- 13. Furthermore, document D1 does not disclose a movable platform attached or attachable to a thermal cycler. Even though the movable platform has to be supported and attached somewhere, it needs not necessarily be attached or attachable to the thermal cycler itself. The mere probability of it being attachable to the thermal cycler is not sufficient to anticipate this feature since a decision on novelty, after due consideration of all available facts and arguments, can only be based on certainty but not on probabilities (cf. point 16 of decision T 646/94 of 21 Mai 1997.
- 14. For these reasons, the fluorescence detection apparatus of claim 1 is novel over the apparatus disclosed in document D1.
- 15. At the oral proceedings, the appellant requested that a new novelty objection based on document D2 be admitted. It argued that the subject matter of claim 1 was a fluorescence detection apparatus attachable to but not necessarily attached to a thermal cycler. The fluorescence detection apparatus of document D2 was also attachable and therefore had all the features of claim 1.
- 16. During the entire opposition procedure and in the written appeal procedure, document D2 has only been cited with regard to inventive step in combination with document D1.

- 12 - T 2056/12

- 17. This novelty objection therefore represents a fresh case which the board, exercising the discretion given to it by Article 114(2) EPC in conjunction with Articles 13(1) and 13(3) RPBA, in view of the advanced state and its effect on procedural economy, does not admit.
- 18. The main request meets the requirements of Article 54 EPC.

Article 56 EPC

- 19. Document D1 represents the closest state of the art. As mentioned in point 10, above, it discloses a set up for monitoring PCR reactions using a total internal reflection element and a fluorescence detection system. In a first embodiment, the excitation source and optics are mounted in stationary position and the reaction vessels are brought (moved) into alignment with the excitation and detection optics. Alternatively, it is proposed to locate the excitation and detection optics on a moving platform while the reaction vessel(s) are kept in stationary position(s) (column 16, lines 9 to 12).
- 20. Based on document D1, the technical problem to be solved is the provision of a more versatile fluorescence detection apparatus for the detection of a target molecule in solution.
- 21. The patent proposes the fluorescence detection apparatus of claim 1 to solve this problem. The apparatus differs from the apparatus suggested in document D1 in that not only the excitation and detection optics are mounted on a movable scan head but

- 13 - T 2056/12

also the excitation light source. Furthermore, said scan head is attachable to the thermal cycler.

- 22. The board is therefore satisfied that the technical problem is solved by the subject-matter of claim 1.
- 23. It remains to be established whether this solution involves an inventive step.
- 24. The appellant argued that the claimed solution was obvious in view of the teaching of document D1 in combination with the teaching of document D2.
- 25. The respondent argued that the skilled person starting from document D1 as the closest prior art would not have turned to document D2 because it related to a different technical field and the optical system described in document D2 would not be useful for the set up disclosed in document D1, unless further modified.
- 26. Document D2 relates to moving head optical scanners for stimulating a target and for reading the fluorescent and reflective signal radiation that is returned from the target (column 1, lines 4 to 7). As stated in column 1, lines 40 to 45, it was an object to provide a versatile optical scanner of simple, lightweight and low-cost design for rapid scanning of a sample using a moving scan head design.
- 27. Document D2 discloses the use of a light emitting diode (LED) as the light source for point imaging of target samples which in one embodiment can be housed "directly within a movable scan head" (column 1, line 53).

 Alternatively, "where there is an optical fiber in the illumination beam path as in Fig. 6, the LED 12 and

T 2056/12

- 14 -

lens 14 need not be mounted on the scan head".

Regarding the position of the detector, document D2

proposes to either place it directly on the scan head

(column 1, line 67), or to transmit reflected light via
an optical fiber to a detector which is positioned off
the scan head (column 3, lines 440-48; Figure 1).

- Document D1 provides a motivation to use a moving 28. platform or a moving scan head comprising the excitation and detection optics. As explained in point 12, above, the term excitation optics as used in document D1 does not include the excitation light source. Thus, while document D1 suggested to adapt a movable scan head system such that it becomes suitable for use with a thermal cycler, it did not provide a motivation to turn to a disclosure describing the use of a movable scan head comprising an LED to probe fluorescent spots on a surface and which also refers, among others, to an arrangement wherein both, light source and detector can be located on or within the movable scan head. Moreover, neither document D1 nor document D2 propose a moving scan head system directly attachable to a thermal cycler. The skilled person, trying to solve the technical problem underlying the invention, had many options to put the proposed movable scan head system into practice, but only with hindsight and in knowledge of the claimed subject-matter it can be argued that the skilled person, on the basis of documents D1 and D2, would have arrived at the specific combination of features defining the fluorescence detection apparatus of claim 1 in an obvious way.
- 29. The apparatus of claim 1 and its use in the method of claim 13 are therefore based on an inventive concept and meet the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



I. Aperribay

M. Wieser

Decision electronically authenticated