BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Publication in the Official Journal Yes / No

File Number: T 90/91 - 3.4.2

Application No.: 85 301 844.8

Publication No.: 0 164 180

Title of invention: Devices for carrying out chemical and clinical tests, and their use

Classification: G01N 33/543, G01N 33/76, B01L 3/00

D E C I S I O N
of 27 November 1991

Proprietor of the patent: UNILEVER PLC, et al

Opponent: (01) Human Gesellschaft für Biochemica und Diagnostica mbH
(02) SANOFI

Headword:

EPC Article 54, 56

Keyword: novelty, inventive step: yes, after amendment

Headnote

Case Number : T 90/91 - 3.4.2

D E C I S I O N
of the Technical Board of Appeal 3.4.2
of 27 November 1991

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Decision under appeal :	**Interlocutory decision of the Opposition Division of the European Patent Office dated 29 November 1990 concerning maintenance of European patent No. 0 164 180 in amended form.**

Composition of the Board :

Chairman : E. Turrini
Members : M. Chomentowski
C. Payraudeau

Summary of Facts and Submissions

I. Appellant 01 is proprietor of European patent No. 0 164 180, which was granted on the basis of European patent application No. 85 301 844.8.

II. Appellants 02 and 03 (Opponents) filed oppositions to the grant of the European patent, based in particular on the grounds that the subject-matter of the claims of the patent in suit lacked novelty and an inventive step having regard inter alia to the disclosure in EP-A-0 031 993 and DE-A-3 215 647.

III. The Opposition Division decided to maintain the patent in amended form according to the second auxiliary request of Appellant 01.

IV. The Appellants (Opponents and Proprietor) appealed against this decision. Appellant 01 requested that the oppositions be rejected and the patent maintained in the form as granted as a main request or that the patent be maintained in amended form according to various auxiliary requests. Moreover, Appellant 01 requested oral proceedings in case the Board of Appeal would consider the main request as not allowable. Appellants 02 and 03 cited additionally inter alia FR-A-2 483 213 and requested that the decision under appeal be set aside and that the patent be revoked.

Auxiliarily, Appellants 02 and 03 requested oral proceedings.

V. In a communication accompanying the invitation to oral proceedings, the Board informed the parties that it was of the provisional opinion that the main request and the

original auxiliary requests of Appellant 01 were not allowable, that new requests of Appellant 01 based on combinations of Claim 1 and dependent Claims 2 and 3 of the last auxiliary request would appear not to be allowable, but that a new request based on a main claim consisting of a combination of Claim 1 and dependent Claims 2 to 4 of said last auxiliary request could be allowable.

VI. In answer to this communication, the Appellant 01 filed further supplementary auxiliary requests.

VII. The Appellants 02 and 03 declared that they would not take part to the oral proceedings.

VIII. During the oral proceedings, the Appellant 01 filed three amended sets of claims and requested that the decision under appeal be set aside and that the patent be maintained on the basis of:

the first set of claims filed at the oral proceedings together with a correspondingly amended description and the drawings of the granted patent (main request);

the second set of claims filed at the oral proceedings together with a correspondingly amended description and the drawings of the granted patent (first auxiliary request);

the third set of claims filed at the oral proceedings together with a correspondingly amended description and the drawings of the granted patent (second auxiliary request).

IX. Main request

Claim 1 reads as follows:

"1. A test kit for carrying out chemical or clinical testing of a liquid sample, for example a urine sample, by a specific binding assay, comprising:

(a) a liquid sample collection device comprising a test component (2) which has a sensitised solid surface (2a) carrying an immobilised component of a specific binding pair relevant to the assay, and a handling piece (1), wherein the test component (2) bearing the sensitised surface (2a) is removably mounted in spaced relationship with a removably mounted accessory component (4) carrying an accessory solid surface (5), the removable accessory component (4) being removably fitted to the test component (2) or to its handling piece (1), and there is a space (4a) between the sensitised surface (2a) and the removable accessory component (4) to act as a container for sample liquid, and passage is left so that, when the device is contacted with a sample liquid source or immersed in liquid which is to provide the test sample, liquid of the sample can enter the space (4a) to contact the sensitised surface (2a), and the accessory surface (5) acts to retain and contain sample liquid in contact with the sensitised surface (2a) even after removal of the device from further contact with or immersion in the source of sample liquid, and the test component (2) is so formed that after removal of the removable accessory component (4) the sensitised surface (2a) is left exposed and accessible to further treatment liquid such as washing liquid and/or reagents; and

(b) a support component (8) such as a base unit which comprises one or more liquid reaction wells (10, 11) for containing reagents for the assay; and wherein:

(c) the removable accessory component (4) which is removably mounted to the test component (2), and the support component (8), are so formed with interlocking means (6, 9) such as flange and groove that they can be interlocked;

said interlocking means enabling a user of the test kit to remove the accessory component (4) from the test component (2) without handling either the test component (2) or the accessory component (4) directly."

Claim 10 reads as follows:

"10. Use of a test kit according to any one of Claims 1 to 9 for immunoassay of urinary components."

Claims 2 to 9 are dependent claims.

X. The Appellant 01 submitted the following arguments in support of his main request. The test device of EP-A-0 031 993 comprises a test component (14) and a tube (20) as an accessory component which indeed fit together but which are not intended for being separated. In particular, the handling piece (12) of the test component (14) is intended only for pushing the test component (14) into the tube (20) but remains then out of reach. No specific features for separating these parts are mentioned in EP-A-0 031 993. Thus, starting from the device of EP-A-0 031 993, there is no suggestion in the art for the skilled person that the parts of the device can be separated without handling either the test component or the accessory component, as required by Claim 1 in suit.

Moreover, the interlocking means known from the further available prior art relate to specific arrangements for dislodging parts of sampling devices in different technical fields and cannot be combined in an obvious way with the device of EP-A-0 031 993. Therefore, the subject-matter of Claim 1 implies an inventive step.

XI. Appellants 02 and 03 had previously submitted in writing essentially the following arguments in support of their requests. Starting from the arrangement of EP-A-0 031 993, which comprises a test component (14) mounted on a handling piece (12) and fitted in a tube (20), and taking into account that the means for dislodging parts of test device by the use of interlocking means are generally known in the art of chemical or clinical testing, for instance from FR-A-2 483 213 or DE-A-3 215 647, the skilled person would arrive at the test kit of Claim 1 in suit in an obvious way. Therefore, Claim 1 lacks an inventive step.

Reasons for the Decision

1. The appeals are admissible.

2. Allowability of the amendments

2.1 Claim 1 results from the combination of the essential features of Claim 1, Claim 2 (for the base unit and the interlocking means), of Claim 3 (which defines the base unit as comprising one or more reaction wells for containing reagents for the assay), and Claim 4 (which specifies that the accessory surface of the removably accessory component is removably fitted to the test component or to its handle), all as granted. It is to be noted that the expression "test kit", which is mentioned

on column 5, lines 3 to 11 as granted, only specifies that the test device of Claim 1 comprises a plurality of test components. Since these features of dependent Claims 2 to 4 as granted are restricting features, the Board is satisfied that Claim 1 meets the requirement of Article 123(3) EPC, that the claims of the European patent may not be amended during opposition proceedings in such a way as to extend the protection conferred.

2.2 Moreover, since the Claims 1 to 4 of the granted patent substantially correspond to the claims of the application as filed, the Board is satisfied that Claim 1 meets the requirement of Article 123(2) EPC, that a European patent may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed.

3. Clarity

3.1 Claim 1 specifies that the removable accessory component (4) is removably fitted to the test component (2) or to its handling piece (1). The Board is satisfied that, since it is derivable from Claim 1, in accordance with the description and the drawings, that the handling piece (1) is the handling piece of the test component (2), and since all the features of the test kit essential to the performance of the invention are included in Claim 1, the claim is clear in the sense of Article 84 EPC.

4. Novelty

4.1 A test device for carrying out chemical or clinical testing of a liquid sample, for example a urine sample, by a specific binding assay is known from EP-A-0 031 993 (see page 13, line 22 to page 22, line 11; Figures 1 to 4);

said test device comprises:

(a) a liquid sample collection device comprising a test component (14) which has a sensitised solid surface carrying an immobilised component of a specific binding pair relevant to the assay, and a handling piece (12), wherein the test component (14) bearing the sensitised surface is removably mounted in spaced relationship with a removably mounted accessory component (20) carrying an accessory solid surface, the removable accessory component (20) being removably fitted to the test component (14), and there is a space between the sensitised surface and the removable accessory component (20) to act as a container for sample liquid, and passage is left so that, when the device is contacted with a sample liquid source or immersed in liquid which is to provide the test sample, liquid of the sample can enter the space to contact the sensitised surface, and the accessory surface acts to retain and contain sample liquid in contact with the sensitised surface even after removal of the device from further contact with or immersion in the source of sample liquid, and the test component (14) is so formed that after removal of the removable accessory component (20) the sensitised surface is left exposed and accessible to further treatment liquid such as washing liquid and/or reagents.

4.1.1 However, the test kit known from EP-A-0 031 993 does not comprise a support component and, moreover, the removable accessory component (20) which is removably mounted to the test component (14), is not formed with interlocking means that can be interlocked with corresponding interlocking means on the support component in such a way that said

interlocking means enable a user of the test kit to remove the accessory component (20) from the test component (14) without handling either the test component (14) or the accessory component (20) directly.

4.2 Neither FR-A-2 483 213 nor DE-A-3 215 647 discloses a test kit comprising a test component which has a sensitised solid surface carrying an immobilised component of a specific binding pair relevant to an assay.

4.3 The other documents of the prior art are less relevant.

4.4 Therefore, the Board is of the opinion that the subject-matter of Claim 1 is novel in the sense of Article 54 EPC.

5. Inventive step

5.1 The device of EP-A-0 031 993 comprises a test component designed as an insert matrix (10) which is not easily separable from the removable accessory component or test tube (20) containing the sample liquid. Thus, the arguments of Appellant 01, that this device does not allow either a reliable contacting of the test component with external reagents in wells of a further kit part or an easy washing of the test component after use, in particular by an unskilled person at home, can be accepted.

5.2 The object of the patent in suit should consist in facilitating such operations. This object "per se" is not considered as contributing to an inventive step because it is generally known in the field of clinical analysis.

5.3 In the device disclosed in EP-A-0 031 993 the insert matrix (10) comprises a handle portion (12) which does not

protrude outside of the test tube (20) when in place; this is in order to avoid splashing (see page 18, lines 26 to 37). Moreover, the separation of the two elements is not generally necessary nor wanted (see page 25, lines 17 to 23). Therefore, the person skilled in the art would have no incentive to look in the state of the art for means for separating the test tube from the insert matrix of this device even if he would have considered preferable to handle the test tube containing the insert matrix mechanically rather than manually as indicated on page 19, lines 34 to 37, that is to retain it in a support by any given means.

5.4 Even if the person skilled in the art would have been aware of documents FR-A-2 483 213 and DE-A-3 215 647, he would not have been led to apply their teachings to the device of EP-A-0 031 993 to solve the mentioned problem since they concern very different technical fields and since the components which are separated according to these documents are a syringe and a test component in FR-A-2 483 213 (see Figure 15(d)) and a screw cap (14) and a test tube (11) in DE-A-3 215 647 (see Figure 4), and not a test component and an accessory component as in EP-A-0 031 993.

5.5 Moreover, the means used for retaining one of the components are friction means (105) in FR-A-2 483 213 (see page 17, line 9 to page 18, line 21; Figures 14 and 15) and a bar (27) activated by pressure cylinders (37) in DE-A-3 215 647 (see page 11, first paragraph; page 13, last paragraph - page 14, first paragraph; Figure 1). These documents do not disclose nor suggest the provisions of interlocking means respectively on one of the components and a separate support means to retain this component in order to allow its easy separation from the other component.

5.6 Therefore, a combination of EP-A-0 031 993 with either FR-A-2 483 213 or DE-A-3 215 647, even if possible, would not result in the object of Claim 1 of the patent in suit.

5.7 Therefore, in the opinion of the Board, the subject-matter of Claim 1 implies an inventive step in the sense of Article 56 EPC.

6. Claim 10

6.1 Claim 10 is a dependent claim for the use of the test kit of any of the test kit Claims 1 to 9. Since the subject-matter of Claim 10 thus includes a combination of use features directly related to the combination of test kit features of the subject-matter of Claim 1, which is considered as non obvious, it is also novel and implies an inventive step.

7. Thus, taking into consideration the amendments made by the proprietor (Appellant 01) of the patent in his main request, the patent and the invention to which it relates meet the requirements of the Convention and the patent as amended may be maintained (Article 102(3) EPC). There is consequently no need to examine the auxiliary requests of Appellant 01.

Order

For these reasons, it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to maintain the patent on the basis of the set of claims

of the main request filed at the oral proceedings by Appellant 01 and of the amended description filed at the oral proceedings by the Appellant 01 together with the drawings of the granted patent.

The Registrar: The Chairman:

P. Martorana E. Turrini