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**Datasheet for the decision
of 14 September 2011**

Case Number: T 2270/08 - 3.2.02

Application Number: 03253439.8

Publication Number: 1369083

IPC: A61B 5/15

Language of the proceedings: EN

Title of invention:
Test strip container system

Patentee:
LifeScan, Inc.

Opponent:
Roche Diagnostics GmbH

Headword:

-

Relevant legal provisions:
EPC Art. 84, 123(2),(3), 54, 56

Relevant legal provisions (EPC 1973):

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Keyword:
"Clarity (yes, after amendments)"
"Added subject-matter (no, after amendments)"
"Extension of the protection (no, after amendments)"
"Novelty and inventive step (yes, after amendments)"

Decisions cited:

-

Catchword:

-



Case Number: T 2270/08 - 3.2.02

DECISION
of the Technical Board of Appeal 3.2.02
of 14 September 2011

Appellant I: Roche Diagnostics GmbH
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Appellant II: LifeScan, Inc.
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted
24 November 2008 concerning maintenance of
European patent No. 1369083 in amended form.

Composition of the Board:

Chairman: D. Valle
Members: C. Körber
A. Pignatelli

Summary of Facts and Submissions

I. Appellant I (opponent) lodged an appeal on 10 December 2008 against the decision of the Opposition Division, posted on 24 November 2008, to maintain the patent in amended form. The fee for the appeal was paid on the same day and the statement setting out the grounds of appeal was received on 12 March 2009.

II. On 29 January 2009 the proprietor (appellant II) also lodged an appeal against the above decision and paid the fee for appeal on the same day. The statement setting out the grounds of appeal was received on 16 March 2009.

III. The following documents are relevant for the decision:

A1 = EP - A1 - 1285629

A2 = EP - A2 - 951939

A3 = US - A - 5591139

A5 = EP - A2 - 1174083

A6 = EP - B1 - 901634.

IV. Oral proceedings took place on 14 September 2011.

At the end of the oral proceedings appellant I (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

Appellant II (proprietor) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the following documents:

a) For the Contracting States GB, FR, DE, IT:

- claims 1-10 as filed for these Contracting States during the oral proceedings before the Board on 14 September 2011

- description:

pages 2, 4-8, 10, 11 as in the patent specification

page 9 filed during the oral proceedings before the Opposition Division on 13 October 2008, pages 3, 3a as filed during oral proceedings before the Board on 14 September 2011

- drawings as in the patent specification

b) For the remaining Contracting States:

- claims 1-10 as filed for these Contracting States during the oral proceedings before the Board on 14 September 2011

- description:

pages 2, 4-8, 10, 11 as in the patent specification

page 9 filed during the oral proceedings before the Opposition Division on 13 October 2008 pages 3, 3a as filed during oral proceedings before the Board on 14 September 2011

- drawings as in the patent specification.

V. Claim 1 for all the states except GB, FR, DE and IT reads as follows:

"A test strip container system comprising:

a plurality of test strips, each including at least one forward facing lancet and face or shoulder portions (54);

a container body (74) defining a plurality of test strip receptacles (46), each receptacle having an access aperture at one end and at least one ledge (52)

for supporting a test strip at its face or shoulder portions (54);
a barrier portion (76) for closing off at least some of said access apertures (64) at said one end; wherein each receptacle is configured to receive and protect a lancet (40), each receptacle having:
an inset portion extending from said at least one ledge (52) to form a sheath portion at another end to house and provide clearance for the lancet, and
an access path to the test strip from its rear via said access aperture (64)."

Claim 1 for GB, FR, DE and IT reads as follows:

"A test strip container system comprising:
a plurality of test strips, each including at least one forward facing lancet and face or shoulder portions (54);
a container body (74) defining a plurality of test strip receptacles (46), each receptacle having an access aperture at one end and at least one ledge (52) for supporting a test strip at its face or shoulder portions (54);
a barrier portion (76) for closing off at least some of said access apertures (64) at said one end such that said test strips can be exposed for use one at a time; wherein
each receptacle is configured to receive and protect a lancet (40), each receptacle having:
an inset portion extending from said at least one ledge (52) to form a sheath portion at another end to house and provide clearance for the lancet, and
an access path to the test strip from its rear via said access aperture (64)."

Independent claim 2 reads as follows:

"A test strip container system comprising:
a container body (74), said container body defining a plurality of test strip receptacles (46) at one end and a waste receptacle at another end;
a waste receptacle cap, and
a barrier portion (76) for closing off at least some of said test strip receptacles (46)."

VI. Appellant I argued essentially as follows:

Claim 1 was not clear because of the introduction of the two terms "inset" and "sheath". If the terms had the same meaning, the claim would be unclear because a term would be superfluous. If the meaning was different, the patent specification could not support any precise distinguishing meaning for the two terms.

Claim 1 did not comply with Article 123(3) EPC since the feature: "an inset portion extending from said at least one ledge (52) to form a sheath portion at another end" was broader than the feature: "at least one sheath portion at another end extending from at least one ledge" since it also comprised the case in which the sheath portion did not extend from the ledge.

Claim 1 contained subject-matter beyond the original disclosure in the wording "an inset portion extending from said at least one ledge (52) to form a sheath portion at another end". The "inset" disclosed in § 14 of the original disclosure was designed to house the needle but there was no mention that it extended from a

ledge. The "sheath portion" (see § 75) was designed merely for accepting and protecting the needle.

Claim 1 in the version for GB, FR, DE and IT was not clear because the feature that the test strips can be exposed for use one at a time was of undetermined scope. Furthermore the feature that "a barrier portion (76) for closing off at least some of said access apertures (64) at said one end such that said test strips can be exposed for use one at a time" was not originally disclosed. The original disclosure contained only the teaching that a seal - not a barrier - afforded the ability to expose the test strips one at a time. The term "barrier" was broader than the term "seal" since it also included the embodiments in which the element was permeable.

The subject-matter of claim 1 in the version for all states except GB, FR, DE and IT was not novel in consideration of the teaching of A2. Paragraph 13 of A2 showed that the strips could be provided with a lancet. Figure 7 showed an inset provided with two ledges one on each side. Furthermore, paragraph 20 contained the general teaching of using ledges ("stufensweise ausgestaltet") in order to fix the strips from several sides. In any case the subject-matter of claim 1 did not involve an inventive step having regard to a combination of the teaching of A2 with A5 or with A3, which, however, was less relevant than A5. A5 showed in particular in Figure 4 a test strip with integrated lancet having shoulders 236 and 238. The skilled person in the field would modify the container of A2 having taken advantage of the hint contained in it of forming supports "stufensweise ausgestaltet" in order to lodge

the integrated test strip disclosed in A5, fixing it by means of its shoulders. Also starting from the test strip with integrated lancet of A5, the skilled person in the field would consider the container of A2 and modify it in order to lodge the known strip in an obvious way.

The subject-matter of claim 1 for GB, FR, DE and IT was not novel having regard to A1. It was clear that the test strips were used one at a time.

The subject-matter of claim 2 was not inventive having regard to the teaching of A6 since providing test strip receptacles at one end and waste receptacles at the other end was a banal measure.

VII. Appellant II contested the arguments of appellant I and argued essentially as follows:

The claims were clear. The terms "inset" and "sheath" referred to the same physical entity. The claims did not confer a protection going beyond that conferred by the claims of the granted version and were supported by the original disclosure. The subject-matter of all the claims was new and inventive having regard to the opposed state of the art.

Reasons for the Decision

1. The appeals are admissible.

2. Clarity

2.1 Claim 1 of both versions

The feature contained in claim 1 for all the Contracting States:

"an inset portion extending from said at least one ledge (52) to form a sheath portion at another end to house and provide clearance for the lancet"

is clear.

The Board interprets the word "inset" and "sheath" as referring to the same physical entity, that is the receptacle to lodge the lancet. The two terms differ merely in that the term sheath stresses the particular function of the inset element as a case for the lancet. This interpretation is supported by the description of the patent in suit, column 3, lines 29-31, where it is said that the inset portion houses the needle, and by the passage at column 16, lines 24, 25 where it is said that the sheath portion accepts and protects the microneedle. In the language of the patent the terms needle, microneedle and lancet are equivalent. On the basis of this interpretation, the two terms "inset" and "sheath" are clear and their introduction into the claims does not cause any ambiguity (Article 84 EPC).

2.2 Claim 1 for GB, FR, DE and IT

The feature "for use one at a time" is clear (Article 84 EPC) and means that the test strips can be taken out of the container one at a time.

3. Article 123(3) EPC

Claim 1 of the main request of both versions does not confer a protection beyond that conferred by the granted claim as far as the feature "an inset portion extending from said at least one ledge (52) to form a sheath portion at another end" is concerned since the two terms "inset" and "sheath" refer in the interpretation of the Board to the same physical entity. Therefore the objection of appellant I that the claims of main request encompasses embodiments in which the sheath does not start from the ledge has no basis any more.

4. Article 123(2) EPC

4.1 Claim 1 for all versions

The feature "an inset portion extending from said at least one ledge (52) to form a sheath portion at another end" is supported by the original description, § 14 and 75 and Figure 3, with the sheath portion and the inset portion referring to the same physical entity.

4.2 Claim 1 for GB, FR, DE and IT

The feature: "a barrier portion (76) for closing off at least some of said access apertures (64) at said one end such that said test strips can be exposed for use one at a time" is disclosed in the original version of the application, § 13 and in claim 1. At § 13 of the application as originally filed it is stated that the seal can be a foil or a rotatable lid or cap in order to be able to expose the test strips one at a time. In the view of the Board this means that this seal corresponds to the barrier for closing off at least some of said receptacles at said access apertures as claimed in the original claim 1. This is evident in the case of a rotatable lid or cap, as illustrated in Figure 2a.

5. Novelty and inventive step of claim 1 for all states except GB, FR, DE and IT

5.1 Novelty

A2 discloses a test strip container system comprising a plurality of test strips, each including face or shoulder portions, a container body (1) defining a plurality of test strip receptacles (3), each receptacle having an access aperture at one end and at least one ledge for supporting a test strip at its face or shoulder portion; a barrier portion for closing off at least some of said access apertures at said one end, an access path to the test strip being provided from its rear via said access aperture.

However, A2 does not disclose a container for test strips each including at least one forward facing lancet, each receptacle of the container being configured to receive and protect a lancet, each receptacle having an inset portion extending from said at least one ledge to form a sheath portion at another end to house and provide clearance for the lancet. By contrast, the embodiments of Figures 4 and 6 show a receptacle for a "Testelement" 2, which is a strip or similar, see paragraph 13 of A2, whereas Figures 7 and 8 show an alternative container with a receptacle (3) for strips and a separate receptacle (20) for lancets (19).

Appellant I argued that paragraph 13 of A2 contained the disclosure that the strips could be provided with lancets. That cannot be accepted by the Board: paragraph 13 contains a list of possible items to be accommodated in the receptacles, among others: strips (Testelemente) and lancets, but it does not disclose that the strips include a lancet.

Appellant I argued further that A2 disclosed in paragraph 20 ledges in the sense of the invention and that these ledges were shown by way of example in Figure 7. However, paragraph 20 refers exclusively to the means of laterally fixing the test strips in the inset and not to ledges to form a sheath portion for housing the lancet. Figure 7, on the other hand, shows merely a separate inset for the lancet, and the ledges do not form a sheath to house the lancet integrally stored with the strip as in the claimed invention.

Accordingly, the subject-matter of claim 1 for all states except GB, FR, DE and IT is novel (Article 54 EPC).

5.2 Inventive step

The skilled person in the field would not combine the teaching of A2 with that of A5. A2 discloses a container presenting separate lodgings for the strip and the lancet, see in particular Figure 8. A2 does not contain any hint to provide strips with integral lancets. On the contrary, in paragraph 13, A2 clearly keeps separate the "Testelemente" on one side and the lancet on the other side of the container, the "Testelemente" being "visuell oder apparativ-optisch auswertbare Teststreifen, elektrochemische Sensoren und dergleichen", that is elements which provide the result of the test. A lancet does not fall among them, since a lancet provides merely a cut on the tissue to be tested. Furthermore, A2, paragraph 43 discloses that the test strip of A2 is taken out from its receptacle by being pushed with a pestle (Stößel) from below through the sealing foil. This would be not suitable for the test strip according to A5 since the pestle would push on it directly and possibly damage the lancet. Therefore it goes against the teaching of A2 to use a strip with an integrated lancet as disclosed by A5. The same applies to a combination of A2 with A3, which, as appellant I conceded, is less relevant than A5.

The same considerations apply to the reverse combination of the teaching of A5 with the teaching of A2.

5.3 The objective technical problem solved by the subject-matter of claim 1 can be formulated as how to modify the container system of A2 to provide protection for a delicate lancet portion of a test strip housed in the test element chamber. The opposed state of the art does not give any hint of the solution provided by the invention as specified by the distinguishing features of the claim (see point 5.1).

Accordingly the subject-matter of claim 1 for all states except GB, FR, DE and IT involves an inventive step (Article 56 EPC).

6. Novelty of claim 1 for GB, FR, DE and IT

Document A1 is state of the art under Article 54(3) EPC 1973 for GB, FR, DE and IT.

A1, Figure 19, paragraphs 255 to 257, discloses a test strip container system comprising a plurality of test strips, each including at least one forward facing lancet and face or shoulder portions; a container body defining a plurality of test strip receptacles, each receptacle having an access aperture at one end and at least one ledge for supporting a test strip at its face or shoulder portion; a barrier portion (63a) for closing off at least some of said access apertures at said one end; wherein each receptacle is configured to receive and protect a lancet, each receptacle having: an inset portion extending from said at least one ledge to form a sheath portion at another end to house and provide clearance for the lancet, and an access path to the test strip from its rear via said access aperture.

However, A1 does not disclose that the closing off happens in such a way that said test strips can be exposed for use one at a time. Contrary to the position taken in the decision under appeal and by the appellant I, it makes no sense to construe the distinguishing feature in the sense that the exposition can be simultaneous and that only the use is of one at a time. The specification in the claim "one at a time" refers to the exposition and not to the use. See also the description of the patent in suit, point 0013 and Figure 21.

7. Inventive step of claim 2

A6, paragraphs 51 and 52 and Figure 1, discloses a cuvette container system comprising a container body, said container body defining a plurality of receptacles (12) for holding used or unused cuvettes (14), and a barrier portion for closing off at least some of said test strip receptacles.

However, A6 does not disclose a test strip container system comprising a container body defining a plurality of test strip receptacles at one end and a waste receptacle at another end nor a waste receptacle cap. A6 concerns a measuring apparatus adapted to accommodate a cassette comprising a plurality of cuvettes and not test strips as in the case of the invention. Cuvettes are small tubes of circular or square cross section, sealed at one end, made of plastic, glass, or fused quartz (for UV light) and designed to hold biological samples.

The objective technical problem solved by the subject-matter of claim 2 has to be seen as how to provide an alternative system for storing used and unused test strips to that disclosed in A6.

A6 specifically relates to a measuring apparatus adapted to accommodate a cassette comprising a plurality of cuvettes. The cassette is a consumable component of the measuring apparatus which is introduced into a bay or recess 3 of the apparatus (see figures 2A and 2B of A6). Once the cassette has been connected to the measuring apparatus, an unused cuvette is moved from its receptacle 12, out of a first end of the cassette and to an operational position, using conveyor means 16 (see figure 2E). After having performed the measurement and used the cuvette, the used cuvette is returned to a receptacle in the cassette, using conveyor means 16 working in the opposite direction 9 (see figures 2F and 2G). The receptacle to which the used cuvette is moved may be the same receptacle from which it was initially removed, or a different receptacle. In either case, due to the arrangement of the conveyor means 16 and the cassette in the measuring apparatus, the used cuvette is always moved into a waste receptacle which is positioned at the same end of the cassette as the receptacles in which the unused cuvettes are stored.

In view of the functionality of the cassette in the measuring apparatus, there is no reason why the skilled person would have considered positioning the waste receptacle at the other end of the cassette away from the receptacles for the unused cuvettes. If the waste receptacle had been positioned at the opposite end of

the cassette to the receptacles 12, 12', it would not have been possible to use the measuring apparatus and the conveyor 16 to move the used cuvettes into the waste receptacle.

Consequently, the skilled person would never have considered positioning the waste receptacles of A6 at the opposite end of the cassette to the receptacles for the unused test strips since, by doing so, he would have destroyed the functionality of the design of A6. Therefore, A6 clearly teaches away from providing a container body having a plurality of test strip receptacles at one end and a waste receptacle at another end.

Accordingly, the subject-matter of claim 2 involves an inventive step (Article 56 EPC).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance with the order to maintain the patent in the following version:
 - a) For the Contracting States GB, FR, DE, IT:
 - claims 1-10 as filed for these Contracting States during the oral proceedings before the Board on 14 September 2011

- Description:
 - pages 2, 4-8, 10, 11 as in the patent specification
 - page 9 filed during the oral proceedings before the Opposition Division on 13 October 2008
 - pages 3, 3a as filed during oral proceedings before the Board on 14 September 2011
- drawings as in the patent specification
- b) for the remaining Contracting States:
 - claims 1-10 as filed for these Contracting States during the oral proceedings before the Board on 14 September 2011
 - description:
 - pages 2, 4-8, 10, 11 as in the patent specification
 - page 9 filed during the oral proceedings before the Opposition Division on 13 October 2008
 - pages 3, 3a as filed during oral proceedings before the Board on 14 September 2011
 - drawings as in the patent specification.

The Registrar:

The Chairman:

D. Hampe

D. Valle