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Datasheet for the decision of 15 April 2015

Case Number: T 0042/11 - 3.2.02

Application Number: 03252883.8

Publication Number: 1360934

IPC: A61B5/15

Language of the proceedings: EN

Title of invention:
Devices and methods for accessing and analyzing physiological fluid

Patent Proprietor:
LifeScan, Inc.

Opponent:
Roche Diagnostics GmbH

Headword:

Relevant legal provisions:
EPC Art. 123(2)
RPBA Art. 13(1)

Keyword:
Amendments - added subject-matter (yes)
Late-filed auxiliary request - admitted (no)

Decisions cited:

Catchword:

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Office européen des brevets

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Case Number: T 0042/11 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 15 April 2015

Appellant: (Patent Proprietor)	LifeScan, Inc. 1000 Gibraltar Drive Milpitas, CA 95035-6312 (US)
Representative:	Brunner, John Michael Owen Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Respondent: (Opponent)	Roche Diagnostics GmbH Sandhoferstr. 116 68305 Mannheim (DE)
Representative:	Dey, Michael Weickmann & Weickmann Patentanwälte Richard-Strauss-Straße 80 DE-81679 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 29 October 2010 concerning maintenance of the European Patent No. 1360934 in amended form.**

Composition of the Board:

Chairman E. Dufrasne
Members: C. Körber
D. Ceccarelli

Summary of Facts and Submissions

I. On 29 October 2010 the Opposition Division posted its interlocutory decision concerning maintenance of European patent No. 1360934 in amended form.

II. An appeal was lodged against this decision by the patent proprietor by notice received on 10 January 2011, with the appeal fee being paid on the same day. The statement setting out the grounds of appeal was received on 8 March 2011.

III. By letter dated 8 September 2011 the respondent (opponent) filed its counter-statement.

IV. By communication of 20 January 2015, the Board forwarded its provisional opinion to the parties and summoned them to oral proceedings.

V. By letter dated 16 March 2015 the appellant (patent proprietor) presented further observations and filed an auxiliary request 1.

VI. Oral proceedings were held on 15 April 2015.

The final requests of the parties were as follows:

The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request, filed with letter dated 8 March 2011 or, in the alternative, of the auxiliary request 1, filed with letter dated 16 March 2015.

The respondent requested that the appeal be dismissed.

VII. The following document is of importance for the present decision:

RD1: WO-A-03/066128.

VIII. Claim 1 of the main request reads:

"A system comprising:
a plurality of devices wherein each said device comprises:
(i) at least one skin-piercing member configured to access physiological fluid beneath the skin surface;
(ii) a biosensor for measuring a characteristic of the accessed physiological fluid wherein said skin-piercing member is integrated with said biosensor; and
(iii) a physiological fluid transfer pathway extending from said at least one skin-piercing member to said biosensor; and
a means for moving each of said plurality of devices in a manner that provides for penetration of the skin surface by said at least one skin-piercing member followed by removal of said at least one skin-piercing member from the skin surface,
characterised in that the means for moving provides for penetration at an oblique angle relative to the skin surface."

Claims 2 to 11 are dependent claims.

Claim 1 of auxiliary request 1 reads:

"A system comprising:
a housing structure having a skin-facing portion configured to be flush against a selected area of a user's skin, the housing structure having an aperture within said skin-facing portion;

a cartridge receivable within said housing structure such that it is planar with the skin facing surface, the cartridge comprising a plurality of devices, wherein each said device comprises:
(i) at least one skin-piercing member configured to access physiological fluid beneath the skin surface;
(ii) a biosensor for measuring a characteristic of the accessed physiological fluid wherein said skin-piercing member is integrated with said biosensor; and
(iii) a physiological fluid transfer pathway extending from said at least one skin-piercing member to said biosensor;
a means for moving each of said plurality of devices in a manner that provides for penetration of the skin surface by said at least one skin-piercing member followed by removal of said at least one skin-piercing member from the skin surface,
wherein the means for moving each of said plurality of devices comprises a means for moving said cartridge within said housing structure so as to operatively position each of said plurality of devices relative to said aperture;
wherein each of said plurality of devices is operatively attached to the cartridge so as to be moveable relative to the cartridge, by deflecting or rotating about an axis which extends radially or perpendicularly to a path through which the devices are caused to travel upon translation of the cartridge;
wherein the means for moving further comprises components fixed within the housing structure relative to the cartridge for advancing or deflecting each device through the housing aperture,
wherein, upon translation of the cartridge, at least one device is moved in a forward and downward direction relative to the aperture to cause the skin piercing

element to penetrate the skin surface at an oblique angle."

IX. The appellant's arguments are summarised as follows:

It was a physical impossibility for a skin-piercing member to penetrate the skin when it was at an angle of 0°, 180° or greater relative to the skin surface. Thus, penetration by itself must be limited, at least, to angles greater than 0° and less than 180°.

Since the term "penetration" was limited to this range of angles, it had to be determined what "angled penetration" meant in addition thereto. It was common sense that the term "angled penetration" was more restricted than "penetration" and thus referred to an angle greater than 0° and less than 180°, excluding 90°, i.e. that the term referred to an oblique angle.

In analogy to what was decided in the United Kingdom in infringement case Catnic Components v. Hill & Smith [1981] before the House of Lords, it was clear that the drafter of the application would not have specified "angled penetration" if this term was to be interpreted as equivalent to "penetration". "Angled penetration" must therefore provide for a more limited range of angles than above 0° and less than 180°. Further weight to this assessment was added by the UK case of Société Technique de Pulverisation STEP v. Emson Europe Ltd. and Others [1993] RPC 513. In the context of the application as filed, the reader would, in fact, understand that the penetration was oblique and not tangential.

The only reasonable interpretation was to exclude an angle of 90° from the claim scope. Any other

interpretation would be non-sensical. Forward and downward motion of a needle tip which was perpendicular to the skin surface would rip through the skin, thus not fulfilling the object of the invention, which was to optimise the angle by which the skin was to be pierced by the skin-piercing means, thereby reducing pain to the patient and trauma to the skin, as described in paragraph [0013] of the application as originally filed. Such movement would never have been contemplated by the pragmatic skilled person.

The term "angled" could not be considered in isolation as a purely mathematical term; it had to be interpreted in the context of the claim as a whole, the application as filed and the common general knowledge of the skilled person. Such common general knowledge was evidenced by paragraphs [114] and [115] in combination with Figures 11 to 15 of RD1.

An implicit basis for "penetration at an oblique angle" could also be found in paragraphs [0013], [0063] to [0065] and [0074] of the application as originally filed.

In paragraph [0013], referring to the optimisation of the penetration angle, it was stated that the skin-piercing elements were advanced and deflected through the housing aperture towards an access site on the user, which was thereby penetrated. Such movement clearly implied that the skin was penetrated at an oblique angle.

From paragraph [0063] it was clear that the biosensor device 304 was held initially in a direction which was parallel to the skin. The movement of the device into a position in which it penetrated the skin was as a

result of the clip 326 forcing the device 304 downwards when the device was rotated sufficiently so that its front end 336 could be deflected through the aperture 316. It was stated that, as device 304a was advanced further forward, in the direction of arrow 338, deflected front end 336 was caused to contact sloped front surface 324 of wedged component 320a (Figure 8C), thereby being further forced or deflected in a downward and forward direction. Thus, forward rotational movement of the device against the sloped front surface of the wedged component caused the device to penetrate the skin at an oblique angle. The skilled person understood that the way in which the device was moved did not permit it to enter the skin at an angle of 90° because the device moved forward and downwards against the sloped surface. It would not be possible for the device to reach an angle of 90° with respect to the skin surface, although any angle less than 90° could be achieved. Since the device moved both forward and downward against a sloped surface, it was impossible for it to ever be at an angle of 90° with respect to the skin-piercing surface of the housing. Thus, the skilled person understood that penetration occurred at any oblique angle. Moreover, oblique penetration was not a feature peculiar to the device of Figure 8C; it also occurred for the device of Figures 9D and 10A-C (where the forward and downward motion was indicated by an arrow in Fig. 9D), and was described in paragraph [0065].

Including the term "penetration at an oblique angle" in claim 1 without reference to a sloped surface did not represent an intermediate generalisation, since it was mentioned at the end of paragraph [0013] that ramp structures and clip mechanisms were merely optional features.

Further support for the amendment could be found in paragraph [0074], where it was described that translation of the cartridge device, positioned planar to the skin surface, translated the biosensor device from an initial or retracted position to a second, extended position wherein the skin surface was pierced.

Auxiliary request 1 was filed to address the opponent's new objection that forward and downward motion of the devices did not necessarily result in oblique penetration. This new objection was raised for the first time in the opponent's appeal counterstatement. The filing of auxiliary request 1 was therefore the first opportunity the proprietor had to respond to this new objection. Claim 1 had been amended to specify forward and downward movement of the devices relative to the aperture of the skin-facing portion of the housing to cause the skin-piercing element to penetrate the skin surface at an oblique angle. Additional features, the basis of which in original claim 6 and paragraphs [0008], [0013], [0061] to [0064], [0067], [0074] and [0075] of the application as originally filed was indicated in detail, were included to ensure that the requirements of Article 123(2) EPC were met. The request was thus clearly allowable and did not raise any complex issues, since the whole application related to piercing of the skin and the passages providing support for the amendments had already been discussed in relation to the main request.

X. The respondent's arguments are essentially those on which the following reasons of the present decision are based.

Reasons for the Decision

1. The appeal is admissible.

2. Amendments – main request

The crucial point to be decided is whether or not there is a basis for the replacement of the expression "for **angled** penetration of the skin surface" in original claim 1 by "penetration at an **oblique angle** relative to the skin surface" in claim 1 of the main request. The term "oblique angle" excludes a right angle, i.e. the angle is either acute or obtuse. As previously mentioned in the claim, penetration of the skin surface is achieved by the at least one skin-piercing member of the device(s). Accordingly, it has to be assessed whether there is support for penetration of the skin piercing member at an oblique angle relative to the skin surface.

As conceded by the appellant, there is no literal support for this limitation which excludes penetration at an angle of 90°.

The appellant argued that the term "penetration of the skin surface" must itself be limited to angles greater than 0° and less than 180°, due to the physical impossibility of the skin piercing member to penetrate the skin at the upper and lower limit values of this range. It is noted that this argument is valid only if the skin surface is planar (which is not always the case) and if the skin-piercing member is also planar (a limitation which is not included in the claim).

The Board does not accept the appellant's argument that, since "penetration of the skin surface" is limited to

angles greater than 0° and less than 180°, the term "angled penetration of the skin surface" includes a further limitation, which, according to common sense and the usual understanding of this term, could only mean that an angle of 90° was excluded. In the Board's view, the common understanding of the term "angled" covers any angle, including 90°.

Also, it cannot be said that it is common general knowledge as evidenced by document RD1 that "angled penetration" means "penetration at an oblique angle". RD1 is not a dictionary, encyclopaedia, basic textbook or handbook, which is usually accepted as respective evidence, but a patent document. A single document of this kind cannot serve as substantiation that the alleged meaning is common general knowledge.

The original drawings themselves, in particular Figures 7 to 10, cannot serve as a basis for the amendment, for the simple reason alone that the skin surface (in relation to which the claimed penetration angle is defined) is not at all depicted therein. The brief description of Figures 7 to 10 in paragraphs [0024] to [0027] also fails to reveal such information.

From the cited passages of the original description it cannot be derived that a penetration angle of 90° is excluded, i.e. that an oblique angle is disclosed implicitly.

Paragraph [0013] is part of the "Summary of the Invention" and mentions that the angle by which the skin is to be pierced is to be optimised in order to reduce pain to the patient or trauma to the skin. From this statement alone it cannot be derived that this angle must necessarily be different from 90°. Further

on in this paragraph it is mentioned that the biosensor device is moved relative to the cartridge by "deflection and/or rotation". In a subsequent sentence, it is stated that the movement of the biosensor devices relative to the cartridge is accomplished by "advancing or deflecting" them. Even if this passage is read as clearly disclosing advancement and deflection, as argued by the appellant, it does not reveal that these movements occur simultaneously (only under this condition, this might imply an oblique angle - yet with respect to the cartridge, and not relative to the skin surface as claimed, since the position of the cartridge in relation to the skin surface is not disclosed in this paragraph).

Paragraphs [0063] to [0065] refer to the specific embodiments of Figures 7 to 9. It has to be established whether or not the feature "oblique angle" can be extracted in isolation from these embodiments.

Paragraph [0063] and Figures 8A to 8F describe the movement of a planar device 304a having a skin-piercing element 340 at its needle end 336. According to lines 19 to 24 of page 22, a simultaneous forward and downward movement is achieved by the front or needle end 336 of the device 304a contacting the sloped front surface 324 of wedged component 320a and thus being forced to move in that direction. The angles between the sloped surface 324 and the upper and lower surfaces of the wedged component are depicted as being oblique. When moving along the sloped front surface 324, the skin-piercing element 340 advances at an oblique angle relative to the upper and lower surfaces of the wedged component 320a. However, since the position of the wedged component 320a in relation to the skin surface ("(not shown)" as stated in line 24) is not disclosed,

this passage does not provide support for penetration of the skin-piercing member at an oblique angle relative to the **skin surface**, as claimed. Contrary to what is stated by the appellant, there is no disclosure in paragraph [0063] that "the biosensor device 304 is held initially in a direction parallel to the skin". Moreover, the simultaneous forward and downward movement (implying the oblique angle) is only disclosed in combination with the **sloped front surface** 324 of the wedged component 320a which is imposing the advancement in that direction.

The embodiment of Figures 9A to 9G, described in paragraphs [0064] and [0065], relates to an angled biosensor device 404 having a front surface 418, an angled back surface 412, a bottom surface 408 and skin-piercing configurations 430. It is noted that the direction of movement of such an angled biosensor is in principle not as well defined as that of the planar device mentioned above. With respect to Figure 9D it is explained that forward movement brings the front surface 418 of the angled biosensor 404 into contact with the inversely sloped surface 416 of component 402b, thereby forcing "the biosensor 404 further downward into the skin surface, causing the skin-piercing configurations 430 of biosensor 404 to penetrate the target skin surface". Again the angles between the inversely sloped surface 416 of component 402b and its top and bottom surfaces (406 and 408) are clearly oblique, but the position of component 402b in relation to the skin surface (the latter not being depicted) is not clearly and unambiguously derivable. Even though the skin surface is explicitly mentioned in the passage cited above, its exact orientation with respect to the bottom surface 408 of component 402b is not disclosed. It merely becomes clear that the skin

surface must be below component 402b. In lines 10 to 13 of page 24 it is mentioned that the bottom surface 408 of the angled biosensor 404 becomes flush with the target skin surface in the position shown in Figure 9C, but the movement described in this passage occurs prior to penetration and along a different sloped surface 410 of another component 402a. This sentence does not reveal the orientation of component 402b relative to the skin. Without this information, there is no clear and unambiguous disclosure of penetration of the skin-piercing member at an oblique angle relative to the **skin surface**, as claimed. Moreover, as in the embodiment of Figures 8A to 8F, the simultaneous forward and downward movement is only disclosed in combination with the **sloped surface** 416 of the component 402b which is imposing the movement in that direction.

Accordingly, in both embodiments penetration of the skin-piercing member at an oblique angle relative to the skin surface is not directly and unambiguously derivable.

Moreover, simultaneous forward and downward movement is by a sloped surface of a further component, being an essential feature of these embodiments. The feature of an oblique penetration angle cannot be extracted in isolation from these embodiments without infringing Article 123(2) EPC. The fact that paragraph [0013] mentions ramp structures as optional is of no relevance in this context, since this paragraph does not define the orientation of the cartridge in relation to the skin surface and fails to address the simultaneous forward and downward movement, as indicated above.

Finally, the appellant referred to paragraph [0074] as providing support for the amendment. Firstly, it is to be noted that paragraphs [0073] et seq. deal with "Methods of the Present Invention", rather than with the system as claimed. It is mentioned that a plurality of biosensor devices (having an integrated biosensor and skin-piercing element) are provided "in operative engagement with the cartridge device", which latter is "positioned planar to a target skin surface of the user". The position of the cartridge in relation to the skin surface does not reveal anything about the orientation of the skin-piercing element relative to the skin surface, since it is only stated that the skin-piercing elements are "in operative engagement" with the cartridge device, which does not disclose anything about their relative position. It is further mentioned that the biosensor device is "moved from an initial, retracted position to a second, extended or skin-contacting position wherein the target surface is pierced ...". In the last sentence of this paragraph it is stated that such movement "may be further defined by deflecting the biosensor device from a substantially planar position to an angled or deflected position for contacting and piercing the skin". Such an "angled or deflected position" does not exclude a right angle and therefore does not provide support for penetration at an oblique angle.

The appellant also referred to two decisions of courts of the United Kingdom. These are not relevant for the present decision, since they relate to national law and do not deal with the issue of added subject-matter.

3. Auxiliary request 1 – admissibility

This request was filed less than one month before the oral proceedings and more than 3½ years after the respondent's reply to the statement of grounds of appeal, where the respondent had raised the above-mentioned objection under Article 123(2) EPC against claim 1 of the main request. The appellant argued that this was the "first opportunity the proprietor ha[d] to respond this new objection, [...] that forward and downward motion of the devices does not necessarily result in oblique penetration", "which was raised for the first time in the opponent's appeal counterstatement". The Board does not accept this as a valid justification for the late filing. It would easily have been possible and appropriate for the appellant to file this request within a reasonable time period after having received the respondent's counterstatement, thus well before the Board issued its summons to oral proceedings, rather than waiting until less than one month before the oral proceedings, i.e. a very late stage of the appeal procedure. Besides the respondent's counter-statement, there were no developments in the present appeal case which could have occasioned the filing of this request.

Moreover, this request is not prima facie clearly allowable. Claim 1 represents a combination of two independent claims, viz. original claims 1 and 6 (the last feature of which has been omitted). No basis in the application as originally filed has been indicated in the accompanying letter in support of this combination and omission. Moreover, features have been included from numerous different and not necessarily interrelated passages of the description (paragraphs [0008], [0013], [0061] to [0064], [0067], [0074] and

[0075]), with some of the wording used in these passages having been changed. It appears that the added features are cherry-picked from these passages. Accordingly, the basis for the amendments is at first sight doubtful. At the very least it would be a complex matter to establish whether or not already this fundamental requirement is fulfilled. At such a late state of the appeal procedure, it is not appropriate for the other party and the Board to be confronted with issues of such nature.

Since auxiliary request 1 is not prima facie clearly allowable and since there are no sound reasons for filing it so late, the Board exercises its discretion under Article 13(1) RPBA and does not admit this request.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated