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D E C I S I O N
of 24 June 1999

Case Number: T 1040/98 - 3.4.1

Application Number: 92304659.3

Publication Number: 0516353

IPC: A61B 8/08

Language of the proceedings: EN

Title of invention:

Ultrasonic transducer assembly

Applicant:

Hologic, Inc.

Opponent:

-

Headword:

-

Relevant legal provisions:

EPC Art. 123(2), 56

Keyword:

"EPC Art. 123(2) amendments - added subject-matter (no)"
"EPC Art. 56 inventive step (yes)"

Decisions cited:

T 0066/85, T 0260/85, T 0496/90, T 0628/91, T 0189/94,
T 0331/87

Catchword:

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Boards of Appeal

Chambres de recours

Case Number: T 1040/98 - 3.4.1

D E C I S I O N
of the Technical Board of Appeal 3.4.1
of 24 June 1999

Appellant: Hologic, Inc.
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Representative: Whitten, George Alan
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Decision under appeal: Decision of the Examining Division of the
European Patent Office dated 11 May 1998 refusing
European patent application No. 92 304 659.3
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: G. Davies
Members: G. Assi
H. K. Wolfrum

Summary of Facts and Submissions

I. The appellant (applicant) lodged an appeal, received on 20 July 1998, against the decision of the Examining Division, dispatched on 11 May 1998, refusing the European patent application No. 92 304 659.3 (EP-A-0 516 353). The fee for the appeal was paid on 20 July 1998. The statement setting out the grounds of appeal was received on 15 September 1998.

In its decision, the Examining Division held that the application did not meet the requirements of Article 123(2) EPC and Article 56 EPC, having regard *inter alia* to the following documents:

(D2) EP-A-0 312 847 and

(D4) US-A-4 484 569 (this document was numbered D5 in the decision under appeal).

II. The appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the documents according to any one of the following requests:

Main Request:

Claims: No. 1-10 as filed with letter of 11 April 1996,

Description: pages 1 to 5 as originally filed, pages 1a,6 as filed with letter of 2 June 1995,

Drawings: sheets 1/3-3/3 as originally filed,

First Auxiliary Request:

Claims: No. 1-9 as filed with letter of 11 April 1996,
Description: pages 1 to 5 as originally filed, pages 1a, 6 as filed with letter of 2 June 1995,
Drawings: sheets 1/3-3/3 as originally filed,

Second Auxiliary Request:

Claims: No. 1-9 as filed with letter of 11 April 1996,
Description: pages 1 to 5 as originally filed, pages 1a, 6 as filed with letter of 2 June 1995,
Drawings: sheets 1/3-3/3 as originally filed,

Third Auxiliary Request:

Claims: No. 1-7 as filed with letter of 7 January 1997,
Description: pages 1 to 5 as originally filed, pages 1a, 6 as filed with letter of 2 June 1995,
Drawings: Sheets 1/3-3/3 as originally filed,

Fourth Auxiliary Request:

Claims: No. 1-8 as filed with letter of 24 March 1998,
Description: pages 3 to 5 as originally filed, pages 1, 1a, 2, 2a, 6 as filed with

letter of 24 March 1998,
Drawings: sheets 1/3-3/3 as originally filed,

Fifth Auxiliary Request:

Claims: No. 1-6 as filed with letter of
12 August 1997,
Description: pages 1 to 5 as originally filed,
pages 1a, 6 as filed with letter of
2 June 1995,
Drawings: sheets 1/3-3/3 as originally filed.

Moreover, the appellant requested oral proceedings "in the event that the Board of Appeal is mindful to refuse this appeal".

III. The wording of **Claim 1** according to the **main request** and the **first auxiliary request** reads as follows:

"Ultrasonic bone testing apparatus comprising:
locating means (13, 15) for holding a body member in position;
an ultrasonic transducer assembly (25, 27);
means (31, 33) for mounting said transducer assembly (25, 27) in contact with a body member in said locating means (13, 15), said mounting means (31, 33) being movable thereby to permit a body member to be placed in said locating means (13, 15);
said transducer assembly (25, 27) including a transducer (41, 51) and an acoustic waveguide which is interposed between the transducer and a body member in said locating means, said waveguide having a body engaging end which changes shape when progressively

advanced against the body member, characterised in that the body member engaging end is in the form of a laterally projecting rounded cone, the length of the projection being roughly equal to the diameter of the base of the cone, whereby air can be progressively excluded from an enlarging area of contact with a body member in said locating means as the transducer assembly is brought into contact with the body member."

The wording of **Claim 1** according to the **second auxiliary request** reads as follows:

"Ultrasonic bone testing apparatus comprising:
locating means (13, 15) for holding a body member in position;
an ultrasonic transducer assembly (25, 27);
means (31, 33) for mounting said transducer assembly (25, 27) in contact with a body member in said locating means (13, 15), said mounting means (31, 33) being movable thereby to permit a body member to be placed in said locating means (13, 15);
said transducer assembly (25, 27) including a transducer (41, 51) and an acoustic waveguide which is interposed between the transducer and a body member in said locating means, said waveguide comprising a filled bladder which changes shape when progressively advanced against the body member, characterised in that the body member engaging end of said bladder being in the form of a laterally projecting rounded cone, the length of the projection being roughly equal to the diameter of the base of the cone, whereby air can be progressively excluded from an enlarging area of contact with a body member in said locating means as the transducer assembly is brought into contact with the body member."

The wording of **Claim 1** according to the **third auxiliary request** reads as follows:

"Ultrasonic bone testing apparatus comprising:
locating means (13, 15) for holding a body member in position;
an ultrasonic transducer assembly (25, 27);
means (31, 33) for mounting said transducer assembly (25, 27) in contact with a body member in said locating means (15, 16), said mounting means (31, 33) being movable thereby to permit a body member to be placed in said locating means (15, 16);
said transducer assembly (25) including a transducer (41) and an acoustic waveguide which is interposed between the transducer and a body member in said locating means, said waveguide comprising a liquid or gel filled bladder (53), characterised in that the body member engaging end of said bladder (53) being in the form of a laterally projecting rounded cone, the length of the projection being roughly equal to the diameter of the base of the cone, whereby air can be progressively excluded from an enlarging area of contact with a body member in said locating means as the transducer assembly is brought into contact with the body member."

The wording of **Claim 1** according to the **fourth auxiliary request** is identical to that of claim 1 of the third auxiliary request, except that the expression "or gel" has been deleted.

IV. The appellant argued essentially as follows:

As regards the main, first auxiliary and second

auxiliary requests, in particular the objection under Article 123(2) EPC against the deletion of the feature "liquid filled bladder", the invention was concerned *inter alia* with the problem of excluding air in between the ultrasonic transducer and the object to be tested. This problem was solved by the form and deformability of the body member engaging end of the acoustic waveguide (bladder). Thus, it was not the content of the bladder that was important but its ability to deform. Moreover, the feature concerning the liquid filled bladder was replaced in the claims by a definition of the function performed by that feature.

As regards the third auxiliary request, in particular the feature "gel filled bladder", the Examining Division's objection under Article 123(2) EPC was based on the mistaken argument that the description merely gave the teaching that gels might be employed as long as they fell under the definition of liquids. Indeed, gels were not liquids and could not fall under the definition of liquids. Moreover, there was nothing in the specification of the application that would suggest that the words "gel" or "liquid" should be given any meaning other than their ordinary meaning.

As regards the objection of lack of inventive step against the subject-matter of claim 1 according to the fourth auxiliary request, it was not disputed that the precharacterising portion of the claim was known from D2. Moreover, D4 disclosed an arrangement in which a fluid under pressure was supplied to a conical shell provided with an aperture at its apex. This caused a membrane to bulge from the opening. However, since the pressure was stabilized to hold the bulge constant, the

bulge could not deform to exclude air from an enlarging area of contact with the body member. D4 did not even show a deformable cone having the claimed dimensions. Thus, D4 did not disclose or suggest any of the features of the characterising portion of claim 1. The Examining Division's arguments based on the combination of D2 and D4 were made with the benefit of hindsight.

Reasons for the Decision

1. The appeal is admissible.
2. *Main, first auxiliary and second auxiliary requests*
- 2.1 Article 123(2) EPC

The originally filed claims include the feature that the acoustic waveguide comprises a liquid filled bladder. This feature has been deleted in the amended claim 1 according to the main, first auxiliary and second auxiliary requests.

- 2.1.1 In deciding whether or not amendment of the application by deletion of a feature from a claim should be allowed, the so-called **essentiality test** has been developed. In particular, attention is drawn to the following case law.

In **T 66/85** (OJ 1989, 167; see Headnote, point 1), it was held that, if a technical feature was deleted from a claim in order not to exclude from protection certain embodiments of the invention, the broadening of the

claim did not contravene Article 123(2) EPC as long as there was a basis for a claim lacking this feature in the application as originally filed. It was immaterial whether or not the feature in question was relevant to the inventive concept of the claimed subject-matter.

In **T 260/85** (OJ 1989, 105; see Headnote, point 2), the board considered that the deletion from an independent claim of a feature which the application as originally filed consistently presented as essential was not permissible.

T 496/90, **T 628/91** and **T 189/94** confirmed this case. In **T 628/91** (see point 2.5 of the reasons), however, the disclosure was such that a structural feature could be replaced by a functional one, firstly because it was not disclosed as essential, secondly because its function was described (see Case Law of the Boards of Appeal of the EPO, 3rd edition 1998, page 212).

In **T 331/87** (OJ 1991, 022; see Headnote; following decision **T 260/85**), it was held that the replacement or removal of a feature from a claim might not violate Article 123(2) EPC provided the skilled person would directly and unambiguously recognise that (1) the feature was not explained as essential in the disclosure, (2) it was not, as such, indispensable for the function of the invention in the light of the technical problem it served to solve, and (3) the replacement or removal required no real modification of other features to compensate for the change.

2.1.2 As regards the present case, an object of the application is the provision of an ultrasonic bone

testing apparatus which permits ultrasonic energy to be efficiently coupled into and out of an appropriate portion of a patient's body (see original page 2, lines 1 to 5). The coupling of ultrasonic energy should occur without requiring immersion in a liquid and, at the same time, the presence of air in between the ultrasonic transducer and the object to be tested should be excluded (see original page 1, last sentence, and the statement of grounds of appeal, point II.A.6, first sentence). A contribution to the solution to this problem is thus seen in the structure of the acoustic waveguide which comprises a body, i.e. a bladder, having a given shape and being deformable. In this respect, the appellant points out that "it is not the content of the bladder that is important; it is its ability to deform that is significant" (see the statement of grounds of appeal, point II.A.6, last sentence). In the Board's view, it rather appears that **both** the structure of the bladder **and** its content solve the problem by providing the required deformability. This means that both features are essential to the performance of the invention, in other words necessary for the solution of the problem. Indeed, throughout the description, the acoustic waveguide is described in the form of a bladder, i.e. an elastic deformable hole body, which is filled with a suitable material like liquid or gel. Therefore, following T 260/85 and T 331/87, the deletion of the expression "liquid filled bladder" is not permissible.

In the statement of grounds of appeal, point II.A.11, the appellant argues that, in claim 1 as amended, the structural feature "liquid filled bladder" has, as a matter of fact, been replaced by a functional one

comprising the limitations that the waveguide end "changes shape when progressively advanced against the body member" and, moreover, that "air can be progressively excluded from ...", such a replacement being permissible in the light of T 628/91. But, in the Board's view, this decision is not relevant for the present case because it concerned a factual situation different from that of the present case. In particular, the structural feature considered in T 628/91 was not disclosed as essential, whereas the liquid filled bladder is essential.

Moreover, it is clear that, in the appellant's intention, claim 1 should confer the best scope of protection, in particular in view of the disclosure that liquids and gels can be used as filling materials. The proposed broadening of claim 1 by deletion of a feature in order not to exclude from protection certain embodiments of the invention would, however, be allowable under Article 123(2) EPC only if the application as filed provided a basis for a claim lacking the feature (T 66/85). There is no such a basis in the present case. On the contrary, claim 1 as amended covers embodiments which are clearly not disclosed in the original application, for instance, a waveguide comprising a gas filled bladder.

2.1.3 For these reasons, claim 1 according to the main, first auxiliary and second auxiliary requests does not meet the provisions of Article 123(2) EPC and, therefore, the requests are not allowable.

3. *Third auxiliary request*

3.1 Article 123(2) EPC

Claim 1 as originally filed has been amended so as to include *inter alia* both alternatives of a liquid filled bladder and a gel filled bladder. In the Examining Division's view, this amendment contravenes Article 123(2) EPC (the decision under appeal, point II.B.1).

Support for the latter alternative is given in the original description, page 4, last sentence of penultimate paragraph. The Examining Division's interpretation that "this passage merely gives the teaching that gels may be employed **as long as** they fall under the definition of liquids" is not followed by the Board. This interpretation may be envisaged from a linguistic but not from a technical point of view, keeping in mind that gels do not normally constitute a subgroup of liquids (see the statement of grounds of appeal, points II.B.17-19). Thus, the disclosed teaching consists in that a gel filled bladder should be considered as technically equivalent to a liquid filled bladder as far as the coupling of ultrasonic energy is concerned. Furthermore, the Examining Division's concern that "the properties of a gel may vary to a great extent from highly liquid to almost solid" is not shared by the Board. Indeed, according to the original disclosure as well as claim 1 under consideration, the properties of the liquids or gels, which can be regarded as suitable for the claimed application, are indirectly limited by the need of deformability of the bladder, in particular the progressive enlargement of the area of contact and the exclusion of air in between the ultrasonic transducer

and the object to be tested.

Apart from the objection mentioned above, the Examining Division did not raise any further objection under Article 123(2) EPC against claim 1; the Board has no further objection either.

For these reasons, claim 1 as amended according to the third auxiliary request meets the requirements of Article 123(2) EPC.

No objections are raised against dependent claims 2 to 7 in view of the original disclosure, in particular claims 2 and 4, page 2, last paragraph, page 3, last paragraph, and page 5, third paragraph, to page 6, first paragraph.

3.2 Article 54 EPC

None of the cited documents discloses an ultrasonic bone testing apparatus comprising all the features of claim 1.

Therefore, the subject-matter of claim 1 according to the third auxiliary request is novel.

3.3 Article 56 EPC

According to the decision under appeal, point II.C, the subject-matter of claim 1 of the fourth auxiliary request does not involve an inventive step, having regard to the combination of documents D2 and D4. However, the Examining Division's line of argumentation is also valid as regards claim 1 of the third auxiliary

request considering that this claim is identical to that of the fourth auxiliary request with the further feature of a gel filled bladder as alternative to a liquid filled bladder.

- 3.3.1 The Board takes the same view as the Examining Division that document D2 represents the most relevant state of the art.

Considering also its implicit disclosure, D2 discloses an ultrasonic bone testing apparatus comprising all the features of the preamble of claim 1 for the case of a liquid filled bladder.

- 3.3.2 As already stated above, an object of the application is the provision of an ultrasonic bone testing apparatus which permits ultrasonic energy to be efficiently coupled into and out of an appropriate portion of a patient's body (see original page 2, lines 1 to 5). The coupling of ultrasonic energy should occur without requiring immersion in a liquid and, at the same time, the presence of air in between the ultrasonic transducer and the object to be tested should be excluded (see original page 1, last sentence, and the statement of grounds of appeal, point II.A.6, first sentence).

This problem is solved by the provision of a bladder having the form and function as recited in the characterising portion of claim 1.

- 3.3.3 Document D4 relates to an ultrasonic diagnostic and therapeutic transducer assembly for ophthalmic applications. The transducer assembly as shown in

Figure 2 is provided with a conical shell 128 retaining an ultrasound coupling fluid, such as water (see column 4, lines 31 to 41). The shell 128 has a front opening 130 covered by a membrane 132, preferably of thin rubber. Figure 5 shows another conical shell 160, which can be used instead of the shell 128 (see column 7, line 45, to column 8, line 16). The shell 160 has a front opening 164. A membrane 172 is stretched across the conical surface and retained by O-rings 174 and 168. The shell 160 is filled with a fluid, such as water, the pressure of which causes the membrane to bulge from the opening 164. The pressure is stabilized, so that the bulge 172', 172'' is held constant. The bulging of the membrane enables the direct application of the shell 160 to the eye region.

The Examining Division looked at D4 for an alternative shape for the bladder known from D2. However, the conical shell 160 with the front bulging portion 172', 172'' according to D4 is quite different from the liquid filled flexible sack 24 shown in Figure 1 of D2. The replacement of the flexible sack 24 of D2 having the shape of an accordion bellows with the conical shell of D4, which is not flexible apart from the bulging portion, would not lead to the claimed apparatus. For the claimed subject-matter to be obvious, it would rather be necessary to find a suggestion in D2 for modifying the flexible sack 24 so that its shape corresponds to that according to the characterising part of claim 1. Such a suggestion is not given by D2. Nor can the claimed shape be inferred from other prior documents, in particular D4 which shows a rigid conical shell with a bulging portion, the shape of which is held constant by stabilizing the

pressure of the fluid in the conical shell. This means that, contrary to the teaching of claim 1, the bulge does not essentially change shape when progressively advanced against the body member to be tested and, therefore, air is not progressively excluded from an enlarging area of contact with the body member.

- 3.3.4 Therefore, the skilled person would not have any reason for combining the prior art documents D2 and D4. Even though such a combination would be possible, it would not lead to the claimed apparatus. Moreover, the other documents cited during the procedure are less relevant than D2 and D4.

For these reasons, the subject-matter of claim 1 of the third auxiliary request involves an inventive step. The same applies to the dependent claims 2 to 7.

The third auxiliary request is allowable.

4. *Fourth and fifth auxiliary requests*

Since the third auxiliary request is allowable, there is no need to consider the fourth and fifth auxiliary requests.

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 the first instance with the order to grant a patent on the basis of the following documents:

Claims: No. 1-7 of the third auxiliary request,
as filed with letter of 7 January 1997,

Description: to be adapted,

Drawings: sheets 1/3-3/3 as originally filed.

The Registrar:

The Chairman:

M. Beer

G. Davies