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**D E C I S I O N**  
**of 22 July 1999**

**Case Number:** T 0814/96 - 3.2.2

**Application Number:** 89902572.0

**Publication Number:** 0353294

**IPC:** A61B 17/00

**Language of the proceedings:** EN

**Title of invention:**

System for angioplasty and ultrasonic contrast imaging

**Applicant:**

Bernstein, Jonathan, et al

**Opponent:**

-

**Headword:**

-

**Relevant legal provisions:**

EPC Art. 84, 123, 54, 56

**Keyword:**

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**Decisions cited:**

-

**Catchword:**

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Boards of Appeal

Chambres de recours

**Case Number:** T 0814/96 - 3.2.2

**D E C I S I O N**  
**of the Technical Board of Appeal 3.2.2**  
**of 27 July 1999**

**Appellant:**

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**Representative:**

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**Decision under appeal:**

**Decision of the Examining Division of the  
European Patent Office posted 1 March 1996  
refusing European patent application  
No. 89 902 572.0 pursuant to Article 97(1) EPC.**

**Composition of the Board:**

**Chairman:** W. D. Weiß  
**Members:** D. Valle  
J. C. M. De Preter

## Summary of Facts and Submissions

I. The appellant (applicant) lodged an appeal received on 13 May 1996 against the decision of the Examining Division on the refusal of the application No. 89 902 572.0, paying the fee for appeal on the same day. The statement setting out the grounds of appeal was received on 11 July 1996.

II. The Examining Division held that the application did not meet the requirements of Articles 84, 123 (2), 54(2) and of the Articles 52 and 56 EPC having regard to the following documents:

(1) US-A-3 352 303

(2) US-A-4 587 958

(3) E. A . NEPPIRAS, "Very high energy ultrasonics", British journal of applied physics, vol. II, April 1960, pages 143 to 150

In the course of the appeal proceedings the appellant filed the new document:

(B1) US-A-4 665 906

Following the communications of the Board of 10 August 1998 and of 15 July 1999 the appellant as a main request filed with letters of 21 December 1998 and 22 June 1999 a new set of 21 claims and amended pages 7, 8, 11 and 13 of the description.

III. The appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the main request consisting of claims 1 to 21 or of one of the five auxiliary requests filed during the examination procedure and taken as a basis for the appealed decision.

Provisionally, he requested also oral proceedings.

IV. The independent claims 1, 2, 4, 9 and 19 of the main request filed on 21 December 1998 read as follows:

- (1) "An ultrasonic system comprising an ultrasonic power generator including a horn, a high efficiency ultrasonic transmission wire connected to said horn, wherein said high efficiency ultrasonic transmission wire is formed from a material having a mechanical quality factor  $Q$ , measured at half the fatigue stress and at 20 KHz, greater than 50.000."
- (2) "A method for testing ultrasonic angioplasty in vitro using an ultrasonic system as set forth in claim 1, which comprises the steps of inserting the high efficiency ultrasonic transmission wire into a blood vessel section to be treated and then applying ultrasonic energy via the high efficiency ultrasonic transmission wire to an occlusion in the blood vessel section for a duration and intensity effective for breaking up the occlusion and restoring good blood flow."
- (4) "A high efficiency ultrasound transmission member comprising a wire which is formed from a material

having a mechanical quality factor  $Q$ , measured at half the fatigue stress and at 20 KHz, greater than 50.0000 and connecting means for connecting the wire to the horn of an ultrasound generator."

(9) "A high efficiency ultrasound transmission wire that has been machined from a bar of material and is formed from a material having a mechanical quality factor  $Q$ , measured at half the fatigue stress and at 20 KHz, greater than 50.0000, and a microtip of a horn connected to one end of said wire for transferring ultrasound thereto."

(19) "An ultrasonic device for reducing an obstruction in a human body lumen defined by an anatomical wall, said device comprising:

a) an ultrasonic power generator (100) for generating ultrasonic energy, said ultrasonic power generator including:

(i) an ultrasonic frequency electric wave generator (110),

(ii) a transducer-converter (120) for converting said ultrasonic frequency electric wave to an ultrasonic frequency mechanical wave, and

(iii) a horn for altering a wave form of said ultrasonic frequency mechanical wave produced by said transducer-converter and for emitting said ultrasonic frequency mechanical wave from said ultrasonic power generator,

b) an ultrasonic transmission wire having a proximal end connected to said horn and a distal end remote therefrom, said transmission wire being disposable within said human body lumen with said distal end adjacent said obstruction for transmitting ultrasonic mechanical energy from the horn of said ultrasonic generator to said obstruction without substantially altering the ultrasonic wave form applied to the proximal end thereof, to thereby reduce the size of said obstruction at said distal end,

c) said transmission wire being made of a material having a mechanical quality factor  $Q$ , measured at half the fatigue stress and at 20 KHz, of not less than 50.000, whereby to permit the efficient transmission of ultrasonic energy through said transmission wire and to prevent said transmission wire when disposed in said lumen from heating up during the transmission of said ultrasonic energy to an extent that would injure said anatomical wall defining said lumen and any body fluid within said lumen."

V. The appellant argued as follows.

The object of the invention is to avoid attenuation of the signal and heating. The basis idea of the invention is using a material for the wire having a  $Q$  greater than 50000.

Document (1) is the closest prior art and it contains no hints to use a  $Q > 50000$ . Document (1) leads away from the invention by using a short transmission time

and cooling to avoid heating, see column 1, lines 54 to 61.

Document (2) discloses only a horn and not a wire.

Document (3) deals with very high energy ultrasonics whereas the invention deals with low energy ultrasonics as required by the field of the invention (angioplasty).

Aluminium alloys in angioplasty are not disclosed in the prior art. This is a sign that the technical development in the field has gone in a different direction. This is an indication for an inventive step, see T 650/90, T 2/81 and T 596/90.

The claims of the main request are concise. To reduce the claim number as in the auxiliary requests would unjustifiedly restrict the scope of the claims.

### **Reasons for the Decision**

1. The appeal is admissible
2. *Amendments*

There are no reasons to challenge the amendments carried out in the main submission having regard to the original disclosure.

The last introduced amendments in claim 2 ("testing in vitro" and: "blood vessel section") are disclosed at

page 20 of the application.

The requirements of Article 123(2) EPC are thus met.

3. *Clarity and conciseness (Article 84 EPC)*

Provided that his invention is novel and inventive, an applicant has as a rule the right to claim all the methods and objects, representing different aspects of the same invention, which he considers necessary in order to fully protect his invention on the market.

In the case that the independent claims are of different categories, an objection of lack of conciseness will not normally be raised. The question of lack of conciseness arises when there are several independent claims of the same category. However, irrespective of the number of independent claims of the same category, the objection of lack of conciseness does normally not arise if the subject-matter of said claims clearly represent different aspects of the same invention, in particular when the same invention can be embodied in different commodities.

If this is the case, an undue burden is not placed on others seeking to establish the extent of the monopoly (see Case Law 1998, pages 169/170, point 2., Conciseness).

Since in the present case the independent claims are either of a different category or clearly refer to different commodities which embody the invention, namely an ultrasonic system, a transmission member, a transmission wire and an ultrasonic device, an

objection of lack of conciseness is not justified.

Contrary to the statement in the appealed decision point 3, (note that claim 1 of the second auxiliary request corresponds to claim 5 of the main request) claim 5 is clear if it is read together with claim 4 to which it refers back. Claim 4 recites that there is a connecting means for connecting the wire to the horn. Claim 5 recites that the horn comprises a microtip and that the flared end of the wire is integral with the free end of the microtip. From all that it follows that the connecting means is the contact surface between the microtip free end (= horn free end) and the flared end of the wire and that there is no contradiction between both claims.

3. *Article 52(4) EPC*

Method claim 2 of the main request does not disclose a method for treatment of the human body but a method for testing the ultrasonic system claimed in claim 1. Therefore the requirements of Article 52(4) are met.

4. *Novelty of the independent claims*

4.1 The common features of the independent claims of the main request are the following:

(a) a horn,

(b) an ultrasonic transmission wire

(bb) formed from a material having a mechanical quality factor  $Q$ , measured at half the fatigue stress and

at 20 KHz, greater than 50.000 and

(cc) connected to the horn.

4.2 Document (1) does not disclose the feature (bb).

Document (2) does not disclose the feature (bb) either.

Document (3) does not disclose the features (b), (bb) and (cc).

Document (B1) discloses medical devices incorporating shape memory alloys and it does not concern the field of the invention.

Accordingly the subject-matter of the independent claims of the main submission is novel.

5. *Definitions*

Definition of some relevant terms occurring in the application (see: Kuttruff, H., *Physic und Technik des Ultraschalls*, Stuttgart, 1988) and the description of the application

- ultrasonic power generator  
generator of ultrasonic waves. These devices use either the piezoelectric effect (electrostriction), for example using as material the PZT, or the magnetostriction effect (induction of a magnetic field).
  
- horn  
the materials used in the ultrasonic power

generator do not allow high velocities of the oscillation. A horn is a short tapered metal stud which raises the velocity of the waves produced by the generator.

- ultrasound damping  
natural attenuation of the oscillation waves with the distance from the source. The oscillation energy is transformed in heat. The mechanism is extremely complicated depending from several factors. There are no generally acknowledged measuring standards.
  
- mechanical  $Q$  of a material

According to the description of the invention, pages 11 and 12, the mechanical  $Q$  is the quality factor; it is deduced from calorimetric measures of energy dissipation.  $Q$  is the inverse of the ultrasonic damping factor. A low damping factor means a great  $Q$ , less attenuation of the vibration and less production of heat.

The mechanical  $Q$  depends among other factors on the form of the vibrating element, on the length of the element (whereby a length of 50 cm is normally sufficient for a wire to bring the distal tip to the water boiling point), on the stress applied, on the frequency of vibration, on the temperature and on the type of the material.

The description of the invention refers to the values of the mechanical  $Q$  for different metals given by Neppiras (document (3), table 4, page 146). These

values have been determined for a stress approximately equal to  $F/2$ , being  $F$  the fatigue stress of the material and for a frequency of 20 HZ. The shape of the element tested is not given, however the whole article refers to horns, i.e. short metal studs and not to wires.

In particular, following values are given:

tool steel	1400
K-Monel	5300
titanium	24000
duralumin	>50000
hiduminium	>100000

6. *Inventive step*

The state of the art coming closest to the invention is contained in document (1) because it discloses a method for blood cloth lysis by means of transmission of ultrasonic energy through a thin metallic probe (2), like a preferred embodiment of the claimed invention. The probe is made of stainless steel or Monel metal (column 5, lines 13, 14).

The disclosure of document (1) addresses only the problem of heat formation by limiting the time of application of the vibrational energy or by cooling the wire (column 1, lines 54 to 61), but not the problem of damping of the oscillation. Document (1) does not contain any hint which can lead the person skilled in the art to use a material for the wire with a  $Q$  according to Neppiras > 50 000.

The independent claims of the main submission distinguish therefrom essentially by the feature that the wire is formed from a material having a mechanical quality factor  $Q$ , measured at half the fatigue stress and at 20 KHz, greater than 50.000.

The technical problem to be solved by the invention is therefore to be seen in minimizing the loss of energy within the wire. The loss of energy has two main disadvantages: first it means loss of efficiency of the apparatus because the vibration fed at one end of the wire does not completely reach the opposite end where the vibration energy is needed in order to loose the blood clots. Secondly the vibration energy lost is transformed in heat which can damage the surrounding organic tissues.

The appealed decision did not recognise that the purpose of the invention was not only avoiding heat, but also damping the vibration.

Document (2) discloses a surgical ultrasonic scalpel to cut and remove tissues by scattering, the horn of which (which comprises the scalpel having a suction duct) is made of duralumin or titanium alloy (column 5, lines 59 to 63). An ultrasonic transducer (34) of the electrostriction type is used which is preferably made of PZT (lead zirconate titanate). The device consists of an electronic circuit for exciting an ultrasonic transducer including a power amplifier circuit adapted to make its output voltage waveform and feedback voltage waveform equal in phase. Thus the device is advantageous in that it is not susceptible to any load applied to the forward end of the horn. Furthermore, in

comparison to other transducers such as a magnetostriction transducer using ferrite and nickel, the mechanical Q is increased, the electric loss is reduced, the heat generation of the transducer is decreased and a satisfactory durability of the device is attained (column 1, lines 52 to 62, column 2, lines 10 to 31, column 7, lines 17 to 30, paragraph starting from line 64).

The problem addressed by the device according to document (2) is reducing heat generation and increasing the durability of the apparatus. This problem is solved by the use of a particular transducer device (electrostriction type).

Document (2) deals with a relatively short surgical scalpel horn, which does not require special measures in order to avoid attenuation of the signal; also the heat formation in a surgical apparatus is less relevant as in a relatively long wire used in angioplasty.

Document (3), cited in the original description of the invention, is an article containing a general overview concerning the applications of very high energy ultrasonics. The field of application is practically delimited to solids (abstract, last sentence, Table 1, page 144), in particular, destructive testing of metals (fatigue studies, page 147) adhesive bonds testing (page 148), investigating non-linear (plastic) behaviour of metals (page 148 to 149) and ultrasonic cold welding (page 149). Surgical applications are not cited.

In designing a transformer (horn), which is basically a

tapered metal stud (page 145, left column, lines 4 and 5), the parameters allowing the maximum possible output velocity are investigated. Thereby, stress should be taken in consideration (page 145, left column): a material should be chosen having a high fatigue strength (F). Furthermore the shape factor should be maximized (page 145, right column, table 4, page 146, last two columns).

The table 4 at page 146 resumes the results of the investigation giving the maximum possible velocity for different metals. Table 4 contains also a column giving the mechanical Q. The table is directed to assessing the conditions which give a maximum possible output velocity. For the purpose of the article the values of Q have no practical relevance. The problem of heat formation and of the damping of the vibration is not considered because not contextually relevant.

The combination of teachings of the documents (1), (2) and (3) in the form of the claimed invention is not obvious for the following reasons.

None of the cited documents addresses the problem of damping of the signal in relatively long wires.

Document (1), the sole document which discloses relatively long wires, leads away from the invention suggesting to avoid the problem of formation of heat by limiting the vibration exposure time and by cooling the wire, that is using measures which lead to a limitation of the signal either in time or by the additional mass of the cooling system.

Document (3) deals with applications of ultrasound in metals and has nothing to do with the claimed invention.

To arrive at the invention the person skilled in the art would have to abandon the method of document (1) of limiting heat formation by cooling, have to recognise the need of avoiding damping of vibration in long wires, have to notice that the mechanical  $Q$  of the material is the crucial feature which allows contemporarily low damping and low heat formation - although neither of the documents (2) and (3) gives any hint in this direction - have to choose the necessary information pieces about the values of  $Q$ , e.g. in document (3), and finally have to find an appropriate inferior limit for the mechanical  $Q$ .

The above long way to arrive at the subject-matter of the independent claims could not have been gone without an inventive step being involved.

6. In view of the above the subject-matter of the independent claims 1, 2, 4, 9 and 19 of the main submission involves an inventive step within the meaning of 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 first instance with the order to grant a patent in the following version:

**Claims:** 1 to 12 (part), 19 (part) to 21 as filed on 23 June 1999 with letter of 22 June 1999  
12 (part) to 19 (part) as filed on 21 December 1998 with letter of 21 December 1998

**Description:** pages 1 to 6, 9, 10, 12 and 14 to 28 as originally filed  
page 7, 8, 11 and 13, as filed on 23 June 1999 with letter of 22 June 1999

**Figures:** sheets 1/3 to 3/3 as filed on 19 October 1989 with letter of 17 October 1989.

The Registrar:

The Chairman:

S. Fabiani

W. D. Weiß