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**Datasheet for the decision  
of 13 September 2007**

**Case Number:** T 0924/05 - 3.2.02

**Application Number:** 97933255.8

**Publication Number:** 0925088

**IPC:** A61M 37/00

**Language of the proceedings:** EN

**Title of invention:**

Ultrasound enhancement of transdermal transport

**Patentee:**

Sontra Medical, Inc.

**Opponent:**

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**Headword:**

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**Relevant legal provisions:**

EPC Art. 52(1), 54, 56, 52(4), 84, 123(2)

**Keyword:**

"Method of treatment or surgery (no)" (see Reasons, point 5)  
"Novelty (yes), inventive step (yes) - after amendment"

**Decisions cited:**

T 0383/03

**Catchword:**

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Case Number: T 0924/05 - 3.2.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.02  
of 13 September 2007

**Appellant:** Sontra Medical, Inc.  
10 Forge Parkway  
Franklin, MA 02038 (US)

**Representative:** Miles, John Stephen  
Eric Potter Clarkson LLP  
Park View House  
58 The Ropewalk  
Nottingham NG1 5DD (GB)

**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 1 March 2005  
refusing European application No. 97933255.8  
pursuant to Article 97(1) EPC.

**Composition of the Board:**

**Chairman:** T. Kriner  
**Members:** S. Chowdhury  
M. J. Vogel

## Summary of Facts and Submissions

- I. This appeal is against the decision of the examining division dated 1 March 2005 to refuse European patent application No. 97 933 255.8.

The application was refused on the grounds that the independent device claims of all requests then on file did not meet the requirements of Articles 84 and 123(2) EPC, and the independent method claims were not allowable under Article 52(4) EPC.

By way of obiter dictum the decision also noted that the independent device claims did not meet the requirements of Article 52(1) EPC.

The following documents were cited during the examination procedure:

D1: US-A-5 016 615  
D2: US-A-5 078 144  
D3: EP-A-0 495 531  
D4: US-A-5 548 140.

- II. On 11 April 2005 the appellant (applicant) lodged an appeal against the decision and paid the prescribed fee on 16 April 2005. On 11 July 2005 a statement of grounds of appeal was filed.

- III. The appellant requests that the decision under appeal be set aside and that a patent be granted on the basis of the following documents:

Claims 1 to 5 filed by telefax dated 13 August 2007,

Claims 6 to 16 filed by telefax dated 8 August 2007,

Description pages 1 to 6, and 8 to 15 filed by telefax dated 13 June 2007,

Description pages 7 and 16 to 23 filed by telefax dated 8 August 2007,

Description page 5A filed by telefax dated 13 August 2007, and

Figures 1 to 4 filed by telefax dated 8 August 2007.

IV. Independent claims 1, 12, and 13 read as follows:

"1. A device for enhancing transdermal transport, the device comprising a chamber with interior walls which form a cavity having a larger opening and a smaller opening, said cavity defining an ultrasound channel connecting the larger and smaller openings, an ultrasound transducer located at the larger opening of the cavity capable of emitting ultrasound at a frequency between 20 kHz and 2MHz, wherein the ultrasound retains at least 50% of its energy as it is channelled from the transducer to the smaller opening, wherein the smaller opening of the cavity is placeable towards the skin to which the device is to be applied, and wherein coupling medium is placed in the channel so that the ultrasound induces cavitation in the coupling medium at the smaller opening of the cavity.

12. A system for transdermal administration of a compound comprising the device of Claim 1 and a drug for transdermal administration.

13. A non-invasive method of collecting analytes from an individual, the method comprising: placing a device according to Claim 2 against the skin of an individual, directing an ultrasound beam from the ultrasound transducer in the device to an area of the skin, and collecting analytes from the individual in the means for analyte recovery."

Claims 2 to 11 and 14 to 16 are dependent claims.

### **Reasons for the Decision**

1. The appeal is admissible.
2. *Amendments*
  - 2.1 New claim 1 is based on originally filed claim 1 (see WO-A-98/00194), which has been amplified essentially to state that the converging ultrasound channel is defined by interior walls of the chamber, an ultrasound transducer is located at the larger opening of the channel and is capable of emitting ultrasound at a frequency between 20 KHz and 2 MHz, and a coupling medium is located in the channel, the ultrasound inducing cavitation in the medium at the smaller opening of the cavity.

These amendments are supported by original Figures 2 to 4, page 12, lines 4 and 5, and page 13, lines 24 to 30

of WO-A-98/00194 and comply with the requirement of Article 123(2) EPC.

2.2 Claim 12 is a system claim including the combination of the device of claim 1 and a drug for transdermal delivery, which combination is disclosed extensively, for example at page 26, lines 22 to 30 of WO-A-98/00194.

2.3 Claim 13 is supported by page 24, lines 11 to 16 of WO-A-98/00194.

2.4 The dependent claims are supported by the originally filed dependent claims and by the description.

2.5 Consequently, the new claims are free from objection under Article 123(2) EPC.

3. *Articles 84 and 123(2) EPC*

Claim 1 has been amended along the lines suggested in the decision to refuse the application. In particular, the claim now clearly states that the device has a chamber with interior walls defining a cavity, and that the cavity has a larger opening and a smaller opening, with the ultrasonic transducer located at the larger opening. The amendments meet the objections under Articles 84 and 123(2) EPC in the decision, accordingly.

4. *Article 52(4) EPC*

The impugned decision states that the method claims are objectionable both as relating to a surgical method as well as a method of treatment of the body. These points are treated in turn below.

#### 4.1 Surgery

The method of claim 13 is directed to collecting analytes from an individual by directing ultrasound at the skin in order to enhance transdermal transport of the analyte. According to the decision to refuse the use of the method might cause skin abrasion, and this renders the claimed method a surgical method.

However, according to T 0383/03 (OJ EPO 2005, 159) if a method involving a physical intervention on the human or animal body is clearly neither suitable nor potentially suitable for maintaining or restoring the health, the physical integrity, or the physical well-being of the person or animal, then the method does not fall under the exclusion from patentability provided for in Article 52(4) EPC.

The presently claimed method is only for collecting an analyte and is, of itself, neither suitable nor potentially suitable for maintaining or restoring the health, the physical integrity, or the physical well-being of the person or animal. Therefore, despite the fact that the ultrasound may cause abrasion of the skin, the method is not a surgical method which falls under the exclusion from patentability provided for in Article 52(4) EPC.

#### 4.2 Treatment

According to the decision to refuse the application, the method claim encompasses methods for the collection of analytes as described on page 14, lines 8 to 16 in

which drugs (e.g. histamine) are delivered to the skin, which is a method of treatment within the meaning of Article 52(4) EPC.

The Board cannot agree with this view since claims must be interpreted narrowly, and claim 14 includes the step of collecting analytes only, there is no step for delivering a drug. According to the cited passage on page 14 drugs may be optionally added to the coupling medium, but this does not form part of the claimed method.

The claimed method does not relate to a method of treatment which falls under the exclusion from patentability provided for in Article 52(4) EPC, accordingly.

5. *Article 52(1) EPC*

5.1 Novelty

5.2 The apparatus of document D1 is for applying a medication to body tissue which medication is encapsulated in an implanted porous receptacle adjacent the body of tissue to be treated. Irradiation of the receptacle with ultrasound accelerates diffusion of the medicament through the walls of the receptacle. This document is not concerned with transdermal transport.

Document D1 does not teach, or even mention, the use of cavitation for any purpose, nor is the apparatus thereof clearly suitable for inducing cavitation at or near the skin. In order to induce cavitation the parameters of the system must be "tuned" such that the



conditions for the onset of cavitation are present. It may not be assumed that such conditions would be present in the device of D1. On the contrary, the occurrence of cavitation in the use of the device of D1 would hinder correct operation of the device since the ultrasound would be scattered by the cavitation and its passage to the medication receptacle implanted within the body would be impaired.

5.3 Document D2 is concerned with a lithotripter device which, like the device of D1, is for treating objects within the body, and is not concerned with transdermal transport. This document also does not teach or mention the use of cavitation, nor is it clearly suitable for this purpose for reasons similar to those given with respect to D1, i.e. the parameters of the system must be properly selected to induce cavitation at or near the skin and, moreover, this would appear to be undesirable because it would hinder the progress of ultrasound into the body where it is required.

5.4 Document D3 is directed at apparatus for the transdermal delivery of a drug in which a horn channels ultrasound from a transducer onto a drug-containing layer from where a drug is released into the skin. There is no coupling medium in the channel and no suggestion that cavitation may be used to enhance drug delivery.

5.5 Document D4 discloses a device for enhancing the permeability of the skin or mucosa to analyte, which employs ultrasound and a chemical enhancer. In order to promote the passage of analytes out of the body a

frequency modulation is used to create a pressure gradient out of the body.

This document does not disclose the use of cavitation in a medium within a channel, nor is it clearly capable of creating cavitation at or near the skin.

- 5.6 As demonstrated above, none of the cited prior art documents discloses a device which makes use of cavitation in order to promote transdermal diffusion of a drug or analyte. For this reason alone none of these documents anticipates the device of claim 1.

The use of cavitation is the essence of the application, but there are other features which also distinguish the device of claim 1 from the prior art. For example, the device of D4 does not disclose a chamber having a small and a large opening or a channel. These less important features have not been discussed since novelty is already established by the ability of the claimed apparatus to induce cavitation.

For these reasons the device of claim 1 is novel.

- 5.7 Inventive step

The application relates to a method and a device for transdermal transport, which employ an ultrasound beam which is channelled and applied to a small area of skin, and also employ cavitation in a medium near the skin in order to enhance drug delivery and analyte collection.

The purpose of the ultrasound channel is to concentrate the ultrasonic energy into a small area of the skin,

and the purpose of cavitation is to enhance transdermal drug transport (see page 9, lines 13 to 19 of WO-A-98/00194).

It will be evident from the discussion on novelty that none of the cited prior art documents teaches or suggests such a mechanism for enhancing transdermal transport of molecules. The only document which mentions the enhancement of transdermal transport is D4, but here a different mechanism is employed, namely that of creating a pressure gradient.

Since none of the cited prior art documents teaches or suggests the use of cavitation in order to enhance transdermal transport of molecules claim 1 also involves an inventive step.

6. The system of claim 12 and the method of claim 13 both employ the device of claim 1, which is found to meet the requirements of Article 52(1) EPC. Claims 12 and 13 also meet the requirements of Article 52(1) EPC, accordingly.

**Order**

**For these reasons it is decided that:**

The decision under appeal is set aside.

The case is remitted to the first instance with the order to grant a patent on the basis of the following documents:

Claims 1 to 5 filed by telefax dated 13 August 2007,

Claims 6 to 16 filed by telefax dated 8 August 2007,

Description pages 1 to 6, and 8 to 15 filed by telefax dated 13 June 2007,

Description pages 7 and 16 to 23 filed by telefax dated 8 August 2007,

Description page 5A filed by telefax dated 13 August 2007, and

Figures 1 to 4 by telefax dated 8 August 2007.

The Registrar

The Chairman

V. Commare

T. Kriner