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D E C I S I O N
of 15 October 2003

Case Number: T 0289/02 - 3.2.2

Application Number: 94911768.3

Publication Number: 0634140

IPC: A61B 17/00

Language of the proceedings: EN

Title of invention:
Applicator for tissue adhesive

Patentee:
JURIDICAL FOUNDATION THE CHEMO-SERO-THERAPEUTIC RESEARCH
INSTITUTE

Opponent:
Baxter Aktiengesellschaft

Headword:
-

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step (yes, after amendments)"

Decisions cited:
-

Catchword:
-



Case Number: T 0289/02 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 15 October 2003

Appellant: Baxter Aktiengesellschaft
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 17 January 2002
rejecting the opposition filed against European
patent No. 0634140 pursuant to Article 102(2)
EPC.

Composition of the Board:

Chairman: W. D. Weiß
Members: D. Valle
R. T. Menapace

Summary of Facts and Submissions

I. The appellant (opponent) filed an appeal against the decision of the opposition division to reject the opposition.

II. The patent was opposed on the ground of lack of inventive step on the basis of the documents:

E1 = EP-A-149 286

E2 = EP-A-156 098

E3 = EP-B-302 410

E4 = EP-B-302 411.

III. Following a request from both parties oral proceedings have been held the 15 October 2003.

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

The respondent (patentee) requested that the appeal be dismissed and the patent be maintained as granted (main request) or that the patent be maintained in amended form on the basis of claim 1 as submitted at the oral proceedings (auxiliary request 1) or as submitted with letter of 15 September 2003 (auxiliary request 2), claims 2 to 7, description and figures as granted.

IV. Claim 1 as granted reads as follows:

"An applicator for applying a biocompatible adhesive containing human or animal protein as a principal ingredient to a surgical site of living body, comprising:

a spray head (20) for spraying two solutions, that is, a protein solution and a coagulation solution, fed from two syringe barrels, respectively, by an ejection sterile-gas, said spray head including:

a housing (21) having a pair of adjacent sterile gas ejecting nozzles (22), longitudinal axes thereof being oriented in a predetermined direction for guiding and ejecting the sterile gas in that direction;

a pair of adapters (26) for receiving respective nozzles (5) of syringe barrels (3);

and a sterile-gas supply tube (28) connected to the interior of the housing (21) for supplying the sterile gas;

characterized by

a pair of solution tubes (27), each arranged and associated within each sterile-gas ejecting nozzle (22) each having a longitudinal axes parallel to the longitudinal axes of the gas ejecting nozzle, each of which has one end thereof connected to the adapter (26) and the other end thereof protrudes a predetermined distance outwardly from the respective sterile-gas ejecting nozzle (22) through an interior of the housing (21), so that the solutions fed from the syringe barrels (3) are conveyed through the solution tubes (27) and ejected therefrom, respectively".

Claim 1 of the first auxiliary request, as filed during the oral proceedings on 15 October 2003, reads as follows:

"An applicator for applying a biocompatible adhesive containing human or animal protein as a principal ingredient to a surgical site of living body, comprising:

a spray head (20) for spraying two solutions, that is, a protein solution and a coagulation solution, fed from two syringe barrels, respectively, by an ejection of a sterile gas, said spray head including:

a housing (21) having a pair of adjacent sterile gas ejecting nozzles (22), longitudinal axes thereof being oriented in a predetermined same direction for guiding and ejecting the sterile gas in that direction;

a pair of adapters (26) for receiving respective nozzles (5) of syringe barrels (3);

and a sterile-gas supply tube (28) connected to the interior of the housing (21) for supplying the sterile gas;

characterized by

a pair of solution tubes (27), each arranged and associated within each sterile-gas ejecting nozzle (22) each having a longitudinal axes parallel to the longitudinal axes of the gas ejecting nozzle, each of which has one end thereof connected to the adapter (26) and the other end thereof protrudes a predetermined distance outwardly from the respective sterile-gas ejecting nozzle (22) through an interior of the housing (21), so that the solutions fed from the syringe barrels (3) are conveyed through the solution tubes (27) and ejected therefrom, respectively".

V. The appellant (opponent) argued as follows:

Document E2 represented the closest state of the art. The features distinguishing the subject-matter of claim 1 from the disclosure of document E2 - namely a pair of solution tubes each being arranged within one of two gas ejecting nozzle and protruding from the respective nozzle - were known from document E1 and aimed at solving the same problem as the one underlying the patent in suit. It was true that the device described in document E1 was especially designed for use as atomizer, which is designed to dissipate an aerosol in the atmosphere. It could however very well also be used for applying a substance onto a surface. The purpose of the two known nozzles was to reduce air pressure, (see E1, column 3, lines 19 to 24). The purpose of positioning the solution tubes within the nozzle was to reduce the size of the particles of the spray. The device according to the invention was therefore an obvious combination of the embodiment of Figure 1 of document E2 with that of Figure 3 of document E1.

Claim 1 of the first auxiliary request contained subject-matter which extended beyond the content of the application as filed insofar as the feature "substantially parallel" was concerned, and lacked clarity.

VI. The respondent (patent proprietor) argued as follows:

Document E1 belonged to a technical field different from that of the invention. The invention was directed to the separate application of two substances to a

surface of a surgical site, whereas the device according to document E1 concerned the dissipation of an aerosol in the atmosphere. In particular, document E1 was concerned with delivering dry fog, which consisted of ultra-fine mist generated by the jets of liquid discharged from the two nozzles and impinging upon each other. The small bubbles of the dry fog did not stick when hitting a surface, but rebounded leaving the surface dry. Document E1 did not know the problem of the invention of avoiding clogging of the delivery tubes due to the hardening of the solutions right after the ejection, around the exit openings.

The device according to document E2 was not suitable for delivering a good mixture of the components and it was also prone to clogging. There was no motivation for combining the teaching of documents E2 and E1 in the way of the invention.

The additional feature of the first auxiliary request - namely that the two nozzles were oriented in the same direction - was supported by the Figures 4 and 6 of the patent in suit and by column 3, lines 19, 20 and 35 of the description.

Reasons for the Decision

1. The appeal is admissible.

2. *Main request*

The Board concurs with the parties that document E2 constitutes the closest state of the art. It discloses

an applicator for applying a biocompatible adhesive containing human or animal protein as a principal ingredient to a surgical site of a living body (see page 1), comprising a spray head (housing 27 and catheter 31, see page 4, line 3) for spraying two solutions, that is, a protein solution and a coagulation solution (fibrinogen, thrombin, see page 4, from line 20), fed from two syringe barrels (1, 2), respectively, by an ejection sterile-gas, said spray head including a housing (27) having a sterile gas ejecting channel (30), a pair of adapters for receiving respective nozzles of syringe barrels; and a sterile-gas supply tube (30) connected to the interior of the housing for supplying the sterile gas; whereby a pair of solution tubes (28, 29, Figure 3) have a longitudinal axis parallel to the longitudinal axis of the gas channel (30), each of which has one end thereof connected to the adapter so that the solutions fed from the syringe barrels are conveyed through the solution tubes and ejected therefrom, respectively.

The subject-matter of claim 1 differs therefrom by the features that the housing (21) has a pair of adjacent sterile gas ejecting nozzles (22), the longitudinal axes thereof being oriented in a predetermined direction for guiding and ejecting the sterile gas in that direction, that each solution tube (27) is arranged and associated within each sterile-gas ejecting nozzle (22) and has a distal end which protrudes a predetermined distance outwardly from the respective sterile-gas ejecting nozzle.

The arrangement of the device according to document E2 suffers from the drawback that the two solution tubes

are placed close to the single gas ejecting nozzle and close to each other. Such disposition has the obvious disadvantage that - due to the asymmetry of the air current with respect to the exit opening of the tubes - mixed solution residues may remain stuck to the tube ends and react there thus causing clogging of their mouths. Furthermore, the asymmetry of the gas exiting nozzle with respect to the solution tubes does not guarantee the formation of uniform spray particles and consequently of a uniform mixing of the two components.

Looking for a solution to avoid the above problems, the person skilled in the field would consider document E1 which is also concerned with producing a spray of a medical solution, see column 1, line 12. Such document provides a solution for the above problems which is exactly the same as that provided by the invention, namely a pair of adjacent gas ejecting nozzles with each solution tube arranged within the nozzle, see Figure 3.

Also the additional feature of claim 1 that the solution tubes protrude outwardly from the nozzle, is known from the same embodiment of Figure 3. As can be seen by comparing the passage of the patent in suit, column 4, point 21, with document E1, column 12, from line 1, and Figures 8a and 8b, this last feature also avoids deposits and subsequent clogging of the mouths of the solution tubes.

It is true that the device according to document E1 is especially designed to function as an atomizer and that the longitudinal axes of the nozzles are arranged to

converge at a point (A). Claim 1 in its granted version does, however, not exclude such an arrangement.

Accordingly the subject-matter of claim 1 of the main request does not involve an inventive step.

3. *The first auxiliary request*

3.1 When compared to the main request, claim 1 of the first auxiliary request contains the additional feature that the longitudinal axes of the nozzles are parallel to each other. This feature is originally disclosed at column 3, lines 18 and 35, of EP-A-634 140 and it does also not represent an extension of the protection conferred by the claims.

3.2 Starting again from document E2 as the closest prior art, a further problem exists which is separate from the clogging problem discussed under point 2 above with respect to claim 1 of the main request. This problem arises from the fact that the two components of the adhesive have a very short reaction time after having been mixed and, when mixed too early, may have reacted with each other, and therefore be inactive, before hitting the targeted surgical site. Consequently, the said separate problem consists in avoiding such premature reaction.

This problem is solved by the additional feature identified under point 3.1 above. The parallel orientation of the longitudinal axes of the nozzles and the possibility of an adequate choice of the distance of the two individual nozzles warrants that the droplets of the two components of the adhesive are kept

separate on their way to and only mix and react on arrival at their target site.

- 3.3 In contrast thereto, document E1 aims at the production of an ultrafine mist and therefore directs the streams against each other to reduce the droplet size by mutual collision. In view of this contrary purpose, document E1 cannot be helpful to solve this separate problem.

The devices disclosed in documents E3 and E4 also provide for a mixing of the two streams of fluids immediately before the common nozzle, since in both cases there is only one common gas ejecting nozzle (see Figure 4 and Figure 1, respectively).

- 3.4 Consequently, the subject-matter of claim 1 of the first auxiliary request involves an inventive step and is allowable.

4. The first auxiliary request being allowable, there is no need to examine the second auxiliary request.

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 maintain the patent in amended form on the basis of the following documents:
 - claim 1 according to the auxiliary request 1 submitted at the oral proceedings;
 - claims 2 to 7, description and figures as granted.

The Registrar:

The Chairman:

V. Commare

W. D. Weiß