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D E C I S I O N
of 15 July 1999

Case Number: T 0124/96 - 3.2.2

Application Number: 91200021.3

Publication Number: 0437291

IPC: A61M 25/00

Language of the proceedings: EN

Title of invention:
Method for manufacturing a soft tip catheter

Patentee:
Cordis Europa N.V.

Opponent:
Guiot, Jean Paul

Headword:
-

Relevant legal provisions:
EPC Art. 56

Keyword:
"Inventive step (no)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0124/96 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 15 July 1999

Appellant: (Opponent)
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Respondent: (Proprietor of the patent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 11 December 1995 rejecting the opposition filed against European patent No. 0 437 291 pursuant to Article 102(2) EPC.**

Composition of the Board:

Chairman: W. D. Weiß
Members: M. Bidet
J.-C. De Preter

Summary of Facts and Submissions

I. The respondent is proprietor of European patent No. 0 437 291.

II. The patent was opposed by the appellant on the ground of lack of inventive step (Article 100(a) EPC). The opposition division rejected the opposition in a decision dispatched on 11 December 1995 having regard to the following documents:

D2: JP-1-18 747 B2 with English translation (and)

D4: US-A-4 551 292

and two others documents D1 and D3.

The two independent Claims 1 and 3 read as follows

"1. Method for manufacturing a catheter, comprising manufacturing a tube-like basic body (2) with a central channel, arranging a connecting member (5) on a connecting end thereof, forming a tube-like end portion (3) with material properties different from said basic body (2) on the other end of said basic body (2), by injection moulding, said end portion (3) during forming being injected in liquid form directly onto said basic body (2), characterised in that during injection in liquid form of the end portion (3) onto the basic body (2), a flow of heated, liquid plastic for forming the end portion (3) is supplied in a position adjacent the connecting end surface and against this surface."

"3. Device for manufacturing a catheter, comprising an

injection moulding device with a die (9,10) which has a mould cavity (12) defining an end portion of the catheter, a feed channel (15) leading to said mould cavity (12) for feeding heated, molten plastic under pressure to said mould cavity (12), wherein connected to said mould cavity is a recess (14) for enclosed arranging of an end of a basic body (2) for a catheter and wherein a mandrel (13) extends from the end of said mould cavity (12) lying opposite said recess (14), through said mould cavity into said recess, which mandrel defines an axial channel of said end portion, characterised in that at least a portion (16) of the feed channel debouches close to the recess (14) such that liquid heated plastic flowing out if this feed channel (15) is directed against the end surface (17) of a catheter basic body (2) arranged in said recess (14)."

III. On 3 February 1996, the appellant (opponent) filed an appeal and paid the appeal fee on the same day. The statement of grounds was filed on 10 April 1996.

The response of the respondent (proprietor) dated 19 August 1996, was answered by the appellant with letter of 2 January 1997.

IV. Although not explicitly stated, the Board admitted that the appellant requested to set aside the decision under appeal and to revoke the European patent in its entirety.

The respondent (proprietor of the patent) requested that the appeal be dismissed and the patent be maintained in unamended form. In the case, however,

amendment or revocation of the patent were envisaged, oral proceedings were requested.

V. The appellant presented the following arguments:

The subject-matter of Claim 1 did not involve an inventive step on the basis of the documents D2 and D4.

Document D2 disclosed the features of the catheter specified in Claim 1 and further showed in Figure 3 how to join by injection moulding the connecting member to the one end of basic body. The skilled person would apply the injecting moulding process disclosed in document D2 to the method of joining the tube-like end portion to the connecting end surface of the basic body disclosed in document D4. The hand drawings a to d annexed to the grounds of appeal, demonstrated the sequence of routine steps the skilled person would have to perform when following this obvious path. More particularly, the skilled person would recognize that document D4, in Figures 4A and 4B and lines 12 to 15 disclosed the process of injection moulding to obtain the junction and that obviously the mould for manufacturing the catheter should have an outer cylindrical inner surface fitting on the main body of the catheter. To the question of how to inject the material the answer was obviously given in Figure 3 of document D2 in that the skilled person will inject the material exactly onto the middle portion of the free end surface of the catheter's main body.

VI. The respondent presented the following arguments:

Claim 1 did not contravene the requirements of

Article 100(a) in view of Article 56 EPC. The arguments of the appellant did not answer the question why the skilled person would combine the teaching of the documents D2 and D4. The main difference of the mould according to document D2 was that the obtained outer diameter was necessarily larger than that of the basic body which was contrary to the fact that the diameter at the junction should be the same for the basic body and the end portion.

Reasons for the Decision

1. The appeal is admissible

2. The Board is satisfied that none of the cited documents discloses a method (and a device) for manufacturing a catheter comprising in combination all the features specified in Claim 1 (and 3).

   Since this has not been disputed by the parties, there is no need for further detailed substantiation. Consequently, the subject-matter set forth in Claim 1 is novel within the meaning of Article 54 EPC.

3. A generally encountered problem with the manufacturing of a soft catheter is to join a soft tip end (tube-like end portion) to the distal end of basic-body of the catheter, so that the risk of internal injury during use is to a large degree excluded.

4. Of the cited prior art, only document D4 relates to a junction of the type mentioned above in which a soft deformable end portion is formed on the connecting end

surface of the basic body. This prior art, however, discloses a method in which the tapered distal end of the basic body of a high durometer polypropylene is inserted into a suitable mould to which a soft plastic of a lower durometer is added (see column 5, lines 3 to 37). The resulting tubular end of soft plastics is finally deformed under heat into the desired ground non-traumatic shape.

The problem to be solved by the patent in suit is to provide a more efficient manufacturing method.

5. The solution according to Claim 1 of the patent in suit is based on the principle that moulding is carried out by injection moulding of a heated liquid plastic, a flow of which being supplied adjacent the connecting end surface of the basic body and against this surface; consequently this surface is well heated and its material is fused with the soft material of the end portion. A good junction of the two materials is made at the connecting end surfaces and the final shape of the end portion is obtained without additional forming step.

6. Document D2 discloses a catheter which is provided at its distal end with a sealing matter B not having a tube-like cross-section, since it should perform a sealing function (see page 2 of the translation, the part: "Prior Art and Problems", lines 1 to 7; page 4, and part: "(III) Detail description of the invention", lines 1 to 7). Therefore, this document does not relate to the above problem of joining a tube-like soft tip end at the distal end of a harder basic body of the catheter and is unable to suggest, for this reason, any

solution to the skilled person.

7. The method to join the connecting member to the basic body at its proximal end disclosed in document D2 can also not guide the person to the subject-matter of the patent in suit.

The connecting member usually consists of a plastic material which is more rigid than the material of the basic body and is joint to the basic body by enclosing its end portion. Consequently, the juncture of these two elements is achieved by a combination of mechanical shrink fit and welding. In contrast thereto, the distal tip according to the patent in suit consists of a material which is softer than the material of the basic body and its diameter must fit the diameter of the basic body at its juncture therewith.

This essential difference would prevent the skilled person searching in the state of the art for a solution to the basic problem of the patent in suit from even considering document D2. If he nevertheless did so, he would not yet arrive at the subject-matter of the patent in suit but would have to considerably modify the mould disclosed in document D2 and direct the feed channel to the head face of the basic body.

8. Following the considerations in the paragraphs 3 to 6 above, the documents D2 and D4 cannot challenge the fact that the subject-matter of the independent Claims 1 and 3 involves an inventive step as required by Articles 52(1) and 56 EPC.

Order

For these reasons it is decided that:

1. The appeal is dismissed

The Registrar: The Chairman:

S. Fabiani W. D. Weiß