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**Datasheet for the decision
of 27 June 2013**

Case Number: T 2474/10 - 3.3.10

Application Number: 01310810.5

Publication Number: 1216717

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A61L 27/44, A61L 27/22,
A61L 27/16, A61L 27/18,
A61F 2/02

Language of the proceedings: EN

Title of invention:
Method of making a reinforced tissue implant

Patent Proprietor:
ETHICON, INC.

Opponent:
Tyco Healthcare Group, LP

Headword:
Method of making reinforced tissue implant/ETHICON

Relevant legal provisions:
EPC Art. 56
EPC R. 111(2)

Keyword:
"Substantial procedural violation (no) - decision adequately reasoned"
"Inventive step (no) - heat pressing of a fabric to render it flat belongs to the common general knowledge of any technically skilled person"

Decisions cited:
T 0020/81, T 0278/00, T 1366/05

Catchword:
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Case Number: T 2474/10 - 3.3.10

D E C I S I O N
of the Technical Board of Appeal 3.3.10
of 27 June 2013

Appellant: ETHICON, INC.
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Respondent: Tyco Healthcare Group, LP
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 12 October 2010
revoking European patent No. 1216717 pursuant
to Article 101(3)(b) EPC.

Composition of the Board:

Chairman: P. Gryczka
Members: J. Mercey
C. Schmidt

Summary of Facts and Submissions

- I. The Appellant (Proprietor of the Patent) lodged an appeal against the decision of the Opposition Division revoking European patent No. 1 216 717.
- II. Notice of Opposition had been filed by the Respondent (Opponent) requesting revocation of the patent in its entirety on the grounds of *inter alia* lack of inventive step (Article 100(a) EPC), the following document being cited as closest prior art:
- (2) EP-A-274 898.
- III. The decision under appeal was based on the patent as amended according to the then pending main request, claim 1 of this request reading as follows:
- "A method for making a reinforced foam, biocompatible tissue implant, comprising:
- providing a solution of a foam-forming polymeric material in a suitable solvent;
- providing a mesh reinforcing material;
- placing the reinforcing material in a mold in a desired position and at a desired orientation;
- adding the solution to the mold in a controlled manner;
- and
- lyophilizing the solution to obtain a tissue implant having a mesh-reinforced foam component, wherein the reinforcing material is pressed flat using a heated press prior to its placement in the mold."

- IV. The Opposition Division held that the subject-matter of the claims according to this request did not involve an inventive step in view of document (2).
- V. The Appellant submitted that a substantial procedural violation had occurred, since the Opposition Division's decision was inadequately reasoned with respect to inventive step, such that the case should be remitted to the first instance and the appeal fee be refunded. It further argued that insofar as any reasoning could be deduced from the decision, it was incorrect, no cited prior art disclosing pressing flat a mesh reinforcing material using a heated press in the field of tissue implants, let alone that such a step would improve the structural integrity of the resulting tissue implants *vis-à-vis* those of document (2), which were not suitable for *in vivo* use. The Appellant submitted that the subject-matter of claim 1 of the main request did not extend beyond the content of the application as filed (Article 123(2) EPC), the feature "the reinforcing material is pressed flat using a heated press prior to its placement in the mold" which was added during the opposition proceedings finding support at page 14, lines 4 to 5 thereof.
- VI. The Respondent considered that the Opposition Division's decision was fully reasoned and agreed with the argumentation and conclusions therein. The Examples of the patent in suit did not provide any comparison with the implants disclosed in document (2), there being no comparison between mesh-reinforced implants manufactured *via* a heat-pressing step with mesh-reinforced implants manufactured without a heat-pressing step. Indeed it was apparent from paragraph

[0089] of the patent in suit that it was the mesh density and not any "ironing" step which had any impact on the structural integrity of the implants. The use of a heat press to flatten a material such as a textile belonged to the common general knowledge of the skilled person. The Respondent argued that claim 1 of the main request contained subject-matter extending beyond the content of the application as filed, since the feature "the reinforcing material is pressed flat using a heated press prior to its placement in the mold" was an unallowable generalisation.

VII. The Appellant requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request before the Opposition Division.

The Respondent requested that the appeal be dismissed.

VIII. At the end of the oral proceedings, held on 27 June 2013, the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible.
2. *Alleged substantial procedural violation*
 - 2.1 The Appellant alleges that the Opposition Division's decision was inadequately reasoned with respect to inventive step which amounted to a substantial procedural violation, such that the case should be remitted to the first instance and the appeal fee be refunded.

2.2 According to established jurisprudence of the boards of appeal, to satisfy the requirement of Rule 111(2) EPC, a decision should contain, in logical sequence, those arguments which support it. The conclusions drawn by the deciding body from the facts and evidence must be made clear. Therefore, all the facts, evidence and arguments which are essential to the decision must be discussed in detail in the decision including all the decisive considerations in respect of the factual and legal aspects of the case. The purpose of the requirement to reason the decision is to enable the parties and, in case of an appeal, also the board of appeal to examine whether the decision could be considered to be justified or not (see T 278/00, OJ EPO 2003, 546 and T 1366/05, not published in OJ EPO).

2.3 In the present case, the Opposition Division decided that the subject-matter of the main request did not involve an inventive step, with the consequence that this request was rejected. In arriving at this conclusion (see point 23 of the decision), the Division employed the problem-solution approach. In so doing, it identified the closest prior art, namely document (2), and on determining that the technical problem as formulated by the Appellant was not solved, the alleged advantages of improved structural integrity and pull-out strength having not been substantiated, reformulated the problem as providing an alternative to the method of document (2). It then argued that the claimed solution was obvious, for the reasons that simply adding an arbitrary additional process step, which did not appear to result in any technical

benefits, but rather made things more complicated, did not fulfil the criteria for inventive step.

2.4 In the Board's judgement, these reasons contain a logical chain of facts and reasoning, each step of the problem-solution approach having been carried out in a sufficiently satisfactory manner to meet at least the minimum requirements for a reasoned decision.

2.5 The Appellant argued that although the first three steps of the problem-solution approach had indeed been applied by the Opposition Decision, on finding that the invention was not advantageous *vis-à-vis* the closest prior art, it had then simply declared the invention to be obvious without providing any reasoning herefor. However, it was not necessary for an invention to show any technical benefits in order for it to fulfil the requirements of inventive step. Even in the case where the technical problem comprised the provision of an alternative, it was still necessary that the decision indicated where the missing step, in this case heat pressing, was disclosed in the prior art, and why the skilled person would have incorporated such a step into the process of the closest prior art, namely in the production of a tissue implant.

This argumentation is, however, in contradiction with the facts. The Opposition Division, on determining that no improvement resulting from the heat-pressing could be ascertained, did not simply then conclude that the claimed subject-matter was as a result not inventive. On the contrary, it reformulated the problem as the provision of an alternative to the process of document (2) and then gave reasons as to why the step of heat-

pressing did not involve inventive skills (see point 2.3 above). By describing the heat pressing step as "arbitrary", the Opposition Division implied that such a step was trivial and belonged to the common general knowledge of the skilled person, rendering the specific citation of a document superfluous.

2.6 The Board thus concludes that the decision under appeal complies with the requirements of Rule 111(2) EPC and that therefore no fundamental deficiency is apparent in the first-instance proceedings in this respect.

3. *Amendments (Article 123(2) EPC)*

The Respondent submitted that claim 1 of the main request contained subject-matter extending beyond the content of the application as filed. In view of the negative conclusion in respect of inventive step as set out in point 4 below, a decision of the Board on this issue is unnecessary.

4. *Inventive step (Article 56 EPC)*

4.1 The patent in suit is directed to a method for making a reinforced foam, biocompatible tissue implant.

4.1.1 A similar method already belongs to the state of the art, namely to the disclosure of document (2). More particularly, this document discloses a process for the production of an implant of an open-cell, foam-like plastic material based on resorbable polyesters and their copolymers, one or more reinforcing elements of a textile nature formed from resorbable plastic being embedded in an open-cell plastic matrix, by dissolving

poly-p-dioxanone, polylactides or polyglycolides in a solvent and freezing the textile reinforcing element in a mould together with the plastic solution and then removing the solvent by freeze drying (see claims 1 and 6). The reinforcing element may have a net-like flat structure in order to improve the mechanical strength in all directions of the corresponding surfaces (see page 3, lines 11 to 13).

4.1.2 Thus, the Board considers, in agreement with the Appellant, the Respondent and the Opposition Division, that in the present case the method of document (2) represents the closest state of the art and, hence, takes it as the starting point when assessing inventive step.

4.2 In view of this state of the art, the Appellant defined the problem underlying the patent in suit as the provision of a method for preparing a tissue implant with improved structural integrity such that it could be used *in vivo*.

4.3 As the solution to this problem, the patent in suit proposes the method according to claim 1, characterised in that the reinforcing material is pressed flat using a heated press prior to its placement in the mould.

4.4 The Appellant and the Respondent were divided as to whether or not the evidence presented convincingly showed the successful solution of the problem defined in point 4.2 above *vis-à-vis* the closest prior art. The Appellant relied mainly on paragraph [0008] of the specification of the patent in suit wherein the implant material of the prior art document (2) was described as

potentially useful, but was believed to lack sufficient strength and structural integrity to be effectively used as a tissue repair implant. In contrast, it could be seen from the Examples of the patent in suit that the implants of the present invention, wherein the reinforcing mesh materials had been rendered flat by ironing (see Example 1) showed good results in both the suture pull-out and burst strength tests (Example 2), in the T-peel test (Example 5), and could be effectively used *in vivo* (Example 3).

However, document (2) itself does not suggest that the implants proposed therein do not have sufficient structural integrity to be used *in vivo*. On the contrary, it describes the problem underlying the invention therein as providing implants which, despite the adequately open-cell structure to permit the growing in of cells and blood vessels, namely which are suitable for *in vivo* use, have an adequate strength and in particular tensile strength (see page 2, lines 51 to 53). It then indicates that the mechanical strength can be increased by using textile reinforcing elements of resorbable plastic such as fibres, yarns, braids and knitted fabrics, net-like flat structures improving the mechanical strength in all directions of the corresponding surfaces (see page 3, line 8 to 13). Hence, the Appellant's argumentation that the implants of document (2) did not have sufficient structural integrity to be used *in vivo* is not supported by the teaching of document (2).

Furthermore, the Appellant has not provided any comparative tests directly comparing an implant comprising a mesh reinforcement rendered flat *via* a

heat-pressing step with an implant differing only in that the mesh reinforcement was rendered flat by another method. In the absence of such comparative data, the Board holds that it is not credible that the implants according to the invention exhibit improved structural integrity *vis-à-vis* those of document (2), let alone whether any improvement has its origin in the distinguishing feature of the invention, namely the heat pressing step. The Appellant has not provided any arguments as to why a reinforcement material rendered flat by ironing should be stronger than a reinforcement material rendered by flat by any other method, and none are apparent to the Board.

4.5 According to the jurisprudence of the Boards of Appeal, alleged but unsupported advantages cannot be taken into consideration in respect of the determination of the problem underlying the invention (see e.g. decision T 20/81, OJ EPO 1982, 217, point 3, last paragraph of the reasons). Since in the present case the alleged advantage, i.e. improved structural integrity, lacks the required experimental support, the technical problem as defined in point 4.2 above needs reformulation in a less ambitious way.

4.6 Consequently, the objective problem underlying the patent in suit in the light of the teaching of document (2) is merely the provision of a method for preparing a tissue implant with sufficient structural integrity to be used *in vivo* (see paragraph [0009] of the specification of the patent in suit).

4.7 Finally, it remains to be decided whether or not the proposed solution to the problem underlying the patent in suit is obvious in view of the state of the art.

4.7.1 The skilled person, seeking to prepare a tissue implant with sufficient structural integrity to be used *in vivo* knows from document (2) that in order to achieve good mechanical strength in all directions, the textile reinforcing element should have a net-like flat structure (see page 3, lines 11 to 13). The skilled person would thus introduce a step into the process of document (2) which rendered the reinforcement material flat, if this were not already the case, before it was placed in the mould. It is common general knowledge that using a heated press is a standard and widespread method for pressing fabrics flat. Thus, the skilled person would incorporate such a heat pressing step, otherwise known as ironing (see Example 1, page 8, line 39 of the specification of the patent in suit), into the process of document (2) without having to exercise any inventive skill. For these reasons, the subject-matter of claim 1 is obvious.

4.8 For the following reasons the Board cannot accept the Appellant's arguments designed for supporting inventive step.

4.8.1 The Appellant argued that the method of heat pressing of materials did not necessarily belong to the common general knowledge of the person skilled in the art of tissue implants, none of the cited art in the field of tissue implants referring to such a method. Ironing might indeed be a well-known method for flattening clothes for aesthetic or hygienic reasons, but not for

rendering a material flat which was intended to be inserted into a tissue implant.

However, the Board holds that it belongs to the common general knowledge of **any** technically skilled person that textiles may be flattened by ironing, such a step being so trivial that it was not even worthy of mention in the prior art. It is also irrelevant that the material to be flattened is to be subsequently used in making a foam tissue implant, since the step of heat pressing and that of adding a solution of a foam-forming polymeric material to the reinforcement in a mould do not interact and are thereby merely an aggregation of steps. Thus the skilled person can consider the aspect of how to render the textile reinforcement material of document (2) flat in isolation. Hence, this argument of the Appellant does not convince the Board.

4.8.2 The Appellant also argued that the adjective "flat" as used in the "net-like flat structures" of document (2) did not necessarily mean that the net was flat, but merely two-dimensional.

However, since the adjective "flat" is also used to describe the reinforcing material of present claim 1, the tissue implants according to the present invention cannot be distinguished from the net-like flat structures of document (2) by virtue of this feature, such that the Board cannot follow this argument of the Appellant.

4.9 As a result the Appellant's main request is not allowable for lack of inventive step pursuant to Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

C. Rodríguez Rodríguez

P. Gryczka