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D E C I S I O N
of 1 June 2005

Case Number: T 0621/01 - 3.2.2

Application Number: 92900780.5

Publication Number: 0556313

IPC: A61B 17/06

Language of the proceedings: EN

Title of invention:
Blunt tip surgical needle

Patentee:
McIntosh, Charles L.

Opponent:
ETHICON LIMITED

Headword:
-

Relevant legal provisions:
EPC Art. 52(1), 54

Keyword:
"Public prior use (yes), novelty (no)"

Decisions cited:
T 0328/87

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0621/01 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 1 June 2005

Appellant: (Proprietor of the patent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 19 February 2001 revoking European patent No. 0556313 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: T. K. H. Kriner
Members: S. S. Chowdhury
E. J. Dufrasne

Summary of Facts and Submissions

I. The appellant (patent proprietor) lodged an appeal against the decision of the opposition division to revoke the European patent No. 0 556 313, which claims a priority date of 7 November 1990. The decision was dispatched on 19 February 2001.

The notice of appeal and the fee for the appeal were received on 17 April 2001. The statement setting out the grounds of appeal was received on 18 June 2001.

An opposition was filed against the whole patent and based on Article 100(a) and 100(b) EPC. The opposition division decided that the opposition was admissible and that the subject-matter of claim 1 of the main and auxiliary requests then on file lacked novelty, and revoked the patent, accordingly.

The opposition was based on various alleged public disclosures before the priority date of the patent, including prior art allegedly made available to the public by written publication, oral presentation, and prior use. The different public disclosures were subsumed under the term "prior use" during the opposition procedure and referred to as prior uses P1 to P6. The prior use P6 was held in the decision under appeal to be fatal to the patent in suit.

II. Of the documents submitted in support of the allegations of prior use P6, the following documents are relied upon in this decision:

Annex 8: Product Release Memoranda of needle codes W9992 to W9999, dated 8-9-89

Annex 9: Ethiguard brochure for Ethiguard sutures, dated 1989

Annex 10: Copy of invoice of Ethicon dated 3 November 1989

Annex 11: Manufacturing specifications for needles W9992 to W9999

Annex 12: Copy of invoice of Ethicon dated 8 November 1989

Statutory Declaration of George M. Blair dated 28 January 1999, including Exhibits GB1 to GB4

Statutory Declaration of William Mackinnon dated 27 January 1999

Cyanamid Report dated August 1993

Exhibits AJC-1 and AJC2: enlargements of GB3, submitted with the grounds of appeal.

III. Oral proceedings (Article 116 EPC) took place on 1 June 2005, at the end of which the following requests were made:

The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted.

The respondent requested that the appeal be dismissed.

IV. Claim 1 of the granted patent reads as follows:

" A surgical needle (10) for use in suturing non-cutaneous soft tissues of the body, comprising: a needle shaft (11); and a needle tip (12), said needle shaft (11) and needle tip (12) integrally formed of a rigid material suitable for use inside the body and containing no fluid passages therethrough, said needle tip (12) having a continuously smooth outer surface lacking any sharp cutting edges, and a body portion (14) integrally formed with and extending from said needle shaft (11), said body portion (14) being tapered along the length thereof, said needle tip (12) further having a blunt head (16), wherein said blunt head (16) has a part spherical shape and a vertex which forms a portion of said part spherical shape, characterised in that said blunt head (16) has a diameter of curvature which is in the range of 25% to 62% of the diameter of said needle shaft and said diameter of curvature is at least about 0.15 mm (0.006"), whereby said blunt head is adapted to penetrate muscle and fascia, muscle alone, adipose, pericostal tissue and other non-cutaneous soft tissues of the body while preventing skin penetration of the gloved hand of an operator wearing a surgical glove."

V. The parties submitted the following arguments:

(a) Appellant

Admissibility of the opposition was not established having regard to Rule 55(c) EPC as interpreted by the

decision T 328/87 since the evidence submitted was not sufficient for the patentee to understand the opponent's case.

Annex 8 described needles that were to be released at a future date but there was no evidence that the needles were actually released to the public before the priority date, especially since the Product Release Memoranda said that the samples will be for home and direct export sales force only.

Surgicon was an extension of Ethicon given the relationship between a manufacturer of an article and a wholesaler of the article. There was no evidence of an onward sale to an end user and there was also considerable disincentive for Surgicon itself to open a sterile, opaque, and multiply packaged needle, thereby rendering its content valueless. Annex 10 did not prove a public disclosure, accordingly.

Although Annex 11 had drawings, lists of manufacturing dies, dimensions, etc, it gave no information about the shape of the needle tips, this shape was the mere consequence of the manufacturing process used and any shape would be acceptable provided that those parameters that were specified were achieved. The drawings of Annex 11 had been revised, as indicated by the addition of the letter "A" but the nature of the revision was not clear.

The point profile charts RTG130-1 and RTG145-1 were "acetates" for checking the needle taper and disclosed an ideal shape but not the actual shape of the tip. The photographs in Exhibit GB3 were meaningless since the

attitude at which the needles were held determined the shape shown in the photographs. The shape of the tip could not be inferred from the photographs, in particular whether the end was faceted or not. The Cyanamid report was evidence that the Ethicon needle tips were faceted, and the enlargements of these photographs (Exhibits AJC-1 and AJC2) also showed faceted ends.

Mackinnon used projection apparatus which would not yield accurate results owing to the use of multiple light sources and shadow effects. This matter could have been clarified if the Ethicon needles were produced, and it was not clear why they were withheld from the procedure.

The term "part-spherical" meant that the tip was spherical to the greatest extent possible given that the needle shaft was tapered, i.e. just less than a hemisphere.

(b) Respondent

A notice of opposition must have an indication of facts, evidence and arguments such that it was understandable on an objective basis. The items of evidence provided in the notice of opposition supported each other and in its entirety the notice fulfilled the requirements of admissibility.

Surgicon was not owned or controlled by Ethicon and delivery of needles to it made them available to the public, regardless of whether or not there was a disincentive to open the packages.

The shape of the needles was indicated in Annex 11, the letter "A" was merely a change of code. The "acetates" showed the tips to be part-spherical and this was confirmed by the Blair and Mackinnon declarations.

Reasons for the Decision

1. The appeal is admissible.

2. *Admissibility of the opposition*

2.1 Rule 55(c) EPC requires a notice of appeal to contain an indication of the facts, evidence and arguments presented in the support of the grounds of opposition. If the opposition is based on an allegation of a public prior use the boards of appeal have required that the evidence be presented in such a way that it is readily apparent how the prior use occurred and the allegation can be understood by the EPO and the other parties without their needing to conduct their own investigations.

T 328/87 (OJ 1992, 701), for example, held that to be able to determine whether an invention has been made available to the public by prior use, the following circumstances have to be clarified:

(a) when the act of prior use occurred

(b) what was made available to the public through that use and

(c) the circumstances of the act of use, i.e. where, how and by whom the subject-matter was made public through that use.

2.2 In the present case, different allegations of public prior use were set out in the notice of opposition, which were referred to during the opposition procedure as P1 to P6, respectively, and of which only P6 was dealt with in the impugned decision. This allegation of prior use will be considered first in this decision, accordingly.

This allegation of prior use was supported in the notice of opposition by Annex 8 which is an internal document of Ethicon Ltd and which states that surgical needles with the codes W9992 to W9999 were to be released for sale on 11-9-89, and by Annex 10 which is a copy of an invoice dated 3 November 1989 which is meant provide evidence of the sale of the needles W9994 and W9996.

Therefore, the "when" component of the allegation of public prior use P6 was clarified in the notice of opposition.

2.3 The structure of the needles W9992 to W9999 is shown in Annex 11. It may be readily ascertained from the notice of opposition that the opponent wishes to prove from these documents that the needles have an integrally formed needle shaft and needle tip having a continuously smooth outer surface, and an integrally formed tapered body portion, as well as the fact that the needle tip has a blunt head with a part spherical vertex, the blunt head has a diameter of curvature

which is in about 50 to 60% of the diameter of said needle shaft, and the diameter of curvature is more than about 0.15 mm.

Therefore, the "what" component of the allegation of public prior use P6 was clarified in the notice of opposition.

2.4 Annex 10 provides evidence of the public sale of the needles W9994 and W9996. Annex 10 is an invoice of a normal sale to a third party (Surgicon Ltd), giving the designations of the objects sold, the date, the price, the quantities, etc., and there is no indication that the sale of the products was delayed or that there was any restriction regarding confidentiality. Therefore, the circumstances of the act of public prior use P6 were clarified in the notice of opposition.

2.5 Since the notice of opposition clarifies the "when", the "what", and the circumstances of the act of use, it contains an adequate indication of the facts, evidence and arguments presented in the support of the grounds of opposition based on the allegation of a public prior use P6. The opposition is, therefore, admissible.

3. *Novelty*

3.1 Since the needles W9994 and W9996 were provided to a distributor without any restriction regarding confidentiality, these needles were made available to the public shortly after 3 November 1989, which is about a year before the priority date.

Surgicon Ltd is a distributor of Ethicon products but is not owned or controlled by Ethicon Ltd. The distributor is a member of the public who was not constrained by any considerations of confidentiality, and was free to inspect the needles himself as soon as they were made available to him, or even to pass them on to a user.

The fact that the needles may have been elaborately packaged in a sterile and opaque container and that there would be no good reason for the distributor to open the container does not negate this fact. Whether or not he actually opened the packaging is not relevant, nor is the fact there may have been a disincentive to do so since this is a matter of economics and not of availability.

3.2 Annex 11 discloses the manufacturing specifications of the needles W9994 and W9996, both of whose shapes are defined by the point profile card RTB145-1. This shows the needles to have a 1.45 mm diameter shaft and a blunt taper point having a part spherical shape and a vertex which forms a portion of the part spherical shape, and the blunt head having a diameter of curvature of 0.7 mm, which is about 50% of the diameter of the needle shaft.

3.3 The above facts regarding the shape of the needle tips and the dimensions are corroborated by the declarations of Blair and Mackinnon. They state that the tips of the needles W9998, made according to the profile card RTB145-1, were generally hemispherical and had a diameter of approximately 50-60% of the needle shaft.

Mackinnon used an optical method of determining these facts.

To summarise Blair's declaration, GB1, GB2, and GB4 identify the needles (i.e. W9992 to W9999) sold to the public before the priority date of the patent in suit, and GB3 provides evidence of the shape and dimensions of the needles and their tips. It appears that all the needles of the W999x series had similar shapes.

The evidence of Blair and Mackinnon is entirely consistent with that of Annexes 8 to 11 and, taken together, the evidence is persuasive of the fact that the needles W9994 and W9996 had a construction according to claim 1 of the patent in suit and were made available to the public before its priority date.

3.4 Therefore, the needles designated by the codes W9994 and W9996 are prior art surgical needles falling within the scope of claim 1 of the patent in suit and anticipate its subject-matter.

4. *Appellant's arguments*

The appellant's arguments regarding the admissibility of the opposition (see point V above) did not convince the Board for the following reasons:

As set out in point 2 above, the criteria of Rule 55(c) EPC as given in T 328/87 have been met by prior use P6 and the evidence submitted was sufficient for the patentee to understand the opponent's case.

The appellant admits that Surgicon was not connected with Ethicon, but argues instead that in practice it was an extension of Ethicon. There is, however, no evidence to suggest that Surgicon was in any way inhibited in law or equity from selling, inspecting, or using the needles in any manner, and in so far as it could have inspected the needles itself or passed them on to other users means that they must be considered to have been made available to the public. It is not necessary to prove an actual instance of use of the needle by a member of the public.

The arguments that the point profile card RTB145-1 does not indicate the actual shape of the needles and that the photographs GB3 are unreliable in this respect are unconvincing given the evidence of Blair and Mackinnon who speak of the shape and size of the tips, and the fact that the photographs, from different angles, show generally hemispherical tips without any facets. The Cyanamid Report must be disregarded in this respect since it bears a date well past the priority date.

Regarding the accuracy of the Mackinnon measurements, the results are plausible given the general agreement with the dimensions of the needles and tips given in Annex 11. Moreover, even if the measurements were a little inaccurate, this would not remove the needles from the scope of claim 1 given the wide range of 25% to 62% of the claimed ratio. It is also noted that the patent in suit gives no details of how the needle dimensions were measured. Regarding the addition of the letter "A" in Annex 11 it is clear that this is merely a change of code rather than a technical change.

5. Since the surgical needle of claim 1 lacks novelty having regard to the public prior use P6 the remaining grounds of opposition need not be considered.

Order

For these reasons it is ordered that:

The appeal is dismissed.

The Registrar: The Chairman:

V. Commare T. K. H. Kriner