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**Datasheet for the decision
of 12 December 2006**

Case Number: T 0620/04 - 3.3.10

Application Number: 97301641.3

Publication Number: 0795335

IPC: A61L 2/20

Language of the proceedings: EN

Title of invention:

Medical instrument and method for lubrication and
sterilization thereof

Applicant:

JOHNSON & JOHNSON MEDICAL, INC.

Opponent:

-

Headword:

Lubrication and sterilization of medical instruments/JOHNSON &
JOHNSON

Relevant legal provisions:

EPC Art. 56, 123(2)

Keyword:

"Main and auxiliary request: inventive step (no) - obvious
solution - no evidence of technical prejudice"

Decisions cited:

T 0119/82

Catchword:

-



Case Number: T 0620/04 - 3.3.10

D E C I S I O N
of the Technical Board of Appeal 3.3.10
of 12 December 2006

Appellant: JOHNSON & JOHNSON MEDICAL, INC.
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 21 November 2003
refusing European application No. 97301641.3
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: P. Gryczka
Members: J. Mercey
D. S. Rogers

Summary of Facts and Submissions

- I. The appeal lodged on 20 January 2004 lies from the decision of the Examining Division posted on 21 November 2003 refusing European application No. 97301641.3 with the European publication No. 795 335.
- II. *Inter alia* the following documents were cited in the examination proceedings:
- (1) US-A-5 073 048,
 - (2) US-A-5 026 607 and
 - (5) EP-A-679 407.

In the decision under appeal, the Examining Division held that document (1), which disclosed an optical fibre bundle lubricated with boron nitride, and wherein the optical fibre bundle may be for use in an endoscope, represented the closest prior art. It considered exposure to an oxidising chemical atmosphere, for example with hydrogen peroxide, to be a common method of sterilisation of medical instruments, as acknowledged in the specification of the present application. For these reasons, the subject-matter according to the then pending main request lacked inventive step (Article 56 EPC). Since it was known, for example from document (2), that powdered graphite and PTFE were commonly used as lubricants in the field of medical devices, the subject-matter of the then pending auxiliary request also lacked inventive step.

III. At the oral proceedings before the Board held on 12 December 2006, the Appellant (Applicant) submitted a main and an auxiliary request superseding any previous request. Claim 1 of the main request read as follows:

"1. A method for lubricating and sterilizing a medical instrument comprising the steps of:
lubricating a surface on the medical instrument with a solid lubricant free from disulfide compounds;
repeatedly exposing the medical instrument, the surface thereon and the lubricant to an oxidizing chemical atmosphere;
protecting the medical instrument from corrosive acids by keeping the medical instrument surface free from disulfide compounds, wherein the medical instrument comprises a flexible endoscope having a fiber optic bundle comprising the surface and an elastomeric cover surrounding the fiber optic bundle."

Claim 1 of the auxiliary request differed from claim 1 of the main request exclusively in that it comprised the further step of selecting the lubricant from the group consisting of PTFE and powdered graphite.

IV. The Appellant argued that the amendments found support in the application as filed, and thus complied with the requirements of Article 123(2) EPC.

With regard to inventive step, the Appellant submitted that the present invention was based on the discovery that the degradation of elastomeric parts of medical instruments during sterilisation in an oxidising atmosphere resulted from the oxidation of certain lubricants such as molybdenum disulphide. In the light

of the disclosure of document (1), which represented the closest prior art, the problem to be solved by the present invention was the provision of an improved method for preparing a medical instrument having elastomeric parts for use. The solution according to claim 1 of the main request, comprising lubricating the instrument with a solid lubricant free from disulphide compounds and repeatedly exposing the instrument and the lubricant to an oxidising chemical atmosphere provided the advantages of sterilisation in an oxidising atmosphere while avoiding the problem of damage to the elastomeric parts. Document (1) did not teach sterilisation at all, let alone with an oxidising chemical atmosphere. Moreover, the skilled person, knowing that oxidative sterilisation of flexible endoscopes often led to degradation of the elastomeric parts, would have avoided the use of an oxidative sterilant. The subject-matter of claim 1 of the main request was thus inventive. Since document (1) did not teach the use of PTFE or powdered graphite as a lubricant, the method according to claim 1 of the auxiliary request also involved an inventive step.

- V. The Appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the main request or on the basis of the auxiliary request, both requests submitted at the oral proceedings on 12 December 2006.

- VI. At the end of the oral proceedings, the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible.

Main request

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

Claim 1 is based on original claims 1 and 7 with the deletion of the phrase "whereby the absence of disulfide compounds prevents the formation of corrosive acids in the hydrogen peroxide atmosphere to protect the medical instrument". Said phrase is merely an explanation of the mechanism by which the medical instrument is protected and not a technical feature of the invention. Thus its deletion does not alter the subject-matter claimed.

For these reasons, the Board concludes that amended claim 1 complies with the requirements of Article 123(2) EPC.

3. *Novelty*

The Board has no objections concerning the novelty of the claimed subject-matter. Since the Examining Division also did not raise objections in this respect, the Board sees no need to consider this matter in more detail.

4. *Inventive step*

For deciding whether or not a claimed invention meets this criterion, the Boards of Appeal consistently apply the problem and solution approach, which essentially involves identifying the closest prior art, determining in the light thereof the technical problem which the claimed invention addresses and successfully solves, and examining whether or not the claimed solution to this problem is obvious for the skilled person in view of the state of the art.

4.1 The Board considers, in agreement with the Examining Division and the Appellant, that the closest prior art is the disclosure of document (1).

4.2 Document (1) discloses an optical fibre bundle wherein the optical fibres are coated with boron nitride, said boron nitride serving as a lubricant (cf. column 4, lines 40 to 41 in connection with lines 32 to 40). It further discloses an optical fibre bundle of that invention for use in an endoscope having a flexible tube made of a polyurethane resin as an outer sheath and thus surrounding the optical fibre bundle (cf. column 6, lines 38 to 40). When boron nitride is used as a lubricant, it replaces the use of molybdenum disulphide (cf. column 4, lines 40 to 41). The fibre optic bundle is thus inevitably protected from corrosive acids by keeping it free from disulphide compounds, in the sense of the present application, as a direct result of lubrication with boron nitride, the specification of the present application not indicating that any further process steps need to be actively taken in order to protect the medical instrument, apart

from the avoidance of molybdenum disulphide (cf. page 11, lines 8 to 12).

- 4.3 In view of this state of the art, the problem underlying the present application consists in preparing this known medical instrument for use.
- 4.4 As the solution to this problem, the present application proposes a process as defined in claim 1 characterised in that the medical instrument, the surface thereon and the lubricant are repeatedly exposed to an oxidising chemical atmosphere.
- 4.5 Having regard to the test results summarised on page 9, lines 16 to 25 of the present application, the Board is satisfied that the technical problem as defined in point 4.3 above has been successfully solved by the claimed process.
- 4.6 Finally, it remains to be decided whether or not the proposed solution to the problem underlying the present application is obvious in view of the cited prior art.
- 4.7 That a medical instrument must be sterilised before use is common general knowledge, as acknowledged by the Appellant. Exposure to strong oxidising agents such as gaseous hydrogen peroxide is a well established method for sterilising delicate medical instruments such as flexible endoscopes, as acknowledged in the specification of the present application (cf. page 1, lines 24 to 26) and confirmed by the Appellant at the oral proceedings before the Board. The person skilled in the art would consider such a method to be particularly suitable for sterilising flexible

endoscopes, since it was known, for example, from document (5), which specifically discloses a process for using hydrogen peroxide vapour to sterilise articles such as medical instruments (cf. page 2, lines 3 to 4), that such a method has advantages for articles having long narrow lumens (cf. page 9, line 57 to page 10, line 2).

The Board concludes from the above that it was obvious for the person skilled in the art, seeking a method for preparing for use a medical instrument comprising a flexible endoscope, wherein the fibre optic bundle is lubricated with a solid lubricant free from disulphide compounds as taught by document (1), to expose the medical instrument and thus the surface thereon and the lubricant to an oxidising chemical atmosphere in order to sterilise it and, thereby, arrive without inventive ingenuity at the process in accordance with claim 1 of the main request.

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

4.8.1 The Appellant submitted that a technical prejudice existed against using an oxidative sterilant for sterilising a flexible endoscope because it had been observed that when such a sterilant was used on flexible endoscopes, many experienced rapid degradation of their elastomeric parts (cf. page 2, lines 5 to 7 of the specification of the present application).

According to the jurisprudence of the Boards of Appeal, appellants who wish to rely on a prejudice which might

have diverted the skilled person away from the alleged invention have the onus of demonstrating such a prejudice (T 119/82, OJ EPO 1984, 217, point 14 of the Reasons for the Decision).

In the present case, however, the Appellant did not provide any evidence which demonstrated the existence of such a prejudice, since none of the cited art suggested that the use of an oxidative chemical atmosphere would lead to degradation of elastomeric parts. On the contrary, according to document (1) the flexible polyurethane resin tube covering the optical fibres has an excellent resistance to chemical corrosion (cf. column 3, lines 7 to 9) and document (5) teaches the sterilisation of endoscopes with gaseous hydrogen peroxide (cf. page 6, lines 41 and 42). In these circumstances it cannot be concluded that the skilled person was diverted away from the claimed process by a technical prejudice.

4.8.2 The Appellant further submitted that the use of boron nitride as a lubricant led to an unexpected improvement when sterilising with an oxidising chemical atmosphere, namely no degradation of the elastomeric parts, compared to when molybdenum disulphide and an oxidising chemical atmosphere was used, referring in this respect to page 9, lines 16 to 25 of the specification of the present application.

However, a process whereby an endoscope lubricated with molybdenum disulphide is sterilised in an oxidising chemical atmosphere does not constitute the closest state of the art and hence this comparison is not

suitable for supporting the presence of an inventive step.

- 4.8.3 Finally, the Appellant submitted in writing that document (1) did not disclose protecting the endoscope from corrosive acids by keeping the endoscope free from disulphide compounds, since it did not exclude the possibility that the endoscope comprised nylon parts, disulphide lubricants being sometimes incorporated into nylon materials in medical instruments (cf. also page 2, lines 17 to 19, page 5, lines 20 to 24 and page 8, lines 14 to 17 of the specification of the present application).

However, there is no reference in document (1) to nylon, let alone to a disulphide-containing nylon, being present in the endoscope described therein, and the Appellant has not provided any evidence which would lead the Board to another conclusion. Thus the Board cannot follow the Appellant's argument, since it is not in line with the disclosure of document (1), the endoscope disclosed therein already being kept free from disulphide compounds in the sense of the present application.

- 4.9 Therefore, in the Board's judgement, the subject-matter of claim 1 of the main request represents an obvious solution to the problem underlying the patent application. As a result, the Appellant's main request is not allowable as the subject-matter of claim 1 lacks an inventive step pursuant to Article 56 EPC.

Auxiliary request

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

Claim 1 is based on original claims 1, 2 and 7, whereby the same deletion has been made as in claim 1 of the main request (cf. point 2 above). Thus, the Board concludes that amended claim 1 complies with the requirements of Article 123(2) EPC.

6. *Inventive step*

6.1 Claim 1 of the auxiliary request differs from claim 1 of the main request exclusively in that it comprises the further step of selecting the lubricant from PTFE and powdered graphite.

6.2 The fact that PTFE and powdered graphite were well-known to the skilled person as suitable lubricants for medical instruments at the priority date of the application in suit, was conceded by the Appellant at the oral proceedings before the Board, and is illustrated in the case of PTFE by, for example, document (2) (cf. column 1, lines 42 to 44 and column 2, lines 19 to 25). The Appellant did not put forward any unexpected technical effect attributable to the use of either of these solid lubricants as compared to the boron nitride of document (1), and none are apparent to the Board, such that the specification of these solid lubricants cannot contribute to the inventiveness of the claimed subject-matter.

6.3 The Appellant argued that the skilled person would not have replaced the boron nitride of document (1) by either PTFE or powdered graphite, since the boron nitride of document (1) served not only as a lubricant but also as a gelation retarding agent. Although it was well-known that PTFE and powdered graphite were lubricants, it was not known whether they also had gelation retarding properties, and thus the skilled person would not have contemplated replacing boron nitride by either of these compounds.

However, document (1) requires the boron nitride to have both lubricating and gelation retarding properties, because the optical fibres are subsequently coated with a gelling fluid in order to increase the mechanical strength of the optical fibres. In the present application, coating with a gelling fluid is not part of the solution to the problem to be solved, such that the presence or absence of this property of gelation retardation in the lubricant is irrelevant.

6.4 As a consequence, the considerations concerning inventive step given in point 4.7 with respect to the main request are not affected by the limitation to PTFE or powdered graphite as lubricant. Therefore the conclusion drawn in point 4.9 above with regard to the main request still applies to the auxiliary request, i.e. the subject-matter of claim 1 of that request is obvious and does not involve an inventive step.

6.5 In these circumstances, the Appellant's auxiliary request is also 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. Moser

P. Gryczka