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**Datasheet for the decision
of 25 July 2008**

Case Number: T 0984/03 - 3.3.10

Application Number: 98116437.9

Publication Number: 0937468

IPC: A61L 25/00

Language of the proceedings: EN

Title of invention:

Adhesive composition for surgical use application

Applicant:

BMG INCORPORATED

Opponent:

-

Headword:

Adhesive composition/BMG

Relevant legal provisions:

EPC Art. 56

Keyword:

"Inventive step (yes) - improvement credible - fair comparative test"

Decisions cited:

T 0197/86

Catchword:

-



Case Number: T 0984/03 - 3.3.10

D E C I S I O N
of the Technical Board of Appeal 3.3.10
of 25 July 2008

Appellant: BMG INCORPORATED
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Representative: Albrecht, Thomas
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 29 April 2003
refusing European application No. 98116437.9
pursuant to Article 97(1) EPC 1973.

Composition of the Board:

Chairman: R. Freimuth
Members: J.-C. Schmid
F. Blumer

Summary of Facts and Submissions

I. The appeal lodged on 26 June 2003 lies from the decision of the Examining Division dated 29 April 2003 refusing European patent application No. 98116437.9 (European publication No. 0 937 468).

II. The decision of the Examining Division was based on claims 1 and 2 as filed on 21 January 2003. The Examining Division found that the subject-matter claimed lacked an inventive step in view of documents:

- (1) WPI Abstract AN 1988-364119 of JP-B-7 116 409 and
- (1a) JP-B-7 116 409 in form of a partial English translation.

Claim 1, which is the sole independent claim of that request, read as follows:

"1. An adhesive composition for use in surgical applications comprising an α -cyanoacrylate adhesive composition and a biodegradable and bioabsorbable co-polymer of DL-lactic acid and an ϵ -caprolactone, wherein the molar ratio of DL-lactic acid and ϵ -caprolactone in the co-polymer is in the range from 70:30 to 30:70 and wherein the weight average molecular weight of the co-polymer is from 10,000 to 120,000."

III. The Examining Division considered that the claims fulfilled the formal requirement of Article 123(2) EPC, claim 1 being based on the combination of claims 1 to 3 of the application as filed and claim 2 on claim 4 of the application as filed, a further basis in the

application as filed for both claims being also found on page 3, first full paragraph.

As regards inventive step (Article 56 EPC), document (1) was considered to represent the most relevant state of the art. The subject-matter of claim 1 of the present application differed from the disclosure of document (1) in that the molar ratio of the two monomers in the copolymer was specified to be in the range from 70:30 to 30:70 and the weight average molecular weight was from 10,000 to 120,000 as opposed to 220,000 for the copolymer according to document (1).

The technical problem in view of document (1), was the provision of α -cyanoacrylate adhesive compositions having reduced cytotoxicity, a softness similar to a soft tissue of a living body organism and good biodegradation and bioabsorption after healing.

The solution was seen in the α -cyanoacrylate adhesive compositions according to claim 1 characterized by a copolymer of DL-lactic acid and ϵ -caprolactone with a molar ratio in the range from 70:30 to 30:70 and a weight average molecular weight from 10,000 to 120,000.

The only technical effect which could be used as an indication for an inventive step of the subject-matter of claims 1 and 2 was the reduced cytotoxicity of the claimed composition compared to the compositions of document (1). However the comparative example on pages 14 and 15 of the application contained no information about the percentage of thickening agent used, so that the measured cytotoxicity value NR_{50} of 998 ± 13 ppm was not comparable to the cytotoxicity values indicated for

the adhesive compositions according to the present invention.

The comparative experimental test report submitted by the Applicant on 21 January 2003 showed the cytotoxicity NR_{50} and the Shore-D hardness of adhesive compositions based on n-butyl cyanoacrylate with DL-lactic acid/ ϵ -caprolactone copolymers (50/50 molar ratio) having weight-average molecular weights of 60,000 (according to the present application) and 240,000 (comparative composition). Although the molecular weight of the DL-lactic acid/ ϵ -caprolactone copolymer of 240,000 used in the test report was similar to the molecular weight of 220,000 used in document (1), the amount of copolymer and consequently also that of α -cyanoacrylate differed considerably in both compositions. The variation of more than one parameter, i.e. the amounts of DL-lactic acid/ ϵ -caprolactone copolymer and α -cyanoacrylate as well as of the molecular weight of the DL-lactic acid/ ϵ -caprolactone copolymer, at the same time did not allow a meaningful comparison. Since α -cyanoacrylate was poisonous as indicated in the application on page 9, first paragraph, a decrease of the amount of α -cyanoacrylate in the adhesive composition was expected to lead to a lowered cytotoxicity, so that the Examining division concluded that the applicant had not convincingly shown that the technical problem underlying the invention was solved by the adhesive composition defined in claim 1 and consequently, no inventive activity could be acknowledged.

IV. The Appellant submitted that the subject-matter claimed was inventive on account of a reduced cytotoxicity and

better homogeneity of the claimed compositions with respect to that of document (1) and filed comparative tests on 29 August 2003 relating to the cytotoxicity and homogeneity of compositions consisting of n-butyl cyanoacrylate and 30 wt.-% of DL-lactic acid/ ϵ -caprolactone copolymer (50/50), wherein only the molecular weight of the DL-lactic acid/ ϵ -caprolactone copolymer varied to demonstrate the presence of an unexpected technical effect resulting from the distinguishing feature of the present invention vis-à-vis the closest state of the art.

- V. The Appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 and 2 as filed on 21 January 2003, the description as amended on 12 September 2003 and the drawings originally filed.

Reasons for the Decision

1. The appeal is admissible.
2. *Amendments (Article 123(2) EPC)*

Claim 1 is based on the combination of original claims 1 to 3. Furthermore it had been indicated that the unspecified "ratio" defining the relative amounts of the co-monomers in the copolymer referred to in claim 1 concerned actually the molar ratio. This amendment is supported by the examples and the explanations of the drawings on page 14 of the application as filed in all of which the copolymer was defined by the molar ratio of its co-monomers.

Therefore, the Board concurs with the Examining Division that the requirements of Article 123(2) EPC are satisfied.

3. *Novelty*

Novelty of the claimed subject-matter was not objected to by the Examining Division. The Board on its own sees no reason to take a different view.

4. *Inventive step*

The sole issue arising from the present appeal consists in deciding whether or not the claimed subject-matter involves an inventive step.

According to the established jurisprudence of the Boards of Appeal it is necessary, in order to assess inventive step, to establish the closest state of the art, to determine in the light thereof the technical problem which the invention addresses and successfully solves, and to examine the obviousness of the claimed solution to this problem in view of the state of the art. This "problem-solution approach" ensures assessing inventive step on an objective basis and avoids an *ex post facto* analysis.

- 4.1 Document (1a) discloses α -cyanoacrylate adhesive compositions for surgical use comprising a DL-lactic acid/ ϵ -caprolactone copolymer. The weight-average molecular weight of the copolymer used in example 2 is 220,000 in concentrations varying from 10 to 30 wt.-%.

The Board considers in agreement with the Examining Division and the Appellant that this document represents the closest prior art and, hence, takes it as the starting point for the assessment of inventive step.

- 4.2 Starting from document (1), the technical problem underlying the invention consists in the provision of α -cyanoacrylate adhesive compositions having reduced cytotoxicity.
- 4.3 The proposed solution is the α -cyanoacrylate adhesive composition according to claim 1 characterized by a weight average molecular weight of the copolymer of DL-lactic acid and ϵ -caprolactone of from 10,000 to 120,000.
- 4.4 In order to show that this problem was successfully solved the Appellant submitted with the letter dated 29 August 2003 comparative data.
 - 4.4.1 In the comparative test, an adhesive composition according to the invention comprising n-butyl cyanoacrylate and 30 wt.-% of a copolymer of DL-lactic acid and ϵ -caprolactone (50/50) having a weight average molecular weight of 60,000 was compared with a composition according to document (1) whereof the sole difference to the composition according to the invention was the weight average molecular weight of the copolymer of 200,000.

This comparative test is pertinent since it truly reflects the impact of the essential technical feature distinguishing the claimed composition from the closest prior art, namely the difference in weight average

molecular weight of 10,000 to 120,000 according to the invention versus the higher weight average molecular weight used in the prior art.

Thus, the comparison provided by in that test is fair and to be taken into consideration when assessing inventive step (see decision T 197/86, OJ EPO 1989, 371).

- 4.4.2 The comparative test reveals a lack of homogeneity in the composition representing the closest prior art document (1) due to a higher viscosity. This difference of viscosity is caused by the use of polymers having a different molecular weight and is unavoidable in order to provide a fair comparison. Thus samples were taken from different parts of the composition according to the invention and according to the prior art, namely from the upper and the lower part of the blending bottle, for testing the cytotoxicity after curing.

Comparable cytotoxicity values were obtained when the samples were taken from the lower part of the blending bottle. However, when they were taken from the upper part of the blending bottle, the cytotoxicity obtained by an adhesive composition according to the invention and comprising the copolymer of weight average molecular weight of 60,000 was significantly reduced compared to the adhesive composition of the prior art comprising a copolymer of higher weight average molecular weight (NR₅₀ value of 985 compared to 1400).

For these reasons, and in the absence of any evidence or fact to the contrary, it appears conceivable that the decrease of the cytotoxicity of the claimed

compositions compared to the composition of the closest prior art is due to the shorter weight average molecular weight of the copolymer, as defined in claim 1.

For these reasons, the Board is satisfied that the technical problem underlying the application has been successfully solved by the proposed solution, i.e. the compositions according to claim 1 characterized by the copolymer having a weight average molecular weight in the range of 10,000 to 120,000.

- 4.5 It remains to be decided whether or not the proposed solution to that objective technical problem is obvious in view of the state of the art.

Document (1) is concerned with the viscosity and the stability of compositions and neither mentions any cytotoxicity effect nor its link to the weight average molecular weight of the copolymer to be used in the composition. Thus, the skilled person would not consider document (1) when looking for a solution to the technical problem underlying the invention, since that document does not address that problem.

Consequently, document (1) on its own does not point to the claimed solution for solving the technical problem as defined above.

In respect of obviousness, the Examining Division did not rely on any further document in the decision under appeal and the Board is not aware of any further document being relevant in this respect.

4.6 Therefore, the subject-matter of claim 1, and for the same reason, that according to dependent claim 2 involve an inventive step within the meaning of Articles 52(1) and 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

The case is remitted to the first instance with the order to grant a patent on the basis of:

Claims:

claims 1 and 2 filed on 21 January 2003;

Description:

pages 1, 2, 4, 5, 9 to 14 as originally filed

pages 3, 3a, 6 to 8, 15 as filed on 12 September 2003;

Drawings:

figures 1 and 2 as originally filed.

The Registrar:

The Chairman:

P. Cremona

R. Freimuth