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**Datasheet for the decision
of 22 August 2007**

Case Number: T 0145/05 - 3.3.10

Application Number: 91915440.1

Publication Number: 0542880

IPC: A61L 25/00

Language of the proceedings: EN

Title of invention:

Tissue bonding and sealing composition and method of using the same

Patentee:

The Trustees of Columbia University in the City of New York

Opponents:

Tissuemed Limited
Baxter Healthcare Corpn

Headword:

Tissue bonding and sealing composition/COLUMBIA UNIVERSITY

Relevant legal provisions:

EPC Art. 84, 123(2)

Keyword:

"Main request and auxiliary request 1: amendments (not allowable) - not unambiguously derivable from application as filed, neither explicitly nor implicitly"

"Auxiliary request 2 (not admitted): late-filed - not clearly allowable - lack of clarity due to trademark"

Decisions cited:

T 0270/90, T 0762/90, T 0288/92, T 0092/93, T 0680/93,
T 0401/95, T 0036/02

Catchword:

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Case Number: T 0145/05 - 3.3.10

D E C I S I O N
of the Technical Board of Appeal 3.3.10
of 22 August 2007

Appellant: The Trustees of Columbia University in the
(Patent Proprietor) City of New York
Broadway and West 116th Street
New York
NY 10027-6699 (US)

Representative: Vossius & Partner
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Respondent: Tissuemed Limited
(Opponent) 11 Killingbeck Drive
Leeds LS14 6UF (GB)

Representative: Jones, Stephen Anthony
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 23 November 2004
revoking European patent No. 0542880 pursuant
to Article 102(1) EPC.

Composition of the Board:

Chairman: R. Freimuth
Members: J. Mercey
J.-P. Seitz

Summary of Facts and Submissions

- I. The Appellant (Proprietor of the Patent) lodged an appeal on 31 January 2005 against the decision of the Opposition Division dated 23 November 2004 revoking European patent No. 542 880 and on 4 April 2005 filed a written statement setting out the grounds of appeal.
- II. Notice of Opposition had been filed by the Respondent (Opponent 1), requesting revocation of the patent in its entirety on the grounds of lack of novelty and inventive step (Article 100(a) EPC), insufficient disclosure (Article 100(b) EPC) and of extending the subject-matter of the patent in suit beyond the content of the application as filed (Article 100(c) EPC).
- III. The Opposition Division held that the amendments made to the patent according to the then pending main request and auxiliary request extended the subject-matter of the patent in suit beyond the content of the application as filed.
- IV. At the oral proceedings before the Board, held on 22 August 2007, the Appellant defended the maintenance of the patent in suit in amended form on the basis of a main and two auxiliary requests, all requests submitted during these oral proceedings and thus superseding any previous requests. Independent claim 1 of both the main request and auxiliary request 1 read as follows:

"1. A composition for bonding separated tissues together or for coating tissues or prosthetic materials comprising 5 parts 1% sodium hyaluronate solution to 1 part 25% human albumin solution, or 2 parts 1% sodium

hyaluronate solution to 1 part 25% human albumin solution, or 1 part 1% sodium hyaluronate solution to 1 part 25% human albumin solution, or 1 part 1% sodium hyaluronate solution to 2 parts 25% human albumin solution, wherein the 25% human albumin solution contains 10 mg/ml indocyanine green dye."

Claim 1 of auxiliary request 2 differed from claim 1 of the main request exclusively in that the feature "1% sodium hyaluronate solution" was replaced at each occurrence by "HealonTM".

V. The Appellant submitted that claim 1 according to all requests found support in the application as filed, most particularly in claim 1 together with samples 4 to 7 in Table 3 on page 26, and thus complied with the requirements of Article 123(2) EPC. With regard to claim 1 of the main request and auxiliary request 1, the Appellant additionally argued that the product HealonTM used in samples 4 to 7 provided support for the feature "1% sodium hyaluronate solution", since the skilled person knew that HealonTM consisted of a 1% sodium hyaluronate solution. In support of its allegation the Appellant further relied on two fresh documents:

(A) US-A-4 328 803 and

(B) print-out "Healon[®]" from the internet webpage <http://www.healon.com/healon/healon.html>, dated 14 august 2007.

both filed during oral proceedings before the Board.

- VI. The Respondent did not provide any substantive arguments.
- VII. The Appellant requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request or, subsidiarily, on the basis of either of the auxiliary requests 1 and 2, all requests submitted during the oral proceedings before the Board.
- The Respondent requested that the appeal be dismissed.
- VIII. Oral proceedings were held in the absence of the Respondent, who, after having been duly summoned, informed the Board with a letter dated 30 July 2007 that it would not attend. At the end of the oral proceedings the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible.

Main and auxiliary request 1

2. *Admissibility of requests*

These two requests were filed during oral proceedings before the Board, claim 1 of each of these requests corresponding to a combination of claims 1 and 3 of the main request filed with the Statement of Grounds of appeal, auxiliary request 1 having been further amended by deletion of the independent process claim. Thus the Appellant has merely restricted the claims of the patent in suit to subject-matter present in claims with

which the Respondent was familiar. Therefore, the claims of the Appellant's main request and auxiliary request 1 do not give rise to any fresh issue.

For these reasons the Board exercises its discretion to admit the Appellant's main request and auxiliary request 1 into the proceedings.

3. *Article 123(2) EPC*

3.1 In order to determine whether or not an amendment offends against Article 123(2) EPC, it has to be examined whether technical information has been introduced which a skilled person would not have objectively and unambiguously derived from the application as filed (see decisions T 288/92, point 3.1 of the reasons; T 680/93, point 2 of the reasons; neither published in OJ EPO), either explicitly or implicitly. In this context, implicit disclosure means disclosure which any person skilled in the art would objectively consider as necessarily implied in the explicit content.

3.2 In the present case, claim 1 of both requests is directed to four specific compositions, basis for which, according to the Appellant, was to be found in samples 4 to 7 in Table 3 on page 26 of the application as filed. However, claim 1 includes the feature "1% sodium hyaluronate solution", said feature not being present in samples 4 to 7, said samples instead referring to the commercial product HealonTM. In the application as filed there is no definition given for HealonTM, as conceded by the Appellant.

- 3.3 The Appellant argued that it was nonetheless clear to the skilled person at the filing date of the application leading to the patent in suit that the product HealonTM consisted of a 1% sodium hyaluronate solution, such that this amendment did not extend beyond the content of the application as filed.
- 3.4 According to the jurisprudence of the Boards of Appeal, each of the parties to the proceedings carries the burden of proof for the facts it alleges (see e.g. decision T 270/90, OJ EPO 1993, 725, point 2.1). If a party, whose arguments rest on these alleged facts, is unable to discharge its onus of proof, it is to the detriment of that party.
- 3.5 In the present case, the Appellant alleges the fact that the commercial product HealonTM consisted of a "1% sodium hyaluronate solution". In support of its allegation, the Appellant filed two fresh documents, (A) and (B), during the oral proceedings. These documents are supposed to prove that "HealonTM" provides a proper basis for the feature "1% sodium hyaluronate solution" in amended claim 1. However, document (A) demonstrates that HealonTM is a very particular solution of 1% sodium hyaluronate, namely it is physiologically buffered, aqueous and the concentration is percentage by weight. Document (B) specifies a particular viscosity and a particular molecular weight for this commercial product. Documents (A) and (B) thus serve to show that HealonTM is necessarily characterised by these further features. The specification in claim 1 of a "1% sodium hyaluronate solution" is thereby not a complete description of that originally disclosed particular commercial product, but rather merely a partial

indication of the particular characteristics implicitly disclosed in combination by means of that specific product. As a consequence, the feature "1% sodium hyaluronate solution" given in claim 1 is not based on the implicit disclosure of the product "HealonTM", but is rather an undue generalisation thereof, since features mandatory for the characterisation of said product have been omitted (see T 36/02, point 5 of the reasons, not published in OJ EPO).

- 3.6 Since, thus, the feature "1% sodium hyaluronate solution" in claim 1 has no adequate support in the application as filed, claim 1 of the main request and of auxiliary request 1 is amended in such a way that subject-matter extending beyond the application as filed is added, contrary to the requirements of Article 123(2) EPC, with the consequence that the main request and auxiliary request 1 are not allowable.

Auxiliary request 2

4. *Admissibility*

- 4.1 Auxiliary request 2 was filed at the very last stage of the appeal proceedings, namely at the end of the oral proceedings before the Board. Claim 1 according to this request differs from claim 1 according to the main request and auxiliary request 1 in that the feature "1% sodium hyaluronate solution" has been replaced at each occurrence by "HealonTM".

- 4.2 Admission into the proceedings of a request filed at such a late stage of the appeal proceedings is a matter of discretion for the Board of Appeal and is not a

matter as of right. In exercising due discretion, it is established jurisprudence of the Boards of Appeal that one crucial criterion is whether or not the amended claims of those requests are clearly allowable (see T 92/93, point B of the reasons; T 401/95, point 5.2 of the reasons, neither published in OJ EPO).

- 4.3 In amended claim 1, one of the components of the claimed mixtures is defined by a trademark, namely HealonTM. It is established jurisprudence that a trademark product in a claim is not necessarily clear, as doubts exist as to whether the meaning of the trademark would remain unaltered from the beginning until the end of the patent term (see decision T 762/90, point 4.1.1 of the reasons, not published in OJ EPO). Thus the use of the trademark Healon in claim 1 casts doubts on the clarity of the subject-matter for which protection is sought.
- 4.4 Since there are doubts as to whether claim 1 meets the requirement of clarity imposed by Article 84 EPC, late filed auxiliary request 2 is not clearly allowable, with the consequence that the Board exercises its discretion not to admit this request into the proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

P. Cremona

R. Freimuth