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# Datasheet for the decision of 20 August 2008

**Case Number:** T 1545/07 - 3.3.10

**Application Number:** 04002645.2

**Publication Number:** 1418188

**IPC:** A61L 27/52

**Language of the proceedings:** EN

**Title of invention:**
Polyacrylamide hydrogel and its use as an endoprosthesis

**Applicant:**
Contura A/S

**Opponent:**
-

**Headword:**
Biocompatible hydrogel/CONTURA

**Relevant legal provisions:**
EPC Art. 54, 76(1), 111(1), 123(2)

**Keyword:**
"Novelty (yes) - fresh feature - no direct and unambiguous disclosure"
"Remittal to the first instance for further prosecution"

**Decisions cited:**
G 0010/93, T 0063/86, T 0139/87, T 0047/90, T 0423/03

**Catchword:**
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Beschwerdekammern | Boards of Appeal | Chambres de recours

**Case Number:** T 1545/07 **-** 3.3.10

# D E C I S I O N
**of the Technical Board of Appeal 3.3.10**
**of 20 August 2008**

**Appellant:** Contura A/S
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**Representative:** Plougmann & Vingtoft A/S
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**Decision under appeal:** **Decision of the Examining Division of the European Patent Office posted 6 March 2007 refusing European application No. 04002645.2 pursuant to Article 97(1) EPC 1973.**

**Composition of the Board:**

**Chairman:** R. Freimuth
**Members:** C. Komenda
F. Blumer

## Summary of Facts and Submissions

I. The appeal lodged on 15 May 2007 lies from the decision of the Examining Division posted on 6 March 2007 refusing European patent application No. 04 002 645.2 published under the publication No. EP 1 418 188.

II. *Inter alia* the following documents were cited in the examination proceedings:

(1) US-A-5 798 096,
(2) WO-A-99/10021,
(3) US-A-5 658 329, and
(4) RU-A-21 27 129 in its English translation.

In the decision under appeal, the Examining Division held that document (4) anticipated the subject-matter of the claims according to the then pending request. In particular it was stated that the hydrogels disclosed in document (4) had a solid content within the claimed range and were prepared from the same monomers and crosslinkers in the molar ratios as claimed in the application in suit. Therefore, the resulting polymer in document (4) would have necessarily the same structure as the claimed polymer. In document (4) the hydrogels, which were used for soft tissue filling, had a solid content of between 1.5 and 2.5 percent by weight, which was within the claimed range. Thus, it was concluded that the claimed elasticity module and complex viscosity, which basically depended on the solid content of the hydrogel and on the structure of the polyacrylamide, were also fulfilled in document (4). Although document (4) stated that the hydrogel was implanted into patients, the expressions "implanted"

and "implantation" were regarded as unreliable translations from the Russian original text and, therefore, were regarded as including also the administration by injection as claimed in the application in suit. Thus, the subject-matter of claim 1 was found to be anticipated by document (4).

III. At the oral proceedings before the Board held on 20 August 2008, the Appellant filed a sole request, which comprised only a single claim reading as follows:

"1. A biocompatible hydrogel obtainable by combining acrylamide and methylene bis-acrylamide in a molar ratio of 150:1 to 1000:1; radical initiation; and washing with pyrogen-free water or saline solution for 80 to 100 hours; so as to give at least 0.5% by weight polyacrylamide and less than 3.5% by weight polyacrylamide, based on the total weight of the hydrogel; and said polyacrylamide having a cross-linking density of 0.2% to 0.5% for use as an injectable endoprosthesis for soft tissue filling by injection into a mammal."

IV. With his Statement of the Grounds of Appeal dated 13 July 2007 the Appellant submitted arguments as to why document (4) did not anticipate the subject-matter of claim 1. He further filed experimental reports in order to demonstrate that document (4) represented a non-enabling disclosure. He further argued that the administration by means of injection were a specific way of administration falling within the general terms of "implantation". However, document (4) was silent on any specific way of administration, such as injection. Further, document (4) did neither explicitly, nor

implicitly disclose the crosslinking density of the polyacrylamide. In a further letter dated 10 March 2008 the Appellant requested acceleration of the appeal procedure, which was granted by the Board.

V. In a written communication according to Article 15(1) of the Rules of Procedure dated 27 June 2008 the Board informed the Appellant *inter alia* that, since the present case was filed as a divisional application, the requirements of Article 76(1) EPC in addition to those of Article 123(2) EPC have to be fulfilled.

VI. The Appellant requested that the decision under appeal be set aside and that the case be remitted to the department of the first instance for further prosecution.

VII. At the end of the oral proceedings the decision of the Board was announced.

## Reasons for the Decision

1. The appeal is admissible.

2. *Scope of examination on appeal*

While Article 111(1) EPC gives the Boards of Appeal the power to raise new grounds in ex-parte proceedings where the application has been refused on other grounds, proceedings before the Boards of Appeal in ex-parte cases are primarily concerned with examining the contested decision (see decision G 10/93, OJ EPO 1995, 172, points 4 and 5 of the reasons), other objections

normally being left to the Examining Division to consider after a referral back, so that the Appellant has the opportunity for these to be considered without loss of an instance.

In the present case the Board, thus, restricts itself to examining whether the amended claim meets the requirements of Articles 76(1) EPC and of Article 123(2) EPC and whether the objection as to lack of novelty pursuant to Article 54 EPC as formulated in the decision under appeal and forming the sole ground for refusal of the application, can still be considered as applying to the amended claims.

3. *Amendments*

The filing of a divisional application is governed by Article 76 EPC which stipulates in paragraph 1, second sentence that a divisional application "may be filed only in respect of subject-matter which does not extend beyond the content of the earlier application as filed". Thus, in case of a divisional application, the requirement of Article 76(1) EPC is to be satisfied separately from and supplementary to that of Article 123(2) EPC. While the former ensures that a divisional application does not extend beyond the content of the earlier parent application, the latter ensures that, once the provisions of Article 76(1) have been met, the divisional application may not be amended after its filing in such a way that it contains subject-matter extending beyond the content of the divisional application as filed (see e.g. decision T 423/03, point 3 of the reasons, not published in OJ EPO).

3.1 *Article 76(1) EPC*

Claim 1 of the present divisional application is based on the wording of claim 1 of the parent application as filed including further restictions: the additional features "so as to give at least 0.5% by weight polyacrylamide", "and said polyacrylamide having a cross-linking density of 0.2% to 0.5%" and "injectable endoprosthesis" are based on original claims 5, 10 and 13, respectively, of the parent application, each of these claims referring back to claim 1 of the parent application. The feature concerning the duration of the washing step, which is to be conducted "for 80 to 100 hours" is based on the parent application page 12, line 32. The characterisation of the hydrogel as being "for use as [...] endoprosthesis for soft tissue filling by injection into a mammal" is based on the parent application page 4, lines 27 to 30, which discloses administering the endoprosthesis for soft tissue filling in a mammal, in combination with page 13, lines 31 to 32, which specifies the way of administering the endoprosthesis by means of injection.

Consequently, the Board comes to the conclusion that the amendments made to claim 1 fulfil the requirements of Article 76(1) EPC.

3.2 *Article 123(2) EPC*

Claim 1 is based on claim 1 of the divisional application as filed in combination with dependent claims 15, 17 and 23 thereof. The feature, that the hydrogel is biocompatible has its basis in the

divisional application as filed on page 7, line 19, the molar ratio of 150:1 to 1000: 1 on page 7, line 27 and the feature concerning the duration of the washing step on page 12, line 32. The administration of the endoprosthesis "by injection" finds a basis on page 13, lines 31 to 32 of the divisional application as filed, the description of which being identical to the parent application as filed.

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

4. *Novelty*

4.1 The decision under appeal exclusively dealt with lack of novelty of the independent claim 1 of the then pending request. Thus, the main issue to be decided in this appeal is whether or not the decision under appeal was right to find that the subject-matter of the claim lacks novelty, the Appellant having challenged that finding.

4.2 Claim 1 is directed to a biocompatible hydrogel for use as an injectable endoprosthesis for soft tissue filling by injection into a mammal, which hydrogel has been further characterized by having a crosslinking density of 0.2 to 0.5% (see paragraph III, *supra*). The latter feature, which was not present in claim 1 on which the decision under appeal was based, represents a further limiting feature of the claimed hydrogels.

4.3 Document (4) describes the hydrogels as being "implanted" or administered by "implantation", but does not disclose that the hydrogels are injected.

The general principle consistently applied by the Boards of Appeal for concluding lack of novelty is that there must be a direct and unambiguous disclosure in the state of the art which would inevitably lead the skilled person to subject-matter falling within the scope of what is claimed.

The expressions "implanted" or "implantation" used in document (4) are generic terms, which are not tantamount to the specific way of administration by means of injection as claimed in the application in suit. Accordingly, although comprised within the general expressions "implanted" and "implantation" used throughout document (4) there is no specific disclosure in that document that the hydrogel is particularly administered by means of injection. Thus, the expressions "implanted" or "implantation" cannot take away the novelty of the claimed hydrogels being administered by means of injection.

Therefore, whether or not the respective expression used throughout the original text of document (4) "был введен", in the context of that document, appeared to have the even more general meaning of "has been incorporated" need not to be decided.

Thus, document (4) does not directly and unambiguously disclose the administration of the hydrogel by means of injection.

4.4 The hydrogels disclosed in document (1) have solid contents of from 3.5 to 9% by weight, whereas the upper limit of the claimed range is less than 3.5% by weight.

4.5 Document (2), which was cited against novelty in the decision under appeal, discloses hydrogels being used as endoprosthesis for soft tissue filling (claim 1). The hydrogels of the prior art are prepared from the same starting and crosslinking monomers as the claimed hydrogels (claim 5). However, document (2) does not disclose the crosslinking density of the resulting polyacrylamides. The crosslinking density depends on the ratio of starting to crosslinking monomers, as well as on the type and amount of initiator and on the polymerisation conditions. However, document (2) is already silent on the ratios of starting to crosslinking monomers as well as on the particular polymerisation conditions so that the crosslinking density now claimed is not automatically and necessarily achieved in that piece of prior art with the consequence that no implicit disclosure of the crosslinking density can be derived from that document. Therefore, this document does neither explicitly, nor implicitly disclose the claimed crosslinking density. Nor does any of documents (1), (3) and (4), which have been cited against novelty in the examination proceedings, specifically disclose hydrogels having the particular crosslinking density of 0.2 to 0.5%.

4.6 Further, document (3) does not disclose the administration by means of injection, but by means of surgical implantation.

4.7 For these reasons, the Board concludes that the subject-matter of claim 1 is novel over documents (1), (2), (3) and (4).

4.8 Thus, the Board considers that the amendments made by the Appellant avoid the novelty objection as formulated in the decision under appeal and are substantial in the sense that in the present case the examination has to be done on a new basis, with the consequence that the appeal is well founded.

4.9 This finding is in line with established jurisprudence of the Boards of Appeal that an appeal is to be considered well founded if the Appellant no longer seeks grant of the patent with a text as refused by the Examining Division and if substantial amendments are proposed which clearly meet the objections on which the decision relies (see decisions T 63/86, OJ EPO 1988, 224; T 139/87, OJ EPO 1990, 68 and T 47/90, OJ EPO 1991, 486).

5. *Remittal*

Having decided on novelty, the Board has not, however, taken a decision on the whole matter, since as set out above substantial amendments to the subject-matter claimed have been made by submitting fresh claim 1 which was only presented at the oral proceedings before the Board. The decision under appeal did not consider the fresh claim 1 in the form of the present request, as such request was never submitted to the first instance. It is only before the Board that the Appellant has reformulated his product claim in order to overcome the objections raised. Thus, fresh

independent claim 1 generates a fresh case not yet addressed in examination proceedings and may induce the Appellant to file dependent claims.

The Decision of the Administrative Council of 28 June 2001 on the transitional provisions under Article 7 of the Act Revising the EPC of 29 November 2000 provided in its Article 1.3 that Article 54(5) EPC shall apply to European patent applications pending at the time of its entry into force, in so far as a decision on the grant of the patent has not yet been taken. Since, therefore, Article 54(5) EPC 2000 applies to the present case, it will have to be examined, whether or not the new claim format is allowable, taking into consideration of whether or not the subject-matter of present claim 1 may cover the mixed use of the claimed hydrogels in cosmetics and in a method according to Article 53(c) EPC 2000.

Under these circumstances, the examination not having been concluded, the Board considers it appropriate to exercise its power conferred on it by Article 111(1), second sentence, second alternative, EPC to remit the case to the Examining Division for further prosecution.

## Order

## For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution.

The Registrar The Chairman

P. Cremona R. Freimuth