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**Datasheet for the decision
of 27 November 2009**

Case Number: T 1575/08 - 3.3.03

Application Number: 03750888.4

Publication Number: 1543053

IPC: C08G 18/10

Language of the proceedings: EN

Title of invention:

Novel thermoplastic hydrogel polymer compositions for use in producing contact lenses and methods of producing said compositions

Applicant:

OCUTECH LIMITED

Opponent:

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Headword:

-

Relevant legal provisions:

EPC Art. 84, 83

Relevant legal provisions (EPC 1973):

-

Keyword:

"Claims - clarity (no)"

"Disclosure - enabling - undue burden"

Decisions cited:

-

Catchword:

-



Case Number: T 1575/08 - 3.3.03

D E C I S I O N
of the Technical Board of Appeal 3.3.03
of 27 November 2009

Appellant:
(Applicant)

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Representative:

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Decision under appeal:

Decision of the Examining Division of the
European Patent Office dated 7 March 2008 and
posted 26 March 2008 refusing European patent
application No. 03750888.4 pursuant to Article
97(2) EPC.

Composition of the Board:

Chairman: R. Young
Members: W. Sieber
C. Vallet

Summary of Facts and Submissions

I. European patent application No. 03 750 888.4, based on International application PCT/GB2003/003802, filed on 1 September 2003, claiming a GB priority of 31 August 2002 (0220312.3) and published as WO 2004/020495 A1, was refused by a decision of the Examining Division announced orally on 7 March and issued in writing on 26 March 2008. The decision was based on two sets of claims, namely a main request and an auxiliary request. Claim 1 of the auxiliary request which contained 35 claims read as follows:

"A method of synthesizing a thermoplastic material which swells in water to produce a hydrogel suitable for moulding for use in producing contact lenses, the method comprising the steps of;

- mixing (i), (ii), and (iii) wherein
 (i) is polyethylene glycol,
 (ii) is a polyisocyanate,
 (iii) is a polyfunctional amine,

wherein the ratios of NCO:(OH + NH₂) are from 2:1 to 1:2 to form a fluid mix for polymerisation to form a thermoplastic material

and wherein the method comprises a step of stopping the reaction before completion such that the thermoplastic material does not form a macrogel."

II. According to the decision of the examining division, the main request did not meet the requirements of

Article 56 EPC and the auxiliary request did not meet the requirements of Article 84 EPC.

As regards the auxiliary request, the examining division found that the feature "*... and wherein the method comprises a step of stopping the reaction before completion such that the thermoplastic material does not form a macrogel*" defined a result to be achieved. Furthermore, they found the term "*macrogel*" to be not sufficiently clear to be an essential distinguishing feature over the cited prior art.

III. On 8 May 2008, the applicant (appellant) filed a notice of appeal and the prescribed fee was paid on 9 May 2008.

A statement setting out the grounds of appeal was filed on 23 July 2008 including a set of 35 claims. The appellant requested that the decision under appeal be set aside and a patent be granted on the basis of these claims. Claim 1 of the claim set was identical to Claim 1 of the auxiliary request before the examining (point I, above).

The appellant argued that the term "*macrogel*" was known to the skilled polymer chemist and would easily and clearly be understood within the context to the application in suit. The claimed process was carried out by heating the reactants at an elevated temperature for a considerable time. It would not require any undue experimentation by the person skilled in the art to know when to stop the reaction before completion such that the thermoplastic hydrogel product did not form a macrogel. A test for determining the point of macrogelation was presented. Several references

relating to the term "macrogel" were attached (D4-D8) and further references were listed to support the definition of macrogels. Reference was also made to an allegedly attached declaration from Professor A.F. Johnson.

D4: IUPAC, vol. 70, no. 6, June 1998, 1271;

D5: Die Angewandte Makromolekulare Chemie 240 (1996), 113-114;

D6: 4th Symposium on Polymer Gels (SPG), Tsukuba Japan, 1995, 2 pages;

D7: 69th Colloid & Surface Science Symposium, University of Utah, Salt Lake City, 1995, 1 page; and

D8: Colloids and Surfaces A; Physicochemical and Engineering Aspects 118 (1996), 231.

IV. In a communication dated 7 September 2009 accompanying the summons to oral proceedings, the board pointed *inter alia* out that the application as filed was silent with regard to a definition of the term "macrogel" as such and, in particular, with regard to a test which would allow to determine when a macrogel was formed. Thus, *prima facie* a person skilled in the art did not know whether he was working within or without the scope of the claims (Article 84 EPC). Also nothing of what had been explained by Professor Graham could be found in the application as filed. The difficulty in defining the invention was emphasized by contradictory explanations relating to the term "macrogel" given in

the application as filed and in Professor Graham's explanations.

Further, the thermoplastic material produced according to the method of Claim 1 could be prepared from starting materials having functionality not higher than 2. Since a macrogel would apparently never form from these starting materials, Claim 1 included a feature (ie the step of stopping the reaction before completion such that the thermoplastic material does not form) which could never be performed for some of the embodiments covered by Claim 1 (Article 83 EPC).

- V. The appellant was not represented at the oral proceedings held before the board.

Reasons for the Decision

1. The appeal is admissible.
2. Claim 1 contains the feature "*and wherein the method comprises a step of stopping the reaction before completion such that the thermoplastic material does not form a macrogel*".
 - 2.1 It cannot be disputed that the application as filed is silent with regard to a definition of the term "macrogel" as such and, in particular, with regard to a test which would allow to determine when a macrogel is formed. Thus, *prima facie* a person skilled in the art does not know whether he is working within or without the scope of the claim. Consequently, the claim does

not clearly define the subject-matter for which protection is sought, contrary to Article 84 EPC.

2.2 In the statement of grounds of appeal, the appellant argued:

"As Professor Graham explained during the oral proceedings [before the examining division], the process claimed is carried out by heating the reactants at an elevated temperature for a considerable time. Typically the reaction takes approximately 20 hours and it would not require any undue experimentation by the person skilled in the art to know when to stop the reaction before completion such that the thermoplastic hydrogel product does not form a macrogel.

Typically in designing a reaction process a very small aliquot of the reaction mixture would be heated at the same time as the reaction mixture in a cylindrical tube and inverting it at regular intervals to monitor the reaction. The point of macrogelation will be when the mixture does not visibly flow within 10 minutes of inversion. In subsequent reactions the thermoplastic material would be guaranteed by stopping the reaction typically 30 minutes before the point of macrogelation."

However, nothing of what has been explained by Professor Graham can be found in the application as filed, in particular as regards the determination of the point of macrogelation. Nor was the appellant in a position to demonstrate that such a test for the determination of the point of macrogelation belonged to the common general knowledge of the person skilled in the art. Documents D4-D8 filed by the appellant with the statement of grounds of appeal apparently do not refer to such a test. Also the listed references in the statement of grounds of appeal cannot bring new facts relating to this issue to light, because the appellant neither provided copies of these references nor did he indicate the relevant passages thereof, although

invited by the board to do so. Hence, the appellant's argumentation cannot overcome the objection that Claim 1 does not clearly define the subject-matter for which protection is sought.

2.3 Further, it was explained in the statement of grounds of appeal that:

"The thermoplasticity of the materials of the present invention is provided in the essentially linear polymeric structures with a controlled degree of covalent branching, or, alternatively with thermally reversible physical branching sites by way of hydrogen bonding of certain polar structures along the polymer chain. The presence of the polyfunctional amine provides for the formation of polar urea structures when reacting with isocyanate groups. These urea structures provide for such non-covalently crosslinked but rather physically, thermally reversible crosslinked via hydrogen bonding, thermoplastic materials."

Again, nothing of said information can be found in the application as filed. The application as filed does not disclose a general concept which would allow the person skilled in the art to implement the "invention".

There are a few examples in the application as filed but they appear not very helpful in identifying the "invention". This is particularly apparent from Example 1. In this example, a material labelled "PUU3130CX" is prepared that is thermoplastic at elevated temperature, and is formed into a contact lens. *Prima facie*, the material produced in Example 1 is a material according to the invention, ie not a macrogel. On the other hand, according to page 14, last paragraph, of the application as filed the polymer swelled to a high degree in tetrahydrofuran but would not dissolve. According to Professor Graham's own

explanation (Attachment 1 to the letter dated 14.02.2008, page 11, 2nd paragraph), this is a property of a macrogel.

These contradictory aspects emphasize the difficulty related to the present application, not only with respect to the definition of the invention (ie the scope of the claims, Article 84 EPC), but also with respect to the implementation of the invention which affects issues relating to Article 83 EPC.

- 2.4 Finally, it is apparent from the statement referred to in point 2.3, above, that Claim 1 covers thermoplastic material where the thermoplasticity is provided by physical branching, ie no covalent branching. It appears that these materials are made from starting compounds having a functionality not higher than 2. A macrogel will apparently never form from these starting materials. Consequently, Claim 1 includes a feature (namely the step of stopping the reaction before completion such that the thermoplastic material does not form a macrogel) which can never be performed for some embodiments covered by Claim 1.

Thus, Claim 1 appears to define "the invention" in too broad terms so that an objection under Article 83 EPC arises out of this broad definition. It is in the board's view an undue burden for the person skilled in the art to find out the appropriate starting materials for an "invention" which has never been properly identified in the application as filed out of an unduly broad definition in the claim.

This aspect is amplified by the examples in the application as filed. Firstly, there is not a single example disclosing a material made of components (i), (ii) and (iii) only. Secondly, the examples even convey the impression that it is not polyethylene glycol which is an essential component but polypropylene glycol since that component is used in amounts of 10-20 times higher than polyethylene glycol. It appears that the person skilled in the art is left completely in the dark when it comes to identifying a general concept of the invention in the application as filed.

3. In summary, Claim 1 of the only request on file does not meet the requirements of Articles 84 and 83 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

E. Görgmaier

R. Young