Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 2 December 2019

Case Number: T 2004/15 - 3.3.07

Application Number: 08723872.1

Publication Number: 2131808

IPC: A61K9/00, A61K47/36

Language of the proceedings: EN

Title of invention:
IMPLANT CONTAINING DESTRUCTURIZED STARCH

Applicant:
De Staat der Nederlanden, vert. door de Minister van Volksgezondheid, Welzijn en Sport, namens de Minister, Projectdirectie ALT, het INTRAVACC

Headword:
Implant Containing Destructurized Starch / DE STAAT DER NEDERLANDEN

Relevant legal provisions:
EPC Art. 84

Keyword:
Claims - clarity (no)

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 2004/15 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 2 December 2019

Appellant: (Applicant)	De Staat der Nederlanden, vert. door de Minister van Volksgezondheid, Welzijn en Sport, namens de Minister, Projectdirectie ALT, het INTRAVACC Antonie van Leeuwenhoeklaan 9 3721 MA Bilthoven (NL)
Representative:	Nederlandsch Octrooibureau P.O. Box 29720 2502 LS The Hague (NL)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 8 May 2015 refusing European patent application No. 08723872.1 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	J. Riolo
Members:	E. Duval
	C. Schmidt

Summary of Facts and Submissions

I. The appeal was filed by the applicant (appellant) against the decision of the examining division to refuse the European patent application No 08723872.1 (hereinafter "the application").

II. The decision was based on a main request and auxiliary requests 1-8 filed by letter dated 26 March 2013, and auxiliary request 9 filed during the oral proceedings.

In particular, claim 1 of the main request read as follows:

"Kinetic implant comprising:
(a) a biodegradable material comprising 50 - 100 wt.% of opened starch, based on the total weight of the biodegradable material, said opened starch having at least 2 tension fields/3.2 cm^2, a bulk density of 1.0 to 1.5 kg/dm^3 and a tensile strength of at least 20 N/mm^2;
(b) a biologically or pharmaceutically active substance; and
(c) a stabilising component stabilising the biologically or pharmaceutically active substance, wherein said stabilising component is a polyol."

III. The examining division decided that the main request did not comply with the requirements of sufficiency of disclosure of Article 83 EPC. The parameter "tension fields" was not a generally known parameter, and the information in the description was not comprehensive enough for the skilled person to determine it. The same objection applied to claim 1 of each of the auxiliary requests 1-9, since they all contained the parameter "tension fields".

IV. With the statement of grounds of appeal, the appellant submitted a main request and auxiliary requests 1-11.

The main request was identical to the main request underlying the decision under appeal (see II. above).

Auxiliary requests 1-5 were identical to the corresponding requests underlying the decision under appeal. In claim 1 of each of auxiliary requests 1 and 2, the number of tension fields/3.2 cm^2 was limited, respectively, to "at least 25" and "at least 50". Claim 1 of each of auxiliary requests 3-5 resulted from the addition of the feature "wherein the number of tension fields is determined utilizing the method described in the description" to claim 1 of the main request and auxiliary requests 1 and 2, respectively.

In claim 1 of auxiliary requests 6-8, the opened starch was further characterised by the process for its preparation, wherein the residence time of the chemically non-modified starch in the heating zones of the extruder was "0.1 to 7 minutes". Additionally, the number of tension fields/3.2 cm^2 was limited to "at least 25" in claim 1 of auxiliary request 7, and "at least 50" in claim 1 of auxiliary request 8.

In claim 1 of auxiliary requests 9-11, the opened starch was also further characterised by the process for its preparation, wherein the residence time of the chemically non-modified starch in the heating zones of the extruder was "0.2 to 5 minutes". Additionally, the number of tension fields/3.2 cm^2 was limited to "at least 25" in claim 1 of auxiliary request 10, and "at least 50" in claim 1 of auxiliary request 11.

V. The appellant filed the following documents together with the statement of grounds of appeal:

Exhibit A: Slide submitted during oral proceedings before the examining division
Exhibit B: Kirk-Othmer, Encyclopedia of Chemical Technology, Vol. 16, pages 665-666, 1995
Exhibit C: W.J. Patzelt, "Polarized light microscopy. Principles, instruments, applications", 3rd Ed., 1985
Exhibit D: A.S. Redner and B. Hoffman, "Residual Stress Testing for Transparent Polymers", Canon, 1999

VI. The Board summoned the parties to oral proceedings.

In a communication pursuant to Article 15(1) RPBA issued on 9 October 2019, the Board expressed the preliminary opinion that the lack of information as to how the tension fields parameter should be determined led to a lack of clarity in the sense of Article 84 EPC.

VII. No substantive submission was made in reply to this communication. The appellant announced by letter dated 10 October 2019 that it would not attend the oral proceedings, and clarified during the telephone conversation held on 24 October 2019 that it no longer wanted oral proceedings.

The oral proceedings were cancelled.

VIII. The appellant's arguments can be summarised as follows:

It was acknowledged that the parameter "number of tension fields" was essential for defining "opened starch" and "destructurized starch", but that it was not a generally known parameter. Standard test methods

to distinguish "opened starch" from "destructurized starch" were not known at the priority date.

However, the patent application informed the skilled person in a qualitative manner about the differences between opened starch and destructurized starch, e.g. in terms of total or partial disruption of the starch particles or susceptibility to hydrolysing enzymes. A quantitative difference between opened starch and destructurized starch in terms of number of tension fields was also disclosed in the description. These differences were correlated. According to the description, the number of tension fields was determined by visual inspection of test specimen using a standard polarized light stereomicroscope.

The skilled person would realise, based on his general knowledge, that destructurized starch was essentially isotropic, because of the complete disruption of the starch particles, whereas opened starch was anisotropic, because the particles were only partly disrupted. The polarized light microscopy was a well known technique to investigate the anisotropy or birefringence of a material, as evidenced by Exhibits B and C. Upon visual inspection of test specimen of destructurized or opened starch by polarized light microscopy, the skilled person would observe differences (as shown in Exhibit A) and would be able to count the number of differently colored areas corresponding to stress areas (as discussed in Exhibit D), i.e. to tension fields, within a certain error margin.

Consequently, the skilled person would be able, without undue burden, to perform the measurements and to distinguish between opened starch and destructurized

starch using his common general knowledge with respect to polarized light microscopy.

IX. The appellant requests that the decision under appeal be set aside and that a patent be granted on the basis of the main request or, in the alternative, on the basis of one of the auxiliary requests 1-11, all filed with the statement of grounds of appeal.

Reasons for the Decision

Main request

1. Article 84 EPC

1.1 Claim 1 relates to a kinetic implant comprising, *inter alia*, a biodegradable material comprising 50 - 100 wt% of opened starch, based on the total weight of the biodegradable material, said opened starch having, in particular, at least 2 tension fields/3.2 cm^2.

1.2 The examining division found that neither the application nor the common general knowledge allowed the skilled person to identify the measurement method by which the tension fields parameter of claim 1 should be determined. While the examining division concluded therefrom that the requirements of Article 83 EPC were not fulfilled, the Board considers this deficiency to result in a lack of clarity pursuant to Article 84 EPC, for the following reasons.

1.3 It is not contested that the parameter "number of tension fields" is not generally known. The expression

"tension field" cannot be found in any of the exhibits A-D either.

According to the description, the number of tension fields is "determined by visual inspection of tensile bars 5 mm wide and 2 mm thick which are made of opened starch using a standard polarised light stereomicroscope" (see page 7, line 28 to page 8, line 2). These tension fields are made visible with the aid of polarised light and counted (see page 10, lines 17-22). However, as stated by the examining division, the application omits to define these tension fields, how they look like and what should be counted. The application does not indicate that the tension fields correspond to colored areas showing under polarised light microscopy.

1.4 According to the appellant, the "tension fields" correspond to the "stress areas" mentioned in Exhibit D. These are areas of a transparent material which become birefringent when subjected to stress and appear as multicolored bands or fringes under polarized light.

The Board notes that Exhibit D pertains to the evaluation, using polarized light, of residual stress in a transparent molded product due to flow patterns and shrinkage in the mold. Nothing in the application of in Exhibit D induces the skilled person to identify the tension fields of claim 1, characterising the partial disruption of starch granules, with these stress areas of Exhibit D. Additionally it is not shown that Exhibit D reflects the common general knowledge. Lastly, Exhibit D does not disclose how to distinguish and count these multicolored stress area.

1.5 In conclusion, the application defines the previously unknown opened starch by a newly formulated and hence unfamiliar parameter. The Board shares the view of the examining division that the skilled person is not provided with any method by which this "number of tension fields" parameter should be measured.

Accordingly, the presence of this ill-defined feature in claim 1 contravenes Article 84 EPC.

Auxiliary requests

2. Article 84 EPC

It follows from the reasoning above that the skilled person is unable, based on the application as a whole and using common general knowledge, to determine the tension fields parameter. This unclear tension fields parameter still appears in claim 1 of each of the auxiliary requests.

The amendments pertaining to the value of this tension field parameter, carried out in auxiliary requests 1-2, do not overcome the above lack of clarity. Neither does the reference to the measurement method described in the description (auxiliary requests 3-5), considering that this measurement method is itself unclear.

In auxiliary requests 6-11, the opened starch of the claimed kinetic implant is additionally defined in terms of the process for its preparation. The unclear tension field parameter is however still a limiting feature of the claim, with the consequence that the requirements of Article 84 EPC are still not met.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

B. Atienza Vivancos J. Riolo

Decision electronically authenticated