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**Datasheet for the decision  
of 22 June 2017**

**Case Number:** T 0571/14 - 3.2.08

**Application Number:** 06735790.5

**Publication Number:** 1863420

**IPC:** A61F9/00, A61K9/00

**Language of the proceedings:** EN

**Title of invention:**  
MICROIMPLANTS FOR OCULAR ADMINISTRATION

**Applicant:**  
ALLERGAN, INC.

**Headword:**

**Relevant legal provisions:**

EPC Art. 54, 56  
RPBA Art. 12(4), 13

**Keyword:**

Novelty - main request (yes)

Inventive step - main request (no)

Late-filed auxiliary request 1 - admitted (no) - justification  
for late filing (no)

Late-filed auxiliary request 2 - admitted (yes) -  
justification for late filing (yes) - need for additional  
search (yes)

**Decisions cited:**

G 0010/93

**Catchword:**



**Beschwerdekammern**  
**Boards of Appeal**  
**Chambres de recours**

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Case Number: T 0571/14 - 3.2.08

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.08**  
**of 22 June 2017**

**Appellant:** ALLERGAN, INC.  
(Applicant) 2525 Dupont Drive  
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**Representative:** Hoffmann Eitle  
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**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted on 31 October 2013  
refusing European patent application No.  
06735790.5 pursuant to Article 97(2) EPC.

**Composition of the Board:**

**Chairwoman** P. Acton  
**Members:** C. Herberhold  
Y. Podbielski

## Summary of Facts and Submissions

- I. By decision posted on 31 October 2013 the Examining Division refused European patent application No. 06735790.5.
- II. The appellant (applicant) lodged an appeal against that decision in the prescribed form and within the prescribed time limit.
- III. Oral proceedings before the Board were held on 22 June 2017.

At the end of the oral proceedings the appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the main request filed with the appellant's letter dated 22 May 2017 or, alternatively, on the basis of one of auxiliary requests 1 or 2 filed at the oral proceedings before the Board.

- IV. Independent claim 1 of the main request (corresponding to claim 1 according to the auxiliary request underlying the appealed decision) reads as follows:

"A batch of ocular microimplants, each microimplant having a diameter of 0.483 mm (0.019 inches) or less and comprising a homogeneous mixture of one or more active ingredients, a bioerodible polylactic acid-polyglycolic acid copolymer and a bioerodible polylactic acid-polyglycolic acid copolymer having a free acid end group, characterized in that the batch has a relative mass standard deviation of 2% or less".

The method claim (claim 10) of the main request played no part in the present decision.

- V. Claim 1 of the first auxiliary request is based on claim 1 of the main request with the additional feature according to which

"the diameters of the microimplants differ by no more than  $\pm 7.62 \mu\text{m}$  ( $\pm 0.0003$  inches) from the mean diameter."

Auxiliary request 1 further comprises method claim 10, which reads as follows:

"Method for making a batch according to any one of the preceding claims comprising the steps of sorting particles of one or more active ingredients, polymers and/or other optional excipients having tolerances in particle size of  $\pm 10\%$  of the desired target diameter, blending these particles into a mixture, extruding this mixture into filaments and cutting these filaments into desired microimplants."

- VI. Claim 1 of auxiliary request 2 reads as follows:

"Method for making a batch of ocular microimplants, each microimplant having a diameter of 0.483 mm (0.019 inches) or less and comprising a homogeneous mixture of one or more active ingredients, a bioerodible polylactic acid-polyglycolic acid copolymer and a bioerodible polylactic acid-polyglycolic acid copolymer having a free acid end group, characterized in that the batch has a relative mass standard deviation of 2% or less and the diameters of the microimplants differ by no more than  $\pm 7.62 \mu\text{m}$  ( $\pm 0.0003$  inches) from the mean diameter, comprising the steps of sorting particles of

one or more active ingredients, polymers and/or other optional excipients to have tolerances in particle size of  $\pm 10\%$  of the desired target diameter, blending these particles into a mixture, extruding this mixture into filaments and cutting these filaments into desired microimplants."

VII. The following document played a role in the present decision:

D4: US-A-2004/0137059.

VIII. The essential arguments of the appellant can be summarised as follows:

*Main request*

Claim 1 of the main request defined a batch of microimplants, the batch having a particular upper limit for the relative mass standard deviation, the batch further comprising implants of particular material and particular diameter. No such combination of features was disclosed in D4.

D4 disclosed in paragraph [0052] a plurality of biodegradable polymer matrices including mixtures of hydrophilic and hydrophobic ended PLGA, of which, however, only one of the listed hydrophilic end groups, the carboxyl, qualified as a free acid end group as claimed. Also in example 2, paragraph [0099], the particular hydrophilic end group to be used was not specified.

Likewise, D4 disclosed in paragraph [0061] a plurality of possible implant diameters for implants to be accommodated in the vitreous chamber. Of these

different diameter ranges only the respective lower end points fell within the claimed range. Moreover, the implant of the only example of a vitreous implant, see example 3 in paragraph [0100], was to be inserted through an incision made by a 20-gauge microvitreoretinal blade and consequently was of considerably larger diameter than the 0.483 mm claimed.

Thus, a selection among a first list of implant materials and a second list of possible implant diameters was required in order to reach the claimed subject-matter, which, therefore, was not clearly and unambiguously disclosed.

Finally, D4 only disclosed properties of individual implants per se but did not address a batch of implants, let alone particular batch properties. In defining a batch of implants, the subject-matter of claim 1 was conceptually different from what was disclosed in D4.

Even if the implants resulting from the extrusion process disclosed in D4, paragraphs [0092] to [0096] and [0099] were considered forming a batch of implants in the sense of claim 1, D4 would still not disclose all these implants to be cut to the same length and desired weight. It was well possible that - in order to suit the needs of different patients - implants of different length were cut from the extrudate. Anyway, D4 did not disclose any property of the batch, in particular not the relative mass standard deviation of the implants in the batch being of 2% or less.

This difference had the technical effect of providing a batch of implants with reliable, predictable properties. As disclosed in the application, page 29,

lines 13 to 17, by looking at a statistically significant sub-group, it was possible to predict the properties of individual implants from the so determined batch properties, without having to evaluate each individual implant.

Conversely, D4 was not only silent on any batch properties, but also on drawing a conclusion based on so determined batch properties and on appropriately selecting a batch of implants.

Assuming that D4 disclosed or rendered obvious a batch of ocular microimplants having the claimed relative mass standard deviation was thus based on hindsight.

Therefore, the subject-matter of claim 1 was novel and involved an inventive step over D4 in combination with the common general knowledge.

*Auxiliary request 1 - admissibility*

While it was true that a claim with the subject-matter of claim 1 of present auxiliary request 1 had been part of auxiliary request 2 dated 17 August 2012, the Board should still exercise its discretion and admit the request into the proceedings. The subject-matter was not complex, there was no other party being disfavoured and the request had been filed at a very early stage of the appeal proceedings. Furthermore, in examination appeal proceedings, the situation was different from opposition appeal proceedings - to which the rules of procedure of the Boards of Appeal mostly related - in that the applicant could only choose one request to proceed to grant, such that it did not make sense to uphold auxiliary requests for which the examining division had indicated a substantial objection. The



appellant should thus not be prevented from resubmitting such a request in appeal.

*Auxiliary request 2 - admissibility*

Claim 1 of auxiliary request 2 had been amended in response to a clarity objection first raised in the Board's summons to oral proceedings. It thus had to be considered a timely *bona fide* response to the course of the proceedings. Therefore, auxiliary request 2 should be admitted into the proceedings.

**Reasons for the Decision**

1. Main request

1.1 Document D4 discloses the manufacture of extruded biodegradable ocular implants (paragraphs [0092]-[0096]; paragraph [0099], example 2 and paragraph [0030], first sentence), the extruded implants being for implantation into the vitreous (see paragraphs [0062], [0065], [0084], [0086]).

1.2 Selection of implant material and implant size

Every extruded implant according to example 2 of D4 needs to be made from a particular material and it needs to have a particular size adapted to the intended implantation site. It is true that D4 explicitly mentions three possible hydrophilic end-groups (carboxyl, hydroxy and polyethylene glycol; see paragraph [0052]) of which only carboxyl is a free acid group as claimed, and that in paragraph [0061] different implant diameter ranges are envisaged for vitreous implants.

However, the diameter ranges suggested are not distinct, alternative ranges, but rather a broader diameter range with its further preferred and most preferred sub-ranges, with the preferred and most preferred sub-ranges lying fully within the respective broader ranges. All lower end points, which for a single parameter range are considered to be explicitly disclosed, are below the 0.483 mm claimed. The person skilled in the art thus finds in D4 direct and unambiguous teaching to provide an extruded implant for the vitreous of a diameter falling under the claimed range. That the diameter of the vitreous implant in example 3 may be larger does not change or contradict this disclosure.

There is, furthermore, nothing in D4 which would suggest a functional link between the implant diameter and a particular hydrophilic end group to be used. Indeed, D4 does not give an indication that any of the three explicitly listed hydrophilic end groups was more or less suitable for a particular implantation site or implant size.

The Board thus considers extruded implants for the vitreous with a diameter as claimed and with the hydrophilic end group being carboxyl disclosed in D4.

### 1.3 Batch and batch properties

#### 1.3.1 As stated above, Document D4 discloses the manufacture of extruded biodegradable ocular implants.

In the example process (see paragraph [0099]), an active agent (micronized dexamethasone), a bioerodible polylactic acid-polyglycolic acid copolymer (hydrophobic end PLGA) and a bioerodible polylactic

acid-polyglycolic acid copolymer having a hydrophilic end (hydrophilic end PLGA) are mixed to form a resulting powder blend. The resulting powder blend is fed into an extruder, with the filament being extruded into a guide mechanism and cut into exact lengths that correspond to the designated implant weight.

The implants produced from a particular mixed powder blend form a "batch of ocular implants" (a "Charge", see in this context the extract from Bauer et. al "Lehrbuch der Pharmazeutischen Technologie", submitted by the appellant during oral proceedings before the examining division). In said batch, the implants inevitably have masses and, consequently the batch inevitably has a relative mass standard deviation. Therefore, D4 discloses a batch of vitreous implants having a relative mass standard deviation, even without the concept of such a batch being explicitly mentioned in D4.

- 1.3.2 The appellant argued that even assuming that D4 disclosed a process for producing a batch of implants, it did not disclose clearly and unambiguously that all the implants in a batch had the same length since it was possible that the implants were cut to different lengths according to patient needs. However, such a change in cutting length within a running extrusion process would be extremely unusual in the context of the large scale implant manufacture typical for the pharmaceutical industry which is explicitly envisaged in D4 (see paragraph [0093]). Hence, the person skilled in the art would understand paragraph [0099] in the sense that the filament is cut into exact lengths corresponding to a single designated implant weight envisaged for the batch.

Aiming at a single designated implant weight implies aiming at a low relative mass standard deviation.

1.3.3 As discussed during the oral proceedings, the starting materials and manufacturing process disclosed in D4, paragraph [0099], are very much alike to the ones used in the application (page 31, example 1): dexamethasone and PLGA are obtained from the same companies (Paramacia, Peapack, NJ and Boehringer Ingelheim), as is the extruder (DACA Microcompounder- Extruder, Goleta, Calif.). Also the extrusion parameters used are similar (D4, paragraph [0096] and the application p. 31, example 1 both mention twin screw extrusion at 80-130°C / 90-110°C respectively). Just as in D4, the implants of the invention are finally cut from the extruded filaments. It is thus to be expected that the relative mass standard deviation of the D4 batches will at least be very close to the claimed cut-off of 2%. The Board accepts, however, in favour of the appellant, that a particular value for the relative mass standard deviation in the batch produced by the process in D4 is not clearly and unambiguously disclosed and that it cannot be excluded that minor differences in the D4 manufacturing process may lead to a relative mass standard deviation above 2%.

1.3.4 Because of the homogenous dispersion of the drug within the polymer matrix (D4, paragraph [0093]), the technical effect of a low relative mass standard deviation around the designated implant weight is a high uniformity of dosage of the implants in the batch. The technical problem can thus be formulated as to increase uniformity of dosage in the batch of implants produced by the extrusion process.

As accepted by the appellant, securing and optimizing uniformity of dosage is a general desire in pharmacology. In the context of example 2 (paragraph [0099]), which, in order to reach uniformity of dosage, discloses cutting the implants to exact lengths corresponding to the designated, i.e. intended implant weight, this obvious desire translates into the skilled person's aim to make the relative mass standard deviation as small as possible, thereby eventually going below the claimed desideratum value.

A batch having the obviously desirable high uniformity of dosage (and thus a relative mass standard deviation below 2%) might become non-obvious and claimable if there was no known way or applicable method in the art for making it and the method for its preparation was therefore the first to achieve this and do so in an inventive manner. However, as discussed in point 1.3.3 above, example 1 of the application and D4, paragraph [0096] show that it required no more than routine adaptation of known extrusion processes, performed with commercially available instruments on commercially available starting products, to make a batch as claimed.

- 1.3.5 The appellant was of the opinion that - contrary to what is disclosed in D4 - the subject-matter defined in claim 1 had the effect of providing a batch of implants with reliable, predictable properties. This effect is, however, likewise reached by the routine adaptation of the D4 manufacturing process in order to improve uniformity of dosage.
- 1.3.6 Furthermore, the appellant argued that the gist of the invention was the idea of analysing only a statistically significant sub-group of implants of a

batch, to predict therefrom properties of individual implants in the batch and to discard batches which do not fulfil the acceptance criterion. Such a process was not disclosed in D4. The appellant thereby essentially argues that a batch according to claim 1 necessarily has undergone a certain selection procedure, i.e. it is accepted as a batch according to the invention only if the relative mass standard deviation of a statistically significant sub-sample taken thereof is below 2%.

However, claim 1 is not limited to batches which have undergone a particular selection and thus fulfil a certain quality criterion. Even if only every second or third of the batches produced by the optimized process according to D4 fulfilled the claimed condition, this batch would still fall under the subject-matter of claim 1, whether it had undergone a selection based on evaluation of a statistically significant sub-sample of its implants or not.

1.4 Consequently, the subject-matter of claim 1 of the main request is not inventive.

2. Auxiliary requests 1 - admissibility

2.1 Auxiliary request 1 was filed during the oral proceedings before the Board. It is based on auxiliary request 2 filed with the statement setting out the grounds of appeal, but differs from that request by the following changes introduced to method claim 10: the term "rigorously high degree of homogeneity" was replaced by the term "particle size of +/- 10% of the desired target diameter" and the term "obtaining" was replaced by "sorting".

- 2.2 Under Article 13(1) RPBA the Board has as discretion whether or not to admit and consider any amendment to a party's case after it has filed its grounds for appeal. Article 13(1) RPBA contains a non-exhaustive list of criteria pursuant to which this discretion is to be exercised: the complexity of the new subject-matter considered, the current state of the proceedings and the need for procedural economy.
- 2.3 In the case before the Board, the amendments were produced at a very late stage in the proceedings. They were not very complex. However, in the Board's view, the overall prosecution history also needs to be taken into account in the present case.
- 2.4 Method claim 10 of auxiliary request 1 refers to a "[m]ethod for making a batch according to any one of the preceding claims". Claim 1 of auxiliary request 1 contains the feature "and the diameters of the microimplants differ by no more than  $\pm 7.62 \mu\text{m}$  ( $\pm 0.0003$  inches) from the mean diameter." This claim is in essence the same as claim 1 presented on 17 August 2012 in examination proceedings.
- 2.5 The subject-matter of claim 1 of said request before the examining division was objected to under lack of inventive step (communication dated 4 October 2012, point 3.2) and later on abandoned, i.e. it was not part of the requests underlying the impugned decision. Thus, considerations usually made in the context of Article 12(4) RPBA are now of relevance.
- 2.6 By the appellant not further pursuing what was then auxiliary request 2, the examining division did not and could not decide on these claims. If auxiliary request 1 was admitted into the proceedings before the

Board, the appellant would have - by its procedural acts - circumvented a decision by the examining division on these device claims and brought the matter for a first and final decision before the Board. This is contrary to the principle established in G 10/93, reasons 4 (OJ 1995, 172) according to which proceedings before the boards of appeal in ex parte cases are primarily concerned with examining the contested decision.

2.7 With respect to the appellant's counter-arguments it is noted that the Rules of Procedure of the Boards of appeal apply in examination and opposition appeal proceedings alike. Furthermore, while only one request can ultimately proceed to grant, there is nothing which prevents an applicant to pursue several requests for decision before the examining division, the decisions on all of which - in case of a refusal - is subject to examination in appeal. Therefore, in view of the state of the proceedings and the need for procedural economy, the Board exercises its discretion not to admit auxiliary request 1 into the proceedings, even though the subject-matter may not appear overly complex.

3. Auxiliary request 2 - admissibility

3.1 Auxiliary request 2 has also been introduced during the oral proceedings before the Board. The situation is, however, different for auxiliary request 2 in which the amended method claim 1 is the only independent claim. A method claim comprising the unclear expression "particle sizes with a rigorously high degree of homogeneity" was part of both requests on which the impugned decision is based (the requests filed respectively on 20 April 2012 and 12 April 2013) and of all method claims treated in examination proceedings.



Though, the feature had never been objected to under Article 84 EPC so far. Defining the method to comprise the step of "of sorting particles of one or more active ingredients, polymers and/or other optional excipients to have tolerances in particle size of  $\pm 10\%$  of the desired target diameter" is a *bona fide* attempt to overcome that lack of clarity. Moreover, it appears that in order to more clearly define the unclear expression, claiming possibly yet unsearched features can hardly be avoided.

Hence, balancing the appellant's right to a patent and the EPO's interest in bringing the procedure to a close, the Board finds it appropriate to admit auxiliary request 2 into the proceedings even though - due to a possibly required additional search - this means a remittal of the case to the examining division.

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the Examining Division for further prosecution on the basis of the claims of auxiliary request 2 filed during the oral proceedings before the Board.

The Registrar:

The Chairwoman:



C. Moser

P. Acton

Decision electronically authenticated