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Datasheet for the decision of 7 June 2022

Case Number: T 1869/19 - 3.3.07

Application Number: 10185774.6

Publication Number: 2329811

IPC: A61K9/16, A61P27/02, A61K31/36

Language of the proceedings: EN

Title of invention:
Ocular implant obtained by double extrusion process

Patent Proprietor:
ALLERGAN, INC.

Opponent:
Generics [UK] Limited

Headword:
Ocular implant obtained by double extrusion process/Allergan Inc.

Relevant legal provisions:
EPC Art. 54
RPBA Art. 12(4)

Keyword:
Main request - Product by process - Novelty (No)
Auxiliary request - Admitted into the proceedings (No)

Decisions cited:
T 0726/16, G 0007/93, T 0640/91

Catchword:

Europäisches Patentamt
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Beschwerdekammern

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Case Number: T 1869/19 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 7 June 2022

Appellant: (Patent Proprietor)	ALLERGAN, INC. 2525 Dupont Drive Irvine, CA 92612 (US)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Respondent: (Opponent)	Generics [UK] Limited (trading as Mylan) Albany Gate Darkes Lane Potters Bar Hertfordshire EN6 1AG (GB)
Representative:	Elkington and Fife LLP Prospect House 8 Pembroke Road Sevenoaks, Kent TN13 1XR (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 27 May 2019 revoking European patent No. 2329811 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	A. Usuelli
Members:	D. Boulois
	L. Basterreix

Summary of Facts and Submissions

I. European Patent No. 2 329 811 is based on European patent application No. 10185774.6, which was filed as a divisional application of earlier European patent application 07 017 089.9. The latter was itself filed as a divisional application of earliest European patent application 05 814 028. The patent was granted on the basis of ten claims.

II. The Patent had been opposed under Article 100 (a), (b), (c) EPC, on the grounds that its subject-matter lacked novelty and inventive step, was not sufficiently disclosed, and extended beyond the content of the application as filed.

III. The opposition division, in a first interlocutory decision taken during the oral proceedings of 28 September 2015 revoked the patent. According to this first interlocutory decision, none of the requests met the requirements of Article 76(1) EPC.

IV. This first decision of the opposition division was set aside by the Board in decision T 100/16. The Board's decision was based on the main request filed during the oral proceedings before the Board on 10 July 2018, which was considered to meet the requirements of Article 76(1) EPC.

The main request comprised one single claim which read as follows:

"1. A bioerodible implant for treating a medical condition of the human eye, the implant comprising PLGA and from 40 to 80 wt% dexamethasone as active agent

dispersed within a biodegradable PLGA matrix, wherein at least 75% of the particles of the active agent have a diameter of less than 10 µm, and the implant being made by a method comprising the steps of: (a) milling the PLGA; (b) blending the milled PLGA and the particles of the active agent, to thereby obtain a blended mixture of the milled PLGA and the particles of the active agent; (c) carrying out a first extrusion of the blended mixture, to thereby obtain a first extrusion product; (d) pelletizing the first extrusion product, and; (e) carrying out a second extrusion of the pelletized first extrusion product, thereby obtaining the bioerodible implant."

V. The present appeal lies from the second decision of the opposition division to revoke the patent. The decision was based on the main request filed on 10 July 2018 before the Board of Appeal and auxiliary request 1 filed on 9 November 2018.

The only claim of auxiliary request 1 differed from claim 1 of the main request in the addition of the feature "wherein the extrusion steps are carried out using a single or twin screw extruder".

VI. The documents cited during the opposition proceedings included the following:
D1= WO 02/43785 A2
D5= US 6 726 918 B1
D6= Expert Declaration A. Salameh, 23 October 2018
D7= Experimental Test Report

VII. According to the decision under appeal, the main request was not novel over D1 and D5. The auxiliary request was not admitted into the opposition

proceedings, since it did not *prima facie* overcome the outstanding issues regarding novelty.

VIII. The patent proprietor (hereinafter the appellant) filed an appeal against said decision.

IX. With the statement setting out the grounds of appeal dated 7 October 2019, the appellant filed again the main and auxiliary requests already on file.

X. A communication from the Board, dated 30 March 2022, was sent to the parties. In it the Board expressed its preliminary opinion that claim 1 of the main request lacked novelty over D1 and D5 and that the Board concurred with the opposition division that the auxiliary request was *prima facie* not novel.

XI. Oral proceedings took place on 7 June 2022.

XII. The arguments of the appellant may be summarised as follows:

Main request - Novelty

Claim 1 of the main request was a product-by-process claim, and it had a certain breadth. It included in particular a double extrusion step. D6 and D7 showed that the prior art products, all made by single extrusion, were not consistent with manufacturing by a method which involved extrusion, pelletization and then extrusion again. D6 explained that an extruded implant of the claimed type would have a dramatically different porosity depending on whether it is produced by an extrusion or by extrusion-pelletization-extrusion. This was backed up by the experimental report D7. Thus there was reliable evidence on file which firstly showed that

the different processing did result in an important and measurable difference in the products. Furthermore, there was evidence on file which showed that the difference in porosity resulting from this change in processing was much greater than the possible porosity impact of altering other variables which were related to the intensity of the mixing in an extrusion process. In view of this, the prior art implants from D1 and D5 could not fall within the scope of claim 1. Moreover, there was no information in D1 or D5 on the extrusion parameters, since the examples were not very elaborate. There was no evidence of an overlapping disclosure, and on the balance of probabilities, the claimed subject-matter was novel.

Auxiliary request - Admissibility

The decision not to admit this request was an improper use of the opposition division's discretion. The Auxiliary request was filed over four months before the oral proceedings and more than two months in advance of the Rule 116 EPC deadline. There were two parallel opposition cases against the present application and the parent application. In the parallel case, it was only at the appeal hearing that it became apparent that a key issue seemed to be the question of whether the product-by-process features were too broad, in particular because the type of extruder was not limited. Hence, the auxiliary request should be admitted:
- the claims were filed well in advance for the opposition division and the opponent to be able to comment;
- the claims did not introduce any new complex issues; and

- the claims did address a key criticism which was brought up in the parallel case, and given that the decision of that case was filed and relied on by the present opponent and mentioned in the decision under appeal, it was not proper to deny patentee a chance to defend himself against these arguments by amendment. Moreover, the type of extruder might make a difference with regard to novelty.

XIII. The arguments of the respondent may be summarised as follows

Main request - Novelty

The respondent agreed with the reasoning of the opposition division, and of the Board of appeal when considering the parent patent in T 726/16, and fully agreed that the double extrusion product-by-process step did not limit the scope of the claim. On this basis, the opposition division was correct to hold that the patent lacked novelty.

Auxiliary request - Admissibility

The decision was correct to hold that the auxiliary request did not change the issues, and *prima facie* did not introduce any new distinguishing feature.

XIV. Requests

The appellant (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained according to the main request filed on 10 July 2018, or, alternatively, that the patent be maintained on the basis of the auxiliary request filed on 9 November 2018.

The respondent (opponent) requested that the appeal be dismissed.

Reasons for the Decision

1. Main request - Novelty

1.1 Claim 1 has been drafted in the form of a mix of "product features" and "product-by-process features".

Hence, claim 1 of the main request comprises as essential "product features" a bioerodible implant comprising PLGA and from 40 to 80 wt% dexamethasone as active agent dispersed within a biodegradable PLGA matrix, wherein at least 75% of the particles of the active agent have a diameter of less than 10 µm.

The claimed bioerodible implant is further characterized by "product-by-process features", comprising the essential following preparation steps:
- (a) milling the PLGA;
- (b) blending the milled PLGA and the particles of the active agent,
-(c) carrying out a first extrusion of the blended mixture
- (d) pelletizing the first extrusion product,
- (e) carrying out a second extrusion of the pelletized first extrusion product.

1.2 D1 discloses in example 4 the preparation of a 50/50 Dexamethasone/PLGA ocular implant:

- 2.5 g of PLGA of particle size approximately 9-12 µm in diameter were placed in a mixing vessel. The vessel was placed in the oven at 130°C for ten minutes.
- 2.5 g of dexamethasone of particle sizes less than approximately 10 µm in diameter, were added to the vessel, and the vessel was returned to the oven for 10 minutes.
- The PLGA/dexamethasone mixture was mixed well, the blend loaded into a barrel, and 650-790 µm diameter filaments were extruded. The resulting filaments were cut into lengths of approximately 0.94 and 1.87 mm for 500 µg and 1000 µg formulations, respectively.

D1 mentions that the extrusion temperature is comprised between 60 and 130°C (see D1 par. [00054] and [00055]).

Since D5 discloses exactly the same experiments in example 6, only D1 will be considered for the assessment of novelty.

1.3 Accordingly, the document D1 discloses the same "product features" as claim 1 of the main request regarding the type and amounts of active and polymer.

With regard to the "product-by-process features", the biodegradable implant of D1 is prepared by a single extrusion and pelletization step. D1 does not discloses the following steps involved in the preparation of the claimed implant:
- step (a) milling the PLGA,
- step (b) blending the milled PLGA and the particles of the active agent, to thereby obtain a blended mixture of the milled PLGA and the particles of the active agent and

- step (e) carrying out a second extrusion of the pelletized first extrusion product, thereby obtaining the bioerodible implant.

With regard to these product-by-process features, such features can only contribute to the novelty of the claimed implant insofar as they give rise to a distinct and identifiable characteristic of the product. Accordingly, in order to establish novelty, it has to be verified that the process features of the "product-by-process" claim are such that the resulting product is influenced by them in a way that it can be distinguished from the products of the prior art produced by a different process.

Moreover, where a process feature is the only feature allegedly conferring novelty to a product, the burden of proof for showing the fact that the process feature results in a distinct and identifiable characteristic of the product is on the patent proprietor, e.g. by means of a convincing technical argumentation or comparative tests.

1.3.1 In the absence of any limitation in claim 1 as to the conditions of the milling steps (a) and (b), and considering that the size of dexamethasone in D1 is identical to the claimed size, namely a diameter of less than 10 µm, and the size of PLGA in D1 is comprised between 9-12 µm in diameter while undefined in claim 1 of the main request, it must be concluded that the milling steps (a) and (b) cannot impart any identifiable differentiating feature to the implant. This conclusion was not disputed by the appellant.

1.3.2 The implant of claim 1 is defined by the further extrusion step (e), specifically comprised in a

sequence of (c) first extrusion, (d) pelletizing the first extrusion product and (e) second extrusion, constituting a double extrusion process, instead of a simple extrusion process in D1. According to the appellant, these steps lead to the preparation of implants having a higher density and less brittleness than a single extruded one.

While the Board has no doubt that a double extrusion process might have an effect on the structure of the obtained implant, in particular its density, this effect on the structure remains linked with the extrusion parameters used in the preparation of the claimed implant. None of the extrusion parameters are however defined in claim 1.

The importance of the extrusion parameter is emphasized in the description of the contested patent which mentions that "extrusion parameters such as temperature, extrusion speed, die geometry, and die surface finish will have an effect on the release profile of the implants produced" (see paragraph [0113]). It appears that in particular the set temperature, the screw speed and the die nozzle diameter (die geometry and die surface finish) are essential extrusion parameters having an incidence on the structure of the extruded implant. D1 also teaches the importance of the extrusion parameters, namely by specifying that "extrusion methods result in implants with a progressive more homogenous dispersion of the drug within the polymer, as the production temperature is increased" (see par. [0054]).

This is also confirmed by the experiments of D7 on which the appellant relied to show that implants obtained by a double extrusion step have a higher

density than implants obtained by a single extrusion step. In the experiments of D7, three implants were prepared. Implant 1 was prepared through a double extrusion, i.e. first extrusion at a barrel temperature of 105°C and screw speed of 120 rpm, second extrusion at a barrel temperature of 107°C and screw speed of 100 rpm. Implants 2 and 3 were prepared using a single extrusion step with barrel temperature of 105°C, the latter with a higher screw speed, namely 200 rpm instead of 120 rpm. Implant 1 shows a greater geometric density as illustrated by the following Table:

Implant No.	*Implant target Diameter (in)*	*Geometric Density (g/cm^3)*	*Length to Achieve Target Weight of 1172 µg calculated using Geometric Density and a nominal implant diameter of 0.0182 in*
1	0.0182	1.124	6.214 mm
2	0.0182	0.883	7.911 mm
3	0.0182	0.974	7.170 mm

Hence, these experiments show that a double extrusion process might be able to produce a product with different characteristics than with a single extrusion, in particular in term of density. The experiments of D7 however cannot reflect the full scope of the claim and are bound to the specific extrusion parameters used therein. Importantly, these experiments show also the weight of the extrusion parameters in the properties and structure of the final extruded product, since it was possible to obtain an implant 3 with a higher geometric density with a single extrusion simply with a higher screw speed, namely 200 rpm, instead of 120 rpm.

The importance of the extrusion parameters is further illustrated by the experiments of example 8 of the contested patent. In this example, it was possible to produce an implant through a first single extrusion step with a final geometric density comprised between 0.85 and 1.14 g/cm3 (see Table D), hence higher than the density obtained for implant 3 of D7 and potentially identical to the density of implant 1 obtained by a double extrusion.

In the present case, the claimed subject-matter includes implants obtained by extrusion processes performed under extreme conditions, such as a cold extrusion at slow screw speed, as well as a melt extrusion at very high speed. Hence, no conclusion can be drawn from the patent on the effect of carrying out the double extrusion, for instance in much less stringent conditions. As a result, claim 1 covers embodiments in which the double extrusion steps is conducted in such mild conditions that the resulting implant cannot differ structurally from those reported in D1. In this respect, the question is not whether the teaching of the prior art is sufficiently complete or can be modified so as to obtain the same properties as obtained in some examples of the patent or in the experiments of D7, but rather whether the claim is so broadly defined, in respect of the process conditions, as to cover implants that are necessarily undistinguishable from that of D1.

In its declaration of 23 October 2018 (document D6), Mr Salameh states that in his opinion a double extrusion method could not be used to achieve a density value which is the same as, or similar to, the density observed in the single extruded sample of the experimental report D7. However, as explained above, in

the absence of any limitation as the conditions in which the double extrusion is performed, claim 1 covers implants that could have very different densities.

1.4 Consequently, the Board concurs with the opposition division that a double extrusion as claimed in claim 1 of the main request does not inevitably cause the obtainable product to have distinctive properties and to be distinguishable from a bioerodible PLGA/ dexamethasone ocular implant made by single extrusion as disclosed in D1 (see Decision of the opposition division, point 2.5).

1.5 Accordingly, the claimed subject-matter is not novel over D1.

2. Auxiliary request 1 - Admission into the appeal proceedings

2.1 The subject-matter of the sole claim 1 of this request specifies that the extrusion steps are carried out using a single or twin screw extruder.

2.2 This request was late filed by the Patentee on 9 November 2018 namely five years after the notice of opposition. An objection of lack of novelty over D1 was already raised and the opposition division had already summoned the parties on 14 September 2018, with a negative preliminary opinion on novelty of the main request. The opposition division did not admit this request since it was late filed and it did not *prima facie* overcome the outstanding issues regarding novelty. The opposition division considered that the use of a certain type of extruder could not address the remaining objections, because in the absence of any limitations as to the processing parameters, the use of

common extruders could not give rise per se to a distinct and identifiable property of the obtainable implant.

Moreover, the auxiliary request was not a response to new issues raised in, or to a change of the facts of, the present case.

Indeed, as explained in the decision, according to the Patentee's own explanation, the filing of the Auxiliary request was a reaction to the Board's decision T 726/16 of revocation of the earlier (parent) patent EP 1 870 092 (07017089.9). The oral proceedings for the case T 726/16 took place on 30 October 2018.

2.3 The question as to whether this request should be admitted must be decided on the basis of Article 12(4) RPBA 2007 (see Article 25(2) RPBA 2020). Article 12(4) RPBA 2007 gives the Board discretion to hold inadmissible requests which could have been presented or were not admitted in the first instance proceedings.

A Board of appeal should only overrule the way in which a department of first instance has exercised its discretion when deciding on a particular case if it concludes that it has done so according to the wrong principles, or without taking into account the right principles, or in an unreasonable way, and has thus exceeded the proper limits of its discretion (see T 640/91 (point 6.3) and G 7/93 (reasons 2.6)).

In the present case, the Board considers, that the opposition division had the discretion not to admit these requests, which were submitted well after the expiry of the time limit set under Rule 79(1) EPC for replying to the opposition. This all the more since the

facts had not changed, because an objection of lack of novelty over D1, in particular in view of the double extrusion step was already present in the opponent's notice of opposition.

The Board agrees furthermore with the opposition division that the amendment introduced in claim 1 only amounts to a recitation of extruder types commonly used in the art. This amendment cannot possibly address the novelty objection in the absence of any limitation as the processing parameters, and the use of common extruders cannot give rise per se to a distinct and identifiable property or structure of the implant. Moreover, as discussed during the oral proceedings before the Board, example 4 of D1 mentions that the PLGA/dexamethasone blend was loaded "into a barrel", which appear to implies that the extruder used in D1 is a single or twin screw extruder.

In view of these facts, the Board concludes that the opposition division exercised its discretion in accordance with the right principles and not in an unreasonable way. Accordingly, the auxiliary request is not admitted into the appeal proceedings (Article 12(4) RPBA 2007).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

C. Rodríguez Rodríguez A. Usuelli

Decision electronically authenticated