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Datasheet for the decision of 10 July 2018

Case Number: T 0100/16 - 3.3.07

Application Number: 10185774.6

Publication Number: 2329811

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

Language of the proceedings: EN

Title of invention:
Ocular implant obtained by double extrusion process

Patent Proprietor:
ALLERGAN, INC.

Opponent:
Generics [UK] Limited (trading as Mylan)

Headword:
Ocular implant / ALLERGAN

Relevant legal provisions:
EPC Art. 76(1), 111(1)
RPBA Art. 12, 13

Keyword:

Late-filed request - submitted during oral proceedings - admitted (yes)
Divisional application - added subject-matter (no) - after amendment
Appeal decision - remittal to the department of first instance (yes)

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Case Number: T 0100/16 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 10 July 2018

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:	Gillard, Richard Edward Elkington and Fife LLP Thavies Inn House 3-4 Holborn Circus London EC1N 2HA (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 9 November 2015 revoking European patent No. 2329811 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	A. Usuelli
Members:	S. Albrecht
	Y. Podbielski

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 (EP 1 870 092), hereinafter referred to as "earlier application". The latter was itself filed as a divisional application of earliest European patent application 05 814 028.6 (EP 1 776 091), which hereinafter is referred to as "root application". The patent was granted on the basis of ten claims.

II. An opposition was filed against the patent on the grounds that its subject-matter lacked novelty and inventive step (Article 100(a) EPC), was not sufficiently disclosed (Article 100(b) EPC) and extended beyond the content of the application as filed and the earlier applications as filed (Article 100(c) EPC).

III. The opposition division's decision to revoke the patent was based on a main request and five auxiliary requests.

The main request was the patent as granted. Auxiliary requests 1 to 4 were filed on 28 July 2015, whereas auxiliary request 5 was filed during the oral proceedings before the opposition division on 28 September 2015.

Claim 1 of the main request read as follows:

"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 milling the PLGA and subjecting the milled PLGA and the particles of the active agent to a double extrusion process".

IV. According to the decision under appeal, claim 1 of the main request did not fulfil the requirements of Article 76(1) EPC, because the subject-matter of this claim constituted an impermissible intermediate generalisation of the features "the implant being made by milling the PLGA and subjecting the milled PLGA and the particles of the active agent to a double extrusion process". These features had been extracted in isolation from their original context, whilst omitting other functionally related features, and subsequently generalised into a broader context for which the earlier application did not provide any basis.

With regard to auxiliary requests 1 to 5, the opposition division admitted these into the proceedings, but considered that the conclusions with respect to the main request equally applied to all of these requests.

V. The patent proprietor (hereinafter appellant) lodged an appeal against the decision of the opposition division. With the statement setting out the grounds of appeal the appellant filed five auxiliary requests, and requested that the decision under appeal be set aside and the patent be maintained as granted or, in the alternative, that the patent be maintained as amended on the basis of one of the five auxiliary requests.

The appellant furthermore requested that the case be remitted to the first instance in the event that any issue which was not addressed in the decision under appeal were to be resolved.

The main request and auxiliary requests 3 to 5 were identical to the corresponding requests forming part of the basis of the appealed decision.

VI. With the reply to the statement of grounds of appeal filed on 25 May 2016 the opponent (hereinafter respondent) requested that the appeal be dismissed. The respondent also requested that auxiliary requests 1 and 2 not be admitted into the proceedings, and that in the event that the Board set aside the opposition division's decision on added matter, the Board consider the other grounds of opposition and do not remit the case to the opposition division.

VII. By letter dated 10 April 2018 the respondent informed the Board that it would not attend the oral proceedings.

VIII. In a communication pursuant to Article 15(1) RPBA issued on 18 June 2018, the Board expressed its preliminary opinion that claim 1 of the main request (i.e. claim 1 as granted) did not fulfil the requirements of Article 76(1) EPC.

As for the first and the second auxiliary requests, the Board indicated that it would be inclined to admit these into the proceedings. Claim 1 of both requests appeared, however, to suffer from the same deficiencies as claim 1 of the main request.

In addition, the feature "mol ratio of lactic acid to

glycolic acid is in the range 52:48 to 48:52", present in claim 1 of the third, fourth and fifth auxiliary request respectively, did not appear to be disclosed in the earlier application as filed and the root application as filed.

The Board further observed that in the case of a request which would meet the requirements of Articles 76(1) and 123(2) EPC, it would consider it appropriate to remit the case to the opposition division for further prosecution.

IX. Oral proceedings took place on 10 July 2018. They were attended by the appellant only. In these proceedings, the appellant filed a new main request and withdrew the previous main, first and second auxiliary requests. Auxiliary requests 3 to 5 filed with the statement setting out the grounds of appeal were maintained. The new main request comprised one single claim which read as follows:

"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."

X. The appellant's arguments, as far as they are relevant for the present decision, can be summarised as follows:

(a) The main request filed during the oral proceedings should be admitted into the proceedings. The amendments made constituted a minimal change of the case, since the additionally introduced features of the blending and the pelletization steps were already present in the third auxiliary request filed with the statement setting out the grounds of appeal. Furthermore, these amendments were appropriate in that they overcame the objections under Article 76(1) EPC.

(b) The main request fulfilled the criteria of Article 76(1) EPC. The subject-matter of claim 1 found basis in the following passages of both the earlier and the root application as filed: claim 7 as dependent claim of claim 1; page 23, lines 4 to 14; page 25, lines 5 to 6 and lines 11 to 12. As for the feature of the PLGA matrix, this was equally supported by both the earlier and the root application as filed. In particular, PLGA was the only matrix material mentioned in the claims and the only biodegradable polymer exemplified in these two applications.

(c) In the event that any issue which was not addressed in the decision under appeal were to be resolved, the present case should be remitted to the department of first instance. Otherwise, the appellant's right of appeal would effectively be taken away.

XI. The respondent's arguments, as far as they are relevant for the present decision, can be summarised at follows:

(a) Both the earlier and the root application as filed did not disclose the combination of the following features: (i) a double extrusion, (ii) a milling step, and (iii) the specific proportions of dexamethasone.

(b) In the event that the Board found that any request meets the requirements of Articles 123(2) and 76(1) EPC, it should consider the other grounds of opposition and should not remit the case to the first instance, the reasons being as follows:

It was established case law that there was no absolute right for a party to have issues decided by two instances. Furthermore, in the present case remittal was not appropriate, given the fact that the patent proprietor had already a decision on the patent which was based on the earlier application, wherein the subject-matter of claim 1 of this patent differed from claim 1 of the present patent only in a couple of trivial product features which could not establish novelty and/or inventive step.

XII. Requests

The appellant requested that the decision under appeal be set aside and the patent be maintained as amended on the basis of the main request filed during the oral proceedings or, in the alternative, on the basis of one of the auxiliary requests filed with the statement setting out the grounds of appeal on 18 March 2016 as auxiliary requests three to five. The appellant furthermore requested that the case be remitted to the

department of first instance in the event that any issue which was not addressed in the decision under appeal were to be resolved.

The respondent requested that the appeal be dismissed. The respondent also requested that in the event that the Board set aside the opposition division's decision on added matter, the Board consider the other grounds of opposition and do not remit the case to the opposition division.

Reasons for the Decision

Main request

1. Non-attendance of the respondent at the oral proceedings

As announced in its letter dated 10 April 2018, the respondent did not attend the oral proceedings.

In accordance with Rule 115(2) EPC and Article 15(3) RPBA, the oral proceedings were held without the respondent. By its decision not to attend the oral proceedings, the respondent has chosen not to make any further submissions during such proceedings. In the Board’s view this also entails that the respondent has chosen not to make submissions on any foreseeable procedural development which occurred during the oral proceedings, such as the filing of a new request in direct response to the Board’s communication.

In the present case, the duly summoned respondent has to be treated as relying only on its written case.

2. Admission of the main request

This request was filed during the oral proceedings before the Board. The only claim of this request corresponds to claim 1 of the main request filed with the statement setting out the grounds of appeal with the exception that the process of manufacture of the claimed implant has been defined in a more detailed manner. These modifications have been made in response to the negative preliminary opinion of the Board expressed in its communication issued on 18 June 2018. They represent a direct, clear and fair attempt by the appellant to defend its patent without adding complexity to the case under consideration.

Accordingly, the Board finds it appropriate to exercise its discretion under Articles 12 and 13 RPBA by admitting the main request into the proceedings.

3. Article 76(1) EPC

3.1 According to G 1/06, in the case of a sequence of applications consisting of a root (originating) application followed by divisional applications, each divided from its predecessor, it is a necessary and sufficient condition for a divisional application of that sequence to comply with Article 76(1), second sentence, EPC that anything disclosed in that divisional application be directly and unambiguously derivable from what is disclosed in each of the preceding applications as filed (see headnote).

3.2 In the present case, the description and the drawings are identical in the root application as filed and the earlier application as filed, whereas their claims as filed differ in content. Hence, if not otherwise

indicated herein, references to the description relate to the description of both the earlier and the root application as filed.

3.3 The subject-matter of claim 1 of the main request is directed to a bioerodible implant for treating a medical condition of the human eye, wherein the implant is further defined by:

(i) features relating to the product as such, namely the presence of 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;

(ii) features pertaining to the manufacturing process of the claimed implant, i.e. the process steps (a) to (e) (see point IX above).

3.3.1 The earlier application and the root application as filed provide on page 23, lines 4 to 14 of the description a general basis for a bioerodible implant for treating a medical condition of the eye, the implant being made by a method which comprises the following steps:

(a) milling a biodegradable polymer;

(b) blending the milled biodegradable polymer and particles of an active agent, to thereby obtain a blended mixture of the milled biodegradable polymer and the particles of the active agent, wherein at least about 75% of the particles of the active agent have a diameter of less than about 20µm;

(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.

The limitation of the claimed use to a human eye can be derived for instance from page 13, lines 7 to 9, and from page 23, line 24 to page 24, line 1 of the description.

The claimed weight range of the active agent is disclosed on page 25, lines 9 to 11, of the description. This passage refers to steroidal anti-inflammatory agents in general. However, the skilled person would consider that this passage also refers to the steroidal anti-inflammatory agent dexamethasone specifically, given the fact that among the different active agents disclosed in the description, dexamethasone is the only one which is singled out as preferred and which is exemplified (see page 25, lines 5 to 6 and the examples).

The claimed particle size distribution of the active agent is narrower than the corresponding particle size distribution disclosed on page 23, lines 4 to 14 of the description, and finds adequate support in the earlier and the root application as filed, for instance on page 21, paragraph 1 to page 22, line 1 of the description and in claim 7.

As to the selection of PLGA as biodegradable polymer, the passage on page 26, lines 16 to 17 of the description teaches that this specific type of polymer is of particular interest. Furthermore, PLGA is the only exemplified polymer as well as the only polymer which is individualised in the claims as filed.

Accordingly, for the reasons provided above, the Board concludes that the earlier and the root application as filed directly and unambiguously disclose all of the features of claim 1 of the main request in combination. Hence, claim 1 of the main request meets the requirements of Article 76(1) EPC.

Remittal

4. Although Article 111(1) EPC does not guarantee the parties an absolute right to have all the issues in the case considered by two instances, it is well recognised that any party should, whenever possible, be given the opportunity of two readings of the important elements of a case. The primary function of appeal proceedings is to consider whether the decision issued by the first-instance department is correct. Hence, a case is normally remitted, if essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the department of first instance.

4.1 This is the situation here, since the opposition division has not yet ruled on essential opposition grounds such as novelty or inventive step.

4.2 The respondent argued that a remittal was not appropriate, given the fact that the appellant had already a decision, after oral argument, on the patent which was based on the earlier application, wherein the subject-matter of claim 1 of this patent differed from claim 1 of the present patent only in a couple of trivial product features which could not establish novelty and/or inventive step.

4.3 Nevertheless, the Board does not consider this argument strong enough to justify a deviation from the principles set out above. Claim 1 of the present main request differs in several aspects from claim 1 as granted of the earlier application. In particular, it is restricted to dexamethasone as active agent which must be present in the implant in a certain weight range, whereas it does not specify any ratio of lactic to glycolic acid monomers in the PLGA. Also, the process of manufacture of the claimed implant comprises five steps a) to e), whereas claim 1 as granted of the earlier application merely refers to the milling of the PLGA and the double extrusion process.

Under these circumstances, the Board considers it appropriate to exercise its discretion under Article 111(1) EPC to remit the case to the opposition 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 opposition division for further prosecution.

The Registrar: The Chairman:

S. Fabiani A. Usuelli

Decision electronically authenticated