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**Datasheet for the decision
of 12 November 2019**

Case Number: T 1520/17 - 3.3.10

Application Number: 10750046.4

Publication Number: 2470230

IPC: A61L27/26, A61L27/52,
A61L27/58, C08L5/08, C08B37/00

Language of the proceedings: EN

Title of invention:
VISCOELASTIC GELS AS NOVEL FILLERS

Patent Proprietor:
Fidia Farmaceutici S.p.A.

Opponent:
ALLERGAN, INC.

Headword:

Relevant legal provisions:
EPC Art. 100(a), 56
RPBA Art. 13

Keyword:

Inventive step - (no) - main request, auxiliary requests 1 to 3

Amendment of the appellant's case. Admitted (no)

Decisions cited:

Catchword:



Beschwerdekammern

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Case Number: T 1520/17 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 12 November 2019

Appellant: ALLERGAN, INC.
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 4 May 2017
rejecting the opposition filed against European
patent No. 2470230 pursuant to Article 101(2)
EPC.**

Composition of the Board:

Chairman P. Gryczka
Members: R. Pérez Carlón
W. Van der Eijk

Summary of Facts and Submissions

I. The appeal lies from the decision of the opposition division rejecting the opposition against European patent No. 2 470 230.

II. Notice of opposition had been filed on the ground of lack of inventive step (Article 100(a) EPC).

III. The documents filed include the following:

D1 WO 2008/068297 A1

D4 WO 99/24070 A2

D5 WO 99/49412 A1

D7 EP 0 341 745 A1

D28 G.D. Prestwich, Biomaterials from Chemically-Modified Hyaluronan, GlycoForum 2001, <http://glycoforum.gr.jp/science/hyaluronan/HA18/HA18E.html>

The respondent (patent proprietor) relies on experimental evidence including the following:

D20 Submission during examination proceedings dated 19 July 2013

D24 Experimental evidence filed with the reply to the grounds of appeal

IV. Claim 1 of the patent as granted, which is the main request of the respondent in these appeal proceedings, reads as follows:

"Biomaterials obtainable by mixing

- the autocrosslinked derivative of hyaluronic acid (ACP) with

- *the derivative (HBC) of hyaluronic acid crosslinked with 1,4-butanediol diglycidyl ether (BDDE)*

in the weight ratio of between 10:90 and 90:10 as novel fillers and/or as body shaping products."

V. The opposition division concluded that document D1, which disclosed biomaterials containing hyaluronic acid and HBC, was the closest prior art. The problem underlying the claimed invention was to provide biomaterials having improved filling effect over a prolonged period of time. The solution, which was characterised by replacing hyaluronic acid by ACP, was not obvious having regard to the prior art.

VI. With a letter dated 9 April 2019, the respondent filed its first to fourth auxiliary requests.

Claim 1 of auxiliary request 1 differs from claim 1 of the patent as granted in that the expression "obtainable by mixing" is replaced by "consisting of".

Claim 1 of auxiliary request 2 reads as follows:

"Biomaterials obtainable by mixing

- *the autocrosslinked derivative of hyaluronic acid (ACP), prepared as described in EP 0341745 and having a mean degree of crosslinking of between 4 and 5%, with*
- *the derivative (HBC) of hyaluronic acid crosslinked with 1,4-butanediol diglycidyl ether (BDDE), BDDE being dissolved in alkaline solution in a stoichiometric ratio from 2.5 to 25% in moles of the repetitive units of hyaluronic acid;*

in the ACP/HBC weight ratio of between 10:90 and 90:10 as novel fillers and/or as body shaping products."

Claim 1 of auxiliary request 3 contains all the features of claim 1 of the first auxiliary request and, in addition, *"in the weight ratio of 25:75 with a volume enhancing effect."*

Lastly, independent claims 1 and 2 of auxiliary request 4 are directed to multistep processes of mixing ACP with HBC. These claims correspond to claims 5 and 6 of the patent as granted.

VII. The arguments of the appellant relevant to the present decision were as follows:

Document D1 was the closest prior art and disclosed biomaterials which lacked ACP. The experimental evidence on file showed that the sole problem solved by the claimed biomaterials was to provide an alternative. The solution, characterised by the presence of ACP, was obvious since document D5 disclosed that ACP acted as a reservoir of hyaluronic acid. For this reason, the claimed biomaterials were not inventive. The conclusion applied in an analogous manner to the biomaterials of auxiliary requests 1 to 3.

The process of independent claim 2 of auxiliary request 4 was not inventive having regard to D1. The appellant saw no need to raise any objection to that subject-matter earlier in the proceedings, as that method for preparing a biomaterial could only have been inventive if the obtained biomaterial was novel and inventive. Once the biomaterials were no longer claimed, it was entitled to put forward its case with respect to the processes for making them. The objection had already

been raised in opposition and should be admitted into the proceedings by the board.

VIII. The arguments of the respondent were as follows:

Document D1 was the closest prior art. It disclosed biomaterials which contained hyaluronic acid instead of ACP. The problem underlying the claimed invention was to provide a biomaterial which made it possible to improve immediate hydration and residence time. The solution, which was a biomaterial containing ACP instead of hyaluronic acid, was not obvious having regard to the prior art. The biomaterials of claim 1 were for that reason inventive.

The arguments applied analogously to claim 1 of each of auxiliary requests 1 to 3.

Auxiliary request 4 restricted the claimed subject-matter to processes of mixing HBC and ACP which were independent claims of the patent as granted. The appellant had not raised any objection against these processes in appeal prior to the oral proceedings before the board. The appellant's arguments were late and should not be admitted, since the respondent was not prepared to address them.

IX. Oral proceedings before the board of appeal took place on 12 November 2019.

X. The final requests of the parties were as follows:

- The appellant requested that the decision under appeal be set aside and that European patent No. 2 470 230 be revoked.

- The respondent requested that the appeal be dismissed and the patent thus be maintained as granted (main request) or, auxiliarily, maintained on the basis of one of auxiliary request 1-4, all filed with a letter dated 9 April 2019.

XI. At the end of the oral proceedings, the decision was announced.

Reasons for the Decision

1. The appeal is admissible.

Main request. Inventive step

2. Claim 1 of the patent as granted relates to biomaterials obtainable by mixing the autocrosslinked derivative of hyaluronic acid (ACP) and the derivative of hyaluronic acid crosslinked with 1,4-butanediol diglycidyl ether (HBC), in the weight ratio of between 10:90 and 90:10, as fillers and/or as body shaping products.

3. Closest prior art

The opposition division agreed with the respondent that document D1 was the closest prior art. The appellant argued that not only D1 but also D4 was a suitable starting point for examining inventive step.

Since the board has come to the conclusion that the claimed biomaterials are not inventive over those of document D1, there is no need to elaborate on whether those of D4 could come even closer to the claimed invention.

It was not disputed that D1 discloses biomaterials which contain HBC and hyaluronic acid, but lacked ACP.

The parties were divided on whether biomaterials containing hyaluronic acid were encompassed by the wording of claim 1 of the patent in suit. In favour of the respondent, inventive step will be examined assuming that the biomaterials of claim 1 differ from those of D1 in that they contain ACP *instead of* hyaluronic acid, which was the respondent's view in this respect, and not *in addition to* hyaluronic acid, as argued by the respondent.

4. Technical problem underlying the invention

The respondent defined the technical problem underlying the claimed invention as providing a biomaterial which made it possible to improve

- immediate hydration of the tissue and
- residence time.

5. Solution

The claimed solution to this technical problem is the biomaterial of claim 1, characterised in that it contains ACP instead of hyaluronic acid.

6. Success

Residence time

- 6.1 In the following, it will be examined whether the subject-matter of claim 1 is inventive on the assumption, to the respondent's advantage, that the part of the technical problem relating to a longer residence time has been credibly solved by the features

of claim 1.

Immediate hydration

6.2 The respondent relied in this respect on the experimental evidence filed as D24.

According to the respondent, immediate hydration was shown by the volume of skin swelling from T0 (day of inoculation) up to T7.

6.2.1 Data at T0

The respondent argued that the median values obtained differed from each other and showed the effect sought at T0.

However, the biomaterial according to claim 1 induces at T0 the same swelling as a biomaterial according to D1 within the measurement error. Thus, contrary to the arguments of the respondent, D24 does not make credible that the claimed biomaterials lead to an enhanced immediate hydration at T0.

6.2.2 Data at T7

Seven days after injection (T7), the biomaterials according to claim 1 induced a larger swelling than those according to D1. This effect, however, does not show an enhanced hydration, but a longer residence time of ACP compared to hyaluronic acid, which is the first part of the technical problem formulated by the respondent.

6.3 For these reasons, D24 does not show that the problem of improved immediate hydration has been credibly

solved.

6.4 The problem underlying the claimed invention needs to be reformulated in a less ambitious manner as how to provide a biomaterial having a longer residence time. This problem is considered in the following as credibly solved by the biomaterials of claim 1.

7. It thus remains to be decided whether the proposed solution to the objective problem defined above would have been obvious for the skilled person in view of the prior art, in other words, whether it would have been obvious to replace hyaluronic acid by ACP in order to improve the residence time of the biomaterial in the tissue.

7.1 Trying to obtain a biomaterial with improved residence time, the skilled person would seek suitable, biocompatible substances which are not only more stable than hyaluronic acid against degradation, but could also act as reservoirs of hyaluronic acid and thus turn to a document such as D5, which discloses biomaterials containing autocrosslinked hyaluronic acid, ACP.

According to D5, ACP acts as a reservoir of native hyaluronic acid which is slowly released upon its degradation (page 6, lines 14-16). ACP has a longer residence time than hyaluronic acid and prolongs the contact time of native hyaluronic acid, obtained by its degradation, with the surrounding tissue. This contact triggers the biological response disclosed in D1 (reducing overexpression of MMP-1 and collagen III).

The skilled person, seeking to prolonge the effect of the biomaterials of D1, would have replaced native hyaluronic acid by more stable ACP and thus arrive at

the claimed invention without using inventive skills.

- 7.2 The respondent acknowledged that crosslinked hyaluronic acids were known to be more stable against hyaluronase than hyaluronic acid. It was also known that crosslinked hyaluronic acids acted as a reservoir of hyaluronic acid, and that the viscosity of HBC and ACP was comparable. This teaching is reflected for example in documents D5 and D7.

The respondent relied on the mechanism of action disclosed in document D1, according to which HBC was responsible for a mechanical filling prolonged in time (page 8, lines 21-22). In contrast, hyaluronic acid inhibited overexpression of MMP-1 (matrix metalloprotease-1) and collagen III (page 8, lines 24-25), which induced an enhancement of skin elasticity. The skilled person, having regard to this mechanism of action, would not have any motivation to remove hyaluronic acid from the implants of D1, as bioimplants needed its biological activity.

- 7.3 According to document D1, the role of HBC in the disclosed bioimplants is not only mechanical. HBC slowly releases hyaluronic acid, both by diffusion of free hyaluronic acid out of its tridimensional network, and by degradation of HBC itself (page 9, lines 20-22). HBC thus prolongs the duration of biological activity due to hyaluronic acid, which is quickly degraded by hyaluronases.

- 7.4 The respondent referred to document D28, which disclosed ACP as barrier to reduce post-operative adhesions (E.2). D28 taught the skilled person to use ACP as a physical barrier, not in biomaterials which relied on the biological activity of hyaluronic acid.

However, the fact that D28 makes no reference to the release of hyaluronic acid from ACP does not preclude the skilled person from following the clear teaching of D5.

- 7.5 The respondent also argued that the skilled person would not have considered combining two crosslinked derivatives of hyaluronic acid.

However, every crosslinked derivative of hyaluronic acid is a mixture of components, as crosslinking does not take place between single defined parts of the molecules, but more or less at random. There is thus no reason why a mixture of different crosslinked derivatives would have been expected to pose any problem.

This argument is also not convincing.

- 7.6 For these reasons, the biomaterials of claim 1 are not inventive (Article 56 EPC), with the consequence that the ground of opposition defined in Article 100(a) EPC precludes the maintenance of the patent as granted.

Auxiliary requests 1 to 3

8. Claim 1 of the first auxiliary request merely differs from claim 1 of the main request in that it requires that the biomaterial consists of ACP and HBC. Since the board has already examined the main request under this assumption, the conclusions apply in the same manner to the first auxiliary request.
9. Claim 1 of auxiliary request 2 requires ACP and HBC to be obtainable by defined processes.

The biomaterials of D1 contain HBC prepared by crosslinking hyaluronic acid with about 11% in moles BDDE per mol of the repeating unit of hyaluronic acid in NaOH. This preparation method is as required by claim 1.

The biomaterials of D5 contain ACP prepared by the method disclosed in EP 0 341 745, as required by claim 1.

Thus, the amendments of claim 1 do not change the analysis of inventive step with respect to that of the main request.

10. Lastly, claim 1 of auxiliary request 3 requires a weight ratio of ACP to HBC of 25:75 with a volume enhancing effect. No effect has been shown to be linked to that feature. The analysis of inventive step with respect to the main request therefore applies analogously.

These requests are therefore not allowable.

Auxiliary request 4

11. Admissibility

Independent claims 1 and 2 of auxiliary request 4 were already independent claims of the patent as granted. By restricting the subject-matter of these claims, no subject-matter has been put forward which was not already on file.

The fourth auxiliary request was filed seven months before the date set for oral proceedings, which gave

the appellant ample time to react to it. This was not disputed.

Under these circumstances, the board saw no reason not to admit this request into the proceedings.

12. At the oral proceedings before the board, the appellant argued for the first time that the process of claim 2 was not inventive having regard to D1. As the requests previously submitted always contained a claim directed to a biomaterial, the appellant argued that it saw no need to address claims directed to a process which could only have been inventive if they had led to an inventive product.

However, although a process is inventive by the mere reason that it leads to an inventive product, the reverse is not necessarily true: a process for preparing a non-inventive product can nevertheless be inventive.

13. If the claims to a product cannot be allowed, it is not uncommon that a patent proprietor limits its invention to a process for preparing said product.

In the present case, such fall-back position was already part of the subject-matter of the granted claims. If the appellant had wished to object against these claims, it should have done it in its notice of appeal.

- 13.1 In the absence of any written argument, the board was not prepared to examine at the oral proceedings the process of claim 2 of auxiliary request 4, which required a large number of steps (nine), starting from a document (D1) which had never been put forward as the

closest prior art for that subject-matter. In addition, in order to allow the respondent a chance to defend itself against this objection (Article 113 EPC), the oral proceedings would have to be postponed.

Under these circumstances, this objection of the appellant cannot be admitted into the proceedings (Article 13(3) RPBA).

14. The appellant's objection against the subject-matter of auxiliary request 4 under Article 56 EPC is not admitted into the proceedings under Article 13(3) RPBA. No other objection against the subject-matter of auxiliary request 4 is immediately apparent.

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 with the order to maintain European patent No. 2 470 230 in amended form on the basis of claims 1 to 4 of auxiliary request 4, filed with letter of 9 April 2019, with a description and figures yet to be adapted to these claims.

The Registrar:

The Chairman:



C. Rodríguez Rodríguez

P. Gryczka

Decision electronically authenticated