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**Datasheet for the decision
of 24 September 2020**

Case Number: T 0175/19 - 3.3.10

Application Number: 10726573.8

Publication Number: 2544652

IPC: A61K8/34, A61K8/73, A61Q19/08

Language of the proceedings: EN

Title of invention:
A FLUID COMPOSITION COMPRISING A HYALURONAN POLYMER AND
MANNITOL FOR IMPROVING SKIN CONDITION.

Applicant:
Allergan Industrie SAS

Headword:

Relevant legal provisions:
EPC Art. 56

Keyword:
Inventive step - (no)

Decisions cited:

Catchword:



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Case Number: T 0175/19 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 24 September 2020

Appellant: Allergan Industrie SAS
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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 17 July 2018
refusing European patent application No.
10726573.8 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chair M. Kollmannsberger
Members: R. Pérez Carlón
F. Blumer

Summary of Facts and Submissions

I. The appellant (applicant) lodged an appeal against the decision of the examining division refusing European patent application No. 10 726 573.8.

II. Claim 1 of the main request in these appeal proceedings, filed with the statement of grounds of appeal, reads as follows:

"A fluid composition comprising:

a) a hyaluronan polymer, wherein the hyaluronan polymer is present at a concentration of 11.5 mg/mL to 15.5 mg/mL, and wherein the hyaluronan polymer is uncrosslinked and constitutes at least 95% by weight of the total hyaluronan polymer present in the composition; and

b) a mannitol; wherein the mannitol is present at a concentration of 2.0% (w/v) to 5% (w/v) of the composition."

III. The documents cited by the examining division include the following:

D3 WO 2004/073759 A1

D5 WO 2008/077172 A2

IV. The examining division concluded that claim 1 of the main request and of the first auxiliary request before it was not novel.

With respect to the composition of claim 1 of the second and third auxiliary requests, which corresponds to claim 1 of the main request in these appeal

proceedings, document D3 was the closest prior art. D3 disclosed a composition containing uncrosslinked hyaluronic acid and mannitol. It also disclosed that mannitol had a stabilising effect, but did not disclose the mannitol concentration required by claim 1. The evidence on file did not show an improvement in terms of hyaluronic acid stability of the claimed composition with respect to the ones of D3, which was therefore an arbitrary selection over those of D3 and not inventive.

- V. The arguments of the appellant relevant for the present decision were as follows.

D3 was the closest prior art and did not disclose the mannitol concentration required by claim 1. The problem underlying the claimed invention was to provide hyaluronic compositions having better stability. The claimed solution, characterised by the relative amount of mannitol (2.0% to 5% w/v), credibly solved the problem of providing better stability having regard to the data in Table 4 of the application. The skilled person would have considered the relative amount of mannitol disclosed in D3, namely 0.2% to 1.0%, to be a "sweet point" which balanced mannitol stabilising effect with other factors. There was no teaching in D3 that stabilisation could increase with mannitol concentration. For these reasons, the claimed solution was inventive.

- VI. Oral proceedings before the board of appeal took place on 24 September 2020.

- VII. The appellant requested that the decision under appeal be set aside and that a patent be granted with the claims of the main request, filed with the statement setting out the grounds of appeal dated

22 November 2018.

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

Reasons for the Decision

1. The appeal is admissible.

2. Inventive step

2.1 Claim 1 relates to a composition comprising uncrosslinked hyaluronan polymer, at a concentration of 11.5 mg/mL to 15.5 mg/mL, and mannitol at a concentration of 2.0% (w/v) to 5% (w/v) of the composition.

2.2 Closest prior art

The appellant agreed with the examining division that document D3 was the closest prior art, and the board sees no reason to differ.

It has not been disputed that document D3 discloses hyaluronic acid compositions which differ from those of claim 1 only by virtue of the concentration of mannitol, which is 0.2% to 1% and thus less than required by claim 1. D3 discloses that mannitol stabilises the composition (page 4, lines 4-7; page 6, lines 14-18).

2.3 Technical problem underlying the invention

The appellant formulated the technical problem underlying the claimed invention as providing a hyaluronan polymer composition having improved

stability.

2.4 Solution

The solution to this technical problem composition of claim 1, comprising a hyaluronan polymer and mannitol and characterised in that the mannitol concentration is 2.0% (w/v) to 5% (w/v).

2.5 Success

In the following, it will be examined whether the subject-matter of claim 1 is inventive on the assumption that the technical problem as formulated by the appellant has been credibly solved by the features of claim 1.

2.6 It thus remains to be decided whether the proposed solution would have been obvious for the skilled person in view of D3.

Document D3 discloses that mannitol increases the stability of hyaluronic acid (page 6, lines 14-18) and acts as radical scavenger (page 6, lines 19-22). D3 discloses mannitol as stabiliser in the broadest sense (claim 1), and does not disclose any measure which could stabilise hyaluronic acid other than the presence of mannitol.

The skilled person having regard to the stabilising role of mannitol disclosed in D3 and trying to enhance the stability of compositions comprising hyaluronic acid and mannitol, would have increased the relative amount of stabilising mannitol, and would thus have arrived at the claimed invention without using

inventive skills.

2.7 The appellant argued that D1 had a specific teaching with respect to the amounts of mannitol to be used as stabiliser. Lacking any experimental evidence and any explanation on the mechanism, the skilled person would have concluded that no further stabilisation could have been obtained beyond the upper limit of 1%.

2.8 However, document D3 discloses that mannitol is a radical scavenger. The skilled person would thus have considered this property as underlying the stabilising effect.

It could be envisaged, as argued by the appellant, that any stabilising effect would not necessarily have increased if the concentration of mannitol went beyond that disclosed in D3, so that D3 disclosed the upper limit for achieving that effect. However, it would be within the skills of the person of the art to check whether or not this was the case. By doing so, it would inevitably have arrived at the claimed invention.

The arguments of the appellant are thus not convincing.

2.9 The appellant also argued that D3 did not contain any experimental data. The skilled person would thus have no expectation of success linked to a higher concentration of mannitol.

However, the skilled person would either have taken the information in D3 at face value, or carry out experiments in order to corroborate the stabilising effect alleged in D3. Once the stabilising effect is either accepted at face value or corroborated, increasing the amount of mannitol to increase stability

would have been an obvious option.

- 2.10 Lastly, the appellant relied on document D5, which disclosed on the passage bridging pages 2 and 3 and with explicit reference to D3 that mannitol could diffuse out of the hyaluronic acid depot. Also for this reason, the skilled person would not have increased its concentration in the composition, as it could have led to undesired effects.

However, if stabilising mannitol diffuses out of the depot, the obvious manner to compensate for the reduced stabilising effect at the depot would actually be to increase its concentration. This argument is also not convincing.

- 2.11 Claim 1 of the sole request of the appellant is thus not inventive, as required by Article 56 EPC, and the appellant's request is not allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chair:



C. Rodríguez Rodríguez

M. Kollmannsberger

Decision electronically authenticated