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**Datasheet for the decision
of 27 March 2025**

Case Number: T 1642/22 - 3.3.10

Application Number: 16706151.4

Publication Number: 3256179

IPC: A61L27/20, A61L27/52, A61L27/50

Language of the proceedings: EN

Title of invention:
IMPLANTS FOR SCULPTING, AUGMENTING OR CORRECTING FACIAL
FEATURES SUCH AS THE CHIN

Patent Proprietor:
Allergan Industrie, SAS

Opponent:
Merz Pharma GmbH & Co. KGaA

Headword:

Relevant legal provisions:
EPC Art. 100(c), 123(2), 83, 54(2), 56
RPBA 2020 Art. 13(2)

Keyword:

Grounds for opposition - added subject-matter (yes)

First auxiliary request - added subject-matter (no)

Sufficiency of disclosure - (yes)

Novelty - (yes)

Inventive step - (yes)

Decisions cited:

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 1642/22 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 27 March 2025

Appellant:

(Opponent)

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Decision under appeal:

**Decision of the Opposition Division of the
European Patent Office posted on 21 April 2022
rejecting the opposition filed against European
patent No. 3256179 pursuant to Article 101(2)
EPC.**

Composition of the Board:

Chair

P. Gryczka

Members:

R. Pérez Carlón

F. Blumer

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal against the opposition division's decision rejecting the opposition against European patent No. 3 256 179, which had been filed on the basis of all of the grounds under Article 100 EPC.

II. The following documents are relevant to the present decision.

D1 US 2006/0194758 A1

D2 WO 2012/062775 A1

D6 S. Pierre, S. Liew, A. Bernardin, "Basics of Dermal Filler Rheology", Dermatologic Surgery, April 2015 supplement, pages S120 to S126

D8 D. Jones, "Injectable Fillers: Principles and Practise", Wiley-Blackwell, 2010, pages 24 and 25

D12 H. Raspaldo, "Volumizing effect of a new hyaluronic acid sub-dermal facial filler: A retrospective analysis based on 102 cases", Journal of Cosmetic and Laser Therapy 10, 2008, pages 134 to 142

III. Claim 1 of the patent as granted reads as follows.

"A sterile composition, implantable subdermally or supraperiostially into the chin area, jawline or nose of a patient in need thereof, the composition comprising a crosslinked hyaluronic acid (HA) crosslinked with 1,4-butanediol diglycidyl ether (BDDE);

wherein the HA concentration of the composition is greater than 20 mg/g;

wherein the HA used for crosslinking is made with a

mixture of low molecular weight hyaluronic acid and high molecular weight hyaluronic acid, where the HA used for crosslinking is a mixture containing at least 50% by weight of low molecular weight HA, based on the total weight of the HA; wherein the composition has an elastic modulus between 500 Pa (+/- 50 Pa) and 900 Pa (+/- 90 Pa) at 5Hz; wherein the composition has a cohesivity above 60 gmf; wherein the composition exhibits an extrusion force between 4N (+/- 0.4N) and 15N (+/- 1.5N) at 13 mm/min using a 1 mL COC syringe and a 27G x 13mm needle."

IV. The opposition division concluded as follows.

The patent as granted did not contain added subject-matter and the claimed invention was sufficiently disclosed. There was no reason why the composition exemplified in the patent should lack the properties defined in claim 1. The patent disclosed the concentration, degree of crosslinking and molecular weights of hyaluronic acids required to obtain the defined properties, and provided guidance on the preparation of the composition.

D1 disclosed neither the cohesivity nor the elastic modulus of the composition in Example 4. The claimed composition was thus novel.

D2 came closest to the claimed invention, as D1 did not focus on dermal fillers. The problem underlying the claimed invention was to provide an injectable hyaluronic acid gel composition suitable for facial sculpting, with sufficient volumising and lifting properties. The claimed solution, characterised by the required combination of cohesivity, elastic modulus and extrusion force, would not have been obvious to a

skilled person. Even though D2 taught that the selection of low and high molecular weight hyaluronic acids depended on the desired characteristics such as extrusion force, elastic modulus, viscous modulus and cohesivity, it did not teach any combination of values, and was silent on the balance of technical characteristics leading to the properties defined in claim 1. The claimed solution was thus inventive.

- V. Claim 1 of auxiliary request 1, which was filed by the patent proprietor (respondent) with its reply to the grounds of appeal, differs from claim 1 of the patent as granted only in that it does not include the features in parentheses preceded by +/- . It thus defines an elastic modulus of between 500 Pa and 900 Pa and an extrusion force of between 4N and 15N.

Auxiliary request 1 has an independent claim directed to a composition (claim 1) and independent claims directed to a kit and to a non-therapeutic method requiring the composition in claim 1 (claims 8 and 9, respectively).

- VI. The appellant's arguments were as follows.

The ground of opposition under Article 100(c) EPC precluded the maintenance of the patent as granted. The reason for this was that the numerical values in parentheses in claim 1 defined ranges which did not correspond to the meaning of "about" in the context of endpoints of ranges as set out in paragraph [00028] of the application as originally filed. As there was no support for the deletion of "about", auxiliary request 1 also contained added subject-matter.

Moreover, the claimed invention was not sufficiently

disclosed. The patent did not show that the sole composition exemplified in the patent had the properties defined in claim 1 and there was no guidance on the preparation of a composition having such properties. The patent did not contain information as to the molecular weight of the HA in claim 1 and its teaching with respect to measuring cohesivity was insufficient.

Furthermore, the claimed composition was not novel over that in Example 4 of D1.

Any of documents D1, D2 and D12 could be considered the closest prior art. Regardless of the starting point, the problem underlying the claimed invention was to provide an alternative composition for face sculpting in the chin and jaw area, with suitable lifting properties. Starting from D12, the claimed solution was characterised by the concentration of HA, elastic modulus, cohesivity and force of injection set out in claim 1 and was not inventive in view of the combination of D12 with D1 or D2.

VII. The respondent's arguments were as follows.

Paragraph [00028] of the application as originally filed disclosed that the modifier "about" meant that a numerical value could be modified by +/-10%. Claim 1 thus had a basis in the application as filed.

Paragraph [00028] also disclosed that "about" could be deleted. Thus, the claims of auxiliary request 1 also had a basis in the application as originally filed.

There was no reason to doubt that Example 1 of the patent had the properties set out in claim 1. The

patent further taught the influence of the molecular weight, crosslinking, proportion and presence of uncrosslinked HA on the properties of the composition. The claimed invention was thus sufficiently disclosed.

As D1 did not disclose the cohesivity of the composition in Example 4 thereof, claim 1 was novel for this reason alone.

The closest prior art was a document relating to chin augmentation. The respondent agreed with the appellant on the formulation of the problem and the features characterising the solution, but argued that the prior art did not teach these and that the claimed solution was thus inventive.

VIII. The board informed the parties in a communication dated 11 July 2024 that it was of the preliminary view that Article 100(c) EPC did preclude the maintenance of the patent as granted but that the problem appeared to be solved by auxiliary request 1.

The board considered the composition in claim 1 to be novel over that in Example 4 of D1.

On inventive step, the board stated that a document relating to chin augmentation, such as D12, appeared to come closer to the claimed invention than D1 or D2.

IX. Oral proceedings before the board of appeal took place on 27 March 2025.

X. The parties' final requests were as follows.

The appellant requested that the decision under appeal be set aside and that European patent No. 3 256 179 be

revoked.

The respondent requested that the appeal be dismissed, or that the patent be maintained with one of the claim sets filed as auxiliary requests 1 to 8 with the reply to the statement setting out the grounds of appeal.

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

Reasons for the Decision

1. The appeal is admissible.
2. Amendments - main request

Claim 1 of the main request relates to a composition having an elastic modulus of between 500 Pa (+/- 50 Pa) and 900 Pa (+/- 90 Pa) and an extrusion force of between 4N (+/- 0.4N) and 15N (+/- 1.5N).

Claim 1 of the granted patent differs from claim 1 of the application as originally filed by the features in brackets, which replaced the modifier "about".

At the oral proceedings before the board, the respondent relied on its written submissions. According thereto, claim 1 had a basis in both claim 1 and paragraph [00028] of the application as originally filed, which disclosed that "about" modified a value by +/- 10%.

However, in the application as filed, the meaning of "about" in the context of numerical values, i.e. that values could be modified by +/- 10%, does not apply to endpoints of ranges. According to paragraph [00028],

the lower endpoint may be reduced by 10% and the upper endpoint increased by the same percentage. Claim 1 of the patent defines that the lower endpoint may be increased by 10% and the upper endpoint reduced by 10%, and therefore the claim defines a range that was not originally disclosed.

Article 100(c) EPC precludes the maintenance of the patent as granted for this reason alone.

3. Objections against auxiliary request 1 - Article 13(2) RPBA

3.1 Facts of the case

The opposition division rejected the opposition. The appellant contested this decision for a number of reasons as set out in its statement of grounds of appeal.

The respondent replied by arguing against those reasons and by filing auxiliary requests. Its reply to the appeal explains why in its view these auxiliary requests overcome the various issues.

The appellant filed no further arguments in writing.

3.2 The respondent argued that any objection made against auxiliary request 1 with respect to added subject-matter or insufficiency of disclosure at the oral proceedings before the board would constitute an amendment of the appellant's case, which could only be admissible in exceptional circumstances (Article 13(2) RPBA).

3.3 The board disagrees.

Claim 1 of auxiliary request 1 only differs from claim 1 of the patent as granted by the absence of the tolerance ranges in parentheses. The subject-matter of claim 1 of auxiliary request 1 is thus just about the same as that of claim 1 of the main request.

3.3.1 On sufficiency, the appellant had already submitted arguments in the context of an almost identical request. The board fails to see that the appellant's case has been amended for this reason alone.

3.3.2 The object of Article 123(2) EPC is that a patent proprietor should not be allowed to improve its position in a way that could damage the legal security of third parties relying on the content of the original application (Case Law of the Boards of Appeal, 10th ed., 2022, II.E.1.1).

This requirement is of fundamental importance and the board has the power to examine it ex-officio for its implications on third parties and on society at large. The board does not see this duty limited by the Rules of Procedure.

4. Auxiliary request 1 - amendments

Other than not including original claims 8 to 13, the claims of auxiliary request 1 differs from the application as originally filed by the fact that it does not include the feature "about".

Paragraph [00028] of the application as originally filed discloses that the modifier "about" in connection with numerical values or ranges can be deleted. The

claims of auxiliary request 1 thus have the required basis (Article 123(2) EPC).

The appellant argued at the oral proceedings that removing all of the instances of "about" created a combination that was not originally disclosed. However, the board fails to see what technical information not present in the application as originally filed has been generated in view of paragraph [00028]. This argument is therefore not convincing.

5. Auxiliary request 1 - sufficiency of disclosure

5.1 Claim 1 relates to a sterile composition. The composition is defined by the starting materials, proportions and properties, namely by its elastic modulus, cohesivity and extrusion force.

5.2 The respondent did not dispute that compositions having the required elastic modulus, cohesivity and extrusion force are not to be prepared merely by crosslinking the starting materials set out in claim 1. However, these properties could be obtained by adjusting variables taught in the patent. Example 1 provided general guidance towards embodiments of claim 1. Paragraph [0017] disclosed that a high proportion of low molecular weight hyaluronic acid increased cohesivity and elasticity. Preferred amounts and molecular weights of hyaluronic acid were disclosed in paragraphs [0030] and [0031], fitting those in Example 1. Paragraph [0036] further disclosed that the addition of uncrosslinked hyaluronic acid facilitated injection. Thus, the patent sufficiently disclosed how the properties in claim 1 could be achieved.

5.3 At the oral proceedings before the board, the appellant added to its written arguments that a skilled person could only obtain the required properties with undue burden. It questioned whether the composition in Example 1 of the patent had the properties set out in claim 1 and whether the general disclosure sufficiently taught how to achieve those properties.

5.4 The board considers the claimed invention to be sufficiently disclosed.

Absent any proof to the contrary, there is no reason to conclude that the product in Example 1 lacks the properties set out in claim 1. Thus, the argument of the appellant in this regard is not convincing.

The appellant's argument that finding further embodiments of the claimed composition represented an undue burden is also rejected absent any supporting evidence and in view of the teaching in the patent (see section 5.2 above).

5.5 The appellant also argued that cohesivity was an ill-defined property for which no standard method of measurement existed, and that the indications in the patent were not clear enough to measure it. For example, it was not apparent when to measure it or whether one point or more than one were required. The appellant concluded that the claimed invention was not sufficiently disclosed also for this reason.

However, even if the cohesivity could not be measured accurately as the appellant argues, the sufficiency issue to be resolved is whether the alleged inaccuracy is enough to prevent a skilled person from carrying out the invention. The board is of the view that this is

not the case. Paragraphs [0039] to [0041] disclose a seemingly reproducible measurement protocol and there is no proof that this would provide values so dissimilar that the claimed invention could not be carried out.

- 5.6 The appellant also argued that the claims did not limit the meaning of high molecular weight hyaluronic acid and of low molecular weight hyaluronic acid. In addition, it was not clear in the patent whether the molecular weight should be considered as weight average molecular weight or as viscous average molecular weight. The claimed invention was not sufficiently disclosed also for these reasons.

However, according to paragraph [0030] of the patent molecular weights are weight average molecular weights, unless otherwise indicated. This paragraph also discloses the molecular weight of high molecular weight hyaluronic acid. Paragraph [0031] discloses the molecular weight of the low molecular weight equivalent. The appellant's argument in this regard is therefore not convincing.

6. Auxiliary request 1 - novelty

- 6.1 At the oral proceedings before the board, the appellant merely referred to its written submissions. In view of this, the board sees no reason to depart from its preliminary view.

- 6.2 D1 is silent on the cohesivity of the composition in Example 4. For this reason alone, and in the absence of any evidence that the cohesivity of that composition must inevitably have fallen within the limits set out

in claim 1, the claimed composition is novel.

7. Auxiliary request 1 - inventive step

7.1 The claimed invention relates to a sterile composition of crosslinked hyaluronic acid suitable for subdermal or supraperiosteal implantation in the chin area (claim 1) and facial sculpturing (claim 9).

7.2 Closest prior art

The opposition division concluded that D2 came closest to the claimed invention.

The appellant argued in writing that D1 was also a suitable starting point for examining inventive step.

The respondent argued that the closest prior art should be a document relating to the same objective as that set out in paragraph [0001] of the patent, i.e. chin augmentation. The board informed the parties in its communication in preparation for oral proceedings that it was of the same view. A document relating to chin augmentation, such as D12, would appear to come closer to the claimed invention than D1 or D2.

At the oral proceedings, the appellant argued on inventive step starting from D12 and referred to its written arguments starting from D1 and D2.

Document D1 relates to a process for producing an injectable composition comprising crosslinked hyaluronic acid (see the abstract). D1 merely indicates that hydrogels obtained by crosslinking polysaccharides can be used as filling materials in plastic, cosmetic and dental surgery, and in ophthalmology and

orthopaedics for preventing tissue adhesion, and for repairing vocal cords (see paragraph [0005]). D1 provides no further details as to these applications or the polymers that could be used for each application.

Document D2 discloses hyaluronic acid compositions as dermal and subdermal fillers (see the abstract). D2 discloses minimising wrinkles and lines (see page 3, lines 15 to 17) and the claims relate to a soft-tissue filling.

Thus, neither D1 nor D2 discloses the augmentation of the lower face, let alone of the chin and jaw. These documents are thus further from the claimed invention than D12.

7.3 Document D12 as the closest prior art

Document D12 discloses chin augmentation with different commercial products including Juvéderm Voluma.

The parties agreed that Juvéderm Voluma differs from the claimed composition by:

- the HA concentration (20 mg/mL)
- the elastic modulus (ca. 400 Pa at 5 Hz in view of Table 1 of D6, third entry)
- the cohesivity (40 gmf in view of Table 1 of D6, third entry) and
- the extrusion force

7.4 Problem underlying the claimed invention

It was not disputed that the problem underlying the claimed invention was to provide an alternative composition for facial sculpting in the chin and jaw

area, with suitable lifting properties.

7.5 Solution

The claimed solution is the composition in claim 1, characterised by its HA concentration, elastic modulus, cohesivity and extrusion force.

7.6 Success

It was not disputed that the composition in claim 1 successfully allows facial contouring in the chin and jaw area.

7.7 It remains to be examined whether the claimed solution would have been obvious to a skilled person in view of the prior art.

Elastic modulus and cohesivity were known to be linked to the lifting ability of hyaluronic acid fillers (see D8, page 24, third full paragraph). However, the prior art does not teach what values of these properties make a composition suitable for a specific use, let alone which combination of values.

D12 discloses that Juvéderm Voluma has an increased cohesivity and thus reduced extrusion and flow (see page 135, last paragraph) but neither quantifies this nor teaches that it could be further enhanced without compromising its use. D12 is silent on elastic modulus. The elastic modulus and cohesivity of Juvéderm Voluma are disclosed in document D6, which is not prior art; both are outside the ranges set out in claim 1.

A skilled person seeking an implantable composition suitable for chin and jaw augmentation could have

considered the values of elastic modulus and cohesivity in claim 1, but there is no reason why they would do so.

The appellant argued that D1 and D2 taught the claimed solution. However, neither of these documents refers to cohesivity. This argument of the appellant is not convincing for this reason alone.

Since the board has arrived at the conclusion that the claimed subject-matter is inventive in view of two of the features distinguishing it from D12, it is not necessary to elaborate on the relevance of the two others.

The claimed composition is thus inventive (Article 56 EPC), as are the kit in claim 8 and the non-therapeutic method in claim 9 requiring the composition in claim 1.

8. Auxiliary request 1 is allowable.

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 the patent on the basis of the claims of auxiliary request 1, filed with the reply to the statement setting out the grounds of appeal, and a description to be adapted.

The Registrar:

The Chair:



C. Rodríguez Rodríguez

P. Gryczka

Decision electronically authenticated