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Datasheet for the decision of 16 September 2025

Case Number: T 1302/23 - 3.3.02

Application Number: 16193473.2

Publication Number: 3138586

IPC: A61L27/26, A61L27/50, A61L27/52

Language of the proceedings: EN

Title of invention:
SOFT TISSUE FILLER

Patent Proprietor:
Allergan Industrie, SAS

Opponent:
Merz Pharma GmbH & Co. KGaA

Headword:

Relevant legal provisions:
EPC Art. 76(1), 100(c), 111(1)

Keyword:
Divisional application - added subject-matter

Decisions cited:
G 0001/24

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

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Case Number: T 1302/23 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 16 September 2025

Appellant: (Patent Proprietor)	Allergan Industrie, SAS Route de Promery Zone Artisanale de Pre-Mairy 74370 Pringy (FR)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Respondent: (Opponent)	Merz Pharma GmbH & Co. KGaA Eckenheimer Landstrasse 100 60318 Frankfurt/Main (DE)
Representative:	Wallinger Ricker Schlotter Tostmann Patent- und Rechtsanwälte mbB Zweibrückenstraße 5-7 80331 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 3 May 2023 revoking European patent No. 3138586 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	M. O. Müller
Members:	S. Bertrand
	B. Burm-Herregodts

Summary of Facts and Submissions

I. The appeal by the patent proprietor ("appellant") is against the opposition division's decision revoking European patent No. 3 138 586.

II. The patent is concerned with the provision of injectable soft tissue fillers and more specifically of hyaluronic acid-based dermal and subdermal fillers. Hyaluronic acid is abbreviated to "HA" in the following.

III. The following document is referred to in the present decision:

D10 Harding, Stephen E. et al., "Advances in Carbohydrate Analysis", JAI Press Ltd, 1991, pages 63-144

IV. In the impugned decision, the opposition division's conclusions included that claim 1 of each of the main request and auxiliary requests 1 to 7 contained subject-matter extending beyond the content of the parent application as filed (Article 76(1) EPC) and the application as filed (Article 123(2) EPC).

V. In the statement of grounds of appeal, the appellant contested the opposition division's decision. It submitted a copy of auxiliary requests 1 to 7 filed before the opposition division.

VI. In the reply to the grounds of appeal, the opponent ("respondent") contested the appellant's submissions and agreed with the opposition division's conclusions.

VII. The board summoned the parties to oral proceedings as per their requests and issued a communication under Article 15(1) RPBA.

VIII. Oral proceedings before the board were held by videoconference on 16 September 2025 with both parties present.

IX. The parties' requests, where relevant to this decision, were as follows.

The appellant requested:

- that the decision under appeal be set aside and the case be remitted to the opposition division for assessment of inventive step under Article 56 EPC should the granted claims comply with Articles 76(1) and 123(2) EPC, or

- that the decision under appeal be set aside and the opposition be rejected, implying maintenance of the patent as granted or alternatively,

- that the patent be maintained in amended form on the basis of the set of claims of one of auxiliary requests 1 to 7 filed before the opposition division on 28 February 2022 and re-filed with the statement of grounds of appeal.

The respondent requested that the appeal be dismissed, implying that the opposition division's decision to revoke the patent be upheld. Alternatively, the respondent requests that should the board arrive at the conclusion that the set of claims of one of the appellant's claim requests meets the requirements under Articles 76(1) and 123(2) EPC, the decision under appeal be set aside and the case be remitted to the

opposition division for the assessment of the grounds of opposition not decided upon by the opposition division.

X. The arguments of both the appellant and the respondent, where relevant to the present decision, are summarised below.

Reasons for the Decision

Main request

1. Added subject-matter – claim 1 – Articles 100(c) and 76(1) EPC

1.1 The patent was granted on European patent application No. 16 193 473.2, which is a divisional application of European patent application No. 11 799 644.7 ("parent application").

1.2 Claim 1 of the main request reads as follows:

"*1. A soft tissue filler composition comprising:*

(1) a crosslinked hyaluronic acid (HA) component comprising a mixture of a first HA material having a ***weight average molecular weight*** *of less than 1.0 MDa and a second HA material having a* ***weight average molecular weight*** *in the range of 1.0-4.0 MDa, wherein* ***the first HA material is contained in the mixture in an amount greater than 50% by weight,*** *and the mixture has a bimodal molecular weight distribution; and*
(2) an uncrosslinked HA material having a weight average molecular weight of at least 1.0 MDa;

wherein each of the HA materials is selected from hyaluronic acid and a pharmaceutically acceptable salt thereof; and
wherein the filler composition has a HA material concentration of 10-40 mg/mL." (emphasis added by the board)

Thus, claim 1 of the main request refers to weight average molecular weights (in bold above) of the first and second HA materials which form a mixture that is comprised in the crosslinked HA component (1). Furthermore, claim 1 of the main request requires the first HA material to be contained in the mixture in an amount greater than 50% by weight (also in bold above). The respondent objected to both features under Article 76(1) EPC.

1.3 The weight average molecular weight of the first and second HA materials in claim 1 of the main request

1.3.1 As set out above, each of the first and second HA materials comprised in the crosslinked HA component referred to in claim 1 of the main request is defined by a **weight average** molecular weight. The numbers given in claim 1 of the main request for these weight average molecular weights are disclosed on page 10, lines 17 and 18 (first HA material) and lines 9 to 11 (second HA material) of the parent application as filed.

However, in contrast to claim 1 of the main request, the passage on page 10, lines 17 and 18 of the parent application as filed discloses that the first HA material has a **molecular weight** of less than 1 MDa. The passage on page 10, lines 9 to 11 of the parent application as filed discloses that the second HA material has a **molecular weight** in the range of 1.0-4.0

MDa. Hence, the two passages above do not specify the type of molecular weight, let alone that it is a weight average molecular weight as required by claim 1 of the main request.

In fact, the first paragraph on page 10 discloses that "[t]*he molecular weight of HA is calculated from an intrinsic viscosity measurement using the following Mark Houwink relation*:

$$Intrinsic\ Viscosity\ (m^3/kg) = 9.78 \times 10^{-5} \times Mw^{0.690}$$".

It was common ground between the parties that the Mark-Houwink equation is used to calculate a viscosity average molecular weight and that the molecular weight values disclosed on page 10 of the application as filed were viscosity average molecular weight values. Hence, if anything, the molecular weights disclosed on page 10, lines 17 and 18 and lines 9 to 11 of the parent application as filed are viscosity average rather than weight average molecular weights, as required by claim 1 of the main request.

1.3.2 The appellant argued that, using the description of the patent to interpret claim 1 of the main request, the skilled person would understand that the weight average molecular weights of claim 1 of the main request were viscosity average molecular weights. The appellant in this respect relied on the following passages of the description of the patent.

- The "Definitions" section in paragraphs [0035] and [0036] stated that the molecular weight of HA was calculated from the intrinsic viscosity and was thus a viscosity average molecular weight.

- Paragraph [0031] of the description of the patent stated that the definitions in this section applied to the entire specification (i.e. including the claims) and overrode conventional definitions if there was a conflict.

Furthermore, according to the appellant the skilled person would know that HA was a complex polymer and that it was difficult to determine its true weight average molecular weight. This was evidenced by pages 65, 66, 105 and 106 of D10. The skilled person would thus realise that the viscosity average molecular weight had to be used instead of the weight average molecular weight. The appellant concluded that the term "weight average molecular weight" in claim 1 of the main request would therefore be understood as the viscosity average molecular weight, which had an explicit basis on page 9 of the parent application as filed.

The board is not convinced by the appellant's submission that the skilled person would interpret the term "weight average molecular weight" found in claim 1 of the main request to mean "viscosity average molecular weight".

Claim 1 of the main request refers to weight average molecular weights rather than viscosity average molecular weights. Weight average molecular weight and viscosity average molecular weight are terms conventionally used in polymer chemistry. As was common ground between the parties, a weight average molecular weight is different from a viscosity average molecular weight. Reading claim 1 of the main request, the skilled person would therefore interpret the term

"weight average molecular weight" as it stands, i.e. not as viscosity average molecular weight.

Furthermore, the board takes the view that the patent proprietor's submission is not convincing even if, for a decision on added matter, the description could be consulted to interpret a claim in the light of G 1/24, and this for the following reasons.

The molecular weight ranges given in claim 1 of the main request for the first and second HA materials are disclosed in paragraphs [0037] and [0038] of the patent. These paragraphs describe these ranges as "molecular weight" ranges. Paragraph [0034] of the patent discloses that "[a]*ll numbers herein expressing 'molecular weight' of HA are to be understood as indicating the weight average molecular weight (Mw) in Daltons*". Hence, in the light of this part of the description, the molecular weight ranges given in claim 1 of the main request are weight average molecular weight ranges. The interpretation of claim 1 of the main request thus does not change when this part of the description is consulted.

Paragraph [0035] of the patent discloses that the molecular weight of HA is calculated using the Mark-Houwink equation, which, as set out above, gives the viscosity average molecular weight. Paragraph [0035] of the patent does not refer to any weight average molecular weight. Thus, this disclosure in paragraph [0035] of the patent is not consistent with that of paragraph [0034].

Hence, the description of the patent is inconsistent as regards the question of how the term "molecular weight" is to be understood. Therefore, the skilled person

would not derive any clear definition of the term "molecular weight" from the description of the patent, let alone the one relied upon by the appellant, namely viscosity average molecular weight.

Therefore, contrary to the appellant's argument, upon consulting the description of the patent the skilled person would not redefine the clear and technically meaningful term "weight average molecular weight" in claim 1 of the main request to mean "viscosity average molecular weight".

This conclusion is not changed by the appellant's argument based on D10, which discloses that "*a single determination of an average molecular weight or even more so, a molecular weight distribution, of any new polysaccharide preparation can still require a research project of some difficulty and duration*" (page 65); HA is among the polysaccharides disclosed in D10 (page 66). D10 also discloses that the intrinsic viscosity is a reliable parameter for characterising polysaccharides and is useful for calculating the molecular weights of polysaccharides (page 105) and that the Mark-Houwink equation ("MHKS equation") is used to determine the viscosity average molecular weight (page 106). However, nowhere in the passages of D10 relied on by the appellant is it stated that a weight average molecular weight of HA is to be understood as a viscosity average molecular weight.

1.3.3 The appellant also submitted, as a different argument, that claim 1 of the parent application as filed referred to weight average molecular weight as required by claim 1 of the main request and was thus a basis for claim 1 of the main request.

The board is not convinced.

Claim 1 of the parent application as filed reads as follows:

"*1. A soft tissue filler composition comprising:*
(1) a crosslinked hyaluronic acid (HA) component comprising a crosslinked mixture of (i) a first, low molecular weight HA material having a weight average molecular weight of between 0.20 about MDa [sic] *and about 0.99 MDa and (ii) a second high molecular weight HA material having a weight average molecular weight of between about 1.0 MDa and about 4.0 MDa;*
wherein the weight average molecular weight of the second, high molecular weight HA material is at least twice that of the first, low molecular weight HA material;
wherein the HA materials are hyaluronic acid or one or more salts thereof;
wherein the crosslinked HA component has a HA concentration of between about 15.0 mg/g and about 20.0 mg/g; and
wherein the crosslinking is achieved by use of a crosslinking agent; and
(2) an uncrosslinked HA component which is HA or a salt thereof, and which has a weight average molecular weight of at least about 1.0 MDa and ispresent [sic] *in the composition in an amount of less than about 5.0% w/w.*"

The board acknowledges that claim 1 of the parent application as filed refers to weight average molecular weights.

However, starting from claim 1 of the parent application as filed, the following deletions/

replacements/additions are needed to arrive at claim 1 of the main request:

- deleting "crosslinked" (mixture)

- replacing a weight average molecular weight of between about 0.20 MDa and about 0.99 MDa with a weight average molecular weight of less than 1 MDa

- deleting "wherein the weight average molecular weight of the second, high molecular weight HA material is at least twice that of the first, low molecular weight HA material"

- deleting "wherein the crosslinked HA component has a HA concentration of between about 15.0 mg/g and about 20.0 mg/g"

- deleting "wherein the crosslinking is achieved by use of a crosslinking agent"

- deleting "the uncrosslinked HA component is present in the composition in an amount of less than about 5.0% w/w"

- adding "wherein the filler composition has a HA material concentration of 10-40 mg/mL"

In relation to the above deletions, the appellant did not provide any disclosure in the parent application as filed indicating that the deleted features may be optional and can be omitted. For instance, as submitted by the respondent, deleting "wherein the crosslinking is achieved by use of a crosslinking agent" in claim 1 of the main request generalises the use for crosslinking of the HA component to any compound that

can induce crosslinking, for instance via ionic interactions, e.g. salts. In relation to the above addition and the above replacement, the appellant did not provide any disclosure for combining the added feature with the replaced feature, let alone for combining the added feature with the replaced feature and omitting the deleted features of claim 1 of the parent application as filed. Thus, claim 1 of the parent application as filed cannot represent a direct and unambiguous disclosure of claim 1 of the main request, as required by Article 76(1) EPC.

1.3.4 For the above reasons, the weight average molecular weight of the first and second HA materials in claim 1 of the main request is not based on the application as filed.

1.4 The feature "wherein the first HA material is contained in the mixture in an amount greater than 50% by weight"

As set out above, claim 1 of the main request comprises the feature whereby "*the first HA material is contained in the mixture in an amount greater than 50% by weight*". This feature is present in claim 1 of the main request in the context of "*a crosslinked hyaluronic acid (HA) component comprising a mixture of a first HA material ... and a second HA material*". The "mixture" in the above feature thus refers back to the mixture of the first and second HA materials which are contained in the crosslinked HA component (1) cited in claim 1 of the main request.

Thus, according to claim 1 of the main request, the reference point on which the amount of greater than 50% by weight is based is the mixture of the first and second HA materials.

1.4.1 In a first line of argument, the appellant argued that this feature was based on the passage on page 5, lines 22 to 24 of the parent application as filed.

The board acknowledges that an amount of the first HA material of greater than 50% by weight is disclosed on page 5, lines 22 to 24 of the parent application as filed. More specifically, this passage discloses that "[g]*enerally, the crosslinked HA component includes more than 50%, for example, at least 70%, for example, about 90% by weight of the first, low molecular weight HA*". However, according to this passage of the parent application as filed, the reference point on which the amount of greater than 50% by weight is based is the crosslinked HA component rather than the mixture of the first and second HA materials.

The crosslinked HA component disclosed on page 5, lines 22 to 24 of the parent application as filed "comprises" a mixture of the first HA material and a second HA material (page 5, lines 16 to 18). The open term "comprises" allows for the presence not only of the mixture of the first and second HA materials but also of additional components, e.g. further polysaccharides, such as glycosaminoglycan, that are subjected to crosslinking in combination with HA (page 15, lines 4 to 11 of the parent application as filed). This was not contested by the appellant. It follows that the reference point in claim 1 of the main request, i.e. the mixture of the first and second HA materials is not the same as the reference point in the parent application as filed, namely the "crosslinked HA component". Also for this reason, claim 1 of the main request adds subject-matter.

The appellant disputed this conclusion. It argued that according to pages 6, 13 and 17 and example 1 of the

parent application as filed, the amount of the first and second HA materials was at most 2.5 wt% based on the crosslinked HA component, which was far lower than the 50% by weight minimum in the passage on page 5, lines 22 to 24 of the parent application as filed. Interpreting the percentage amounts in the passage on page 5, lines 22 to 24 of the parent application as filed as being relative to the crosslinked HA component was therefore inconsistent with the disclosure on pages 6, 13 and 17 and example 1 of the parent application as filed. In view of this inconsistency, the skilled person would reinterpret the amount of greater than 50% by weight, disclosed in the passage on page 5, lines 22 to 24 of the parent application as filed, as being based on the amount of the mixture of the first and second HA materials.

The appellant's submission is not convincing.

Pages 6, 13 and 17 and example 1 in the parent application as filed relied on by the appellant disclose the following.

The third complete paragraph of page 6 of the parent application as filed discloses that "[t]*he crosslinked HA component has a total HA concentration of at least 10.0 mg/g. In certain specific embodiments, the crosslinked HA component has a total HA concentration of at least about 10.0 mg/g, for example, about 15.0 mg/g, about 17.0 mg/g, about 17.5 mg/g or about 20.0 mg/g, or about 25.0 mg/g*".

Likewise, the first paragraph of page 13 of the parent application as filed discloses: "*In certain embodiments, the HA concentration in the crosslinked component of the present compositions is no greater*

than about 25 mg/g, for example, about 20.0 mg/g, for example, about 18.0 mg/g, about 17.0 mg/g, about 16.0 mg/g, about 15.0 mg/g, about 13.0 mg/g, about 12.0 mg/g, about 11.0 mg/g or about 10.0 mg/g. In one embodiment, the HA concentration in the crosslinked component is about 17.5 mg/g. In another embodiment the HA concentration in the crosslinked component is 15.0mg/g. In another embodiment, the HA concentration in the crosslinked component is about 25.5 mg/g."

Page 17, lines 23 to 27 of the parent application as filed discloses: "*In some embodiments, the HA concentration of the crosslinked component of the compositions is adjusted to between about 15 mg/g and about 20 mg/g. For example, the HA concentration of the crosslinked portion of the compositions may be adjusted to yield an HA concentration of about 15 mg/g, about 17 mg/g or about 20 mg/g.*"

Example 1 of the parent application as filed discloses that "*90% of NaHA fibers or powder having a low molecular weight and 10% of NaHA fibers or powder having a high molecular weight, (ratio of high molecular weight to low molecular weight of 2:1) are hydrated in an alkaline solution*", implying a concentration of the first HA material of 90% relative to the amount of the mixture of the first and second HA materials. After several preparation steps, an "HA concentration" of about 24 mg/g is produced (page 22, lines 13 and 14), implying a concentration of the first HA material of less than 2.4 wt% relative to the crosslinked HA component.

The board acknowledges that the amount of the first HA component in example 1 is within the range as disclosed

on page 5 when based on the amount of the mixture of the first and second HA materials.

The board also acknowledges that, from all the above passages referred to by the appellant, it can be derived that the amount of the first HA material is below 2.55 wt% when based on the crosslinked HA component, which is less than the amount of more than 50% by weight disclosed on page 5, lines 22 to 24 of the parent application as filed.

However, firstly, the fact that the amount of the first HA material relative to the amount of the mixture of the first and second HA materials in example 1 is within the range disclosed on page 5, lines 22 to 24 does not by any means imply that this range on page 5 must also be based on the amount of the mixture of the first and second HA materials rather than that of the crosslinked HA component. In fact, merely looking at this disclosure of example 1 as such does not allow any conclusion to be made about the amount of the first HA material relative to the amount of crosslinked HA component, let alone that this is less than and thus, according to the appellant's argument, in contradiction with the lower limit of 50% by weight disclosed on page 5, lines 22 to 24.

Secondly, the fact that specific values of less than 50% by weight relative to the amount of crosslinked HA material are disclosed in the parent application as filed for "*certain specific embodiments*" (page 6), "*in certain embodiments*" (page 13), "*in some embodiments*" (page 17) or in one example (example 1) does not necessarily represent an inconsistency with the disclosure on page 5, lines 22 to 24.

Indeed, the amount of more than 50% by weight is preceded on page 5, lines 22 to 24 by the term "Generally", implying that this value is not necessarily present in all cases and thus not excluding the possibility that a different amount is present in certain embodiments or in one specific working example.

1.4.2 In a separate argument, the appellant submitted that the claims of the parent application as filed represented a basis for claim 1 of the main request. Claim 6 of the parent application as filed clearly disclosed the feature "wherein the first HA material is contained in the mixture in an amount greater than 50% by weight".

The board does not share the appellant's opinion.

Claim 6 of the parent application as filed reads as follows:

"*6. The composition of claim 1 wherein the first HA material is contained in the mixture in an amount greater than 50% by weight*."

Thus, claim 6 of the parent application as filed discloses the feature found in claim 1 of the main request.

However, claim 6 of the parent application as filed is dependent on claim 1. Therefore, besides this feature, claim 6 of the parent application as filed contains all the features of claim 1 of the parent application as filed.

As set out above (point 1.3.3), claim 1 of the parent application as filed is not a direct and ambiguous

disclosure of claim 1 of the main request in view of the deletions/replacements/additions needed to arrive at claim 1 of the main request. Thus, claim 1 of the parent application as filed discloses a different soft tissue filler composition from that of claim 1 of the main request.

It follows that claim 6 of the parent application as filed, being a specific embodiment of the soft tissue filler composition of claim 1 of the parent application as filed, cannot be a basis for the feature "wherein the first HA material is contained in the mixture in an amount greater than 50% by weight" for the soft tissue filler composition of claim 1 of the main request.

1.5 In view of the above, claim 1 of the main request adds subject-matter beyond the content of the parent application as filed, contrary to the requirements of Article 76(1) EPC.

1.6 The ground for opposition under Article 100(c) EPC in combination with Article 76(1) EPC prejudices the maintenance of the patent as granted.

Auxiliary requests 1 to 7

2. Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that the weight average molecular weight of the uncrosslinked HA material was specified to be "in the range of 1.0-4.0 MDa" (at least 1.0 MDa in claim 1 of the main request).

3. Claim 1 of auxiliary request 2 differs from claim 1 of the main request in that the weight average molecular weight of the uncrosslinked HA material was specified to be "in the range of 1.35-3.3 MDa".

4. Claim 1 of auxiliary request 3 differs from claim 1 of the main request in that the weight average molecular weight of the uncrosslinked HA material was specified to be "in the range of 1.5-3.0 MDa".

5. Claim 1 of auxiliary request 4 differs from claim 1 of the main request in that the weight average molecular weight of the uncrosslinked HA material was specified to be "in the range of 2.7-3.3 MDa".

6. Claim 1 of auxiliary request 5 differs from claim 1 of auxiliary request 1 in that the uncrosslinked HA material was amended to read "*an uncrosslinked HA solution which comprises between 10 mg/g and 50 mg/g of an uncrosslinked HA material*" and the "*uncrosslinked HA solution ... is contained in the composition in an amount between 0.5% and 10% by weight*".

7. Claim 1 of auxiliary request 6 differs from claim 1 of auxiliary request 3 in that the uncrosslinked HA material was amended to read "*an uncrosslinked HA solution which comprises between 10 mg/g and 50 mg/g of an uncrosslinked HA material*" and the "*uncrosslinked HA solution ... is contained in the composition in an amount between 0.5% and 10% by weight*". Claim 1 of auxiliary request 6 is a combination of claim 1 of auxiliary requests 3 and 5.

8. Claim 1 of auxiliary request 7 differs from claim 1 of the main request in that the first HA material has a weight average molecular weight of at least 0.2 MDa and less than 1.0 MDa (less than 1.0 MDa in claim 1 of the main request) and the second HA material has a weight average molecular weight in the range of 1.5-3.0 MDa (1.0-4.0 MDa in claim 1 of the main request).

9. During the oral proceedings, it was concluded – and the appellant did not dispute – that auxiliary requests 1 to 7 were not allowable for the same reasons as those given with respect to the main request.

Consequently, auxiliary requests 1 to 7 are not allowable.

10. Remittal – Article 111(1) EPC

10.1 Both parties requested that, if the board concludes that the set of claims of one of the appellant's claim requests meets the requirements under Articles 76(1) and 123(2) EPC, the decision under appeal be set aside and the case be remitted to the opposition division for the assessment of the grounds of opposition not decided upon by the opposition division.

10.2 Since the board concluded at the oral proceedings that none of the sets of claims of the appellant's claim requests met the requirements under Articles 76(1) and 123(2) EPC, it was not necessary to decide on the remittal of the case to the opposition division for further prosecution.

11. None of the appellant's requests is allowable.

Order

For these reasons it is decided that:

1. The appeal is dismissed.

The Registrar: The Chairman:

U. Bultmann M. O. Müller

Decision electronically authenticated