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Datasheet for the decision of 5 December 2025

Case Number:	T 0209/25 - 3.3.07
Application Number:	19180298.2
Publication Number:	3574901
IPC:	A61K31/445, A61K31/728, A61K8/49, A61K8/73, A61Q19/08, A61P1/02, A61P17/00, A61P17/02, A61P17/16, A61P17/18, A61P19/00, A61P23/00
Language of the proceedings:	EN

Title of invention:

INJECTION DEVICES COMPRISING A COMPOSITION OF HYALURONIC ACID AND MEPIVACAINE HYDROCHLORIDE

Patent Proprietor:

Teoxane

Opponent:

Laboratoires Vivacy

Headword:

Injection devices comprising a composition of hyaluronic acid and mepivacaine hydrochloride / TEOXANE

Relevant legal provisions:
EPC Art. 56
RPBA 2020 Art. 12(6), 12(4)

Keyword:
Inventive step - (no)
Late-filed evidence - admitted (no)

Decisions cited:
T 2342/16

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Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0

Case Number: T 0209/25 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 5 December 2025

Appellant: (Patent Proprietor)	Teoxane Les Charmilles Rue de Lyon 105 1203 Geneva (CH)
Representative:	August Debouzy 7, rue de Téhéran 75008 Paris (FR)
Respondent: (Opponent)	Laboratoires Vivacy 44 rue Paul Valéry 75116 Paris (FR)
Representative:	Tripoz, Inès Cabinet Tripoz Le Pôle Sud 22 rue Seguin 69002 Lyon (FR)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 6 February 2025 revoking European patent No. 3574901 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	A. Usuelli
Members:	E. Duval
	S. Ruhwinkel

Summary of Facts and Submissions

I. The appeal was filed by the patent proprietor (appellant) against the decision of the opposition division to revoke the patent.

II. The decision was based on a main request with claims filed as auxiliary request 1 on 5 July 2024, auxiliary request 1 corresponding to the patent as granted, and auxiliary requests 2 and 3 both filed on 5 July 2024.

Claim 1 of the main request read as follows:
"An injection device suitable for an intraepidermal and/or intradermal and/or subcutaneous administration comprising a sterile and injectable composition, said composition being prepared by a method comprising at least the steps of:
a) providing at least one gel of hyaluronic acid or a salt thereof, said hyaluronic acid being selected from a crosslinked hyaluronic acid form, a non-crosslinked hyaluronic acid form or a mixture thereof;
b) adding to said gel of hyaluronic acid at least mepivacaine hydrochloride as anesthetic agent;
and
c) sterilizing the mixture obtained in step b),
wherein the sterile and injectable composition further comprises an antioxidant selected from polyols."

Claim 1 of auxiliary request 3 additionally mandated that the hyaluronic acid is "a mixture of a crosslinked hyaluronic acid form and a non-crosslinked hyaluronic acid form".

III. The following documents were in particular cited in the appealed decision:

D1: FR 2979539, 8 March 2013
D3: WO 2012/104419, 9 August 2012
D37: Experimental data
D37a: Corrected experimental data
D39: Experimental data
D39b: Experimental data of D39 with correction of the formula

IV. In the following,
- LD stands for lidocaine,
- MV for mepivacaine,
- MV.HCl for the hydrochloride salt of mepivacaine
- HA for hyaluronic acid.

V. With respect to inventive step, the opposition division decided that:

(a) Starting from D1, the subject-matter of the main request differed by the specific use of MV.HCl, the specific order of adding MV.HCl to a HA gel composition, and the presence of a polyol. No effect had been shown for any of these differences. The objective technical problem was the provision of an alternative HA composition. The solution was obvious in light of D1 and D3.

(b) Auxiliary requests 1-3 did not satisfy the requirements of Article 56 EPC either.

VI. With their statement setting out the grounds of appeal, the appellant defended their case on the basis of the main request underlying the appealed decision and of auxiliary request 1 corresponding to auxiliary request 3 underlying the appealed decision (see II. above).

Furthermore, the appellant filed the following document D44:

D44: experimental data - 2 June 2025

VII. The Board set out their preliminary opinion in a communication under Article 15(1) RPBA.

VIII. Oral proceedings were held before the Board on 5 December 2025.

IX. The requests of the parties were the following:

(a) The appellant requested that the decision under appeal be set aside and that the patent be maintained according to the main request corresponding to the main request underlying the appealed decision, or, alternatively, that the patent be maintained according to auxiliary request 1 corresponding to auxiliary request 3 underlying the appealed decision.

(b) The opponent (respondent) requested that the appeal be dismissed. The respondent further requested that neither D44 nor the new alleged facts regarding a technical effect linked to the specific combination of MV.HCl and polyols be admitted into the proceedings.

X. The appellant's arguments can be summarised as follows:

(a) D44 had been filed in response to the appealed decision and was to be admitted into the proceedings.

(b) The invention aimed at providing an injection device comprising a composition having improved stability upon sterilization. This was not the aim of D1. D1 was not a suitable closest prior art.

If D1 was taken as closest prior art, the starting point could not be a composition comprising HA and MV, but a composition comprising HA and LD, because LD was the most preferred anesthetic agent and the one used in the examples of D1.

If the composition comprising HA and MV in D1 was taken as starting point, the subject-matter of claim 1 differed in that:
- hydrochloride was used as a salt,
- a polyol was used, and
- the MV.HCl was added to a pre-formed HA-gel.

D44 showed that a composition comprising both MV and polyol had an improved stability upon sterilisation compared to a composition comprising MV alone. The objective technical problem was to provide an injection device wherein the composition has a reduced loss upon sterilization. Starting from D1 alone or in combination with D3, the skilled person was not led to the claimed invention in order to solve the technical problem.

XI. The respondent's arguments can be summarised as follows:

(a) D44 should have been filed in the first instance proceedings. No circumstances justified the admittance of document D44 in the appeal proceedings.

(b) The purpose of the patent in suit was to develop an injectable composition containing HA, which limited the sensation of pain and without the drawback of LD. D1 also disclosed this purpose and was thus suitable as closest prior art.

D1 disclosed an injectable and sterile composition comprising HA, MV and an antioxidant. The differentiating features were the selection of the hydrochloride salt, the polyol as antioxidants and the order of addition. These differences did not result in any surprising technical effect. The problem was the provision of an alternative to D1. The use of the hydrochloride salt and the addition order were obvious for the skilled person following the teaching of D3.

Reasons for the Decision

1. Admittance of D44

1.1 With their statement setting out the grounds of appeal, the appellant submitted the new experimental report D44. D44 aims at demonstrating that the presence of the polyol has a technical effect on the rheological stability of the composition upon sterilization.

This new experimental report D44 is an amendment to the appellant's case whose admittance is subject to the Board's discretion under Article 12(4) and (6) RPBA.

1.2 According to the appellant, the filing of D44 is justified by the facts that the inventive step reasoning starting from the MV embodiment in D1 first appeared in the appealed decision and that the

opposition division surprisingly considered the data of D37b and D39b as not suitable to demonstrate a technical effect in view of the prior art. The Board does not share this view.

An objection of lack of inventive step starting not only from D1 but specifically from the MV embodiment disclosed therein was already raised in the notice of opposition (see page 23). Furthermore, in their communication issued on 17 September 2024, the opposition division expressed the preliminary opinion that the claimed subject-matter lacked an inventive step using as starting point in "both documents D1 and D3 the suggested HA/MV composition" (see §41.3). The appellant had already reacted by successively filing, on 30 August 2024, 25 October 2024 and 15 November 2024, the experimental reports D37, D39 as well as the corrected versions D37a and D39b. Article 12(6), second sentence, RPBA expresses and codifies the principle that each party should submit all relevant facts, evidence, arguments and requests as early as possible to ensure a fair and efficient procedure. Accordingly, the Board considers that the experimental data D44 could and should also have been filed in response to the opposition division's communication, if not already in response to the notice of opposition. For this reason already, D44 is not to be admitted under Article 12(6), second sentence, RPBA.

1.3 In addition, the admission of D44 is subject to the Board's discretion under Article 12(4) RPBA. This discretion is exercised in view of, *inter alia*, the suitability of the amendment to address the issues which led to the decision under appeal. D44 studies the stability upon sterilization of compositions comprising MV, LD, MV + mannitol, and LD + mannitol. Thus D44 only

provides evidence regarding the effect of mannitol, a polyol which is nowhere exemplified or mentioned in the patent. No rationale was given to justify why any effect observed with this single polyol could be extrapolated to all antioxidant polyols. The appellant attempted, for the first time during the oral proceedings before the Board, to complement the results of D44 with those of D35. However, it remains that D44 does not on itself provide any reason why its results should arise over the whole scope of the claims. Thus, D44 is not *prima facie* suitable to overturn the findings in the appealed decision.

1.4 Accordingly, the Board did not admit D44

2. Main request, inventive step

2.1 The invention as defined in the main request relates to the field of sterile and injectable compositions comprising HA, especially soft tissue filler compositions, and is directed to an injection device comprising such a composition, defined by the process for its preparation comprising in particular the addition of MV.HCl as anaesthetic agent, and by the presence of a polyol antioxidant.

The invention seeks to provide HA gels which overcome the technical problems of the painful sensation for the patient during the injection and which also do not involve any problem of allergies nor exacerbated occurrence of hematoma (see [0016]). The patent further states that a filler composition including MV.HCl as anaesthetic agent may be sterilized without significantly affecting the stability of the HA gel, as compared with LD (see e.g. paragraphs [0042] and [0043]).

2.2 D1 also relates to sterile and injectable compositions comprising HA for dermatological use, e.g. for use as soft tissue filler compositions. Its stated goals are better aesthetic effects and lower pain during administration (see page 2, lines 21-28).

The compositions of D1 comprise among others HA, an anesthetic agent, and alpha-lipoic acid (an antioxidant) (see claim 1). MV is cited among the preferred anesthetics, although it is not as preferred as LD (see page, 6 lines 8 to 12; claims 3 and 4). D1 further indicates the optional presence of additional components such as antioxidant polyols (see page 9, lines 27 to 32). Lastly, in the context of LD examples, D1 concludes that a composition of the invention possesses "an excellent stability toward heat sterilization" (see page 16, lines 13-15).

Thus D1 discloses in one alternative a composition comprising HA and MV. However D1 does not disclose this composition in combination with the presence of an antioxidant polyol.

2.3 In the Board's view, the MV embodiment of D1 is a suitable starting point for the assessment of inventive step.

D1 belongs to the same technical field and addresses the same problem of pain upon injection. Furthermore, stability upon sterilization is also a purpose in D1. Contrary to the appellant's opinion, the fact that this stability is only mentioned in the context of LD examples does not disqualify the MV alternative of D1 as starting point for the assessment of inventive step, because the LD examples, which exemplify the more

general disclosure of D1, show that stability was of concern to the authors of D1 (in which the present case differs from the situation in case T 2342/16, see point 3.1.2 of the reasons). In any case, it is not necessary for the purposes of this decision to determine whether D1 implicitly refers to rheological stability. This is because the absence of mention of rheological properties would in any case not disqualify D1 as starting point for the assessment of inventive step. D1 fulfils the criteria of relating to the same or a similar technical problem or, at least, to the same or a closely related technical field as the patent in suit. The closest prior art does not have to disclose all the problems solved by the claimed invention.

The appellant further expresses the view that starting from the HA+MV composition of D1 would constitute an *ex post* analysis with hindsight of the claimed invention, or a singling out in the disclosure of D1, because MV is disclosed in a list and is less preferred than LD. The appellant contends that, for selection inventions, it is not allowed to start from one selection in the prior art, in particular in this field, because the skilled person cannot derive from D1 that MV would allow to prepare a stable sterilized HA-containing composition.

The Board does not concur. Under Article 56 EPC, an invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. The state of the art for the purposes of considering inventive step is as defined in Article 54(2) EPC.

In the case at hand, a composition comprising both HA and MV, which results from a single selection among the

limited list of preferred anesthetics of D1, is directly and unambiguously derivable from D1 and belongs to the prior art under Article 54(2) EPC, just as the HA + MV + polyol compositions of claim 1 of the main request are directly and unambiguously derivable from the (earlier) application as filed, as they result from a single selection of polyols from the additional components recited therein (see page 13 of the application as filed, especially lines 32-35). In this respect, the Board recalls the importance of applying a uniform concept of disclosure for the purposes of Articles 54 and 123(2) EPC (see G 2/10, point 4.6 of the reasons, referring to G 1/03, point 2.2.2 of the reasons).

The Board can thus not share the appellant's view that, for the purposes of inventive step for selection inventions, it would never be allowed to start from one selection in the prior art. In the Board's view, an embodiment that is directly and unambiguously derivable from the prior art may be a suitable starting point for the assessment of inventive step also in respect of "selection inventions". The sole circumstance that this embodiment results from a selection is not enough to disregard it as a starting point.

In the present case, the Board does not consider that the choice of the above embodiment disclosed in D1 amounts to any *ex post facto* analysis, or involves any conclusion going beyond what the skilled person would have objectively inferred from the prior art, without the benefit of hindsight knowledge of the invention. The skilled person would infer from D1 and from the mention of the known anesthetic MV among the preferred anesthetics that MV is at least suitable for the preparation of a HA injectable composition. Even if the

examples of D1 are limited to LD, there is no ground for regarding the mention of MV as speculative, and its use in place of the exemplified LD would not require any additional effort on the part of the skilled person. To disregard this embodiment disclosed D1 as an unrealistic starting point, some reason would be needed for the skilled person to have doubts about this disclosure. Neither the fact that the HA + MV composition is not exemplified, nor the fact that this preferred embodiment is not as preferred as the exemplified HA + LD compositions, are sufficient to ignore this disclosed embodiment. Accordingly, the HA + MV composition of D1 is a realistic starting point.

2.3.1 The subject-matter of claim 1 differs from the teaching of D1 in that:
- MV is used as a hydrochloride salt,
- an antioxidant polyol is used, and
- the MV.HCl is added to a pre-formed HA-gel.

Regarding the effect of the differentiating features, the appellant does not contest the opposition division's finding that no particular technical effect is shown in relation with the order of addition to the HA-gel or the selection of the hydrochloride salt of MV. However, the appellant contends, based on D37b and D39b, that, in the presence of a polyol, MV has an improved technical effect in order to reduce the loss upon sterilization.

In the Board's view, the alleged effect of the presence of a polyol is not suitably demonstrated by any of D37b or D39b, as none of these documents contains a comparison of HA+MV compositions with and without polyol.

2.3.2 Since no effect of the polyol can be taken into account, the objective technical problem is the provision of an alternative injection device comprising a HA composition.

The appellant did not present any arguments justifying that the opposition division's reasoning regarding inventive step be set aside in the case where the problem would be the provision of an alternative. The Board concurs with the opposition division that the claimed solution does not involve an inventive step. The use of polyols as antioxidants is suggested in D1 (see page 9, lines 27 to 32). The selection of the only pharmaceutically approved HCl-salt of MV does not involve any inventive skills either. Lastly, the order of addition of MV to the HA gel is not shown to result in any surprising technical effect, is disclosed in D3 (see the examples) and, consequently, would be considered as an alternative.

The appellant contends that the skilled person would not consider D3 for the preparation method when attempting to solve the technical problem (i.e. in the appellant's view, the provision of an injection device wherein the composition has a reduced loss upon sterilization), because D3 has an opposite objective compared to the claimed invention. The Board is not convinced. D3 indeed targets the problem of the ability of lidocaine to counteract the G'(viscosity and/or elastic modulus) reducing effect of the sterilization, and solves this problem by the use of ascorbic acid, which reduces the G' value. However, D3 is relevant here not regarding this effect of lidocaine or ascorbic acid, but as teaching the claimed order of addition of MV to the HA gel. The skilled person seeking an

alternative to D1 would thus consider the order of addition shown in D3.

Accordingly, the main request does not fulfil the requirement of Article 56 EPC.

3. Auxiliary request 1

Claim 1 of auxiliary request 1 additionally mandates that the HA is "a mixture of a crosslinked hyaluronic acid form and a non-crosslinked hyaluronic acid form". The appellant did not provide any specific argument regarding inventive step in relation with auxiliary request 1. The use of a mixture of crosslinked and non-crosslinked HA is explicitly suggested in D1 (see claim 15) and D3 (page 7, lines 11-21).

Accordingly, auxiliary request 1 does not meet the requirement of Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated