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Datasheet for the decision of 21 April 2021

Case Number: T 2988/18 - 3.3.07

Application Number: 09785850.0

Publication Number: 2326302

IPC: A61K8/73, A61L27/20, A61K47/36

Language of the proceedings: EN

Title of invention:
HYALURONIC ACID-BASED GELS INCLUDING LIDOCAINE HYDROCHLORIDE

Patent Proprietor:
Allergan Industrie SAS

Opponents:
Merz Pharma GmbH & Co. KGaA
Galderma Holding SA
Laboratoires Vivacy

Headword:
Hyaluronic acid-based gels including lidocaine Hydrochloride/ ALLERGAN

Relevant legal provisions:
RPBA 2020 Art. 13(2)
EPC Art. 123(2)

Keyword:
Admission of new arguments (Yes)
All requests - Amendments (No)

Decisions cited:
G 0001/93, G 0002/10, G 0004/92, T 0247/20

Catchword:
See point 1.4

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Case Number: T 2988/18 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 21 April 2021

Appellant: (Patent Proprietor)	Allergan Industrie SAS Route de Promery - Z.A. de Pre-Mairy 74370 Pringy (FR)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Respondent: (Opponent 1)	Merz Pharma GmbH & Co. KGaA Eckenheimer Landstrasse 100 60318 Frankfurt/Main (DE)
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Respondent: (Opponent 2)	Galderma Holding SA Rue d'Entre-deux-Villes 10 1814 La Tour-de-Peilz (CH)
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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 3 December 2018 revoking European patent No. 2326302 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman A. Usuelli
Members: D. Boulois
Y. Podbielski

Summary of Facts and Submissions

I. European patent No. 2 326 302 was granted on the basis of a set of 2 claims.

Independent claim 1 as granted read as follows:

"1. A method of preparing a soft tissue filler composition, the method comprising the steps of:
providing a hyaluronic acid component crosslinked with at least one crosslinking agent selected from the group consisting of 1,4-butanediol diglycidyl ether (BDDE), 1,2- bis(2,3-epoxypropoxy)ethylene and 1-(2,3-epoxypropyl)-2,3-epoxycyclohexane, or combinations thereof;
wherein the hyaluronic acid component comprises greater than 10% uncrosslinked hyaluronic acid by volume;
adjusting the pH of said hyaluronic acid component to an adjusted pH above 7.2; and
adding a solution containing at least one anesthetic agent to said hyaluronic acid component having said adjusted pH to obtain a hyaluronic acid-based soft tissue filler composition,
wherein the at least one anesthetic agent is lidocaine HCl."

II. Oppositions were filed under Article 100 (a), (b) and (c) EPC on the grounds that the subject-matter of the granted patent lacked novelty and inventive step, was not sufficiently disclosed, and extended beyond the content of the application as filed.

III. The appeal lies from the decision of the opposition division to revoke the patent. The decision was based on the claims as granted as the main request, on

auxiliary request 1 filed with letter of 16 October 2017 and auxiliary requests 2-6 filed with letter of 6 September 2018.

IV. According to the decision under appeal, none of the requests met the requirements of Article 123(2) EPC.

Original claim 1 did not mention upon what the % values were based. There was no guidance in the original application as a whole to select "by volume". The main request did not meet the requirements of Article 123(2) EPC for this reason.

In claim 1 of auxiliary request 1, the range defining the uncrosslinked hyaluronic acid component was defined as "greater than 10% to 20%... by volume", for which there was also no clear and unambiguous disclosure. Therefore, auxiliary request 1 did also not meet the requirements of Article 123(2) EPC.

Each of auxiliary requests 2-6 comprised the feature "wherein the hyaluronic acid component comprises greater than 10% uncrosslinked hyaluronic acid by volume", and the same arguments as for the main request applied mutatis mutandis to each of auxiliary requests 2-6.

V. The patent proprietor (hereinafter the appellant), filed an appeal against said decision.

VI. Opponent 01, opponent 02, and opponent 03 are referred to hereinafter as respondents 01, 02 and 03 respectively.

VII. A communication from the Board, dated 17 September 2020, was sent to the parties. In it the Board

expressed its preliminary opinion that none of the requests on file met the requirements of Article 123(2) EPC.

VIII. With a letter dated 26 March 2021, the appellant filed a new auxiliary request replacing all the previously filed auxiliary requests. In this new auxiliary request, claim 1 was identical to claim 1 of the main request and claim 2 was deleted.

IX. Oral proceedings took place on 21 April 2021.

X. The arguments of the appellant may be summarised as follows:

Admission of late filed arguments

In its submissions dated 26 March 2021 the appellant presented an argument based on G 1/93 to meet the objection that the amendment to claim 1 of the main request, whereby the amounts of uncrosslinked hyaluronic acids were amounts expressed in percent "by volume", did not comply with Article 123(2) EPC. The appellant submitted that this argument did not amount to an amendment of its appeal case as it was a purely legal argument which could be brought at any time of the proceedings.

Main request - Amendments

In the present case, claims 7 and 8 of the application as filed disclosed the ranges of uncrosslinked HA (hyaluronic acid) recited in the claims of the main request, but did not mention the basis on which the percent values were calculated. A skilled reader, seeking to interpret claims 7 and 8 on a technical and

reasonable basis and with a mind willing to understand their meaning, would therefore have turned to the description of the application as filed in order to interpret those claims. The skilled reader would have noted that the only passages which provided a counterpart to both of original claims 7 and 8 were paragraphs [0019], [0049] and [0086] of the description.

Paragraph [0019] did not elaborate on the manner in which the percent values are calculated and, for this reason, did not assist the skilled reader with its interpretation of the amounts recited in claims 7 and 8. Paragraph [0049] however disclosed a range of "about 10% to about 20% or greater of free HA by volume" and paragraph [0086] disclosed also a range of "at least 10% to about 20% free HA by volume".

Thus, paragraphs [0049] and [0086] were the only passages of the description which provided a direct counterpart to both of original claims 7 and 8 and which, moreover, elaborated on the manner in which the percent values were to be calculated, namely "by volume". The feature "by volume" did therefore not present the skilled reader with a new technical teaching and the only possible intention for defining the amounts in original claims 7 and 8 was in amounts "% by volume".

Moreover, the amendment by the feature "by volume" was also allowable in view of G 1/93, since it did not provide a technical contribution to the claimed subject-matter. The application as filed was concerned with the provision of HA-based soft tissue filler compositions which overcome problems of degradation caused by anesthetic agents such as lidocaine, and the

calculation of the amounts of HA by volume did not provide a technical contribution with regard to the technical problem of the application as filed.

Auxiliary Request - Amendments

The auxiliary request differed from the main request only in that claim 2 has been deleted and was allowable for the reasons presented in connection with claim 1 of the main request. In particular, since paragraphs [0049] and [0086] of the description provided the only counterpart to the range recited in original claims 7, the skilled person would have understood that original claim 7 necessarily referred to an amount in percent per volume..

XI. The arguments of the respondents may be summarised as follows

Admission of late filed arguments

According to respondent 01, the argument based on G 1/93 was not limited to a reference to the case law, but a new argument had been developed on the basis of this case law. This constituted a new line of argument which amounted to an amendment to the appellant's appeal case. Article 13(2) RPBA 2020 applied and there were no exceptional circumstances, justified by cogent reasons, within the meaning of that article. Therefore, this line of argument should not be taken into account.

Main request - Amendments

Claim 7 and 8 as filed did not refer to "% by volume", and none of the passages of the description mentioned an amount "greater than 10% by volume" of

"uncrosslinked HA". There was no counterpart in the description for the subject-matter of claims 7 and 8, and there were several different definitions of the amounts in the original description.

Free HA as disclosed in the application as filed was not interchangeable with "uncrosslinked HA", since "free HA" was broader than "uncrosslinked HA". Moreover, paragraphs [0049] and [0086] could in particular not serve as a basis for this feature, and related to a different specific composition.

It was also not correct to assume that there was no technical effect or contribution linked with this feature, as shown for instance in example (par. [0097]). The amount of uncrosslinked HA had an effect on the lidocaine release, as well as on the cohesion of the gel which was a factor of stability of the final gel.

Auxiliary Request - Amendments

The same arguments applied to the auxiliary request.

XII. Requests

The appellant (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained as granted, or that the patent be maintained on the basis of auxiliary request 1 filed with letter dated 26 March 2021. The appellant requested as an auxiliary measure that, if the Board found that the claimed subject-matter of one of the requests complied with the requirements of Article 123(2) EPC, the case be remitted to the opposition division for examination of the other grounds of opposition.

The respondents requested that the appeal be dismissed. They also requested that the auxiliary request not be admitted into the proceedings.

Respondent 01 requested that allegedly late-filed arguments made in the appellant's letter dated 26 March 2021, especially arguments with regard to decision G 1/93, not be admitted into the proceedings.

The respondents also requested remittal of the case to the opposition division if the Board found that the claimed subject-matter of one of the requests complied with the requirements of Article 123(2) EPC.

Reasons for the Decision

1. Admission of late filed arguments

1.1 In its submissions dated 26 March 2021 the appellant presented two arguments to meet the objection that the amendment to claim 1 of the main request, whereby the amounts of uncrosslinked hyaluronic acids were amounts expressed in percent "by volume", did not comply with Article 123(2) EPC. The first one was that this amendment did not add new technical teaching. The second was that even if the feature was not derivable from the application as filed it would nevertheless comply with Article 123(2) EPC in view of decision G 1/93. It is this second argument that was objected to by the respondent 01. Respondent 01 requested that it was not admitted into the proceedings.

1.2 In the present case the Board issued the summons to oral proceedings in July 2020. Notification of the summons occurred before the appellant filed its

argument based on G 1/93. This means that Article 13(2) RPBA 2020 is relevant (Article 25(3) RPBA 2020). That provision suggests that: *"Any amendment to a party's appeal case made…after notification of a summons to oral proceedings shall, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned."*

The Board concurs with the interpretation of Article 13(2) EPC given in decision T 247/20 (Reasons 1.3) as summarised below.

The test under Article 13(2) RPBA 2020 is a two-fold one. The first question is whether the submission objected to (the argument based on G 1/93) is an amendment to a party's appeal case. If that question is answered in the negative, then the Board has no discretion not to admit the submission. If, however, that question is answered in the positive, then the Board needs to decide whether there are exceptional circumstances, justified by cogent reasons, why the submission is to be taken into account.

An amendment to a party's appeal case is a submission which is not directed to the requests, facts, objections, arguments and evidence relied on by the party in its statement of grounds of appeal or its reply. In other words: it goes beyond the framework established therein. As there was no argument based on G 1/93 in the statement of grounds of appeal the question arises whether this argument is an amendment to the appellant's appeal case. The Board considers that it is not for the reasons set out below.

1.3 There is no definition of the term "argument" in the RPBA 2020. In G 4/92 the Enlarged Board contrasted arguments to grounds or evidence and suggested that arguments "are reasons based on the facts and evidence which have already been put forward" (Reasons 10). This leaves open the question whether the type of argument made by the appellant, namely one where the Enlarged Board interpreted Article 123(2) EPC (the argument based on G 1/93), also falls under the ambit of Article 13(2) RPBA 2020.

1.4 Arguments pertaining to the interpretation of law are arguments generally accepted at any stage of the proceedings (see e.g. for German nullity proceedings Hall/Nobbe in Benkard, PatG, 11th edition, § 83 Rz. 14 and Voit in Schulte, Patentgesetz mit EPÜ, 10th edition, § 83 PatG, Rz. 20, for German civil proceedings Saenger, Zivilprozessordnung, Nomos, 8th edition, § 282, Rz.12; for English civil proceedings *Pittalis v Grant* [1989 QB 605], at p.611). This has been recognised in the explanatory remarks to the RPBA 2020 according to which submissions of a party which concern the interpretation of law are not an amendment (Supplementary publication 1, OJ EPO 2020, p.218). The Board concurs with this view.

Respondent 01 submitted that the argument based on G 1/93 was not limited to a reference to the case law, but that a new argument had been developed on the basis of this case law. This constituted a new line of argument which amounted to an amendment to the appellant's appeal case. The Board is not convinced. The appellant's argument based on G 1/93 is essentially that G 1/93 permits an undisclosed feature to be added to a claim in certain limited circumstances, and that these circumstances existed in the present case. In

short: the principle set out in headnote 2 of G 1/93 applied to the present case. The Board is of the opinion that this argument is precisely what was meant by the passage of the explanatory remarks to the RPBA 2020 referred to above, because an argument about the interpretation of law will naturally concern how that interpretation applies to the facts of the case before the Board.

2. Main request - Amendments

2.1 Claim 1 as granted differs from claim 1 as originally filed by *inter alia* the introduction of the feature "wherein the hyaluronic acid component comprises greater than 10% uncrosslinked hyaluronic acid by volume".

As also argued by the appellant, said feature originates from original dependent claim 7 which reads:

"7. The method of claim 1 wherein the HA component comprises greater than about 10% uncrosslinked HA".

Original claim 8 related to the same subject-matter and disclosed a more restricted range of concentration of uncrosslinked HA, namely:

"8. The method of claim 1 wherein the HA component comprises at least about 20% uncrosslinked HA".

None of original dependent claims 7 and 8 indicate however the nature of the concentration unit of uncrosslinked HA, which is given in "% ...by volume" in claim 1 of the main request. The introduction of the concentration in "% ... by volume" is therefore not

derivable directly or unambiguously from the original claims, in particular original dependent claims 7 or 8.

2.2 In view of the absence of any indication of the nature of the concentration unit in original dependent claims 7 and 8, i.e. in % "by volume", there remains the possibility of turning to the description as originally filed to determine a possible basis or correspondence for said concentration unit in % "by volume". For the sake of clarification, this feature of % "by volume" corresponds to a concentration of "volume/volume %" or "v/v %.

2.2.1 In the description as originally filed, the concrete concentration of HA is given in several different units, namely:
- in % without further specification, in paragraphs [0018], [0019], [0026] and [0048],
- in weight by volume %, i.e. w/v%, in paragraph [0043] and paragraph [0096] of example 2,
- in weight by weight %, i.e w/w%, in paragraphs [0050], [0052] or [0097],
- in % by volume, in paragraphs [0048], [0049] or [0086].

Consequently, there is no uniform disclosure in the description of the application as filed regarding the unit concentration of HA, and the skilled person is not in a position to deduce therefrom that the concentration of "uncrosslinked HA" should be unambiguously in % "by volume".

2.2.2 Moreover, none of the passages cited above, namely paragraphs [0018], [0019], [0026], [0043], [0048], [0049], [0050], [0052], [0086] and [0097], refers explicitly to the concentration of specifically

"uncrosslinked HA" as disclosed in claim 1 of the main request or original dependent claims 7 and 8.

All passages refer indeed to the concentration of "free HA", with the exception of paragraph [0043] which refers to the concentration of "free or lightly crosslinked HA" and not to "uncrosslinked HA".

The application as filed makes though a clear distinction between what is meant by "free HA" and by "uncrosslinked HA"."Free HA" is defined as "uncrosslinked HA as well as lightly crosslinked HA chains and fragments" in paragraph [0018]. In paragraph [0036] the term "free HA" refers to "individual HA polymer molecules that are not crosslinked to, or very lightly crosslinked". In the same paragraph it is stated that "free HA" can be defined as "the uncrosslinked, or lightly crosslinked component of the macromolecular component". In view of this distinction made in the description the Board does not accept the appellant's argument that the skilled person, relying on his common general knowledge, would use free and uncrosslinked HA interchangeably.

Consequently, the skilled person is neither in a position to deduce immediately that the concentration of "uncrosslinked HA" used in claim 1 of the main request or in orignal dependent claims 7 and 8 should unambiguously correspond to the concentration of "free HA" disclosed in the description.

2.2.3 The Board can also not follow the appellant's argument that paragraphs [0049] and [0086] were the only passages of the description which provided a directly identifiable counterpart to both of original claims 7 and 8 and which elaborated on the manner in which the

percent values were to be calculated, namely "by volume".

Paragraphs [0049] and [0086] disclose respectively that "the composition can include about 10% to about 20% or greater of free HA by volume" and "the precursor gel is a relatively less cohesive gel comprising at least 10% to about 20% free HA by volume".

However, said passages neither relate to the concentration of "uncrosslinked HA" nor to a general "soft tissue filler composition" as given in claim 1. Both paragraphs [0049] and [0086] relate indeed to the concentration of free HA rather than uncrosslinked HA. Moreover, they concern specific forms of the precursor composition, i.e a dispersion of a solid phase in a fluidic phase in paragraph [0049], and a "relatively less cohesive gel" in paragraph [0086]. Instead, claim 1 of the main request relates very generally to a "soft tissue filler composition" without any further specification of the type of composition.

Furthermore, the circumstance that in paragraphs [0049] and [0086] the percentage is expressed by volume does not remedy the general confusion with regard to the concentration of HA in the description as a whole. For instance, the disclosure of paragraph [0049] is immediately followed by two paragraphs, which give the concentration of free HA in another concentration unit, i.e in "% by weight" (cf. par. [0050] and [0052]). Paragraph [0052] states in particular that "the free HA makes up greater than about 20% by weight of the HA component", and this specific passage could also have be seen as an identifiable counterpart to at least original claim 8.

It follows that the skilled person cannot consider the disclosure of paragraphs [0049] and [0086] as a directly identifiable counterpart to both of original claims 7 and 8.

2.3 The Board can also not follow the appellant's argument that, even if the wording "by volume" would not be derivable from the application as filed, the main request would nevertheless comply with Article 123(2) EPC in view of the findings in G 1/93 regarding the addition to a claim of an undisclosed limiting feature.

2.3.1 In this decision, it was acknowledged that a feature which was not disclosed in the application as filed but which was added to a claim during examination was not to be considered as contravening Article 123(2) EPC if it merely limited the protection conferred by the patent as granted by excluding protection for part of the subject matter of the claimed invention as covered by the application as filed, without providing a technical contribution to the subject matter of the claimed invention. These principles were confirmed by the Enlarged Board in its decision G 2/10 (see point 4.3 of the reasons).

2.3.2 Hence, according to the appellant, the wording "by volume" was introduced into the claims during examination of the application for the patent and it would have been clear to a skilled reader that said wording "by volume" merely had the effect of excluding protection for part of the subject matter of the claimed invention as covered by the application as filed. Said feature did furthermore not provide for a technical contribution to the subject matter of the invention claimed therein, which was concerned with the provision of a method of manufacture of a HA-based soft

tissue filler compositions which overcome problems of degradation caused by anesthetic agents such as lidocaine (see, e.g., paragraphs [0012]-[0014] of the application as filed). There was nothing in the application as filed to indicate that the use of uncrosslinked hyaluronic acid in these amounts when calculated on a percent by volume basis provides a technical contribution to the invention claimed therein.

For this reason, this feature could not to be considered as subject-matter which extends beyond the content of the application as filed in the sense of Article 123(2) EPC.

2.3.3 In the present case, as pointed out by the respondents, the concentration level of free HA affects several technical effects, such as the kinetics of release of lidocaine from the composition (see paragraph [0097]), and the general cohesive level of the soft filler tissue composition which can be a highly cohesive gel with an amount of free HA not greater than 10% by volume, or a less cohesive gel when the free HA is over 10 % by volume (see par. [0086]). The cohesive level has very likely an impact on the stability of the composition, as was argued by the respondents. Thus, it directly affects one of the technical contributions provided by the invention as defined by the appellant, namely overcoming the problems of soft-tissue filler composition degradation caused by anesthetic agents such as lidocaine.

Thus the concentration "greater than 10% uncrosslinked hyaluronic acid by volume" is clearly a feature having a technical effect and providing a technical

contribution to the claimed invention, contrary to the argument presented by the appellant.

Moreover, the application as originally filed mentions several technical objectives, such as a long term stability, a good usability *in vivo*, an absence of allergic reactions in patients and a good biocompatibility (see par. [0012]-[0014]). All these technical objectives play a role when determining the technical contribution of the application as filed. In the Board's view it cannot be excluded that the amount of free HA has an impact of the effects underlying these objectives.

2.3.4 Consequently, the conclusion reached in G 1/93 in relation to the addition to a claim of an undisclosed limiting feature cannot apply to the present case, since the feature "by volume" provides a technical contribution to the subject-matter of the claimed invention.

In the present case, the relevant question for the purposes of Article 123(2) EPC remains therefore whether an amendment made to the claims remains within the limits of what a skilled person would derive directly and unambiguously, using common general knowledge, from the whole of the application as filed (according to the "gold standard" of G 2/10, OJ 2012, 376). This is not the case with the feature "by volume" in claim 1.

2.4 Hence, the main request does not meet the requirements of Article 123(2) EPC for this reason.

3. Auxiliary Request - Amendments

The auxiliary request differs from the main request only in that claim 2 has been deleted, while claim 1 remains unchanged; the conclusion reached for claim 1 of the main request applies therefore also to claim 1 of the auxiliary request.

The introduction of the concentration in % "by volume" in claim 1 of the auxiliary request is therefore not derivable directly or unambiguously from the original application and the auxiliary request does not meet the requirements of Article 123(2) EPC for this reason.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

S. Sánchez Chiquero A. Usuelli

Decision electronically authenticated