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Datasheet for the decision of 20 October 2022

Case Number: T 2555/18 - 3.3.10

Application Number: 05732235.6

Publication Number: 1734894

IPC: A61F2/00, A61L15/20, A61L15/52, A61L15/58

Language of the proceedings: EN

Title of invention:
PARTICLES FOR SOFT TISSUE AUGMENTATION

Patent Proprietor:
Q-Med AB

Opponent:
Schiweck Weinzierl Koch Patentanwälte Partnerschaft mbB

Headword:

Relevant legal provisions:
EPC Art. 100(b), 56, 84
RPBA 2020 Art. 13(1)
RPBA Art. 12(2)

Keyword:
Grounds for opposition - insufficiency of disclosure (no)
Amendment to appeal case - justification by party (no)
Inventive step - (yes)

Decisions cited:
G 0003/14

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 2555/18 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 20 October 2022

Appellant: (Opponent)	Schiweck Weinzierl Koch Patentanwälte Partnerschaft mbB Ganghoferstrasse 68 B 80339 München (DE)
Representative:	Schiweck Weinzierl Koch Patentanwälte Partnerschaft mbB Ganghoferstraße 68 B 80339 München (DE)
Respondent: (Patent Proprietor)	Q-Med AB Seminariegatan 21 752 28 Uppsala (SE)
Representative:	Aera A/S Niels Hemmingsens Gade 10, 5th Floor 1153 Copenhagen K (DK)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 8 August 2018 concerning maintenance of the European Patent No. 1734894 in amended form.**

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 decision of the opposition division concerning maintenance of European patent No. 1 734 894 in the form of the first auxiliary request then pending, which is the main request of the respondent (patent proprietor) in the present appeal proceedings.

II. Independent claims 1 and 7 of the main request read as follows:

"1. Particles of a viscoelastic medium selected from stabilized hyaluronic acid, which are injectable gel particles suitable for implantation having a size, when subjected to a physiological salt solution, in the range of from 1.5 to 5 mm;
wherein said viscoelastic medium is selected from the group consisting of cross-linked hyaluronic acid;
wherein the physiological salt solution has the same osmolarity as a 0.154 M NaCl solution.

7. A soft tissue augmentation implant comprising particles of a viscoelastic medium selected from stabilized hyaluronic acid, wherein a major volume of said particles are injectable gel particles having a size, when subjected to a physiological salt solution, in the range of from 1.5 to 5 mm;
wherein said viscoelastic medium is selected from the group consisting of cross-linked hyaluronic acid;
wherein the physiological salt solution has the same osmolarity as a 0.154 M NaCl solution."

III. Notice of opposition was filed on the grounds of added subject-matter (Article 100(c) EPC), insufficiency of

disclosure (Article 100(b) EPC), and lack of novelty and inventive step (Article 100(a) EPC).

IV. The documents filed include the following:

D1 EP 0 402 031 B1

D2 F. Manna *et al.* "Comparative chemical evaluation of two commercially available derivatives of hyaluronic acid (Hylaform® from rooster combs and Restylane® from streptococcus) used for soft tissue augmentation", Journal of the European Academy of Dermatology and Venereology 13 (1999) 183-192

D3 D. R. Jordan "Soft-tissue fillers for wrinkles, folds and volume augmentation" Can J Ophthalmol 2003;38:285-288

D11 US 6,063,061

D12 Declaration of Dr. Katarina Edsman of 20 October 2017

D13 WO 2004/016275 A1

D13a EP 1 552 839 A1

D21 US 2002/0193448 A1

D23 Experimental evidence filed by the appellant with letter of 15 December 2020

D24 "Evaluating the rheological properties of hyaluronic acid hydrogels for dermal filler applications" Malvern Instruments Worldwide, Application Note 2015

V. The opposition division concluded that the claimed invention was sufficiently disclosed for it to be carried out by a skilled person. Document D2, which disclosed particles smaller than those of claim 1, was the closest prior art. The problem underlying the claimed invention was to provide improved particles of viscoelastic medium suitable for implantation, capable

of reducing migration and/or displacement from the desired site of soft-tissue augmentation. The claimed solution, characterised by the the particle size, would not have been obvious for the skilled person in view of the prior art and was thus inventive.

VI. The arguments of the appellant were as follows.

Experimental evidence D23 and document D24 had been filed as soon as the required experimental work could be carried out. At the time of filing of the statement of grounds of appeal, Article 12(2) RPBA 2007 applied and therefore the case did not necessarily have to be complete. Thus, D23 and D24 should be admitted into the proceedings.

Particle size could be measured by different methods, with different results. Since the method for determining the particle size was not defined in the patent, the claimed invention was not sufficiently disclosed for it to be carried out by a skilled person.

The feature "major volume" in claim 7 was not clear.

Document D2 was the closest prior art. The claimed subject-matter differed from that of D2 only by virtue of the particle size. The available evidence could not prove a reduction in implant migration compared to the prior art, meaning that the problem underlying the claimed invention was the mere provision of an alternative. The claimed solution, characterised by the particle size, would have been obvious for a skilled person in view of D1, D11, D13 or D21. It was thus not inventive.

VII. The arguments of the respondent were as follows.

The statement of grounds of appeal merely repeated the arguments of the opponent/appellant before the opposition division concerning the issues of clarity and sufficiency of disclosure. With regard to inventive step, it did not elaborate on why the claimed invention was obvious. The appeal should thus be rejected as inadmissible.

Experimental evidence D23 and document D24 were late-filed, the appellant had not provided reasons for filing them at that point in time, and they were not prima facie relevant as they did not compare particles according to claim 1 with those of D2. For these reasons, D23 and D24 should not be admitted into the proceedings.

The particles of the viscoelastic medium of claim 1 differed by virtue of their size from the particles disclosed in the closest prior art D2. The problem underlying the claimed invention was to provide particles and implants with reduced migration but, even if the technical problem to be solved by the invention had been seen only as to provide an alternative, the claimed solution would not have been obvious for a skilled person and was thus inventive.

VIII. The board informed the parties in a communication dated 6 August 2020 that it was likely to consider the appeal admissible, that the clarity of the feature "major volume" was not open to examination in the present opposition appeal proceedings, and that the claimed invention was sufficiently disclosed for it to be carried out by a skilled person. With regard to inventive step, it had to be discussed at the oral proceedings whether the problem of providing an

improvement over the implants of D2 had been credibly solved having regard to the evidence on file.

IX. Oral proceedings before the board of appeal took place on 20 October 2022.

X. The final requests of the parties were as follows:

The appellant requested that the decision under appeal be set aside and that European patent No. 1 734 894 be revoked.

The respondent requested
- that the appeal not be admitted; or
- that the appeal be dismissed; or
- that the patent be maintained with the claims of any one of auxiliary requests 1 to 4,
  - auxiliary requests 1, 2 and 4 being as filed with the reply to the grounds of appeal dated 29 April 2019,
  - auxiliary request 3 being as filed with a letter dated 16 December 2020.

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

Reasons for the Decision

1. Admissibility of the appeal

1.1 The respondent requested that the appeal not be admitted. The arguments concerning sufficiency of disclosure amounted to a mere repetition of those before the opposition division, clarity could not be examined following G 3/14 and the analysis of obviousness was not complete. For these reasons, the

statement of grounds of appeal did not indicate the reasons why the appealed decision should be set aside meaning that it did not fulfil the requirements of Rule 99(2) EPC.

1.2 The appeal is admissible for the following reasons.

The opposition division concluded that it was credible that the implants of the claimed invention migrated less than those of the closest prior art D2. As the prior art did not hint at the claimed solution to the problem of providing an improvement, that solution was inventive.

In the grounds of appeal the appellant set out its arguments as to why such an improvement over D2 had not been achieved. The problem underlying the claimed invention should thus be seen as the mere provision of an alternative, which was not inventive.

In the board's view, this line of argument is sufficient for the appeal to comply with Rule 99(2) EPC. The appellant provided arguments as to why the opposition division's conclusion concerning inventive step was not correct. In these circumstances, the matters of whether other issues of the appealed decision were sufficiently reasoned in the grounds of appeal and whether the appellant's line of argument is convincing have no bearing on the admissibility of the appeal.

2. Admissibility of D23 and D24.

2.1 The board decided not to admit D23 and D24 into the proceedings.

2.2 Experimental evidence D23 and document D24 were filed with a letter dated 15 December 2020, after the board's communication under Rule 15(1) RPBA 2020.

The filing of D23 and D24 represent an amendment of the appellant's case. Their admissibility into the proceedings is thus enshrined by Article 13(1) RPBA 2020.

2.3 Article 13(1) RPBA 2020 requires the appellant to provide reasons for submitting D23 and D24 at that stage of the appeal proceedings. No reason was provided, however, prior to the oral proceedings before the board.

2.4 As far as the relevance of these documents is concerned, the appellant argued that experimental evidence D23 compared particles of the the size required by claim 1 with smaller particles and showed that no effect in terms of cohesion and hence on implant migration arose from that size difference. D24 was to provide background for the experimental evidence provided.

The particles of the closest prior art D2 (0.561 mm) are, however, an order of magnitude larger than those used in D23 as comparison (0.050 mm). Therefore, the evidence provided does not reflect the particles of D2 and is thus not suitable for showing a lack of technical effect. For this reason, D23 and D24 are not prima facie relevant.

2.5 The appellant argued that Article 12 RPBA 2007 only required a party's case to be as complete as possible, but not necessarily complete, in the statement of grounds of appeal.

Article 12(2) RPBA 2007 stipulates, however, that the statement of grounds of appeal and the reply are to contain a party's complete case. The appellant's argument is not convincing.

2.6 For these reasons the board decided to exercise its discretionary power not to admit D23 and D24 into the proceedings (Article 13(1) RPBA 2020).

3. Sufficiency of disclosure

3.1 The opposition division concluded that the alleged dependence of the particle size on the method of measurement could, at the most, affect the clarity of the claimed subject-matter but not the sufficiency of disclosure of the claimed invention.

3.2 The board informed the parties in a communication that it was leaning towards agreeing with the opposition division's conclusion.

3.3 The appellant brought no subsequent argument on this issue either in writing or at the oral proceedings before the board.

There is thus no reason to depart from the board's preliminary view that the claimed invention is sufficiently disclosed for it to be carried out by a skilled person.

4. Clarity

The appellant argued that the feature "major volume" in claim 7 was not clear. It is, however, a feature of the granted claims and is thus excluded from examination of

its clarity in the present opposition appeal proceedings following G 3/14. This was undisputed at the oral proceedings before the board.

5. Inventive step

5.1 Claim 1 is directed to particles which are injectable and suitable for implantation and have a size of from 1.5 to 5 mm in saline. Claim 7 relates to a soft-tissue augmentation implant comprising particles, wherein a major volume of said particles have a size of from 1.5 to 5 mm when subjected to saline.

5.2 Closest prior art

The opposition division and the parties considered that document D2 was the closest prior art.

It was not disputed that document D2 discloses particles and implants which differ from those of the subject-matter of claims 1 and 7 only by virtue of the particle size.

The particles disclosed in D2, subjected to demineralised water, have a size of 0.561 mm, 0.390 mm and 0.220 mm (paragraph 2.1) and are thus smaller than required by claims 1 and 7. The latter should have a size in the range of from 1.5 to 5 mm.

5.3 Technical problem underlying the invention

5.3.1 The respondent defined the technical problem underlying the claimed invention as being to provide implants with reduced migration after implantation in soft tissue.

The respondent relied on the examples of the opposed

patent and the experimental evidence filed as D12 during opposition proceedings to show that this problem had been credibly solved.

The appellant argued that the problem as formulated by the respondent had not been credibly solved. In the examples of the patent, the particles were deeply implanted. Any effect on migration was only the result of the implantation technique. In addition, the evidence filed as D12 could not show an effect across the whole scope of the claimed subject-matter.

5.3.2 The question of whether the problem as formulated by the respondent has been solved in all aspects can, however, be left aside. The reason is that, even if the technical problem is formulated merely as the provision of alternative particles and implant suitable, like those of D2, for soft-tissue augmentation, the proposed solution is not obvious for the reasons that follow.

5.4 Solution

The solution to this technical problem is provided by the claimed particles and implant, characterised by a particle size in the range of from 1.5 to 5 mm when subjected to a physiological salt solution.

5.5 Success

5.5.1 At the oral proceedings before the board, the appellant argued that even this less ambitious problem had not been credibly solved.

The appellant argued that experimental evidence D12 merely contained two points, which could not represent every embodiment of claims 1 and 7. In addition, the

evidence in the patent only related to the implantation of particles with homogeneous size distribution. This was, however, not a feature of claim 7, which only required a "major volume" of such particles to be present.

5.5.2 However, according to example 2 of the patent, satisfactory chin augmentation could be obtained for at least three months. Example 4 relates to breast-tissue augmentation and discloses that, twelve months following implantation, the breasts were still in good shape with thin nodular implants. This is the same time span as for Restylane implants of the closest prior art D2, as disclosed on page 286, left column, lines 22-23, of D3. The data in the patent thus shows that the claimed particles and implants are, like those of D2, suitable for implantation.

The board thus concludes that the problem of providing alternative particles and implants that are suitable, like those of D2, for soft-tissue augmentation has been credibly solved.

5.6 It thus remains to be decided whether the proposed solution to the objective problem defined above would have been obvious for the skilled person in view of the prior art.

5.6.1 The appellant argued at the oral proceedings before the board that D3 taught the claimed solution.

Like D2, D3 relates to soft-tissue fillers for wrinkles, folds and volume augmentation. The first full paragraph on page 286 of D3 mentions products of the patent proprietor.

Restylane has 100 000 particles per millilitre. According to paragraph [0004] of the patent this product has a particle size of 0.4 mm.

Perlane has, according to D3, 8000 particles per millilitre. Paragraph [0004] of the patent refers to this product as having about 10 000 particles per millilitre and a mean particle size of approximately 0.8 mm.

Lastly, D3 mentions that the thickest product, Perlane Plus, will have 4000 particles per millilitre. Its particle size is not disclosed.

According to the appellant, in the absence of an effect in terms of migration, particles larger than those of D2 would have been obvious for the skilled person.

However, the largest particles in D3 are nevertheless smaller than those of claim 1. D3 thus teaches that the particle size of the closest-prior-art particles, Restylane, could be increased to some extent, but not as much as required by claims 1 and 7.

A skilled person, seeking alternative particles for a soft-tissue implant, would have had no reason to conclude that particles having thrice or more the size of those of D2 could form a suitable implant and be injected despite their size.

5.6.2 The appellant argued that the claimed particles would have been obvious from D2 alone. However, D2 merely relates to the commercial product Restylane, with smaller particles. It does not hint at larger particles.

5.6.3 In its written submissions, the appellant argued that, as a mere alternative, documents D1, D11, D13 and D21 taught the claimed solution.

5.6.4 Documents D13 and D21 were only relied upon at the oral proceedings before the opposition division. Neither the minutes nor the decision explicitly refer to any particular passage of these documents. The appealed decision only mentions that D13 and D21 did not relate to implant migration.

In the absence of specific details, the board cannot see the relevance of these arguments.

5.6.5 With respect to D1 and D11, the appellant referred to its notice of opposition dated 2 May 2017.

Both D1 and D11 relate to particles for implants, which can have the size required by claims 1 and 7.

D1 discloses implants made of acrylonitrile, which is chemically very different from cross-linked hyaluronic acid.

D11 discloses a long list of materials, among which gelatin is preferred. Glycosaminoglycan, mentioned in column 5, line 44, includes not only hyaluronic acid but also other substances. Cross-linking is only disclosed as an option in column 5, lines 53 and following.

The skilled person looking for an alternative to the particles of D2 would not have considered the particle sizes disclosed in D1 or D11 to be of general application to every implant material, let alone to cross-linked hyaluronic acid. Documents D1 and D11 thus

do not hint at the claimed solution.

5.7 The board thus concludes that the particles of claim 1 and the implant of claim 7 are inventive, as required by Article 56 EPC.

6. The appellant has not put forward further arguments against the subject-matter of independent claims 6, 10 and 11, or any of the dependent claims on file other than those already rejected in the context of claims 1 and 7.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

C. Rodríguez Rodríguez P. Gryczka

Decision electronically authenticated