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**Datasheet for the decision  
of 13 September 2024**

**Case Number:** T 2022/22 - 3.2.02

**Application Number:** 07761461.8

**Publication Number:** 2012707

**IPC:** A61B18/02

**Language of the proceedings:** EN

**Title of invention:**

CRYOPROTECTANT FOR USE WITH A TREATMENT DEVICE FOR IMPROVED  
COOLING OF SUBCUTANEOUS LIPID-RICH CELLS

**Patent Proprietor:**

Zeltiq Aesthetics, Inc.

**Opponent:**

August Debouzy

**Headword:**

**Relevant legal provisions:**

EPC Art. 111(1), 123(2)  
RPBA 2020 Art. 11, 12(2), 13(2)

**Keyword:**

Amendment after notification of Art. 15(1) RPBA communication  
- exceptional circumstances (yes) - taken into account (yes)  
Amendments - extension beyond the content of the application  
as filed (no)  
Appeal decision - remittal to the department of first instance  
(yes)

**Decisions cited:**

T 1857/19, T 2295/19, T 2455/19, T 0424/21

**Catchword:**



**Beschwerdekammern**

**Boards of Appeal**

**Chambres de recours**

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Case Number: T 2022/22 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 13 September 2024**

**Appellant:**

(Patent Proprietor)

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**Respondent:**

(Opponent)

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**Representative:**

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**Decision under appeal:**

**Decision of the Opposition Division of the  
European Patent Office posted on 1 July 2022  
revoking European patent No. 2012707 pursuant to  
Article 101(3)(b) EPC**

**Composition of the Board:**

**Chairman**

M. Alvazzi Delfrate

**Members:**

D. Ceccarelli

Y. Podbielski

## **Summary of Facts and Submissions**

- I. The patent proprietor appealed against the Opposition Division's decision to revoke the patent for added subject-matter and/or extension of the scope of protection of all the requests on file.

The patent was opposed on the grounds of added subject-matter, lack of novelty and lack of inventive step.

- II. The Board summoned the parties to oral proceedings and provided its preliminary opinion in which it considered that while claims 1, 9 and 14 of the patent as granted did not include added subject-matter, dependent claim 15 did.

- III. By letter of 28 August 2024, the appellant filed new requests in which claim 15 had been deleted.

- IV. Oral proceedings took place on 13 September 2024.

The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request filed on 28 August 2024 or one of auxiliary requests 1 to 16, of which auxiliary requests 1, 2, 4 to 7 and 9 were filed on 28 August 2024 and auxiliary requests 3, 8 and 10 to 16 were filed with the statement of grounds of appeal on 1 November 2022.

The respondent requested that the appeal be dismissed.

- V. Claims 1, 9 and 14 of the main request read as follows:

1. "A cryoprotectant for use in a method of

removing heat from subcutaneous lipid rich cells of a subject having skin, the method also using:

a treatment device having a housing, a thermal mass, and a heat exchanging surface in thermal communication with the thermal mass, wherein the thermal mass reduces a temperature of a region of the skin during the method such that lipid rich cells in the region are disabled, destroyed, removed or killed while non-lipid rich cells proximate to the heat exchanging surface are preserved; and

an absorbent preloaded with an excess of the cryoprotectant sufficient to continually supply the cryoprotectant to the skin during the method to be absorbed in the epidermis, wherein the absorbent is positioned at least partially between the heat exchanging surface and the region during the method, and wherein the absorbent is a mesh, a foam, a porous plastic material and/or a porous metal material,

wherein the cryoprotectant substantially covers an interface between the treatment device and the skin during the method, and wherein the cryoprotectant contacts the treatment device and the skin during the method."

9. "A system for removing heat from subcutaneous lipid rich cells of a subject having skin, the system comprising:

a treatment device having a housing, a thermal mass, and a heat exchanging surface in thermal communication with the thermal mass, wherein the thermal mass is configured to reduce a temperature of a region of the skin

such that lipid rich cells in the region are affected while non-lipid rich cells proximate to the heat exchanging surface are preserved; a cryoprotectant according to any preceding claim, wherein the cryoprotectant is configured to substantially cover an interface between the treatment device and the skin, wherein the cryoprotectant is configured to contact the treatment device and the skin; and an absorbent preloaded with an excess of the cryoprotectant sufficient to continually supply the cryoprotectant to the skin to be absorbed in the epidermis, wherein the absorbent is configured to be positioned at least partially between the heat exchanging surface and the region, and wherein the absorbent is a mesh, a foam, a porous plastic material and/or a porous metal material."

14. "The system of claim 9 wherein the absorbent is configured to continually supply the cryoprotectant to the skin while the system removes heat from the subcutaneous lipid rich cells."

VI. The appellant's arguments relevant to this decision can be summarised as follows.

*Main request - admittance*

The main request had been filed in response to the Board's preliminary opinion. Compared with the claims of the patent as granted, claim 15 had been deleted and the claim dependency had been adapted.

The deletion of claim 15 merely removed a point in dispute, resulting in the appeal proceedings converging

towards less volume to be discussed during the oral proceedings. In as much as the appeal proceedings concerned the subject-matter of the independent claims, their interpretation and whether the subject-matter of the independent claims extended beyond the content of the application as filed, nothing had changed. No new or changed substantiation, either for the appellant or the respondent, was required. The filing of the main request contributed to procedural economy.

The main request had to be admitted, either because it should not be considered an amendment to the appellant's case, as held in T 995/18, or because the presence of exceptional circumstances within the meaning of Article 13(2) RPBA had to be acknowledged (T 2080/18).

*Main request - extension of subject-matter*

The Opposition Division had wrongly concluded that there was no disclosure, in the application as filed, for the claimed feature of an absorbent being a mesh, a foam, a porous plastic material and/or a porous metal material, or an absorbent being preloaded with an excess of cryoprotectant.

The term "absorbent" meant a material which could take up some fluid or gel. Paragraph [0029] of the application as filed disclosed an intermediate portion in the form of "a reservoir constructed from a mesh, a foam material, a porous plastic and/or metal, or other materials that may at least temporarily contain a fluid and/or a gel". If these materials were used to construct the reservoir, they could contain a fluid or gel as stated in paragraph [0029]. As a consequence, they were absorbents within the meaning of the claims.

Paragraph [0030] disclosed that the intermediate portion was "pre-loaded with excess cryoprotectant".

The respondent had objected to the features of the absorbent as defined in claims 1 and 9 as constituting an unallowable intermediate generalisation. This objection should be held inadmissible for lack of substantiation. Moreover, neither the portions of the coupling device nor other elements of the embodiment disclosed in Figures 2 and 3 were inextricably linked with the claimed absorbent preloaded with an excess of the cryoprotectant, the function of which was to ensure a good and prolonged supply of cryoprotectant. According to paragraph [0036] of the application as filed, the coupling device could "be configured and/or incorporated into other structures". The apertures on the front side portion of the coupling device were only one of several equivalent possibilities for letting the cryoprotectant pass through from the reservoir to the skin.

A basis for the treatment device having a thermal mass as claimed was provided by claim 17 of the application as filed. Paragraph [0030] of the application as filed provided a basis for the subject-matter of claim 14.

VII. The respondent's arguments relevant to this decision can be summarised as follows.

*Main request - admittance*

The filing of the main request after the notification of the communication with the Board's preliminary opinion under Article 15(1) RPBA was an amendment of the appellant's case which should not be admitted in accordance with Article 13(2) RPBA. There were no



exceptional circumstances justifying this amendment. The objection of added subject-matter against claim 15 as granted had been raised during the proceedings before the Opposition Division and again with the reply to the statement of grounds of appeal. Moreover, the deletion of claim 15 altered the discussion of added subject-matter in claims 1 and 9 because it could affect the interpretation, in these claims, of the term "absorbent", which was defined as comprising a cotton pad or gauze. Considerations about the complexity of the amendment were irrelevant for establishing whether there were exceptional circumstances, as held in T 2455/19, point 20 of the Reasons.

*Main request - extension of subject-matter*

In claims 1 and 9 of the main request, the feature of the absorbent preloaded with an excess of the cryoprotectant and being a mesh, a foam, a porous plastic material and/or a porous metal had no basis in the application as filed.

Originally, the materials mentioned for the absorbent had only been disclosed for the intermediate portion of a coupling device in accordance with the embodiment of Figures 2 and 3, not for an absorbent. The coupling device and the absorbent had been presented as separate alternatives (claims 9 and 15, claim 18, claim 40, and paragraph [0051] of the application as filed). Paragraph [0029] of the application as filed, which recited "a reservoir constructed from a mesh, a foam material, a porous plastic and/or metal, or other materials that may at least temporarily contain a fluid and/or a gel", did not disclose that these materials functioned as absorbents that would retain the cryoprotectant. The listed materials were not

inherently absorbents. "Absorb" was not a synonym of "contain". It was the housing of the intermediate portion of the coupling device which functioned as a reservoir and retained the cryoprotectant. Similarly, according to paragraph [0030], it was the intermediate portion of the coupling device, not an absorbent, that could be preloaded with an excess of cryoprotectant.

In claims 1 and 9 of the main request, the combination of a "thermal mass" with the absorbent preloaded with cryoprotectant was not originally disclosed either. The only mention of "thermal mass" in the application as filed was in claim 17. However, claim 17 did not disclose the thermal mass in combination with an absorbent preloaded with excess cryoprotectant or made of the material recited in claims 1 and 9 of the main request.

Moreover, claims 1 and 9 did not recite several of the features originally disclosed in the embodiments of Figures 2 and 3. Therefore, these claims included an unallowable intermediate generalisation. More specifically, paragraph [0029] described an intermediate portion of a coupling device, which also comprised a back side, a front side, a reservoir and apertures on the front side. These features were inextricably linked and could not be omitted from claims 1 and 9 without adding subject-matter.

Claim 14 of the main request defined that the absorbent was configured to continually supply the cryoprotectant to the skin. However, in the application as filed, there was no mention or explanation of how the absorbent could be configured to continually supply the cryoprotectant to the skin.

The respondent requested remittal of the case to the Opposition Division if any of the appellant's requests were regarded as fulfilling the requirements of Articles 123(2) and (3) EPC.

## **Reasons for the Decision**

### 1. The subject-matter of the patent

The patent relates to systems and methods for removing heat from subcutaneous lipid-rich cells involving the use of a cryoprotectant. It finds application in the removal of body fat in various locations of the body for improving personal appearance and/or reducing health risks associated with an excess of body fat.

According to the patent (paragraph [0035]), by cooling the subcutaneous tissues to a low temperature, in particular below 0°C, subcutaneous lipid-rich cells may be selectively affected. In general, the epidermis and dermis of a subject have lower amounts of unsaturated fatty acids compared to the underlying lipid-rich cells forming the subcutaneous tissues. Non-lipid-rich cells usually withstand colder temperatures better than lipid-rich cells. Hence, the subcutaneous lipid-rich cells may be selectively affected while maintaining the non-lipid-rich cells in the dermis and epidermis.

However, intracellular and/or extracellular ice formation may damage the cells in the epidermis and/or dermis. Applying a cryoprotectant may reduce the risk of ice formation by reducing the freezing point of water in the body fluid affected by the cryoprotectant. It is believed that after the cryoprotectant is absorbed into the epidermis and/or dermis, the

cryoprotectant dissolves in or otherwise combines with water of the intracellular and/or extracellular fluid to delay the onset of ice formation by lowering the freezing point of the solution in which it resides (paragraph [0044] of the patent).

Claim 1 of the main request is directed to a cryoprotectant for use in a method of removing heat from subcutaneous lipid-rich cells of a subject having skin.

The method uses a treatment device having a housing, a thermal mass and a heat-exchanging surface in thermal communication with the thermal mass. The thermal mass reduces the temperature of a region of the skin during the method such that lipid-rich cells in the region are disabled, destroyed, removed or killed while non-lipid-rich cells proximate to the heat-exchanging surface are preserved. The cryoprotectant covers an interface between the treatment device and the skin and contacts the treatment device and the skin during the method.

The method also uses an absorbent preloaded with an excess of the cryoprotectant sufficient to continually supply the cryoprotectant to the skin during the method. The cryoprotectant is then absorbed in the epidermis. The absorbent, which is positioned between the heat-exchanging surface and the region of the skin during the method, is a mesh, a foam, a porous plastic material and/or a porous metal material.

Claim 9 of the main request relates to a system for removing heat from subcutaneous lipid-rich cells of a subject having skin, the system comprising the treatment device, the absorbent and the cryoprotectant

defined in the preceding claims.

2. Main request - admittance

The appellant filed the main request after the notification of the communication with the Board's preliminary opinion under Article 15(1) RPBA.

Under Article 13(2) RPBA, any amendment to a party's appeal case made after notification of a communication under Article 15(1) RPBA must, as a rule, not be taken into account unless there are exceptional circumstances justified with cogent reasons by the party concerned.

The main request differs from the claims of the patent as granted merely in that dependent claim 15 has been deleted and the claim dependency has been adapted. As explained by the appellant, this removes a point in dispute, i.e. an objection of added subject-matter against claim 15 as granted, and promotes procedural economy also in view of the Board's preliminary assessment of the case.

The filing of the main request does not affect the issue of the extension of subject-matter of claims 1 and 9 - the main apparatus and method claims of the patent in suit - on which the impugned decision was based and to which the parties dedicated most of their submissions in the appeal proceedings. Hence, it does not result in a situation for which the respondent or the Board could arguably be unprepared. In this respect, the respondent's argument that the deletion of claim 15 altered the discussion of added subject-matter in claims 1 and 9 is not convincing. Claim 15 merely specified a particular absorbent in the form of a cotton pad or a gauze. It is not disputed that a cotton

pad and a gauze are kinds of absorbents. However, the Board does not see how, and the respondent has not explained why, their specific nature could have an impact on the interpretation of the more general term "absorbent" in claims 1 and 9.

In summary, the admittance of the main request is compatible with both the principles of procedural economy and procedural fairness and does not add anything to the subject of the appeal procedure.

In cases where new requests satisfying such a condition were filed, a considerable amount of case law concluded that there were exceptional circumstances within the meaning of Article 13(2) RPBA justifying the admittance of the new requests (e.g. T 2295/19, points 3.4.9 to 3.4.14 of the Reasons; T 1857/19, point 1.1 of the Reasons and T 424/21, point 21 to 26 of the Reasons). In T 2295/19, the competent Board held that the amendment did not have to be caused by the exceptional circumstances; it could also be justified where "there are" exceptional circumstances. The exceptional circumstances could also be of a legal nature, such as the legal assessment of the procedural situation (T 2295/19, point 3.4.12 of the Reasons).

The Board shares the view of this case law irrespective of the conclusions drawn in the circumstances of T 2455/19, point 20 of the Reasons, cited by the respondent. Hence, for this reason alone, the main request is considered to form part of the appeal proceedings. There is no need to decide whether the mere deletion of a dependent claim is to be considered a change of the appellant's case.

3. Main request - added subject-matter

In the impugned decision, the Opposition Division concluded that the subject-matter of claims 1 and 9 of the main request included added subject-matter because of the feature of the "absorbent preloaded with an excess of the cryoprotectant sufficient to continually supply the cryoprotectant to the skin to be absorbed in the epidermis, wherein the absorbent is configured to be positioned at least partially between the heat exchanging surface and the region, and wherein the absorbent is a mesh, a foam, a porous plastic material and/or a porous metal material".

3.1 The respondent had objections against the same feature and argued that the application as filed did not disclose the combination of an absorbent preloaded with an excess of the cryoprotectant and in the form of a mesh, a foam, a porous plastic material and/or a porous metal material.

The application as filed discloses an intermediate portion of a coupling device preloaded with an excess of the cryoprotectant and in the form of a mesh, a foam, a porous plastic material and/or a porous metal material in an embodiment of a treatment device (depicted in Figures 2 and 3). Paragraph [0029] of the application as filed recites that "the intermediate portion 506 may be a reservoir constructed from a mesh, a foam material, a porous plastic and/or metal". Paragraph [0030] recites that "in certain embodiments, the intermediate portion 506 is pre-loaded with excess cryoprotectant".

The respondent argued that the application as filed did not disclose that the intermediate portion was an

absorbent within the meaning of claims 1 and 9 of the main request.

The Board notes that the term "absorbent" is general and merely defines a material that can take up some fluid or gel. This definition was not contested by the parties.

A reservoir for a fluid made of a porous (plastic or metal) material, as recited in paragraph [0029] of the application as filed, implies that the material must be able to absorb the fluid. Moreover, paragraph [0029], describing intermediate portion 506, states that it can be constructed from "a mesh, a foam material, a porous plastic and/or metal, or other materials that may at least temporarily contain a fluid and/or a gel". According to this sentence, the mesh, the foam material, the porous plastic and/or metal are materials that can contain fluid and/or gel. Since the ability to contain the fluid and/or gel is due to the material, not the shape of the intermediate portion, the material of the intermediate portion must be absorbent.

Paragraph [0030] of the application as filed defines the intermediate portion as being "pre-loaded with excess cryoprotectant". This not only provides a basis for the intermediate portion preloaded with an excess of the cryoprotectant but is in accordance with the nature of an absorbent for the person skilled in the art reading the application in its totality. The term "pre-loaded" is expressly associated with an absorbent in paragraph [0051]: "an absorbent (e.g., a cotton pad, a gauze, or other absorbents) pre-loaded with the cryoprotectant".

It is irrelevant whether paragraphs [0051] and claim 15



of the application as filed, referred to by the respondent and the Opposition Division in the impugned decision, disclose the absorbent nature of the mesh, the foam material, the porous plastic and/or metal from which the intermediate portion according to the embodiment of Figures 2 and 3 is made. The absorbent nature finds a basis in other parts of the application as filed, as explained above.

In conclusion, the application as filed discloses the combination of an absorbent preloaded with an excess of the cryoprotectant and in the form of a mesh, a foam, a porous plastic material and/or a porous metal material in the embodiment depicted in Figures 2 and 3.

- 3.2 The respondent and the Opposition Division in the impugned decision argued that claiming only this combination of features of the embodiment according to Figures 2 and 3 amounted to an unallowable intermediate generalisation. The Opposition Division stated that "since granted dependent claim 9 is not limited to that embodiment, but is open to an embodiment wherein a mesh, a foam, a porous plastic material and/or a porous metal material is applied directly on the skin, the subject-matter of that claim constitutes an intermediate generalisation which is not allowable under Article 123(2) EPC" (point 2.1.1.2.2 of the Reasons).

For establishing whether an intermediate generalisation is allowable, it must be considered whether it discloses subject-matter which was not directly and unambiguously derivable, using common general knowledge, from the application as filed. This is the case when other non-claimed features of the embodiment from which the claimed combination of features is

extracted are inextricably linked with the claimed ones for the technical purpose of the claimed subject-matter. Considerations about the scope of the claims are, at most, of secondary importance in this respect.

Paragraphs [0026] to [0031] of the application as filed describe several features of the coupling device according to the embodiment of Figures 2 and 3 as optional. Moreover, the application as filed does not inextricably link any further features to the ones of the absorbent defined in claims 1 and 9 of the main request for the technical purpose of providing a continuous supply of the cryoprotectant, this being the aim of the claimed absorbent being preloaded with excess cryoprotectant and in the form of a mesh, a foam, a porous plastic material and/or a porous metal material (paragraphs [0029] and [0030], first and second sentence on page 8 of the application as filed). The Board notes that neither the Opposition Division nor the respondent explained why this should be the case.

In conclusion, the subject-matter of claims 1 and 9 does not include any unallowable intermediate generalisation resulting in added subject-matter.

3.3 The respondent argued that the definition of the "thermal mass" of the treatment device in claims 1 and 9 of the main request added subject-matter too.

However, every physical element has a "thermal mass". Moreover, a treatment device having a thermal mass is disclosed verbatim in claim 17 of the application as filed. The embodiment of Figures 2 and 3 of the application as filed comprises such a treatment device and an absorbent preloaded with cryoprotectant and

being a mesh, a foam, a porous plastic material and/or a porous metal material, as explained above.

In conclusion, the definition of the "thermal mass" in claims 1 and 9 of the main request does not add subject-matter either.

- 3.4 The respondent argued that claim 14 of the main request included added subject-matter too because in the application as filed there was no mention or explanation of how the absorbent could be configured to continually supply the cryoprotectant to the skin.

However, paragraph [0030], which describes the (absorbent) intermediate portion of the embodiment of Figures 2 and 3, explains that the continuous supply of the cryoprotectant can be obtained by having the intermediate portion preloaded with excess cryoprotectant and "constantly replenished to provide a continuous supply" (first to third full sentences on page 8 of the application as filed).

Hence, claim 14 does not include added subject-matter either.

- 3.5 In conclusion, none of the objections of added subject-matter raised by the respondent prejudice the maintenance of the patent on the basis of the main request in view of Article 123(2) EPC.

4. It follows that the decision under appeal is to be set aside.

The Opposition Division did not consider in its decision the grounds for opposition of lack of novelty and inventive step raised by the respondent. In view of

the primary object of the appeal proceedings to review the decision under appeal in a judicial manner (Article 12(2) RPBA 2020) and the respondent's request of remittal, which was not objected to by the appellant, there are special reasons within the meaning of Article 11 RPBA 2020 which justify remittal of the case to the Opposition Division for further prosecution under Article 111(1) EPC.

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the Opposition Division for further prosecution.

The Registrar:

The Chairman:



A. Chavinier-Tomsic

M. Alvazzi Delfrate

Decision electronically authenticated