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D E C I S I O N
of 4 May 2005

Case Number: T 1172/03 - 3.2.2

Application Number: 96914574.7

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IPC: A61B 17/36

Language of the proceedings: EN

Title of invention:
Apparatus for skin resurfacing

Applicant:
Thermage

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 52(4)

Keyword:
"Method of treatment by surgery excluded from patentability
(yes) "

Decisions cited:
G 0005/83, G 0002/88, T 0144/83, T 0081/84, T 0116/85,
T 0290/86, T 0385/86, T 0774/89, T 0780/89, T 0182/90,
T 0024/91, T 0438/91, T 0820/92, T 1077/93, T 0329/94,
T 0775/97, T 0383/03,

Catchword:
The patentability of a surgical method claimed as a cosmetic method must be excluded, if the cosmetic use of the method is only expressed in the claim as a mere intention of the person using the method.



Case Number: T 1172/03 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 4 May 2005

Appellant: Thermage
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 3 July 2003
refusing European application No. 96914574.7
pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: T. K. H. Kriner
Members: M. G. Noël
A. Pignatelli

Summary of Facts and Submissions

- I. The appeal lies against the decision of the Examining Division posted on 3 July 2003 refusing the application No. 96 914 574.7 claiming a cosmetic method of tightening a skin surface overlying a collagen containing tissue site.

The reason for the refusal was that according to the Examining Division claim 1 related to a surgical method excluded from patentability according to Article 52(4) EPC.

The applicant filed a notice of appeal on 21 August 2003 and paid the appeal fee on the same day. On 24 October 2003 he filed a statement of grounds of appeal. Oral proceedings took place on 4 May 2005.

- II. The applicant requested the grant of a patent on the basis of the following independent claims:

Main request and auxiliary requests 1 and 2

"A cosmetic method of tightening a skin surface overlying a collagen containing tissue site, the method comprising:

- a) providing an electromagnetic energy source;
- b) delivering energy from the energy source through the skin surface and an epidermis to the collagen containing tissue site, wherein a temperature of the skin surface is less than a temperature of the collagen containing tissue site; contracting at least a portion of collagen in the collagen

- containing tissue site with a minimal cellular destruction in the epidermis; and
- c) tightening the skin surface."

Auxiliary request 3

"A cosmetic method of tightening a skin surface overlying a collagen containing tissue site, the method comprising:

- a) providing an electromagnetic energy source;
- b) transcutaneously delivering energy from the energy source through the skin surface to heat the collagen containing tissue without substantially modifying melanocytes and other epithelial cells in the epidermis, and applying a reverse thermal gradient by cooling the skin surface while the collagen containing tissue site is heated such that the temperature of the skin surface is less than the temperature of the collagen containing tissue site:
- c) contracting the collagen containing tissue site; and
- d) tightening the skin surface to create a cosmetic effect."

Auxiliary requests 4, 5 and 6

"Use of electromagnetic energy in the cosmetic tightening of a skin surface overlying a collagen containing tissue site, wherein:

- a) an electromagnetic energy source is provided;

- b) energy is delivered from the energy source through the skin surface and an epidermis to the collagen containing tissue site, wherein a temperature of the skin surface is less than a temperature of the collagen tissue site; at least a portion of collagen in the collagen containing tissue site is contracted with a minimal cellular destruction in the epidermis; and
- c) the skin surface is tightened."

Auxiliary requests 7, 8 and 9

"Use of an apparatus in the cosmetic tightening of a skin surface overlying a collagen containing tissue site, wherein:

- a) an electromagnetic energy source is provided;
- b) energy is delivered from the energy source through the skin surface and an epidermis to the collagen containing tissue site, wherein a temperature of the skin surface is less than a temperature of the collagen containing tissue site; at least a portion of collagen in the collagen containing tissue site is contracted with a minimal cellular destruction in the epidermis; and
- c) the skin surface is tightened."

Auxiliary request 10

"Use of an apparatus in the cosmetic tightening of a skin surface overlying a collagen containing tissue site, wherein:

- a) an electromagnetic energy source is provided;

- b) energy is delivered transcutaneously from the energy source through the skin surface to heat the collagen containing tissue without substantially modifying melanocytes and other epithelial cells in the epidermis, and a reverse thermal gradient is applied by cooling the skin surface while the collagen containing tissue site is heated such that the temperature of the skin surface is less than the temperature of the collagen containing tissue site:
- c) the collagen containing tissue site is contracted; and
- d) the skin surface is tightened to create a cosmetic effect."

Auxiliary request 11

"Use of an apparatus comprising thermal delivery means and an interface surface configured to conform to the exterior skin layer surface in the cosmetic tightening of a skin surface overlying a collagen containing tissue site for the treatment of laxity and wrinkling, wherein:

said apparatus provides an electromagnetic energy source;

wherein energy is delivered transcutaneously from the energy source through the skin surface to heat the collagen containing tissue without substantially modifying melanocytes and other epithelial cells in the epidermis, and a reverse thermal gradient is applied by cooling the skin surface while the collagen containing tissue site is heated such that the temperature of the skin surface is less than the temperature of the collagen containing tissue site; wherein

the collagen containing tissue site is contracted; and wherein the skin surface is tightened to create a cosmetic effect."

Auxiliary request 12

"Use of an apparatus comprising thermal delivery means and an interface surface configured to conform to the exterior skin layer surface in the cosmetic tightening of a skin surface overlying a collagen containing tissue site for the treatment of laxity and wrinkling of the face or neck, wherein: said apparatus provides ... cosmetic effect." (as in the previous auxiliary request).

Auxiliary request 13

"A method for the treatment of laxity and wrinkling, said method comprising the use of an apparatus comprising thermal delivery means and an interface surface configured to conform to the exterior skin layer surface in the cosmetic tightening of a skin surface overlying a collagen containing tissue site, wherein: said apparatus provides ... cosmetic effect." (as in the previous auxiliary request).

Auxiliary request 14

"A method for the treatment of laxity and wrinkling of the face or neck, said method comprising the use of an apparatus comprising thermal delivery means and an interface surface configured to conform to the exterior

skin layer surface in the cosmetic tightening of a skin surface overlying a collagen containing tissue site, wherein:

said apparatus provides ... cosmetic effect."
(as in the previous auxiliary request).

Auxiliary request 15

"A cosmetic method of treating laxity and wrinkling of the face or neck, said method comprising the use of an apparatus comprising thermal delivery means and an interface surface configured to conform to the exterior skin layer surface in the cosmetic tightening of a skin surface overlying a collagen containing tissue site, wherein:

said apparatus provides ... cosmetic effect."
(as in the previous auxiliary request).

The applicant further requested that the following question be referred to the Enlarged Board of Appeal, if the Board considered the auxiliary request 12 or 15 to be unallowable under Article 52(4) EPC:

"If patents can be granted for particular cosmetic methods using a chemical compound, is it correct that patent protection should be excluded for the same or similar cosmetic methods using another form of product, such as a device or apparatus, even if those cosmetic methods were to include a surgical step?"

III. The applicant's arguments can be summarised as follows:

- i) As to the main request and auxiliary requests 1 to 3 and 13 to 15

Even if the surgical method at issue potentially had both cosmetic and non-cosmetic uses, claim 1 was clearly limited to only the cosmetic use. Decision T 144/83 recognised the patentability of the cosmetic use of a substance even though the method might also have non-cosmetic (e.g. therapeutic) uses. The principle underlying this decision should be applied also to surgical methods.

Furthermore, as stated in decision T 116/85, the principle behind the exclusion from patentability according to Article 52(4) EPC was that a person should not be inhibited by patents from carrying out a surgical or therapeutic method as part of the medical treatment of humans or animals. Since claim 1 was clearly limited to the cosmetic use of the surgical method, it did not contravene the policy behind Article 52(4) EPC and should be allowable.

Surgery was associated with the maintenance of health and preventing, diagnosing, alleviating or curing disease. The method claimed was clearly limited to a cosmetic method and was therefore not concerned in any way with maintenance of health or preventing, diagnosing, alleviating or curing disease. The broader interpretation of the term "surgery" given in decision T 182/90 should not be

applied when interpreting Article 52(4) EPC because that was not what was meant when the EPC was established.

Article 52(4) EPC was an exception and as such should be interpreted narrowly.

ii) As to auxiliary requests 4 to 6

The claims of these requests were formulated as a second non-medical use of electromagnetic energy. They were allowable in view of the decision G 2/88 since the principle behind this decision should be applied also to the use of electromagnetic energy, which could be equated with the use of a compound.

iii) As to auxiliary requests 7 to 12

These claims were formulated as a second non-medical use of an apparatus. They were also allowable in view of the decision G 2/88 for the same reasons as set out before.

Reasons for the Decision

1. The appeal is admissible.
2. The claims of the main request and of the auxiliary requests 1 to 3 and 13 to 15 explicitly concern a method. In the present case, the method steps consist principally in:
 - providing an electromagnetic energy,

- delivering this electromagnetic energy through the skin surface and the epidermis to a deeper collagen containing tissue site,
- applying a reverse thermal gradient by heating the collagen in the collagen containing tissue site and cooling the skin surface,
- such that the temperature of the skin surface is less than the temperature of the collagen containing tissue site, thereby
- contracting the collagen in the collagen containing tissue site and
- tightening the skin surface to create a cosmetic effect.

2.1 First, it has to be considered whether this method is a surgical method in the sense of Article 52(4) EPC.

According to the jurisprudence of the boards of appeal of the EPO, a surgical method is any method comprising a non-insignificant intentional physical intervention performed directly or indirectly by one human being on another by manual and instrumental procedures (cf. T 182/90, OJ EPO 1994, 641).

Such methods are in principle excluded from patentability unless they are clearly neither suitable nor potentially suitable for maintaining or restoring the health, the physical integrity, and the physical

well being of a human being (cf. T 383/03, OJ EPO 2005, 159).

The present method involves an intentional physical intervention by an instrumental procedure performed directly by one human being on another i.e. the application of electromagnetic energy through the skin surface of the body to a collagen-containing tissue site, in order to achieve controlled contraction of collagen and skin tightening. The intervention is non-insignificant since the skin is burned.

As stated in the description of the patent application and as admitted by the appellant itself the method can be used for several therapeutic purposes including the application on the face or neck for reconstructive purposes (cf. page 2, lines 9 to 11; page 5, lines 13 to 19 and page 6, lines 13 to 15). It follows that the method is suitable for maintaining or restoring the health, the physical integrity and the physical well being of a human being.

The present method is therefore surgical and therapeutic in character and consequently falls under the exclusion of Article 52(4) EPC.

The Board cannot follow the opinion of the appellant that the meaning of a word ("surgery") used in law should always remain that which it meant at the moment of entry into force of the law and that therefore the broader interpretation of the term "surgery" given in T 182/90 should not be applied. On the contrary, the law must be adapted to the current situation keeping in mind the aim of the legislator when he wrote the law,

the so called "*ratio legis*". This adaptation is particularly important in a field such as patent law, in which the technology is rapidly developing so that the legislator could never foresee all the possible applications of the law.

- 2.2 The appellant is of the opinion that the limitation of the wording of the claims to a cosmetic method can avoid the exclusion from patentability established by Article 52(4) EPC.

The appellant refers to the jurisprudence in the field of the patentability of compounds and chemical substances, and especially to decision T 144/83, OJ EPO 1986, 301. This decision states that the exclusions from patentability must be construed narrowly and should not apply to treatments which are not therapeutic **in character** (emphasis added by this Board) (cf. point 3 of the reasons). The same line was adopted by the jurisprudence in many other decisions where the protection of a cosmetic use of a substance was only accepted if the cosmetic effect was a technical feature of the treatment and always refused when the cosmetic effect of the method was actually caused by a therapeutic effect or was not distinguishable from the therapeutic effect (cf. e.g. T 81/84, OJ EPO 1988, 207; T 116/85, OJ EPO 1989, 13; T 774/89; T 780/89, OJ EPO 1993, 440; T 820/92, OJ EPO 1995, 113; T 290/86, OJ EPO 1992, 414; T 438/91, T 1077/93). In other words, the cosmetic effect of the method must be functional or a technical feature defining the method, which clearly distinguishes the cosmetic method from a therapeutic method, so that in fact the word "cosmetic" in the claim should not be necessary.

The appellant considers that the same criteria should be applied to surgical methods.

The Board shares the appellant's opinion but it also considers that a claim must be judged for the purpose of Article 52(4) EPC on the basis of substantive and not of formal aspects of the claim (T 775/97). As stated in decision T 1077/93, the exclusion under Article 52(4) EPC cannot be simply avoided by a wording of the claims defining the method as a cosmetic method in a formal way, if in substance the method is a therapeutic one (cf. point 3.1.2 of the reasons).

It follows that, applying the criteria used by the boards for the cosmetic use of substances, patentability must be excluded if the cosmetic use is not expressed as a technical feature inherent in the claimed method, but only expressed in the claim as a mere intention of the applicant (cf. also G 2/88, OJ EPO 1990, 93, where a feature which is only reflected in the mind of the person carrying out the claimed invention is considered to be a subjective, non-technical feature which is not relevant for the assessment of patentability).

- 2.3 In the present case, the cosmetic effect is not distinguishable from the therapeutic one for the following reasons.

By applying a reverse thermal gradient through the skin by means of electromagnetic energy, which provides a variation in temperature throughout the various tissue layers, a selected underlying collagen-containing

tissue site is heated with the result of burning some cells and producing nascent scar collagen in the underlying dermis. The scar collagen is subsequently contracted and the skin is tightened correspondingly.

More specifically, electromagnetic energy is delivered through the tissue surface to the selected tissue site for a sufficient time to induce scar collagen deposition in the selected tissue site, so that the method is particularly useful in soft tissue sites that are devoid of or deficient in collagen (cf. patent application, page 5, lines 2 to 3).

As also specified in the patent application (page 2, lines 9 to 11): "The deposition and subsequent remodelling of this nascent scar collagen provides the means to alter the consistency and geometry of soft tissue for both aesthetic and reconstructive purposes".

Because collagen is to be found in many places in the human body, thermal gradient contraction of scar collagen is suitable for many therapeutical applications (cf. page 5, lines 13 to 19) and in particular for the removal of skin wrinkles by replenishing the collagen matrix that has been lost with aging (cf. page 5, lines 20 to 23).

In the present case, the thermal induction of scar collagen deposition as a reaction to inflammation induced by thermal injury has a therapeutic reconstructive effect. Thus, the claimed method can be regarded as restoring the patient's physical integrity. This effect is not distinguishable from the aesthetic effect of skin tightening, resulting from the

subsequent contraction of both the existing and the produced nascent scar collagen.

In the claims according to the auxiliary requests 13 to 15, the limitation of the method to the treatment of laxity and wrinkling of the face or neck, for cosmetic purposes, does not alter the above conclusion, since the skin tightening method can be applied equally to many areas of the body, such as the face and neck (cf. patent application, page 10, lines 14 to 19), always with the effect of correcting or restoring the physical integrity of the patient.

Therefore, it is not a technical feature of the method which renders it cosmetic and different from a therapeutic method, but only the intention of the person using the method for cosmetic purposes. This is clearly neither a functional nor a technical feature inherent to the method (cf. also a similar situation in T 116/85 where the Board decided that it was not possible as a matter of law to draw a distinction between a method as carried out by a farmer and the same method as carried out by a veterinarian, and to say that the method when carried out by a farmer was an industrial activity and therefore patentable under Article 57, and when carried out by a veterinarian was a therapeutic treatment not patentable under Article 52(4)).

It follows that the claims of the main request and of the auxiliary requests 1 to 3 and 13 to 15 are excluded from patentability under Article 52(4) EPC since they are related to a method of treatment of the human body by surgery and are therapeutic in character.

3. The appellant is of the opinion that since the claims according to the auxiliary requests 4 to 12 are written as second non-medical use claims which are considered patentable by the jurisprudence, they should be allowed.

3.1 As the Enlarged Board of Appeal has made clear in decision G 5/83, OJ EPO 1985, 64 (point 11 of the reasons), there is no difference in substance between an activity claimed as a method of carrying out said activity and the use of a thing for a stated purpose. The Enlarged Board of Appeal excluded the grant of claims directed to the use of a substance or composition for the treatment of the human or animal body by therapy on the ground that such a claim is in no way different in essence from a claim directed to a method of treatment of the human or animal body by therapy using the substance or composition. The difference between the two categories being one of form only, and the second form (method of treatment) being plainly in conflict with Article 52(4) EPC, no European patent could be granted including such claims whatever their formulation (point 13 of the reasons).

The Board considers that the same applies to claims related to the use of an apparatus or of a device for the treatment of the human or animal body. There are no legal reasons which would justify a different evaluation with respect to substances and other products in this respect.

3.2 The Enlarged Board of Appeal held in the second part of its order that a European patent could be granted with claims directed to the use of a known substance or

composition for the manufacture of a medicament for a specified new and inventive therapeutic application.

The reason why claims in the second format ("Swiss type claims") qualify as representing a patentable "industrial" activity outside the scope of the exclusion from patentability under Article 52(4) EPC, is simply the fact that the mere manufacturing of a product, irrespective of whether that product is (also) a "medicament" because of its capacity to produce certain effects on or in the human or animal body when administered to it, does not necessitate or comprise any action on an individual human or animal body and, therefore, does not constitute a treatment of such body by therapy. The manufacturing and distribution of medicaments is a matter of industry and commerce which is performed by persons who need not and normally do not have a medical qualification, whereas the exercise of therapeutic activities including those involving the treatment by medicaments is reserved for medical practitioners or other persons having medical knowledge (cf. T 385/86, OJ EPO 1988, 308; T 24/91, OJ EPO 1995, 512 and T 329/94, OJ EPO 1998, 241).

The jurisprudence on "Swiss type claims" is based on Article 54(5) EPC which explicitly confers novelty on medical products which are obtained through the use of known substances and compositions provided this use is new.

In this respect, a difference should be made between substances and other products because Article 54(5) EPC only provides an exception for substances, having regard to novelty. Exceptions must be construed

narrowly and cannot be extended. Therefore, the provision of Article 54(5) EPC cannot be extended to other products, such as an apparatus.

- 3.3 In the present case, although the claims according to the auxiliary requests 4 to 12 are formulated as "use of ... for ..." these claims still describe a method for tightening a skin surface, incorporating the same steps and technical features as in the previous method claims, but expressed in the passive form. Moreover, unlike the second non-medical use of a substance or compound for making a medicament, in the present situation the use of electromagnetic energy or the use of an apparatus for tightening the skin or for treating skin laxity and wrinkling would not result in the provision of a new product or physical entity. The two situations, therefore, are not to be compared.

The independent claims according to the auxiliary requests 4 to 12 are, therefore, method claims despite their formulation as use claims.

It follows that the same considerations as those made in relation to the main request and the auxiliary requests 1 to 3 and 13 to 15 apply also to these claims, so that they cannot be allowed under Article 54(2) EPC. They are directed to the treatment of the human body by surgery and are therapeutic in character.

4. The question whether the jurisprudence concerning a new non-medical use of a known substance (G 2/88) is applicable to other products such as an apparatus, is not relevant in this case because the use of the

apparatus is medical in character, as demonstrated above and therefore governed by Article 52(4) EPC. By contrast, G 2/88 only relates to the question of novelty and the new use of a known compound under Article 54(5) EPC and cannot be applied to the overriding question of the medical or non-medical character of an invention.

5. The request to refer the question to the Enlarged Board of Appeal must be refused since this question is not of fundamental importance because the answer to it can be found in the present jurisprudence as set out above.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

A. Counillon

T. Kriner