

Decision of Technical Board of Appeal 3.2.2 dated 1 October 2004

T 383/03

(Language of the proceedings)

Composition of the board:

Chairman: T. K. H. Kriner

Members: S. S. Chowdhury

A. Pignatelli

Applicant: THE GENERAL HOSPITAL CORPORATION

Headword: Hair removal method/THE GENERAL HOSPITAL CORP.

Article: 52(4), 57 EPC

Keyword: "Method of treatment by surgery excluded from patentability (no)"

Headnote

If a method involving a physical intervention on the human or animal body (treatment by surgery) is clearly neither suitable nor potentially suitable for maintaining or restoring the health, the physical integrity, or the physical well-being of the person or animal, then the method does not fall under the exclusion from patentability provided for in Article 52(4) EPC.

Summary of facts and submissions

I. This appeal is against the decision of the examining division dated 25 November 2002 to refuse European patent application No. 02 076 295.1.

The ground of refusal was that claims 1 to 19 were not allowable in that they pertained to methods of treatment by surgery which were practised on the living human or animal body which shall not be regarded as inventions susceptible of industrial application under Article 52(4) EPC.

II. On 6 January 2003 the appellant (applicant) lodged an appeal against the decision and paid the prescribed fee on the same day. On 26 March 2003 a statement of grounds of appeal was filed.

III. The appellant requests that the decision under appeal be set aside and that the application proceed on the basis of claims 1 to 18 filed with the grounds of appeal (herein referred to as the main request), or on the basis of claims 1 to 11 filed as claims of second preference, also filed with the grounds of appeal. Oral proceedings were requested on an auxiliary basis.

IV. Claim 1 of the main request reads as follows:

"A cosmetic method for the simultaneous removal of a plurality of hairs from a skin region, each hair being in a follicle extending into the skin from a skin surface, the method comprising:

- (a) positioning an element over the skin surface in the said skin region through which optical radiation may be passed; and
- (b) applying optical radiation of a selected wavelength and of a selected fluence through the element to the said skin region for from 5 ms to 200 ms."

Claims 2 to 18 are dependent on claim 1.

V. The appellant submitted the following arguments:

T 182/90 recognised that methods falling within the definition of medical treatment may nevertheless be patentable and there was nothing in that decision which precluded the finding that the present invention was patentable. Moreover, there was no public interest requirement to exclude the claimed method from patentability.

The invention was concerned solely with the removal of hair for cosmetic purposes. While a cosmetic method may have a surgical character, the present method was neither a treatment nor a surgical method in the sense of Article 52(4) EPC. The fact that unwanted hair may be caused by a medical condition did not render the treatment therapeutic since the method did not affect the underlying medical cause of the unwanted hair. The claimed method was non-invasive and no more surgical than removing hair by plucking.

The examining division did not explain why a medically trained person was required to use the method, but the question of who could carry out the method was not relevant to the question of patentability under Article 52(4) EPC, whose exclusion should be interpreted narrowly.

Reasons for the decision

1. The appeal is admissible.

2. Although the claims are directed to a cosmetic method for the simultaneous removal of a plurality of hairs from a skin region, the impugned decision states that the claims pertain to methods of treatment by surgery which are practised on the living human or animal body and, therefore, not susceptible of industrial application. The first instance department referred to decisions T 182/90 (OJ EPO 1994, 641) and T 1077/93 and based its finding on the interpretation of the term "surgery" as a non-insignificant intentional physical intervention. It considered that medical treatments also encompass treatments by surgery for non-curative purposes such as cosmetic treatments. The application was refused under Article 52(4) EPC, accordingly.

The Board does not share this view for the following reasons.

3. According to Article 52(4) EPC methods of treatment of the human or animal body by surgery or therapy shall not be regarded as inventions susceptible of industrial application.

3.1 The Boards of Appeal have defined the term "medical treatment" as any non-insignificant intentional physical or psychic intervention performed directly or indirectly by one human being - who need not necessarily be a medical practitioner - on another (or, by analogy, on animals) using means or methods of medical science (cf. T 182/90, OJ EPO 1994, 641) and have tried to determine which treatments fall within the scope of Article 52(4) EPC.

(a) T 36/83 (OJ EPO 1986, 295) ruling on the allowability of a claim directed to the cosmetic use of thenoyl peroxide stated that the cosmetic indication of a product having medical indications as well does not fall within the scope of Article 52(4) EPC and may be patentable. Decision T 144/83 (OJ EPO 1986, 301) stated that the exclusion from patentability of Article 52(4) EPC should not apply to treatments which are not therapeutic in character and that the patentability of the invention claimed (a method of improving the bodily appearance of a non-opiate-addicted mammal which comprises orally administering a certain product in a determined dosage to lose weight) was not in doubt since it could be used by enterprises whose object was to beautify the human or animal body. The fact that a chemical product has both a cosmetic and a therapeutic effect when used to treat the human or animal body does not render the cosmetic treatment unpatentable.

(b) In T 182/90 (OJ EPO 1994, 641) the board stated that the term surgery implies a treatment by manual and instrumental procedures and found that the term "treatment by surgery" has apparently undergone a change in meaning in so far as it nowadays may also comprise particular treatments which are not directed to the health of the human or animal body. The board went on to say that in today's medical and legal linguistic usage, non-curative treatments are, if carried out by surgery, regarded as surgical treatments. Some of these treatments were considered in national case law and led to their exclusion from patentability (cf. *R. Moufang*, "Medizinische Verfahren im Patentrecht", GRUR Int. 1992, pages 10 to 24, in particular page 19; English version published in IIC, Vol. 24, No. 1/1993, pages 18 to 49).

In T 35/99 (OJ EPO 2000, 447), the board held that the wording "methods for treatment of the human or animal body by surgery or therapy" means any (by its nature) surgical or therapeutic method which can be carried out as such on the human or animal body. The board also confirmed that as regards the European Patent Convention, the policy behind the exclusion of the methods set out in Article 52(4) EPC was clearly to ensure that those who carry out such methods as part of the medical treatment of humans or the veterinary treatment of animals should not be inhibited by patents. In the light of this clear and deliberate choice on the part of the legislator, the terms "treatment" and "surgery" in Article 52(4) EPC cannot be considered as constituting two distinct requirements for the exclusion. The exclusion encompasses any surgical activity, irrespective of whether it is carried out alone or in combination with other medical or non-medical measures (cf. Headnote).

In T 775/97, the board referring to G 5/83, point 22 of the reasons, held that it is the intention of Article 52(4) EPC to free from restraint non-commercial and non-industrial medical and veterinary activities and said provision, in respect of the exclusion from patentability of methods for treatment of the human or animal body, in no way differentiates between therapy and surgery - for good reasons, in that both serve the same purpose, namely maintaining or restoring the health of the body on which they are performed, and very often a successful treatment requires the combined use of methods of both kinds. The criteria for deciding whether a certain format of claims is per se allowable in view of Article 52(4) EPC or not must be the same for both surgical and therapeutic methods.

(c) Although it emerges from the above cited decisions that methods of treatment which are not directed to improving or maintaining the health of a human being or an animal may be patentable, the case is not so clear where the treatment involves manual and/or instrumental procedures (treatment by surgery).

It is therefore necessary to examine whether Article 52(4) EPC intends to exclude from patentability this type of intervention as such or whether a therapeutic effect plays a decisive role in determining which interventions are excluded from patentability as stated for example in T 329/94 (OJ EPO 1998, 241, point 5 of the reasons). The answer to this question is all the more important as the term "surgery" has undergone a change in meaning as explained in T 182/90.

3.2 To clarify this question, further interpretation is necessary and to this end it is necessary to refer to the ratio legis of Article 52(4) EPC.

(a) As may be seen from the Travaux préparatoires, the intention of the legislator was to exclude from patentability curative methods of human or veterinary medicine including diagnostic methods. In 11821/IV/64-F it is said that the aim of the provision is "indiquer l'exception des méthodes curatives du corps humains ou des animaux y compris les méthodes de diagnostic" or in 11821/IV/64-D that "Heilmethoden der Human- und Veterinärmedizin einschließlich diagnostischer Verfahren vom Begriff der Erfindung ausgenommen sind". An English version of this document does not exist. In BR/219/72 in connection with a discussion on the treatment on animals it is stated that " the intention behind this text was merely to exclude from patentability all therapeutic treatments practised on animals, the aim of this provision being to exclude from patentability treatments falling within the meaning of treatment intended to cure or alleviate the suffering of animals." For human beings the intention was never put into question so that it can be concluded that the provision had the same aim for human beings (see *Benkard*, EPÜ, Art. 52 Rdnr. 230).

(b) Decision G 5/83 (OJ EPO 1985, 64, point 22 of the reasons) and the jurisprudence of the Boards of Appeal have repeatedly confirmed this ratio legis of Article 52(4) EPC stating that the policy behind the exclusion of the methods set out in Article 52(4) EPC was clearly to ensure that those who carry out such methods as part of the medical treatment of humans or the veterinary treatment of animals should not be inhibited by patents (see the above cited decisions and also T 116/85 (OJ EPO 1989,13); T 24/91 (OJ EPO 1995, 512); T 329/94 (OJ EPO 1998, 241)).

Evidently the exclusion aims at protecting curative activities. As the BGH stated it in its decision of 28 November 2000, X ZB 20/99, the doctor must be free to take the most suitable measure to treat his patient.

The above-cited jurisprudence has given many definitions of what constitutes curative activities. Summarising, it may be said that curative activities are those activities aimed at maintaining and restoring the health, the physical integrity, and the physical well-being of a person (and also preventing diseases). The same applies to activities performed on animals.

(c) It follows that the intention of the legislator was that only those treatments by therapy or surgery are excluded from patentability which are suitable for or potentially suitable for maintaining or restoring the health, the physical integrity, and the physical well being of a human being or an animal and to prevent diseases.

3.3 Article 52(4) EPC is an exclusion clause and as a general principle of law should be construed narrowly (see also T 385/86 (OJ EPO 1988, 308) and the jurisprudence cited above). No difference should be made between treatments which do not involve surgery and those which do (see also T 35/99, T 775/97).

Even if in medical linguistic usage the term "treatment by surgery" nowadays also comprises treatments which are not directed to the health of human beings or animals, they do not fall within the exclusion from patentability if they are not covered by the ratio legis of Article 52(4) EPC.

Just as this principle has already been recognised in the jurisprudence in the case of treatments without a surgical step which have a purely cosmetic effect (see above), so must it also be applied to treatments by surgery.

3.4 Thus, treatments by surgery which are clearly neither suitable nor potentially suitable for maintaining or restoring the health, the physical integrity, or the physical well-being of human beings or animals do not fall within the exclusion from patentability of Article 52(4) EPC.

4. As stated in point 3 above the claimed method is patentable only if it is clearly not potentially suitable for maintaining or restoring the health, the physical integrity, and the physical well-being of a human being or an animal.

4.1 The present application relates to methods for hair-removal using optical radiation. Excess hair (hypertrichosis) and/or unwanted hair are common dermatological and cosmetic problems, and can be caused by heredity,

malignancy, or endocrinologic diseases, for example hirsutism (i.e., excess hair due to hormones such as androgens).

While the underlying cause of excess hair may be malignancy or endocrinologic diseases, excess hair itself is not harmful and its removal does not treat the underlying cause of unwanted hair, nor is it relevant to the physical health of the treated person; the treatment merely results in an aesthetic improvement of the appearance of the person. The claims are directed to a "cosmetic method" in order to emphasise that the purpose of the claimed method is to improve the aesthetic appearance of the person treated rather than to cure the underlying malady. Therefore, the underlying medical condition of itself is not sufficient ground for classifying the method as a method of medical treatment.

4.2 The essence of the present solution to the problem is to apply optical radiation of a selected wavelength and of a selected fluence through the element to the said skin region for from 5 ms to 200 ms. The purpose of the method is to damage the hairs and follicles without causing significant damage to surrounding tissue. The apparatus disclosed for carrying out the treatment irradiates the hair and skin with a view to damaging the hairs and follicles, while the skin is cooled so as to avoid significant damage to surrounding tissue. This is a non-insignificant intentional physical intervention which is to be regarded as a surgical operation.

Although the method involves an intentional physical intervention on the body, it is clearly not potentially suitable for maintaining or restoring the health, physical integrity, or physical well-being of a person or animal.

The present method falls into that category of methods which includes tattooing and piercing, for example, whose only possible object is to beautify the human or animal body and which are used by enterprises such as cosmetic salons and beauty parlours which are part of industry in the sense of Article 57 EPC. These methods are fundamentally different from those methods which, although they can be used to beautify the human or animal body, may also be used to restore the physical integrity of the body, such as a method of breast enlargement by surgery (following a cancer operation, for example) or a correction of the shape of the nose (after a car accident, for example).

The latter kinds of methods are excluded from patentability because they are potentially suitable for maintaining or restoring the health, physical integrity, or physical well-being of a person, in contrast to methods whose only application is for aesthetical purposes and which could not be used for medical reasons and therefore need not be excluded because they do not contravene the ratio legis of Article 52(1) EPC.

Thus since, for the reasons set out above, the present method is clearly neither suitable nor potentially suitable for maintaining or restoring the health, physical integrity, or physical well-being of a person, the method is not to be considered as falling under the exclusion of protection foreseen in Article 52(4) EPC.

4.3 Claims 2 to 18 are dependent on claim 1 and define no further steps that would render the method clearly suitable or potentially suitable for maintaining or restoring the health, physical integrity, or physical well-being of a person.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance for further prosecution according to claims 1 to 18 of the main request.