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D E C I S I O N
of 5 May 1994

Case Number: T 0024/91 - 3.2.2

Application Number: 89 103 409.2

Publication Number: 0 331 082

IPC: A61F 9/00, A61F 2/14

Language of the proceedings: EN

Title of invention:

Apparatus and process for application and adjustable
reprofiling of synthetic lenticules for vision correction

Applicant:

Thompson, Keith, P.

Opponent:

-

Headword:

Cornea/THOMPSON

Relevant legal norms:

EPC Art. 52(4)

Keyword:

"Patentable inventions - medical treatment (yes) "

Decisions cited:

T 0182/90, T 0245/87, T 0426/89

Headnote:

(To follow)



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Boards of Appeal

Chambres de recours

Case Number: T 0024/91 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 5 May 1994

Appellant: Thompson, Keith P.
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Representative: Leiser, Gottfried, Dipl.-Ing.
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Decision under appeal: Decision of the Examining Division of the
European Patent Office dated 30 August 1990
refusing European patent application
No. 89 103 409.2 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: H. Seidenschwarz
Members: P. Dropmann
J. Van Moer

Summary of Facts and Submissions

- I. The Appellant (Applicant) lodged an appeal against the decision of the Examining Division refusing application No. 89 103 409.2.

The Examining Division held that the process according to Claim 1 dated 15 February 1990 was not patentable in view of Article 52(1) and (4) EPC, but allowed the apparatus Claims 2 to 4 of the same date.

- II. In a communication dated 25 March 1994, the Board raised objections under Articles 84, 123(2) and 52(4) EPC against the process claim.

Oral proceedings were held on 5 May 1994. At these proceedings, the Appellant submitted a set of Claims 1 to 6 according to a main request and a set of Claims 1 to 3 together with an adapted description according to an auxiliary request.

- III. The Appellant requested that the decision under appeal be set aside and a patent granted on the basis of the following documents:

Main request:

Claims 1 to 6 submitted at the oral proceedings,
Description pages 1 to 21 filed with the letter of 2 May 1994,
Figures 1 to 11 as originally filed.

Auxiliary request:

Claims 1 to 3 submitted at the oral proceedings,
Description pages 1 to 21 submitted at the oral proceedings,
Figures 1 to 11 as originally filed.

IV. Claim 1 according to the main request reads as follows:

"A process for adjustable reprofiling the anterior curvature of a synthetic lenticule having been secured to the cornea of the human eye for correcting vision, with corneal epithelium optionally grown over said lenticule having been removed prior to the presently claimed process, said lenticule being constructed so as to correct a patient's particular refractive error, wherein predetermined portions of said lenticule are ablated by laser for refining its refractive power."

Claim 1 according to the auxiliary request reads as follows:

"An apparatus for placing a prepared synthetic lenticule (40) over the cornea of a human eye for correcting a patient's refractive error, the cornea having a peripheral groove etched therein with an adhesive means disposed therein for receiving the peripheral edge (52) of said lenticule (40), said apparatus comprising a chamber (69) having means (50) at the lower edge thereof for securing said chamber (69) to the limbal region (46) of the eye for preventing substantial movement of the eye with relation to said chamber (69), a micro-manipulation system disposed in said chamber, including a horizontal carriage means (62), a vertical carriage means (64), and a gimbal means (66) operatively associated together for effecting movement along any axis and in translations across said axes, a motor (65) and power source for selectively driving said micro-manipulation system, a suction ring means (60) secured to said gimbal means (66) for holding said lenticule (40) prior to application thereof, and control means (68) operable by the physician for manipulating said lenticule."

- V. The Appellant essentially argued that Claim 1 according to the main request was not directed to a method for treatment of the human body by surgery or therapy, but rather to a process for physical treatment of a synthetic lenticule secured to the cornea of the human eye. Such a process did not fall within the scope of Article 52(4) EPC, which should be construed narrowly.

Reasons for the Decision

1. The appeal is admissible.
2. *Main request - Article 52(4) EPC*
 - 2.1 Claim 1 according to the main request is essentially based on Claim 15 as originally filed. It relates to a process for adjustably reprofiling the anterior curvature of a synthetic lenticule which is constructed so as to correct a patient's particular refractive error and has been secured to the cornea of the human eye for correcting vision. The adjustable reprofiling is performed by ablating predetermined portions of said lenticule with a laser for refining the refractive power of the lenticule. Claim 1 furthermore states that, prior to the claimed process, epithelium grown over the lenticule has been removed.
 - 2.2 The wording of Claim 1 thus indicates, by using what the Appellant considers a disclaimer, that the **claimed** teaching does not cover the steps of securing the synthetic lenticule to the cornea of the human eye and of removing the epithelium grown over the lenticule, which steps have been admitted by the Appellant to be surgical and have necessarily to be carried out before reprofiling the secured lenticule.

Whether or not such a disclaimer is effective for the decision on exclusions under the first sentence of Article 52(4) EPC can be left undecided in the present case in view of the findings set out in the following points that the claimed process falls within the exclusion of this Article.

2.3 The question to be answered is whether or not the claimed process, which consists of ablating by laser predetermined portions of the anterior surface of a synthetic lenticule secured to the cornea of a human eye, represents a method for treatment of the human body by surgery or therapy within the meaning of the first sentence of Article 52(4) EPC. Such a method must be regarded as not susceptible of industrial application and, therefore, excluded from patentability.

2.4 It is generally accepted that the exclusions from patentability under Article 52(4) EPC are based on social-ethical and public health considerations. The intention underlying this Article is to ensure that nobody who wants to use the methods specified in this Article as part of the medical treatment of humans or animals should be prevented from this by patents.

Such medical treatments need not necessarily be carried out by physicians (cf. point 2.2 of decision T 182/90, to be published, headnote published in OJ EPO 11/1993). However, where, in view of the health risks connected with such a treatment, a claimed method for treatment has to be performed by a physician or under his supervision, it will normally fall within the exclusion of the first sentence of Article 52(4) EPC.

2.5 As to the present case, the Board cannot accept the Appellant's argument that the claimed process is carried out by a technician having no medical knowledge rather

than by a physician. It is well-known that it is the ophthalmic surgeon who directs the excimer laser used for photorefractive keratectomy which differs from the claimed process only in that, in keratectomy, corneal tissue is removed from the cornea whereas, in the claimed process, portions of the synthetic lenticule are ablated. In both processes the same laser can be used. It should be borne in mind that the lenticule is secured to the cornea and forms, when covered with epithelium, a real implant integrated into the organic structure of the eye. Directing the laser beam to the lenticule bears the severe risk of damaging the neighbouring tissue of the eye. Since the physician is bound to exercise extreme care both during the medical treatment and during the use of medical-technical apparatus and, moreover, is responsible for the surveillance of his medical and non-medical staff, the Board is convinced that the claimed process is and has to be carried out by the ophthalmologist or ophthalmic surgeon himself or at least under his supervision. This fact indicates that the claimed process falls under the exclusion of Article 52(4) EPC.

The claimed process, in addition, comprises inherently the step of fixing the patient's eye at the limbus to a housing by a limbal suction ring (cf. pages 14 and 18 of the description as originally filed). This is also done by an ophthalmologist or a person having the necessary medical knowledge.

- 2.6 The Appellant further argued that the claimed process did not comprise any surgical step or therapeutic **treatment of the human body** but, instead, comprised physical treatment of a synthetic lenticule, i.e. a specific type of prosthesis, only. As already stated in point 2.5 above, the lenticule having been secured to the cornea of the eye is a real implant, in contrast to,

for example, an arm or leg prosthesis. The lenticule is secured at the same place and has the same function as a lens made of a donor cornea and secured on top of the cornea in the epikeratophakia technique (cf. page 3 of the description as filed). Both the lens and the lenticule form a unit with the patient's cornea and serve to correct the patient's refractive error.

Ablating portions of the lenticule as claimed in Claim 1, therefore, directly results in a change of the refractive power of the patient's eye. Because of this direct influence of the claimed process on the refractive power of the patient's eye and his vision, the process is to be considered as **treatment of the human body**. The situation is thus different from that considered in decision T 245/87, OJ EPO 1989, 171, where there was no functional link and hence no physical causality between the steps of a method carried out in relation to an implanted therapy device and the therapeutic effect produced on the body by that device (point 3.2.3); cf. also point 3.2, second paragraph of decision T 426/89, OJ EPO 1992, 172.

- 2.7 Moreover, the Board takes the view that the claimed process represents a **treatment by therapy**. The Board cannot agree with the Appellant's argument that the claimed treatment is not therapeutic since it does not affect the disease causing the refractive error of an eye. The meaning of the term "therapy" is not restricted to curing a disease and removing its causes. Rather, this term covers any treatment which is designed to cure, alleviate, remove or lessen the symptoms of, or prevent or reduce the possibility of contracting any disorder or malfunction of the human or animal body.

The claimed process removes, by treatment of the patient's eye, the symptoms of myopia, hyperopia and astigmatism and is therefore a therapeutic treatment.

2.8 It follows from the above considerations that the process according to Claim 1 of the main request represents a method for treatment of the human body by therapy within the meaning of the first sentence of Article 52(4) EPC. It is therefore excluded from patentability. Hence, the main request cannot be allowed.

3. *Auxiliary request*

Apparatus Claims 1 to 3 according to the auxiliary request correspond to Claims 2 to 4 dated 15 February 1990 which were considered allowable by the Examining Division. This assessment was not challenged during the appeal proceedings.

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 with the order to grant a patent in the version according to the auxiliary request set out in point III above.

The Registrar:

The Chairman:



S. Fabiani



H. Seidenschwarz