BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

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File Number: T 227/91 - 3.2.2

Application No.: 86 306 762.5

Publication No.: 0 230 089

Title of invention: A61B 17/36

Classification: Laser instrument

D E C I S I O N
of 15 December 1992

Applicant: Codman & Schurtleff Inc.

Headword: Second surgical use/CODMAN

EPC Articles 84, 54(1)

Keyword: "lack of clarity; indefinite parameter"
"lack of novelty; generic claim anticipated by a specific disclosure"
"relations between use claim and device-by-process claim"
"second surgical use"

- HEADNOTE FOLLOWS -

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number : T 227/91 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 15 December 1992

Appellant : Codman & Shurtleff Inc.
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Massachusetts 02368 (US)

Representative : Jones, Alan John
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Decision under appeal : Decision of the Examining Division of the European Patent Office dated 23 November 1990 refusing European patent application No. 86 306 762.5 pursuant to Article 97(1) EPC.

Composition of the Board :

Chairman : G. Szabo
Members : M. Noel
W. Moser

Summary of facts and submissions

I. European patent application No. 86 306 762.5 (publication No. 0 230 089) was refused by decision of the Examining Division for the reasons that the subject-matter of the claims was neither novel nor involved an inventive step having regard to the prior art document

(1) EP-A-0 157 593

II. The Appellant (Applicant) lodged an appeal on 24 January 1991 against this decision, with the simultaneous payment of the fee. A Statement of Grounds received on 26 February 1991 was accompanied by a new set of amended Claims 1 to 11 and revised pages of the description.

III. In a communication dated 2 April 1992, the Board informed the Appellant of its provisional opinion, that a positive decision could be expected on condition that further amendments were made to the main claim. In the Appellant's reply, the claims were left unchanged.

IV. During oral proceedings held on 15 December 1992, the Appellant submitted new amended main claims according to a main request and an auxiliary request, respectively. These claims read as follows:

"1. (Main Request) A laser surgery system comprising in combination:

a laser having a wavelength and an effective pulse time; and

an instrument, for intercepting an incident laser beam from the laser after the laser beam has energised a desired surgical target site but before the laser beam energises material adjacent to the surgical target site, comprising

(i) substrate means (16) for transmitting energy received from the laser beam away from the surgical target site, said substrate means having a high thermal conductivity and an exterior surface, and

(ii) coating means (18) for absorbing laser energy at the wavelength of the laser beam, said coating means covering substantially the entirety of the exterior surface of the substrate means, having a high absorptivity for energy at the wavelength of the laser beam and having a thickness in excess of one quarter of the wavelength of said laser beam,

characterised by said coating means having a thickness substantially equal to $0.1\ (a.t)^{0.5}$, where

a = thermal diffusivity of the coating means

t = effective time pulse of the laser."

"1. (Auxiliary Request) Use, in the manufacture of a laser surgical instrument for intercepting an incident laser beam having a particular wavelength after the laser beam has energised a desired surgical target site but before the laser beam energises material adjacent to the surgical target site, of:

substrate means (16) adapted to transmit energy received from said laser beam away from said surgical target site, said substrate means having a high thermal conductivity and an exterior surface; and

coating means (18) adapted to absorb laser energy at said wavelength, said coating means covering substantially the entirety of the exterior surface of the substrate means, having a high absorptivity for energy at that wavelength and

having a thickness in excess of one quarter of the wavelength of the laser beam;

characterized by said coating means having a thickness substantially equal to $0.1\ (a.t)^{0.5}$, where

a = thermal diffusivity of the coating means

t = effective pulse time of the laser beam."

V. In support of these new requests the Appellant argued substantially as follows:

(i) The subject-matter of Claim 1 according to the main request referred generally to a laser surgery system comprising an instrument in combination with a laser, in conformity with the teaching of the application as originally filed. Accordingly Claim 1 incorporated features of both elements and did not cover the instrument alone for intercepting an incident laser beam. In contrast the subject-matter of prior art document (1) was confined to the features of the instrument alone, without the laser beam.

(ii) Claim 1 was limited to a specific thickness of coating material, namely the preferred thickness discussed on page 10 of the application, which lay in the range between a minimum and a maximum thickness. As Claim 1 now specified both wavelength and pulse time of the laser, its scope was fully determinate. Since nothing in the cited prior art indicated a coating thickness given by the formula specified in Claim 1, its subject-matter must therefore be novel.

(iii) The subject-matter of Claim 1 according to the auxiliary request referred to the use of selected

materials and parameters suitable for the fabrication of a surgical instrument for therapeutical purposes. Since the use of an optimum coating thickness as defined in Claim 1 was not known from document (1), the novelty of Claim 1 as a use claim had to be recognised. Furthermore, such a claim would be fully analogous to those relating to the manufacture of a medicament for a new therapeutic purpose.

VI. The Appellant requests that the decision under appeal be set aside and that a patent be granted on the basis of the main claim submitted during oral proceedings, according to either the main or the auxiliary request.

Reasons for the decision

1. The appeal is admissible.

2. Amendments (main request)

The Board agrees that the scope of Claim 1 can be broadened from "an instrument for intercepting an incident laser beam" to "a laser surgery system" comprising a laser as well as this instrument, since it is clear from the introductory part of the application that the instrument is usable only in combination with the appropriate laser and at certain times.

There is also no objection against the reincorporation of the minimum thickness of the coating means (one quarter of the wavelength of the laser beam) in Claim 1, as this feature was present in Claim 1 as originally filed.

A basis for the formula giving the coating thickness according to the characterising portion of Claim 1 is to be found on page 10 of the description.

The Board is thus satisfied that the amendments made to Claim 1 do not extend beyond the content of the original application, as required by Article 123(2) EPC.

3. Clarity (main request)

In the Board's view, Claim 1 lacks clarity under Article 84 EPC for the following reasons.

The coating thickness as defined by the formula $0.1\ (a.t)^{0.5}$ depends on both parameters a and t. Parameter a represents the thermal diffusivity of the coating means, i.e. the absorptivity of the material forming the external layer 18 of the instrument rod 14. It is therefore a feature inherent in the instrument.

In contrast, parameter t which represents the effective pulse time of the laser is related to the laser operating conditions, and not to the structure of either the laser or the instrument. According to the patent application (cf. page 10), t is the time the laser energy impinges on the coating surface. Since most lasers are operated intermittently with prescribed pulse times, the effective pulse time is made dependent on the ratio duration/period, i.e. the ratio between the on-time for each pulse and the off-time between pulses, as explained on pages 10 and 11 of the description. The thickness of the surface material can thus take any value within the shaded area of the graph of Fig. 9, depending on the effective pulse time controlled by the operator for a selected coating material.

Even if the thickness defined by the simplified Einstein equation can be regarded as an optimum from the Appellant's point of view, it is still connected with the mode of operation of the laser, that is, with a human factor irrelevant to the instrument per se. Therefore, the extent of the protection conferred by the subject-matter of Claim 1 is regarded by the Board as ambiguous and indefinite.

4. Novelty (main request)

4.1 The present application is an improvement of the subject-matter of document (1), also originating from the Appellant. In fact, the US priority filing of the application in suit is a continuation-in-part of the first US priority filing of document (1).

The disclosure of document (1) is presented from the very beginning in the same wording as that of the present application (see in particular the strict similarity between the respective introductory parts and between many other passages in the subsequent descriptions). The Board therefore concludes that the subject-matter of document (1) is not only restricted to an instrument for intercepting an incident laser beam but also includes, as is the case in the present application (cf. Point 2 above), a laser surgery system having all the features recited in the pre-characterising portion of Claim 1, in particular coating means having a minimum thickness of one quarter of the wavelength of the laser beam. Claim 1 is therefore delimited against the teaching of document (1) in the sense that the known technical features introduced by the Appellant in the first portion of Claim 1 are unquestionably part of the prior art, in conformity with Rule 29(1)(a) EPC.

4.2 The characterising feature of Claim 1 apparently limits its scope to a maximum thickness which varies with the Einstein equation approximation referred to on page 10 of the application, after introduction of a safety factor of 0.10 to ensure that approximately ninety percent of the laser beam energy is transferred.

As explained on page 10, this equation represents only a satisfactory approximation, which in fact results in the conditions to be observed for defining the maximum thickness qualitatively as the thickness where the coating starts to act as a thermal insulator and inhibits the heat from being readily conducted to the high thermal conductivity substrate material (cf. page 9, last paragraph). In other words, the surface material (coating) must not only be thick enough to provide high absorptivity but also thin enough to permit most of the absorbed energy to be conducted to the high conductivity substrate before the next application of the laser beam impinges upon the surface (cf. page 5, line 23 to 27).

This definition of the maximum thickness by reference to the conditions imposed on the heat transfer characteristics of the coating material is to be found again in the same document (1) in exactly the same terms, (cf. page 5, lines 1 to 4 and page 8, lines 7 to 11). For the Board, the claimed equation therefore represents no more than the mathematical expression of the known conditions defining, in a different manner, a suitable and optimum coating thickness. A simple change of definition for characterising a known feature cannot, however, confer novelty on this feature, if by following the instructions in the prior art document the skilled person falls inevitably and necessarily within the scope of the claim.

4.3 In a preferred embodiment, document (1) recommends a maximum thickness of 25 microns for a coating made of anodised aluminium oxide over a substrate of aluminium material (cf. page 5, lines 4 to 10). This thickness falls within the range given in table A of the application. With a CO_2 laser operated intermittently with a one second pulse time and an intercepting instrument having a surface material made of aluminium oxide, table A indicates a range thickness from 2.7 to 250 microns, illustrated by the shaded area of Fig. 9 between the values X (min) and X (max) with a one second pulse time. Since the thickness range defined by the Einstein equation approximation is indefinite as demonstrated in Point 3 above and the user controls the effective pulse time of the laser, any thickness falling within the previous range is obtainable, including the specific thickness recommended in document (1).

Therefore, the specific disclosure made in document (1) takes away the novelty of the generic Claim 1 embracing that disclosure, particularly as the said specific value cannot be regarded in document (1) as individual in view of the broader teaching disclosed there (Point 4.2). Apart from the fact that Claim 1 is unclear, the Board is thus also satisfied that this claim lacks novelty within the meaning of Article 54(1) EPC.

5. Novelty (auxiliary request)

5.1 Claim 1 according to the auxiliary request has substantially the same content as Claim 1 according to the main request, but was worded so as to fall into another category, that is, a claim to the use of elements for the fabrication of a surgical instrument. The Appellant submitted that owing to the application of the instrument to surgery, this claim was acceptable in view of the

reference to the new medical use, analogously to the preparation of a known medicament for a second therapeutic use (cf. G 5/83, OJ EPO 1985, 64).

5.2 The claim in fact represents the assembly of the known instrument already defined in Claim 1 of the main request. The indication of purpose, i.e. intercepting the laser beam, is a characteristic of the surgical use of the instrument and is not affecting the structure or composition of the entity itself. This kind of functional reference cannot normally impart novelty to an otherwise known article, unless the function implies a necessary modification of the article itself. The only exceptions so far recognised are based on Article 54(5) EPC and on a new therapy for a known medicament when the manufacture of the same is also characterised by the new use of the product (i.e. second or further therapeutic indication - G 5/83).

However, a surgical use of an instrument is not analogous to a therapeutic use in the above mentioned cases, since the former is not consumed in the application and could be repeatedly used for the same or even for other purposes as well (cf. application, page 7, lines 24 and 25). Medicaments, on the other hand, are expended in the process of use and have only a once for all utility. Any new use is exactly correlated with a corresponding expansion of the manufacture of the entity for the purpose.

This rendered novelty for the new purpose acceptable in therapeutic cases, since any overlap with existing other uses for other purposes could be excluded and thereby any confusion about the scope of protection could be avoided. The same does not apply to surgical instrumentation in view of the possibility of repeated and even different

uses. The purpose of limitation becomes therefore meaningless in the manufacturing stage. For these reasons it is the view of the Board that the purpose of surgical use alone cannot render a subject-matter of a claim relating to the use of the components of a known instrument for its manufacture, i.e. assembly, novel. In view of the fact that the instrument itself was known together with its components, the claim to its manufacture must also be considered as lacking novelty.

5.3 The surgical aspect being disregarded, Claim 1 according to the auxiliary request is not a use claim in the sense of the use of a product or a particular physical entity to achieve an extraneous effect, this being the normal subject of a use claim (G 2/88, OJ EPO 1990, 93; Point 5.1, second paragraph). In fact, in document (1) as well as in the present application the coating materials are of the same nature and the minimum and maximum thicknesses are defined by similar physical requirements and properties (Point 4.2 above). Under these circumstances, no novel technical effect can be seen in the present case.

5.4 Claim 1 according to the auxiliary request is therefore regarded by the Board as a claim for making a device, i.e. a laser surgical instrument defined by its process of fabrication, i.e. by the use of the component parts (substrate, coating) necessary for producing the device.

As suggested in decision T 150/82, OJ EPO 1984, 309, claims for products defined in terms of a process of manufacture are admissible only if the products as such are new and inventive and cannot be satisfactorily defined by reference to a composition, structure or some other testable parameter (cf. Headnote (II) and points 8 and 10

of T 150/82). The principle is obviously also applicable to a device-by-process claim (Point 7 of the same decision).

Since in the present case the device can be clearly defined by its structure (cf. main request) and moreover is not regarded by the Board as novel in itself, the subject-matter of the claim according to the auxiliary request is not novel as a process of assembly and is thus not patentable.

6. Since neither of the claims according to the main or the auxiliary request is acceptable for lack of novelty, the application is not patentable under Article 52(1) EPC. A further examination by the Board of the requirements for inventive step can thus be dispensed with.

Order

For these reasons, it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

N. Maslin G. Szabo