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**Datasheet for the decision
of 24 September 2013**

Case Number: T 1487/09 - 3.2.02

Application Number: 00303475.8

Publication Number: 1090600

IPC: A61B 18/26

Language of the proceedings: EN

Title of invention:

Electromagnetically induced cutting with atomized fluid particles for dermatological applications

Applicant:

Biolase, Inc.

Headword:

-

Relevant legal provisions:

EPC Art. 53(c), 54, 56, 84, 123(2)

Keyword:

"Method for treatment by surgery - main request"
"Clarity of a disclaimer - auxiliary request I (no) - point 3
of the Reasons"
"Novelty - auxiliary request II (yes)"
"Inventive step - auxiliary request II (yes)"

Decisions cited:

G 0001/03, G 0001/07

Catchword:

-



Case Number: T 1487/09 - 3.2.02

DECISION
of Technical Board of Appeal 3.2.02
of 24 September 2013

Appellant: Biolase, Inc.
(Applicant) 4 Cromwell
Irvine, CA 92618 (US)

Representative: Weber-Bruls, Dorothee
Jones Day
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 24 February 2009
refusing European patent application
No. 00303475.8 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: E. Dufrasne
Members: D. Ceccarelli
C. Körber

Summary of Facts and Submissions

- I. The appellant lodged an appeal against the decision of the Examining Division, dispatched on 24 February 2009, to refuse European patent application No. 00 303 475.8.
- II. The notice of appeal was received on 24 April 2009 and the appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 22 June 2009.
- III. In the statement setting out the grounds of appeal, the appellant requested that the Examining Division's decision be cancelled in its entirety and that a patent be granted on the basis of a main request or, in the alternative, of an auxiliary request.

The appellant also requested oral proceedings if the Board did not intend to allow the application on the basis of the main or the auxiliary request.

- IV. The Board summoned the appellant to oral proceedings and provided its provisional opinion.

In particular, the Board raised objections under Article 53(c) and 84 EPC to the independent method claims of both requests.

- V. With letter of 26 August 2013 the appellant filed a new main request and auxiliary requests I to V for consideration during the oral proceedings.
- VI. Oral proceedings took place on 24 September 2013. During the oral proceedings, the appellant presented

claims 1-19 and an adapted description according to new auxiliary request II.

The appellant's final request was that the decision under appeal be set aside and that a patent be granted on the basis of the main request, filed with letter dated 26 August 2013 or, in the alternative, of one of auxiliary request I, filed with letter dated 26 August 2013, auxiliary request II, filed during the oral proceedings, and auxiliary requests III to V, filed with letter dated 26 August 2013.

VII. The following document is of importance for the present decision:

D1: WO-A-97/07928.

VIII. Claim 29 of the main request reads as follows:

"A method of imparting disruptive forces onto a target surface (57), comprising:

using a moisture output to dynamically place a first layer of moisture in form of fluid particles and/or mist above a plurality of points of the target surface so that different parts of the first layer of moisture are simultaneously disposed over different ones of the plurality of points; and

automatically scanning electromagnetic energy via a scanner relative to the moisture output being attached to a scanning housing of the scanner, the electromagnetic energy being scanned by a motor assembly for scanning an optical fiber of an electromagnetic energy output or by reflectors and focusing optics or dynamically controlled deflectors

for scanning collimated or non collimated electromagnetic energy above a plurality of points of the target surface; whereby at least portions of the electromagnetic energy above the plurality of points are at least partly absorbed by the moisture above the plurality of points."

IX. Claim 29 of auxiliary request I reads as follows:

"A method of imparting disruptive forces onto a target surface (57), with the exception of such uses that comprise or encompass an invasive step representing a substantial physical intervention on the body of a human or an animal which requires professional medical expertise to be carried out and which entail a substantial health risk even when carried out with the required professional care and expertise, comprising:

using a moisture output to dynamically place a first layer of moisture in form of fluid particles and/or mist above a plurality of points of the target surface so that different parts of the first layer of moisture are simultaneously disposed over different ones of the plurality of points; and

automatically scanning electromagnetic energy via a scanner relative to the moisture output being attached to a scanning housing of the scanner and formed as a mist disk, the electromagnetic energy being scanned by a motor assembly for scanning an optical fiber of an electromagnetic energy output or by reflectors and focusing optics or dynamically controlled deflectors for scanning collimated or non collimated electromagnetic energy above a plurality of points of the target surface; whereby at least portions

of the electromagnetic energy above the plurality of points are at least partly absorbed by the moisture above the plurality of points."

X. Claim 1 of auxiliary request II reads as follows:

"An apparatus for imparting disruptive forces onto a target surface (57), comprising:

a first output constructed to place fluid above a target surface; and

a second output constructed to scan electromagnetic energy above the target surface;

wherein the first output comprises a moisture output (71) constructed to place a layer of moisture in form of fluid particles and/or mist above a plurality of points of the target surface so that different parts of the layer of moisture are simultaneously disposed over different ones of the plurality of points; and the second output comprises a scanner (51, 53, 55) constructed to scan electromagnetic energy, whereby electromagnetic energy is scanned over the different parts of the layer of moisture, the electromagnetic energy from the scanner being absorbed above the plurality of points by the different parts of the layer of moisture, the absorption of the electromagnetic energy by the layer of moisture causing the layer of moisture to expand by explosive vaporization wherein disruptive forces are imparted onto the target surface, characterized in that

the scanner (51, 53, 55) has a scanning housing and

(i) comprises a motor assembly for scanning an optical fiber of the second output or

(ii) comprises a motor for controlling a reflector assembly and a focusing assembly or dynamically controlled deflectors for scanning collimated or non collimated electromagnetic energy, wherein the moisture output is attached to the scanning housing and the scanner is constructed to scan automatically the electromagnetic energy within the scanning housing relative to the moisture output."

The other claims of auxiliary request II are dependent claims.

XI. The appellant's arguments are summarised as follows:

Main request

Claim 29 did not include any feature that constituted a method step for treatment of a human body by surgery. According to decision G 1/07 it would therefore not fall under the exception of Article 53(c) EPC.

Auxiliary request I

In claim 29 a disclaimer which excluded uses that comprised surgical or therapeutic method steps had been added. According to decision G 1/03, the incorporation of a disclaimer was generally allowable if it was used to exclude subject-matter that was not patentable pursuant to Article 53 EPC. The added disclaimer excluded only the method uses that represented surgical steps according to decision G 1/07.

Since the exact wording used in decision G 1/07 had been added, the claim could not be unclear.

Furthermore, it was clear from the originally filed application that the claimed method was not intended to encompass uses on "problematic" soft tissues of a human or animal body, which would fall under the exception of Article 53(c) EPC.

Auxiliary request II

As also found by the Examining Division in the impugned decision, document D1 should be considered as the closest prior art. The subject-matter of claim 1 differed from the disclosure of document D1 in particular in that the claimed apparatus was configured to move the electromagnetic energy relative to the moisture output using a motor.

The layer of moisture provided by the moisture output constituted a blanket of fluid particles which was maintained over the target surface while the laser beam was scanned over it. Accordingly, owing to the movement of the laser beam relative to the position of the blanket of moisture, the scanner would scan electromagnetic energy independently of the moisture output. This independence meant that placement of water and energy in relation to the target was highly co-ordinated and precise, spatially and temporally, for absorption of the energy in such a way as to generate a controlled and reproducible laser-powered water cutting. The subject-matter of the claims was therefore inventive over document D1.

Reasons for the Decision

1. The appeal is admissible.
2. Main request
 - 2.1 Independent claim 29 seeks protection for a method for imparting disruptive forces onto a target surface.

Although the claim does not explicitly mention the nature of the target surface, the disclosure of the patent application as a whole makes clear that said target surface may include hard and soft tissues which are part of the human or animal body. As some examples of such tissues, inner vital organs of the body such as the heart, the liver, the kidney and the brain are given (paragraph [0005] of the application as published).

It follows that the method according to claim 29 encompasses embodiments in which disruptive forces are imparted on such vital organs. Therefore, these embodiments are associated with an invasive step involving a substantial physical intervention on the body which requires professional medical expertise to be carried out and which entails a substantial health risk even when carried out with the required professional care and expertise. Moreover, paragraphs [0057], [0061] and [0063] for example, explicitly refer to preferred embodiments which involve the delivery of medication to a patient.

For these reasons, in accordance with decision G 1/07 (Order, points 1 and 2a, and Reasons, point 4.1), the

Board considers that such embodiments are excluded from patentability as methods for treatment of the human or animal body by surgery and therapy pursuant to Article 53(c) EPC. A claim which comprises a step encompassing such embodiments cannot be left to encompass them.

- 2.2 As regards the appellant's argument that claim 29 does not include any feature that constitutes a method step for treatment of a human body by surgery, the Board notes that it is not decisive whether such features are explicitly defined in the claim, as long as the subject-matter of the claim encompasses embodiments which constitute such method steps.

In order to establish whether said embodiments are encompassed in the claimed method, not only the wording of the claim is of importance. Rather, the description and the figures are also to be considered. As a matter of fact, the usual practice is that particular embodiments of a claimed invention are only disclosed in detail in the description and drawings.

- 2.3 Hence, the main request cannot be allowed as it does not comply with Article 53(c) EPC.

3. *Auxiliary request I*

- 3.1 Compared to claim 29 of the main request, claim 29 of auxiliary request I comprises a disclaimer aiming at excluding uses that "comprise or encompass an invasive step representing a substantial physical intervention on the body of a human or an animal which requires professional medical expertise to be carried out and

which entail a substantial health risk even when carried out with the required professional care and expertise."

- 3.2 However, the uses excluded are not explicitly defined, but rather must be derived from a condition which is to be fulfilled. Whether this condition is fulfilled or not would have to be established by the reader of the claim.

In particular, it would be left to the reader's own evaluation to establish whether a particular use potentially falling within the scope of the claim was thus excluded.

This evaluation contains several subjective aspects, such as establishing whether the physical intervention and the health risk are to be considered "substantial".

Leaving room for such an assessment by the reader inevitably introduces uncertainty as to the matter for which protection is sought. Hence a lack of clarity arises, which is in breach of Article 84 EPC.

Moreover, it is not clear how suitable the wording of the disclaimer is for excluding the embodiments relating to therapy as described in paragraphs [0057], [0061] and [0063].

- 3.3 The Board can follow the appellant's arguments regarding the introduction of a disclaimer in view of decision G 1/03. In particular, it is accepted that in the present case introducing a disclaimer for excluding subject-matter which would not be patentable under

Article 53(c) EPC may not contravene Article 123(2) EPC. However, as also affirmed in said decision G 1/03 (point 3 of the Reasons) and in decision G 1/07 (point 2b of the Order), all the requirements of the EPC have to be considered when examining said disclaimer, in particular those of Article 84 EPC.

The fact that the wording chosen for the disclaimer is the same as the one used in decision G 1/07 for describing a surgical method does not mean that the claim fulfils the clarity requirements of Article 84 EPC.

In decision G 1/07 said wording is used in the general context of the explanation that if a method in which maintaining the life and health of a subject is important and which comprises or encompasses an invasive step representing a substantial physical intervention on the body which requires professional medical expertise to be carried out and which entails a substantial health risk even when carried out with the required professional care and expertise, then said method is of surgical character for the purposes of Article 53(c) EPC. Consequently, an acceptable disclaimer would have to exclude all methods fulfilling this condition. However, why this is the case for a specific method should objectively be clear from the wording of the disclaimer. In the present case, simply introducing the condition in the disclaimer does not enable the reader to objectively assess whether said condition is fulfilled or not. As a matter of fact, the difficulty often involved in this assessment is also explicitly mentioned in decision G 1/07 itself: under point 3.4.2.6 of the Reasons it is stated that "in many

situations it will not be an easy task to determine whether or not an invasive step constituting a substantial physical intervention on the body comprised or encompassed by a claim requires professional medical skills to be carried out and involves a substantial health risk even when carried out with the required care and expertise [and ...] such a criterion could be expected to be handled on a case-by-case basis [...]."

A similar situation may occur when a disclaimer aiming at establishing novelty over subject-matter of a conflicting application under Article 54(3) EPC is to be introduced. If the disclaimer merely comprised general wording mentioning the conflicting application (e.g. "except what is already known from European application No. [...]"), without explicitly and precisely excluding the features anticipated by the conflicting application, then a lack of clarity could also arise.

As regards the reference to the filed application allegedly making clear that the claimed method was not intended to encompass uses on "problematic" soft tissues of a human or animal body, the Board is firstly of the opinion that, in general, the claims should be clear in themselves. Moreover, no clear distinction between "problematic" or non-problematic tissues can be found in the filed application. As a result, not even the content of the application as a whole gives assistance in interpreting the disclaimer.

- 3.4 Hence, auxiliary request I cannot be allowed as it does not comply with Article 84 EPC.

4. *Auxiliary request II*

4.1 The invention as defined in claim 1 of auxiliary request II concerns an apparatus for imparting disruptive forces onto a target surface by explosive vaporisation of fluid particles and/or mist placed above the target surface, said explosive vaporisation being caused by the absorption of electromagnetic energy.

4.2 *Basis in the original application (Article 123(2) EPC)*

The subject-matter of claim 1 is based on claims 1, 13 and 14, column 10, lines 8-10, column 13, lines 30-31, column 14, lines 19-30, column 15, line 36, column 18, lines 35-38, and figures 1a, 2a, 3a, 4aa, and 5a of the original application as published. The Board is satisfied that the requirements of Article 123(2) EPC are fulfilled.

4.3 *Exceptions to patentability (Article 53(c) EPC)*

Since auxiliary request II no longer comprises method claims and since the amended description no longer refers to embodiments excluded from patentability, this request is free from objections under Article 53(c) EPC.

4.4 *Novelty (Article 54(1) and (2) EPC)*

Document D1 describes an apparatus providing electromagnetically induced cutting. An atomiser is adapted to place atomised fluid particles into a volume of air adjacent to a target surface. An electromagnetic

energy source is adapted to focus electromagnetic energy in the form of a laser beam into said volume of air. The wavelength of the laser is such that the energy, in use, is substantially absorbed by the atomised fluid particles, the latter thereby exploding and applying cutting forces to the target surface.

Document D1 discloses in particular an apparatus for imparting disruptive forces onto a target surface with a first output comprising a moisture output (nozzle 71, figures 5 and 13) and a second output comprising a scanner constructed to scan electromagnetic energy above the target surface (fiberoptic guide 23, figure 5 and page 35, lines 7-11). The moisture output can place a layer of moisture in the form of fluid particles above a plurality of points of the target surface, the electromagnetic energy provided by the scanner being absorbed above the plurality of points and causing the layer of moisture to expand by explosive vaporisation and to impart disruptive forces onto the target surface (figure 13 and page 38, lines 15-27).

The subject-matter of claim 1, in particular both alternatives as defined in the characterising portion, differs from the disclosure of document D1 in that the scanner comprises a motor and is constructed to scan automatically the electromagnetic energy within the scanning housing relative to the moisture output.

With respect thereto, the Board does not share the Examining Division's view, as expressed in the impugned decision, that the device of document D1 anticipates a scan of the electromagnetic energy relative to the moisture output.

According to the established case law of the boards of appeal, for the assessment of novelty a strict approach is to be followed. In particular, a claimed feature lacks novelty only when it is beyond doubt - not merely probable - that said feature is directly and unambiguously disclosed in a prior-art document.

While it is accepted that document D1 generally discloses a focussed cutting beam which can be scanned across portions of the target surface (page 35, lines 7-11), no detailed disclosure of the structural elements involved in the performance of the scanning action is given. It is therefore at least plausible that, according to D1, the electromagnetic energy is scanned together with the moisture output. Since there is no disclosure to the contrary, the claimed feature of scanning electromagnetic energy relative to the moisture output is not directly and unambiguously derivable from document D1.

Hence, the subject-matter of claim 1 of auxiliary request II is novel in accordance with Article 54(1) and (2) EPC.

4.5 *Inventive step (Article 56 EPC)*

Undisputedly, document D1 represents the closest prior art.

The mentioned differentiating features of the subject-matter of claim 1 over the disclosure of document D1 allow a more controllable and precise distribution of

fluid particles and/or mist above the target surface to be achieved.

The objective technical problem to be solved is therefore how to increase the precision with which the disruptive forces are imparted above selected points of the target surface.

On page 34, line 31 to page 35, line 11 document D1 discloses the use of precision equipment for implementing shallow surface layer removal patterns on a silicon wafer. To that end, it proposes a rapid scanning of a focussed cutting beam or the use of a non-scanned larger defocussed cutting beam or a number of beams (page 35, lines 7-11). However, it neither discloses how to solve the objective technical problem, nor hints at the solution proposed by the present invention. The Board therefore sees no reason why the skilled person would implement the claimed differentiating features in the device of document D1.

Hence, the subject-matter of claim 1 of auxiliary request II is inventive in accordance with Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to grant a patent on the basis of:
 - claims 1 to 19 of auxiliary request II filed during oral proceedings;

 - adapted description, columns 1 to 20, filed during oral proceedings; and

 - figures 1 to 8, 1a to 11a, 4b, 6b to 8b and 4aa of the published application.

The Registrar:

The Chairman:

D. Hampe

E. Dufrasne