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**Datasheet for the decision  
of 17 January 2023**

**Case Number:** T 0261/18 - 3.2.02

**Application Number:** 04812972.0

**Publication Number:** 1701651

**IPC:** A61B3/14

**Language of the proceedings:** EN

**Title of invention:**

PATTERNED LASER TREATMENT OF THE RETINA

**Patent Proprietor:**

The Board of Trustees of the Leland Stanford  
Junior University

**Opponents:**

Valon Lasers Oy  
Carl Zeiss Meditec AG

**Headword:**

**Relevant legal provisions:**

EPC Art. 54, 56, 112(1)(a), 123(2)

**Keyword:**

Novelty - (yes)

Inventive step - (yes)

Referral to the Enlarged Board of Appeal - (no)

Amendments - added subject-matter (no)

Interpretation of prior art documents - norms and standards

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**  
**Boards of Appeal**  
**Chambres de recours**

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Case Number: T 0261/18 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 17 January 2023**

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**Decision under appeal:**      **Decision of the Opposition Division of the  
European Patent Office posted on 29 November  
2017 rejecting the opposition filed against  
European patent No. 1701651 pursuant to Article  
101(2) EPC.**

**Composition of the Board:**

**Chairman**                    M. Alvazzi Delfrate  
**Members:**                    S. Böttcher  
                                      N. Obrovski

## Summary of Facts and Submissions

- I. Opponent 2 filed an appeal against the opposition division's decision to reject the opposition lodged by opponents 1 and 2 against the patent No. 1 701 651.
- II. Oral proceedings took place on 17 January 2023 in the absence of opponent 1, who had been duly summoned to attend the oral proceedings.
- III. The appellant requested that the decision under appeal be set aside and the patent be revoked.
- IV. The respondent requested that the appeal be dismissed and that the patent be maintained as granted or, alternatively, on the basis of one of auxiliary requests 1 to 10, all filed with the reply to the statement of grounds of appeal.
- V. The following documents are relevant to this decision.
  - D1 WO 01/37769
  - D4 WO 97/17011
  - D5 Feuerstein, M. et al., "Preselectable Intensity Distribution in Large-Area Laser Coagulation by Electronically Controlled Beam Deflection", SPIE, Optical Instrumentation for Biomedical Applications, Vol. 658, 1986
  - D6 EP 0 236 377 B1
  - D7 Dowler, Jonathan, "Laser management of diabetic retinopathy", Journal of the Royal Society of Medicine, Vol. 96, June 2003
  - D8 DIN EN 60601-2-22, December 1996
  - D9 US 2003/179344 A1
  - D10 JP 2001 149403 A

- D10a English translation of D10
- D12 EP 0 391 376 B1
- D15 Davies, Nigel, "Alternating the pattern of panretinal photocoagulation: could the visual field for driving be preserved?" Eye, Royal College of Ophthalmologists, Vol. 13, August 1999, pages 531 to 536
- D16 US 4,901,718
- D17 US 2002/173778 A1
- D18 L'Esperance Jr., Francis A., "Ophthalmic Lasers", The C. V. Mosby Company, 1989
- D20 US 4,887,019

VI. Claim 1 of the patent as granted (main request) reads as follows.

"1. A system for laser treatment of the retina of an eye of a patient, the system comprising:

an alignment source (411) producing an alignment beam, and  
a laser source (413) producing a laser beam for providing doses of laser energy to at least two treatment locations on said retina and responsive to an operator action,  
a scanner for moving the laser beam from one of said treatment locations to another of said treatment locations, for providing all of said doses of laser energy to said treatment locations substantially sequentially, and in less than about 1 second, characterised in that the alignment beam provides a visible alignment pattern comprising a plurality of separated spots projected onto said retina, wherein said treatment locations are spaced apart and are coincident with said separated spots and wherein said scanner moves the alignment beam from one of said

separated spots to another of said separated spots."

VII. The appellant's arguments relevant to the decision can be summarised as follows.

*Added subject-matter*

Claim 1 covered an embodiment in which the alignment beam had the form of a multiple beam that provided the alignment pattern, comprising e.g. three spots. Figure 9 of the patent showed a multiple beam. According to the last feature of claim 1, this pattern would be moved from one of the separated spots to another. No such embodiment was disclosed in the original application documents, in which the alignment beam was in fact a single beam and the pattern was provided by the scanner moving this single beam.

*Interpretation of the term "separated" used in claim 1*

"Separated spots" were spots that were optically distinguishable but did not necessarily have to have a space between them.

*Novelty in view of D9*

D9 disclosed all the features of claim 1 of the main request (Figures 1 and 2a). In particular, Figure 9A showed a visible alignment pattern comprising a plurality of spots. Although the spots were abutting, they had to be considered separated. As mentioned in paragraphs [0026] and [0111], the pattern of Figure 9A was variable. With the zoom optics 60 mentioned in paragraph [0122], it was possible to provide spaced-apart alignment spots as described in paragraph [0111] (page 6, left-hand column, lines 51 to 53).

It was implicitly disclosed that this pattern was projected onto the retina since an acousto-optical deflector 62 as described in paragraph [0111] for the therapeutic laser was also arranged in the optical path of the aiming laser 54 (Figure 1). Paragraph [0118] (first sentence) stated that both the therapeutic laser and the aiming laser were deflected by the same scanner.

Furthermore, the aiming laser 54 had the same spot size as the therapeutic laser since it was transmitted through the same optics. This could also be derived from Figures 3a and 3b and from paragraphs [0125] (page 8, left-hand column, lines 8 to 12) and [0009] (page 1, right-hand column, lines 6 to 11).

*Novelty in view of D10*

D10 disclosed (Figures 2 and 5) a treatment system comprising a therapeutic laser beam and an aiming laser beam. Both beams were deflected by the same scanner onto the retina (Figure 2 showing the treatment laser 10, aiming laser 19 and scanner comprised of mirrors 37, 38 with drives 37a, 38a; paragraphs [0016] to [0019] of D10a).

The fact that D10 aimed at treating a uniform coagulation spot (paragraph [0039]) did not mean that D10 did not disclose separated spots. Moreover, the spot diameter could be changed by means of the aperture 23 and the zoom lens 25 (paragraphs [0018] and [0019]). Hence, instead of the contour shown in Figure 5a, the system of D10 could provide a pattern with distinguishable spots.



Therefore, the subject-matter of claim 1 lacked novelty over D10.

*Common general knowledge as exemplified in D8 or D18*

D8 was a standard for medical devices and implicitly disclosed (or at least rendered it obvious) that for every treatment location there had to be a corresponding spot of the aiming beam (section 59.101).

D18 taught that to treat diabetic retinopathy a grid pattern of coagulation spots had to be provided on the retina (Figure 12-60). It was described that these spots were treated by a single laser shot.

*Inventive step starting from D5 or D6*

D5 and D6 disclosed coagulation of a pattern of separated treatment locations (D5: Figures 5a and 6a; D6: column 5, lines 24 to 31 and 54 to 58). The therapeutic beam was deflected by a scanner in combination with a fast shutter (D6: column 5, lines 25 to 31). Both documents mentioned a target beam that was coincident with the therapeutic beam (D5: page 87, first paragraph; D6: column 5, lines 32 to 42). However, D5 did not disclose that the alignment beam was guided through the fast shutter. Hence, D5 did not disclose an alignment pattern coincident with the treatment pattern that was projected by the aiming beam.

The standard D8 for medical laser equipment (point 59.101) required the treatment location of the therapeutic laser to be visibly indicated. The person skilled in the art would seek to provide an apparatus that conformed to this standard. Hence, it was obvious

for the person skilled in the art to couple an aiming beam into the optical path of the therapeutic laser of D5 and to project an alignment pattern of separated spots that were coincident with the treatment locations. The chopper would be arranged such that both the treatment beam and the aiming beam would be guided through it.

D6 disclosed that the target beam had to be flush with the treatment beam. Hence, the person skilled in the art would arrange the fast shutter in D5 such that the target beam could project the alignment pattern.

Conversely, the teaching of D5 would motivate the person skilled in the art to modify the apparatus of D6 such as to arrive at the subject-matter of claim 1.

Moreover, the teaching of D7 would prompt the person skilled in the art to adjust the pattern of D5 to the grid structure of Figure 2.

*Inventive step starting from D10*

The apparatus of D10 allowed the treatment pattern to be adjusted. Hence, instead of coagulating a complete area it was possible to coagulate a grid of separate treatment locations as shown in D7 (Figure 2) or mentioned in D6 (column 5, lines 25 to 31). When attempting to comply with the standard of D8, the person skilled in the art would project a visible alignment pattern coincident with the treatment pattern on the retina.

Thus, combining the teaching of D10 with the common general knowledge (exemplified by D18 and D8) or with the teaching of D7 or D6 rendered the subject-matter of

claim 1 obvious.

*Inventive step starting from D7*

D7 related to the treatment of diabetic retinopathy by manually applying individual laser beam spots. The treatment locations were arranged in a pattern defining a grid structure (Figure 2).

Starting from this document, the objective technical problem to be solved was to perform this treatment more quickly and accurately. To solve this problem, the person skilled in the art would envisage an automated scanning of the grid structure.

D10 or D9 disclosed the automated scanning of a treatment pattern. It would be obvious for the person skilled in the art to adjust the scanners of D10 or D9 to provide the grid structure of Figure 2 of D7.

Hence, combining the teaching of D7 with that of D10 or D9 would result in the subject-matter of claim 1.

The device of D6 was configured to provide the grid structure of Figure 2 of D7. It would be obvious for the person skilled in the art seeking to comply with the standard of D8 to guide the target beam such that it was coincident with the treatment beam. This would result in the subject-matter of claim 1.

*Inventive step starting from D1*

D1 related to a laser treatment device in which a treatment laser was superposed with an aiming laser. A pattern of treatment locations on the retina was provided by dividing the beams into plural sub-beams

using a diffraction grating 36 (page 6, first paragraph, Figure 1).

Starting from this teaching, the objective technical problem would be to reduce the power required for the treatment laser. D9 taught that with a scanning approach the whole energy of the laser beam was available for every single spot. Hence, the teaching of D9 prompted the person skilled in the art to replace the diffraction grating of the device in D1 with a scanner and to control the scanner to provide the pattern of spots.

Thus, the subject-matter of claim 1 was rendered obvious by the combination of D1 with D9.

*Inventive step starting from D15*

D15 related to panretinal photocoagulation patterns and disclosed that in usual patterns the burns were spaced apart. However, D15 was silent about any technical implementation of this treatment. Both the devices of D10 and D9 were adapted to coagulate a grid structure of separated treatment locations. It was obvious for the person skilled in the art to adjust the devices accordingly.

Thus, the subject-matter of claim 1 was rendered obvious by the combination of D15 with D10 or D9.

*Referral of a question to the Enlarged Board of Appeal*

The appellant requested that questions be referred to the Enlarged Board of Appeal about whether a prior art document concerning a medical device for the therapeutic treatment of the human body had to be

interpreted such that it complied with standards for protecting patients which had been published subsequently. The appellant provided these questions orally as well as in writing in German, and the respondent received a translation of the written version by the interpreters during the oral proceedings. The German version of the questions reads as follows:

"Ist bei der Auslegung eines Dokumentes, das ein medizinisches Gerät betrifft, welches am Menschen therapeutisch eingesetzt werden soll, für den Fachmann eine Einhaltung von Normen, die dem Schutz von Patienten dienen, zwingend zu berücksichtigen?"

Falls die Frage davon abhängt, in welcher zeitlichen Reihenfolge das Dokument und die Norm publiziert sind, ist die Auslegung zwingend für den Fall, dass die Norm nach dem Dokument publiziert wurde?"

The appellant argued that compliance with standards was essential for medical devices since such devices had to be approved by authorities. The question to be referred had not yet been the subject of any G-decision. Hence, the referral was justified.

VIII. The respondent's arguments relevant to the decision can be summarised as follows.

*Added subject-matter*

Due to the use of the singular, the expression "the alignment beam" in claim 1 could not be regarded as encompassing multiple beams. This was also in line with the wording "said scanner moves the alignment beam from one of said separated spots to another of said

separated spots". Multi-beam implementations were not covered by the invention, as mentioned in paragraph [0034] of the description with regard to the embodiment of Figure 9.

Furthermore, the appellant's interpretation that the alignment beam provided the alignment pattern in the form of a multi-beam having three spots was incompatible with the requirement that the scanner moved the alignment beam from one of the spots to another. Therefore, this interpretation should be ruled out as it did not make technical sense.

Rather, it was clear from the claim that the alignment beam was a single beam that produced the pattern by means of the scanner moving the beam from one spot to another. Hence, the combination of the alignment beam and the scanner provided the pattern.

Consequently, claim 1 did not include added subject-matter.

*Interpretation of the term "separated" used in claim 1*

All the embodiments of the patent disclosed separated spots, i.e. spots which were physically disconnected or spaced apart. Furthermore, it was clear to the person skilled in the art that all the spots had to be separated. Since the spaced-apart treatment locations had to be coincident with the aiming spots, the aiming spots had to be separated.

*Novelty in view of D9*

D9 was concerned with applying an array of adjacent and overlapping treatment spots to a single location or

spot on the retina so that these adjacent or overlapping spots effectively completely covered this single treatment location. D9 did not disclose separated spots in which a scanner moved an alignment beam from one of the separated spots to another of the separated spots, as required by claim 1.

Figure 9a showed the treatment beam 52, not an aiming beam. The component 62 in the aiming beam path was for pulsing purposes. D9 did not disclose that one and the same scanner was used to deflect the treatment beam and the aiming beam.

*Novelty in view of D10*

D10 failed to disclose a visible alignment pattern comprising a plurality of separated spots. In addition, the apparatus of D10 did not project an alignment spot for each treatment location onto the retina, but only the contour shown in Figure 5a.

Hence, the subject-matter of claim 1 does not lack novelty in view of D10.

*Common general knowledge as exemplified in D8 or D18*

The standard referred to in D8 did not imply that there had to be an alignment spot for every treatment spot.

D18 disclosed manual spot-by-spot placement of coagulation spots. The grid shown in Figure 12-60 was not a template.

*Inventive step starting from D5 or D6*

D5 and D6 did not disclose a scanner for projecting a

visible alignment pattern comprising a plurality of separated spots onto the retina. Figure 6a was merely showing the treatment locations, not a visual alignment pattern.

The aiming requirement referred to in the standard D8 could be realised by an aiming laser generally targeting the treatment area.

Since D7 did not disclose a visual alignment pattern either, the combination of D5 with D7 would not lead to the subject-matter of claim 1. The same applied to the combination of D5 with D6 and vice versa.

*Inventive step starting from D10*

D10 was concerned with uniform confluent coagulation and provided for the scanning of the contour of a laser irradiation region by an aiming beam.

Neither the common general knowledge nor the teaching of D7 would motivate the person skilled in the art to adapt the system of D10 to arrive at a system according to claim 1.

D6 did not disclose or suggest using the target light beam for providing an alignment pattern.

*Inventive step starting from D7*

D7 disclosed individual treatment spots which were manually applied by a physician. There was no template or other arrangement for the spots.

D10 and D9 did not address the problem solved by the subject-matter of claim 1. The person skilled in the



art would have no motivation to combine these documents in order to provide a visual alignment pattern comprising a plurality of separated spots projected onto the retina.

D6 taught providing an outline of an area to be irradiated which was projected by a target light beam onto the retina. This outline area was then filled with the scan of the working beam. The treatment locations were neither spaced apart nor coincident with separated alignment spots.

Hence, combining D7 with any of D10, D9 and D6 did not result in the subject-matter of claim 1.

*Inventive step starting from D1*

D1 related to the multi treatment beam which had already been discussed in the patent. D9 was concerned with microphotocoagulation.

There were a considerable number of steps required in order to modify D1 to incorporate features of D9 and end up with the combination of features of claim 1.

*Inventive step starting from D15*

D15 taught that a spacing was required between the treatment locations. Since neither D10 nor D9 disclosed separated treatment locations - and even less so a visual alignment pattern comprising separated spots - the person skilled in the art would not envisage combining D15 with D10 or D9.

*Referral of a question to the Enlarged Board of Appeal*

The referral of the question to the Enlarged Board of Appeal was neither justified nor necessary. It did not concern a point of law of fundamental importance but rather an assessment which depended on the factual circumstances of each individual case, in particular with regard to whether a certain standard had to be complied with and, if so, which one that would be. A lack of case law by the Enlarged Board of Appeal on a certain issue was not a sufficient reason for a referral. Moreover, the question to be referred was not decisive for the case in hand.

## **Reasons for the Decision**

1. The patent

1.1 The patent relates to laser treatment of the retina, i.e. for the treatment of proliferative diabetic retinopathy, a diabetes complication that is caused by damage to the blood vessels of the light-sensitive tissue at the back of the eye. Panretinal photocoagulation (PRP) is the current standard of care for proliferative diabetic retinopathy. During the procedure, the areas of the retina away from the macula are treated with scattered laser burns.

Retinal photocoagulation is typically performed point-by-point, where each individual dose is positioned and delivered by the laser. The system of the patent uses a scanner to move the laser beam from one treatment location to another.

1.2 The system according to claim 1, as shown in Figure 4, comprises:

- an alignment source 411 producing an alignment beam

- a laser source 413 producing a laser beam for providing doses of laser energy to at least two treatment locations on said retina and responsive to an operator action
- a scanner for moving the laser beam from one of said treatment locations to another of said treatment locations.

All of said doses of laser energy are provided substantially sequentially to said treatment locations, and in less than about 1 second.

The alignment beam provides a visible alignment pattern comprising a plurality of separated spots projected onto said retina.

The treatment locations are spaced apart and are coincident with said separated spots of the alignment beam, and the scanner moves the alignment beam from one of said separated spots to another of said separated spots.

1.3 Since the non-visible beam of the treatment laser is aligned with the visible alignment beam, the treatment locations can be determined on the retina. By delivering all the doses of laser energy in less than 1 second, the requirement for retinal tracking is eliminated.

2. Added subject-matter

2.1 According to the claims as originally filed, the system comprised an alignment subsystem providing a visible alignment pattern comprising a plurality of separate spots projected onto said retina (claim 1), and the alignment subsystem comprised an alignment source (claim 2) and a scanner (claim 21).

Claim 1 as granted recites that the alignment beam itself "provides" an alignment pattern. In the opponent's view, this amendment infringed Article 123(2) EPC as the subject-matter of claim 1 as granted encompassed an alignment beam that was divided into multiple sub-beams, and the separated spots of the alignment pattern were projected by this multiple beam, while the scanner was not involved at all.

2.2 The Board considers that, taken in isolation, the feature "the alignment beam provides a visible alignment pattern comprising a plurality of separated spots" could be implemented by a single beam or a multiple beam. However, the feature "said scanner moves the alignment beam from one of said separated spots to another of said separated spots" cannot be carried out by a multiple beam. The appellant's interpretation according to which the pattern is created by a triplet beam that was moved by the scanner is illogical and does not make technical sense. If the separated spots are only created by the triplet beam, the (triplet) beam cannot be moved from "one spot" of the pattern to "another spot" of the pattern. Hence, such an embodiment does not fall under the subject-matter of the claim.

Contrary to the appellant's view, its interpretation is not supported by Figure 9 either. It is true that this figure shows a multi-beam laser. During examination, however, the passage referring to said drawing (paragraph [0034]) was amended to bring the description in line with the amended claims and now clearly indicates that the arrangement shown in Figure 9 is "not part of the invention".

2.3 Therefore, claim 1 does not include added subject-matter.

3. Interpretation of the term "separated" used in claim 1

The term "separated spots", in its normal meaning as understood by the person skilled in the art, means that the spots are physically disconnected or spaced apart. This is also in accordance with what is shown in the embodiments (Figures 6a to 6h). Hence, contrary to the appellant's view, a pattern with abutting or overlapping spots cannot be regarded as a "pattern comprising a plurality of separated spots".

4. Novelty in view of D9

4.1 D9 discloses a laser system for microphotocoagulation of the retina. It is undisputed that the system comprises the features of the preamble of claim 1 as granted (Figure 1 showing two laser sources 52, 54 and an acousto-optic modulator 62; paragraph [0111] mentioning an acousto-optic deflector as an alternative to the acousto-optic modulator 62). It is mentioned in paragraphs [0114] and [0116] that one of the laser sources (the laser source 54) can have a wavelength in the visible range (630-670 nm) for aiming purposes. Figure 9a shows a two-dimensional pattern of spots. This grid of 10 by 10 spots, or an alternative pattern, is scanned by the therapeutic beam, which is deflected by the acousto-optic deflector according to one embodiment of the device of D9 (paragraphs [0026] and [0111], Figure 1).

4.2 However, D9 does not disclose that the scanner for moving the beam of the therapeutic laser 52, i.e. the acousto-optic deflector arranged in the optical path of

the laser 52, also moves the alignment beam, i.e. the beam of the aiming laser 54, from one of the spots to another. Figure 9a, showing the movement of the beam 52 to the different treatment locations via the element 62, does not show the aiming beam 54. Figure 1 does not disclose the formation of the alignment pattern. Although it can be derived from paragraph [0118] (first sentence) that a two-dimensional acousto-optic modulator can act on both beams 52 and 54, this passage does not refer to the embodiment with the alignment pattern.

4.3 Furthermore, it is not disclosed that the grid shown in Figure 9a is actually projected as a visible alignment pattern by the aiming laser onto the retina. In paragraph [0111] it is mentioned that this grid and several other patterns can be programmed. Hence, the Board considers Figure 9a to be a mere schematic illustration of the pattern (non-filled circles) scanned by the therapeutic beam 52 (black circles).

4.4 Moreover, Figure 9a shows a pattern of touching spots with no spacing between them. Hence, D9 does not disclose a pattern of separated spots. Since D9 is directed to evenly covering a single treatment location with microspots, applying separated spots would not make sense.

4.5 Consequently, the subject-matter of claim 1 does not lack novelty in view of D9.

5. Novelty in view of D10/D10a

5.1 It is also undisputed that D10 discloses a laser treatment system having the features of the preamble of claim 1 (Figure 2 showing the treatment laser 10,

aiming laser 19 and scanner comprised of mirrors 37, 38 with drives 37a, 38a; paragraphs [0016] to [0019] of D10a).

Figure 5a shows the contour of the irradiation region scanned by the aiming beam (paragraph [0027]). This contour is actually projected onto the retina. Figure 5b shows the scanning pattern of the treatment laser. By irradiating the small spots one after the other, the entire irradiation region becomes coagulated (paragraph [0028]).

5.2 However, the abutting hexagonal spots forming the contour in Figure 5a cannot be regarded as separated spots of a visible alignment pattern. D10 only mentions the contour which is projected. Furthermore, it is clear that to fulfil the purpose of the system of D10, namely treating a uniform coagulation spot (paragraph [0039] of D10a), it is not necessary to project individual spots of the contour onto the retina. Hence, it is irrelevant whether it is possible to change the spot size of the laser beam since D10 does not provide a disclosure of an alignment pattern comprising a plurality of separated spots or indicate that the system would be suitable to provide said separated spots.

5.3 Consequently, the subject-matter of claim 1 does not lack novelty in view of D10.

6. Inventive step starting from D5 or D6

6.1 D5 and D6 both relate to applying a small low-energy beam that is scanned over a larger treatment area to completely coagulate that area (D5: Figures 5a and 6a; D6: column 1, line 57 to column 2, line 22).

Figure 8a of D5 shows a ring-shaped illumination by the aiming beam. Figure 6a shows a pattern of separated treatment locations. This pattern is not projected by an alignment beam onto the retina.

D6 discloses a target light source producing a target light beam that surrounds the area to be treated by the working light beam (column 5, line 53 to column 6, line 8).

Hence, neither D5 nor D6 discloses projecting a visible alignment pattern comprising a plurality of separated spots.

6.2 The common general knowledge exemplified by the standard disclosed in D8 does not motivate the person skilled in the art to project an alignment pattern of spaced-apart spots by an alignment beam onto the retina.

The Board agrees with the appellant that the standard of D8 requires the treatment location of any therapeutic laser to be visibly indicated (section 59.101). However, to comply with the standard of D8 it is not necessary to visibly indicate every single treatment spot. Hence, D8 does not disclose or suggest using the scanner of the therapeutic laser of D5 or D6 to project an alignment pattern of separated spots which are coincident with the treatment locations.

6.3 As mentioned before, neither D5 nor D6 discloses a visible alignment pattern comprising a plurality of separated spots which are coincident with the treatment spots. In fact, D6 even teaches that instead of guiding the target beam and the treatment beam flush with each



other, the target beam surrounds the beam spot of the treatment beam (column 5, lines 54 to 58). Thus, the combination of D5 with D6 or vice versa does not result in the subject-matter of claim 1.

6.4 D7 relates to the treatment of diabetic retinopathy by manually moving the treatment laser (page 277, left-hand column, last paragraph, Figure 2). Projecting a pattern of the spots to be coagulated onto the retina is neither taught nor suggested. Hence, combining D5 or D6 with D7 does not result in the claimed subject-matter either.

6.5 Consequently, the subject-matter of claim 1 does not lack an inventive step over the combination of D5 or D6 with any of D6, D5, D7 and the common general knowledge (D8).

7. Inventive step starting from D10

7.1 D10 is directed to coagulating a spot or an area on the retina with a small laser beam that scans a pattern of microspots to cover the entire area. For this purpose, there is no reason to project an alignment pattern with separated spots onto the retina. In D10, the treatment laser beam can be moved to another area manually. This further treatment area or its contour is indicated by the aiming beam.

7.2 Neither the common general knowledge (exemplified by D18 and D8) nor the teaching of D7 or D6 would prompt the person skilled in the art to use the scanner of D10 to project an alignment pattern of spaced-apart spots by an alignment beam onto the retina, to move the treatment laser beam from one of the spots/areas of the alignment pattern to at least one other spot/area and

to fill it with microspots, and to do that still in less than 1 second.

- 7.3 Both D18 and D7 relate to the treatment of diabetic retinopathy by manually moving the treatment laser. The standard of D8 requires that the treatment location, rather than every single treatment spot, is indicated by a visible aiming beam. Projecting a pattern of the spots to be coagulated onto the retina is neither taught nor suggested.

D6 mentions projecting a pattern of treatment spots (column 5, lines 25 to 31). However, it cannot be derived that this pattern is projected by the target light beam mentioned in the subsequent paragraph, or that the treatment beam is then aligned with this pattern.

- 7.4 Thus, combining the teaching of D10 with that of D7 or D6 or with the common general knowledge does not render the subject-matter of claim 1 obvious.

8. Inventive step starting from D7

- 8.1 D7 relates to the treatment of diabetic retinopathy by applying individual laser beam spots manually (page 277, left-hand column, last paragraph, Figure 2). This is actually the procedure described in paragraph [0002] of the patent as prior art. D7 does not disclose a scanner for moving a laser beam and an alignment beam or projecting a visible alignment pattern comprising separated spots onto the retina by the alignment beam.

- 8.2 Since D9 and D10 do not disclose projecting a visible alignment pattern comprising separated spots (D9 does not disclose any projection of a pattern at all, and

D10 does not disclose separated spots), combining D7 with any of D9 or D10 would not result in the subject-matter of claim 1.

8.3 D6 relates to scanning a treatment area with a small laser beam spot (column 1, line 57 to column 2, line 22). D6 discloses a target light source producing a target light beam that surrounds the area to be treated by the working light beam (column 5, line 53 to column 6, line 8). Hence, it teaches away from projecting an alignment pattern the spots of which are coincident with the treatment beam spots. The pattern mentioned in column 5, lines 25 to 31 is the treatment spot pattern. Hence, combining D7 with D6 would not result in the subject-matter of claim 1.

9. Inventive step starting from D1

9.1 D1 relates to a multiple treatment beam, i.e. a main laser beam that is divided into a multiplicity of sub-beams which are to be focused on the retina. Hence, multiple burns can be placed with one shot of the laser beam, thereby avoiding the drawbacks of the spot-by-spot technique.

9.2 D9 is concerned with microphotocoagulation and relates to the problem of individual spot quality on a particular area.

9.3 Since D1 and D9 relate to different techniques solving different problems, the person skilled in the art would not envisage combining these documents. The subject-matter of claim 1 is therefore inventive over this combination.

10. Inventive step starting from D15
  - 10.1 D15 is a scientific paper relating to panretinal photocoagulation patterns. It discloses that in usual patterns the burns are spaced apart (page 531, right-hand column, penultimate paragraph, second sentence). However, D15 is silent about any projection of such a pattern onto the retina by an alignment beam.
  - 10.2 Since neither D9 nor D10 discloses separated treatment locations - and even less so a visual alignment pattern comprising separated spots - the person skilled in the art would not envisage combining D15 with D10 or D9.
  - 10.3 Hence, the subject-matter of claim 1 is not rendered obvious by the combination of D15 with D10 or D9.
11. Consequently, none of the objections raised by the appellant prejudices the maintenance of the patent as granted.
12. Referral of a question to the Enlarged Board of Appeal
  - 12.1 Under Article 112(1) (a) EPC a Board of Appeal refers a question to the Enlarged Board of Appeal if it considers that a decision is required in order to ensure uniform application of the law or because a point of law of fundamental importance arises. A Board can refer questions either of its own motion or following a request from a party.

Whether or not to refer a question is a discretionary decision by the Board (see Case Law of the Boards of Appeal, 10th edition 2022, V.B.2.3.2). In order for a referral to be admissible, the referred question must be relevant for deciding the case in question (see Case

Law of the Boards of Appeal, 10th edition 2022, V.B. 2.3.3).

- 12.2 The appellant requested that questions be referred to the Enlarged Board of Appeal about whether a prior art document concerning a medical device for therapeutic treatment of the human body had to be interpreted such that it complied with norms serving the protection of patients which had been published subsequently.
- 12.3 In the case in hand, the documents in the context of which these questions were raised were prior art document D5 and the standard D8. As set out in point 6.2 above, the subject-matter of claim 1 would involve an inventive step even if, in line with the appellant's suggestion, it were accepted that the standard of D8 had to be complied with when interpreting D5 or implementing the device according to D5. Accordingly, the questions to be referred were not relevant for deciding the case.

In addition, the Board notes that norms and standards for medical devices are part of a regulatory framework which may vary locally (e.g. from country to country or from region to region) and change over time (e.g. becoming stricter or less strict, on the basis of considerations which may not be limited to patient interests). It may also be that a medical device described in a certain prior art document deliberately does not comply with a certain standard or norm. For these reasons, it would not be justified to consider that, as a matter of principle (i.e. detached from the circumstances of the individual case), the person skilled in the art always interprets prior art documents in a way that is compliant with any possibly applicable standard or norm (besides the fact that

there may also be conflicting standards in different countries or regions).

12.4 In conclusion, the Board rejected the appellant's request to refer questions to the Enlarged Board of Appeal.

## Order

### **For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:



A. Chavinier-Tomsic

M. Alvazzi Delfrate

Decision electronically authenticated