

## Decision on Opposition

Opposition No. 2019-700965

Patentee	Carl Zeiss Meditec AG
Patent Attorney	ONDA, Makoto
Patent Attorney	ONDA, Hironori
Patent Attorney	HONDA, Atsushi
Opponent	YOKOCHI, Mina

The case of opposition against the invention "Device for swept-source optical coherence domain reflectometry" in Japanese Patent No. 6523349 has resulted in the following decision.

### Conclusion

The correction of the scope of claims of Japanese Patent No. 6523349 shall be approved as the corrected scope of claims attached to the written correction request, as for Claims [1-21] after correction.

The patents for Claims 1, 2, 4-18, 20 and 21 of Japanese Patent No. 6523349 shall be revoked.

The opposition to a granted patent regarding the patents according to Claims 3 and 19 of Japanese Patent No. 6523349 shall be dismissed.

### Reason

#### No. 1 History of the procedures

The application of the patent relating to Claims 1-21 of Japanese Patent No. 6523349 is a divisional application filed on January 4, 2017 from Japanese Patent Application No.2015-93007 filed on April 30, 2017, which is a divisional application from Japanese Patent Application No.2011-542712 filed on December 21, 2009 as an international filing date (priority claim under the Paris Convention received by the foreign receiving office on December 23, 2008, Germany). The establishment of the patent right of the invention was registered on May 10, 2019, and the gazette containing the

patent was issued on May 29, 2019.

The history of the opposition to a granted patent of the case is as follows.

November 28, 2019 : Opposition to a granted patent regarding the patent according to Claims 1-21, filed by the patent opponent YOKOCHI, Mina (hereinafter, referred to as "the Opponent")

Dated February 10, 2020 : Notice of reasons for revocation

May 14, 2020 : Submission of written opinion and written correction request by the Patentee

(The request for correction by the above written correction request shall be deemed to have been withdrawn pursuant to the provisions of Article 120-5 (7) of the Patent Act.)

June 5, 2020 : Submission of supplemental statement by the Patentee (the original of an experiment report submitted as Evidence B No. 2)

June 27, 2020 : Submission of written opinion by the Patentee

Dated July 29, 2020 : Notice of reasons for revocation (advance notice of decision)

November 2, 2020 : Submission of written opinion and written correction request (hereinafter, referred to as "the Written Correction Request")

December 15, 2020 : Submission of written opinion by the Opponent

## No. 2 Suitability of correction

### 1 Contents of correction

The object of the request by the Written Correction Request is to request to correct the scope of claims to Claims 1-21 after correction as described in the corrected scope of claims attached to the Written Correction Request, and the contents thereof are as follows.

#### (1) Correction A

"A device for swept source optical coherence domain reflectometry, wherein a control and evaluation unit controlling the tuning of the light source and digitizing backscattered light detected by the receiver during a single tuning at a rate of more than  $\Delta k/(\tau \times \delta k)$  is provided" in Claim 1 of the scope of claims is corrected to "a device for swept source optical coherence domain reflectometry, wherein a control unit (note by the body: referred to as "Correction A-3") controlling the tuning of the light source and digitizing backscattered light detected by the receiver during a single tuning at a frequency (note by the body: referred to as "Correction A-1") of more than  $\Delta k/(\tau \times \delta k)$  is provided, a ratio of a tuning range  $\Delta k$  and the laser line width  $\delta k$  is greater than 360, and a quotient of the tuning rate  $(\Delta k/\tau)$  and the laser line width  $\delta k$  is less than 40 MHz (note

by the body: referred to as "Correction A-2"). (Underlines indicate amended portions given by the Patentee. The same applies hereafter.)

Claims 2, 4-6, 10-18, 20, and 21 which are dependent on the citation of Claim 1 are similarly corrected.

(2) Correction B

Claim 3 of the scope of claims is deleted.

(3) Correction C

"The device for swept source optical coherence domain reflectometry according to any one of Claims 1-4" in Claim 5 of the scope of claims is corrected to "the device for swept source optical coherence domain reflectometry according to any one of Claims 1, 2, and 4"

Claims 6, 10-18, 20, and 21 which are dependent on the citation of Claim 5 are similarly corrected.

(4) Correction D

"The device for swept source optical coherence domain reflectometry according to any one of Claims 1-5" in Claim 6 of the scope of claims is corrected to "the device for swept source optical coherence domain reflectometry according to any one of Claims 1, 2, 4, and 5"

Claims 10-18, 20, and 21 which are dependent on the citation of Claim 6 are similarly corrected.

(5) Correction E

"A device for swept source optical coherence domain reflectometry for the eyes, wherein the light source has a spectral tuning range  $\Delta k$  about a centroid wave number  $k_0$  of at least  $\Delta k > 18000 \text{ m}^{-1}$ ,

wherein an interferometer with a sample arm and a reference arm is provided, the reference arm having a reference plane properly set with respect to a retina or a cornea in the A-scan, the light source having a maximum laser line width corresponding to a position of the reference plane with respect to the retina or the cornea in the A-scan,

wherein since the reference plane is set between the retina and the cornea, a laser line width of  $\delta k < 162 \text{ m}^{-1}$  of the light source corresponding to the reference plane set between the retina and the cornea is generated,

wherein since the reference plane is set behind the retina, a laser line width of

$\delta k < 93 \text{ m}^{-1}$  of the light source corresponding to the reference plane set behind the retina is generated,

wherein since the reference plane is set in front of the cornea, a laser line width of  $\delta k < 81 \text{ m}^{-1}$  of the light source corresponding to the reference plane set in front of the cornea is generated,

wherein since the reference plane is set behind the retina and a minimum space of 64 mm is set between the reference plane and an optical element that lies closest to the eye, a laser line width of  $\delta k < 47 \text{ m}^{-1}$  of the light source corresponding to the reference plane set behind the retina at the minimum space of 64 mm between the reference plane and the optical element that lies closest to the eye is generated" in Claim 7 of the scope of claims is corrected to

"a device for swept source optical coherence domain reflectometry for the eyes, wherein the light source has a spectral tuning range  $\Delta k$  about a centroid wave number  $k_0$  of at least  $\Delta k > 18000 \text{ m}^{-1}$ ,

wherein a ratio of a tuning range  $\Delta k$  and the laser line width  $\delta k$  is greater than 360, and a quotient of the tuning rate ( $\Delta k/\tau$ ) and the laser line width  $\delta k$  is less than 40 MHz (note by the body: referred to as "Correction E-1")

wherein an interferometer with a sample arm and a reference arm is provided, the reference arm having a reference plane set at any one of the following first to fourth positions (note by the body: referred to as "Correction E-2" including this underlined portion and the following underlined portions) with respect to a retina or a cornea in the A-scan, the light source having a maximum laser line width corresponding to a position of the reference plane with respect to the retina or the cornea in the A-scan,

wherein when the reference plane is set at a first position between the retina and the cornea, the light source is designed to have a laser line width of  $\delta k < 162 \text{ m}^{-1}$ ,

wherein when the reference plane is set at a second position behind the retina, the light source is designed to have a laser line width of  $\delta k < 93 \text{ m}^{-1}$ ,

wherein when the reference plane is set at a third position in front of the cornea, the light source is designed to have a laser line width of  $\delta k < 81 \text{ m}^{-1}$ ,

wherein when the reference plane is set at a fourth position behind the retina and a minimum space of 64 mm is set between the reference plane and an optical element that lies closest to the eye, the light source is designed to have a laser line width of  $\delta k < 47 \text{ m}^{-1}$ .

Claims 8-18, 20, and 21 which are dependent on the citation of Claim 7 are similarly corrected.

(6) Correction F

"A device for swept source optical coherence domain reflectometry for the eyes according to any one of Claims 1-9" in Claim 10 of the scope of claims is corrected to "a device for swept source optical coherence domain reflectometry for the eyes according to any one of Claims 1, 2, and 4-9".

Claims 11-18, 20, and 21 which are dependent on the citation of Claim 10 are similarly corrected.

(7) Correction G

"A device for swept source optical coherence domain reflectometry for the eyes according to any one of Claims 1-10" in Claim 11 of the scope of claims is corrected to "a device for swept source optical coherence domain reflectometry for the eyes according to any one of Claims 1, 2, and 4-10".

Claims 12-18, 20, and 21 which are dependent on the citation of Claim 11 are similarly corrected.

(8) Correction H

"A device for swept source optical coherence domain reflectometry for the eyes according to any one of Claims 1-11" in Claim 12 of the scope of claims is corrected to "a device for swept source optical coherence domain reflectometry for the eyes according to any one of Claims 1, 2, and 4-11".

Claims 13-18 which are dependent on the citation of Claim 12 are similarly corrected.

(9) Correction I

"A device for swept source optical coherence domain reflectometry for the eyes according to any one of Claims 1-12" in Claim 13 of the scope of claims is corrected to "a device for swept source optical coherence domain reflectometry for the eyes according to any one of Claims 1, 2, and 4-12".

Claims 14-18 which are dependent on the citation of Claim 13 are similarly corrected.

(10) Correction J

"A device for swept source optical coherence domain reflectometry for the eyes according to any one of Claims 1-13" in Claim 14 of the scope of claims is corrected to "a device for swept source optical coherence domain reflectometry for the eyes according

to any one of Claims 1, 2, and 4-13".

Claims 15-18 which are dependent on the citation of Claim 14 are similarly corrected.

(11) Correction K

"A device for swept source optical coherence domain reflectometry for the eyes according to any one of Claims 1-14" in Claim 15 of the scope of claims is corrected to "a device for swept source optical coherence domain reflectometry for the eyes according to any one of Claims 1, 2, and 4-14".

Claims 16-18 which are dependent on the citation of Claim 15 are similarly corrected.

(12) Correction L

"The camera has reactivity to the wavelengths of the measurement beam and the aiming markers" in Claim 16 of the scope of claims is corrected to "the camera has sensitivity to the wavelengths of the measurement beam and the aiming markers".

Claims 17 and 18 which are dependent on the citation of Claim 16 are similarly corrected.

(13) Correction M

"A device for swept source optical coherence domain reflectometry for the eyes according to any one of Claims 1-16" in Claim 17 of the scope of claims is corrected to "a device for swept source optical coherence domain reflectometry for the eyes according to any one of Claims 1, 2, and 4-16".

Claims 18 which are dependent on the citation of Claim 17 is similarly corrected.

(14) Correction N

"A device for swept source optical coherence domain reflectometry for the eyes according to any one of Claims 1-17" in Claim 18 of the scope of claims is corrected to "a device for swept source optical coherence domain reflectometry for the eyes according to any one of Claims 1, 2, and 4-17".

(15) Correction O

Claim 19 of the scope of claims is deleted.

(16) Regarding a group of claims

Although Claims 1 and 7 before correction are respectively independent claims, since Claims 10-19 directly or indirectly depend on Claims 1-9 and Claims 20 and 21 depend on Claim 11, Claims 1-21 are a group of claims. Also, since Corrections A-O are made in the group of claims, those are requested for each group of claims stipulated in Article 120-5(4) of the Patent Act.

2 Propriety of the purpose of the correction, presence or absence of new matter, and existence of enlargement or alternation of the scope of claims

(1) Regarding Correction A

A Propriety of the purpose

(A) The Correction A-1 that corrects "digitizing at a rate of more than  $\Delta k/(\tau \times \delta k)$ " to "digitizing at a frequency of more than  $\Delta k/(\tau \times \delta k)$ " is made in response to the indication that "although it is described as 'control and evaluation of digitizing light at a rate of more than  $\Delta k/(\tau \times \delta k)$ ,' it is unclear what 'digitizing at a rate' intends to technically specify" in (2) of Reason 1 for revocation (clarity) in a notice of reasons for revocation dated February 10, 2020 (hereinafter, referred to as "the notice of reasons for revocation"), and thus is intended to clarify a description which is ambiguous in accordance with Article 120-5(2)(iii) of the Patent Act.

(B) Correction A-2 limits "the tuning of the light source" by adding the matter that "a ratio of a tuning range  $\Delta k$  and the laser line width  $\delta k$  is greater than 360, and a quotient of the tuning rate ( $\Delta k/\tau$ ) and the laser line width  $\delta k$  is less than 40 MHz," and thus is intended for restriction of the scope of claims in accordance with Article 120-5(2)(i) of the Patent Act.

(C) Correction A-3 that corrects "a control and evaluation unit digitizing" to "a control unit digitizing" is made in response to the indication that "the term 'evaluation' is generally a judgment of value, and furthermore, in a field of signal processing, even if it is used to judge the pros and cons by comparing data to be evaluated with reference data, it cannot be assumed that 'evaluation' is used as a term to mean digitization and Fourier transform...it still cannot be said that 'evaluation' is clear," in (3) of Reason 1 for revocation (clarity) in a notice of reasons for revocation (advance notice of decision) dated July 29, 2020 (hereinafter, referred to as "the notice of reasons for revocation (advance notice of decision)"), and thus is intended to clarify a description which is ambiguous in accordance with Article 120-5(2)(iii) of the Patent Act.

B Presence or absence of new matter

(A) Regarding Correction A-1, since a unit of  $\Delta k/(\tau \times \delta k)$  is 1/s and digital devices generally digitize according to a clock frequency, considering the unit and common general technical knowledge, it cannot be said that the correction of "digitizing at a rate of more than  $\Delta k/(\tau \times \delta k)$ " to "digitizing at a frequency of more than  $\Delta k/(\tau \times \delta k)$ " introduces a new technical matter in relation to the technical matters derived by totalizing all the descriptions in the specification, scope of claims, and drawings attached to the present application (hereinafter, referred to as "the Specification, etc.") and thus it can be said that it is made within the scope of the matters described in the Specification, etc.

(B) Regarding Correction A-2, the Specification describes that  
"[0019]

Thus, it is predominantly undisturbed signals that result, without the need for active tracking of the measurement beam with sample movements.

It is advantageous in this case when the light source has a spectral tuning range  $\Delta k$  about a centroid wave number  $k^0$  of at least  $\Delta k > 18000 \text{ m}^{-1}$ . In this case, the ratio of the tuning range  $\Delta k$  and line width  $\delta k$  is advantageously greater than 360, further preferably greater than 2000, further preferably greater than 4000, and yet further preferably greater than 9000. This ratio ensures the implementation of an adequate ratio between the measurement depth and measurement resolution.

[0020]

A further advantage results when the quotient of the tuning rate ( $\Delta k/\tau$ ) and laser line width  $\delta k$  is greater than 18 kHz, preferably also greater than 4 MHz, with further preference greater than 40 MHz. (The underlines were given by the body. The same applies hereafter.)

Since [0019] above describes that "the ratio of the tuning range  $\Delta k$  and line width  $\delta k$  is advantageously greater than 360," and [0020] describes that "a further advantage results when the quotient of the tuning rate ( $\Delta k/\tau$ ) and laser line width  $\delta k$  is greater than 18 kHz, preferably also greater than 4 MHz, and further 40 MHz," it can be said that the quotient of the tuning rate ( $\Delta k/\tau$ ) and laser line width  $\delta k$  that is smaller than 40 MHz is described, so that it can be said that the matter "the quotient of the tuning rate ( $\Delta k/\tau$ ) and laser line width  $\delta k$  that is smaller than 40 MHz" is made within the scope of the matters described in the Specification, etc.

Therefore, it can be said that the matter "the ratio of the tuning range  $\Delta k$  and line width  $\delta k$  is advantageously greater than 360 and the quotient of the tuning rate ( $\Delta k/\tau$ ) and laser line width  $\delta k$  that is smaller than 40 MHz" is made within the scope of the matters

described in the Specification, etc.

(C) Regarding Correction A-3, the Specification describes that

"[0044]

The control and evaluation unit 10 controls the tuning of the laser 1 via the data acquisition apparatus 9 (with a spectral tuning range  $\Delta k$  in the tuning time  $\tau$ ), and the light backscattered by the sample 3 and measured by the detector 4 is digitized and subjected in a known way to a Fourier transformation, for example, a discrete Fourier transformation (DFT), for the reconstruction of the A-scan," so that it can be said that "a control unit digitizing" is made within the scope of matters described in the Specification, etc.

(D) Therefore, it cannot be said that Correction A introduces a new technical matter in relation to the technical matters derived by totalizing all the descriptions in the Specification, etc. and thus it is made within the scope of the matters described in the Specification, etc.

C Existence of enlargement or alternation of the scope of claims

Correction A does not substantially enlarge or alter the scope of claims.

(2) Regarding correction E

A Propriety of the purpose

Correction E-1 is the same matter as Correction A-2, and thus is intended for restriction of the scope of claims in accordance with Article 120-5(2)(i) of the Patent Act.

(B) Correction E-2 is made in response to the indication that

"A Regarding 'a reference plane properly set with respect to a retina or a cornea in the A-scan,' it is unclear how to set the reference plane with respect to the retina and cornea 'properly'.

B In the description that 'since the reference plane is set between the retina and the cornea, a laser line width of  $\delta k < 162 \text{ m}^{-1}$  of the light source corresponding to the reference plane set between the retina and the cornea is generated,' although it is understood that the reference plane is set between the retina and the cornea to make the laser line width of the light source become  $\delta k < 162 \text{ m}^{-1}$ , it cannot be said that the laser line width of the light source becomes  $\delta k < 162 \text{ m}^{-1}$  due to the reference plane being set between the cornea and the retina, and thus it is technically unclear.

The same is applied to the matters that 'since the reference plane is set behind the retina, a laser line width of  $\delta k < 93 \text{ m}^{-1}$  of the light source corresponding to the reference plane set behind the retina is generated,' 'since the reference plane is set in front of the cornea, a laser line width of  $\delta k < 81 \text{ m}^{-1}$  of the light source corresponding to the reference plane set in front of the cornea is generated,' and 'since the reference plane is set behind the retina and a minimum space of 64 mm is set between the reference plane and an optical element that lies closest to the eye, a laser line width of  $\delta k < 47 \text{ m}^{-1}$  of the light source corresponding to the reference plane set behind the retina at the minimum space of 64 mm between the reference plane and the optical element that lies closest to the eye is generated' in (3) of Reason 1 for revocation (clarity) in the notice of reasons for revocation, and thus is intended to clarify a description which is ambiguous in accordance with Article 120-5(2)(iii) of the Patent Act.

B Presence or absence of new matter

(A) Correction E-1 is made within a scope of the matters described in the Specification, etc., as described in (1) B (B) above.

(B) Regarding Correction E-2, the Specification describes that  
"[0039]

The present invention will be explained in more detail below with reference to the drawings. The basic design for implementing the invention in FIG. 1 consists of a suitable tunable laser 1 that is characterized by the following variables: tuning time  $\tau$ , wavelength  $\lambda$ , spectral tuning range  $\Delta k$ , centroid wave number  $k_0$ , and laser line width  $\delta k$ ".

"[0068]

It has emerged that the maximum laser line width  $\delta k$  depends on the measurement regime. The laser line width must be smaller than  $162 \text{ m}^{-1}$  in the case of measuring the autocorrelation function; that is to say, with a blocked reference arm.

[0069]

If use is made of an arrangement with a reference arm, it is possible by suitable definition of the reference plane in the sample to ensure that: 1. the signals from the cornea, lens, and retina are detected with sufficient strength, and that 2. mirror artifacts can be suppressed or identified and eliminated by computation. FIG. 3 shows this schematically for various positions of the reference plane, which can be set via the wavelength differences between the reference and sample light paths.

[0070]

In FIG. 3a, the reference plane was set behind the retina (R), the result being a maximum laser line width of  $93 \text{ m}^{-1}$  (signal drop of 80 dB over a total measuring range of 54 mm, represented schematically as a curve). R' and C' denote the mirror artifacts here and below.

[0071]

In FIG. 3b, the reference plane is set in front of the cornea (C), the result being a maximum laser line width of  $81 \text{ m}^{-1}$  (it is possible to think signal drop of 60 dB over a total measuring range of 54 mm, since the cornea reflects better than the retina).

[0072]

In FIG. 3c, the reference plane was set between the cornea (C) and retina (R), the result being a maximum laser line width of  $162 \text{ m}^{-1}$ .

As in FIG. 3a, in FIG. 3d, the reference plane was set behind the retina (R); given a target signal drop of only 20 dB over a total measuring range of 54 mm, the result is a maximum laser line width of  $47 \text{ m}^{-1}$ . This is the preferred laser line width  $\delta k$ . It is necessary here to implement a minimum space of 64 mm between the reference planes and the optical element that lies closest to the eye and is traversed by the measurement beam".

Regarding the position of the reference planes, four cases of "set between the cornea (C) and retina (R)" (a first position), "set behind the retina (R)" (a second position), "in front of the cornea (C)" (a third position), and "set behind the retina (R) at a minimum space of 64 mm between the reference planes and the optical element that lies closest to the eye and is traversed by the measurement beam" (a fourth position) are described, and in each case in turn, it becomes the maximum laser line width of  $162 \text{ m}^{-1}$  ( $\delta k < 162 \text{ m}^{-1}$ ), the maximum laser line width of  $93 \text{ m}^{-1}$  ( $\delta k < 93 \text{ m}^{-1}$ ), the maximum laser line width of  $81 \text{ m}^{-1}$  ( $\delta k < 81 \text{ m}^{-1}$ ), and the maximum laser line width of  $47 \text{ m}^{-1}$  ( $\delta k < 47 \text{ m}^{-1}$ ); that is, it can be said that the tunable laser 1 (light source) is "designed" so that the laser line width has such a value as "a basic design".

Then, it cannot be said that Correction E-2 introduces a new technical matter in relation to the technical matters derived by totalizing all the descriptions in the Specification, etc.

(C) Therefore, it cannot be said that Correction E introduces a new technical matter in relation to the technical matters derived by totalizing all the descriptions in the Specification, etc. and thus it is made within the scope of the matters described in the Specification, etc.

C Existence of enlargement or alternation of the scope of claims

Correction E does not substantially enlarge or alter the scope of claims.

(3) Regarding Correction L

A Propriety of the purpose

Correction L is made in response to the indication that "although Claim 16 describes that 'the camera has reactivity to the wavelengths of the measurement beam and the aiming markers,' it is technically unknown that the camera has "reactivity" and it is not described in the Specification," in Reason 1 for revocation (clarity) in the notice of reasons for revocation, and thus is intended to clarify a description which is ambiguous in accordance with Article 120-5(2)(iii) of the Patent Act.

B Presence or absence of new matter

Regarding Correction L, the Specification describes that  
"[0035]

It is further advantageous in this case when the observation unit, for example a camera, is provided for checking the adjustment of the measurement beam relative to the eye, the observation unit preferably being sensitive to the wavelengths of the measurement beam and the aiming markers. Cameras with a silicon sensor seem to be particularly suitable here because of their adequate residual sensitivity in the near infrared". Since it is described that the camera has "sensitivity," Correction L is made within the scope of the matters described in the Specification, etc.

C Existence of enlargement or alternation of the scope of claims

Correction L does not substantially enlarge or alter the scope of claims.

(4) Regarding Corrections B and O

Each of Corrections B and O are a correction to delete a claim, and thus are intended for restriction of the scope of claims in accordance with Article 1120-5(2)(i) of the Patent Act. The deletion of a claim does not add a new matter and does not substantially enlarge or alter the scope of claims.

(5) Regarding Corrections C, D, F-K, M and N

Corrections C, D, F-K, M and N, with the deletion of Claim 3 by Correction B, delete Claim 3 from claims which are dependent, and thus it can be said that those are intended to explain a description which is not clear in accordance with Article 120-

5(2)(iii) of the Patent Act. The deletion of a part of claims from claims which are dependent does not add a new matter and does not substantially enlarge or alter the scope of claims.

### 3 Summary

As described above, the corrections according to Claims A-O aim at matters prescribed in Article 120-5(2)(i) or (iii) of the Patent Act, and fall under the provisions of Article 126 (5) and (6) of the Patent Act which is applied mutatis mutandis pursuant to Article 134 (9) of the Patent Act.

Therefore, the correction of the scope of claims shall be approved as the corrected scope of claims attached to the written correction request, as for Claims [1-21] after correction.

### No. 3 The Invention

The inventions according to Claims 1, 2, 4-18, 20, and 21 which are corrected by the correction request of the case (hereinafter, each claims is referred to as "Invention 1" and the like, and when collectively describing "Inventions 1-21" or "the Invention," those corresponding to deleted Claims 3 and 19 shall be excluded) are as described in Claims 1, 2, 4-18, 20, and 21 of the corrected scope of claims, and among them, Inventions 1, 4-8, and 14 directly related to "Judgment by the body" of No. 5 below are described as follows.

"[Claim 1]

A device for swept source optical coherence domain reflectometry (SSOCDR) on the human eye that is a movable sample, for the purpose of obtaining A-scans, having a measuring range corresponding to a sample size, comprising:

a tunable laser light source capable of tuning wavelength about a centroid wave number  $k_0$ ; and at least one receiver for light backscattered from the sample,

wherein the sample is illuminated on the sample surface with a measurement beam of diameter  $D$ ;

wherein the light source has a laser line width of  $\delta k < 168 \text{ m}^{-1}$ ;

wherein tuning of the light source is performed in  $\tau < 44 \text{ sec}/(D \times k_0)$  about a centroid wave number  $k_0$ ;

wherein the light source has a spectral tuning range  $\Delta k$  about a centroid wave number  $k_0$  of at least  $\Delta k > 18000 \text{ m}^{-1}$ ;

wherein the light source has a wavelength of 600 nm to 1150 nm;

wherein a control unit controlling the tuning of the light source and digitizing

backscattered light detected by the receiver during a single tuning at a frequency of more than  $\Delta k/(\tau \times \delta k)$  is provided, a ratio of a tuning range  $\Delta k$  and the laser line width  $\delta k$  is greater than 360, and a quotient of the tuning rate ( $\Delta k/\tau$ ) and the laser line width  $\delta k$  is less than 40 MHz.

[Claim 2]

The device for swept source optical coherence domain reflectometry according to Claim 1, wherein the measurement beam diameter  $D$  is smaller than 3 mm".

"[Claim 4]

The device for swept source optical coherence domain reflectometry according to Claim 1 or 2, wherein a value obtained by dividing the tuning rate  $\Delta k/\tau$  by the laser line width  $\delta k$  is greater than 18 kHz.

[Claim 5]

The device for swept source optical coherence domain reflectometry according to any one of Claims 1, 2, and 4, wherein the laser line width  $\delta k$  of the light source lies between  $22 \text{ m}^{-1}$  and  $50 \text{ m}^{-1}$ .

[Claim 6]

The device for swept source optical coherence domain reflectometry according to any one of Claims 1, 2, 4, and 5, wherein the bandwidth of the at least one receiver is greater than  $2 \times \Delta k/(\tau \times \delta k)$  and less than 80 MHz.

[Claim 7]

A device for swept source optical coherence domain reflectometry (SSOCDR) on the human eye that is a movable sample, for the purpose of obtaining A-scans, having a measuring range corresponding to a sample size, comprising:

a tunable laser light source capable of tuning wavelength about a centroid wave number  $k_0$ ; and at least one receiver for light backscattered from the sample,

wherein the sample is illuminated on the sample surface with a measurement beam of diameter  $D$ ;

wherein the light source has a laser line width of  $\delta k < 168 \text{ m}^{-1}$ ;

wherein tuning of the light source is performed in  $\tau < 44 \text{ sec}/(D \times k_0)$  about a centroid wave number  $k_0$ ;

wherein the light source has a spectral tuning range  $\Delta k$  about a centroid wave number  $k_0$  of at least  $\Delta k > 18000 \text{ m}^{-1}$ ;

wherein a ratio of a tuning range  $\Delta k$  and the laser line width  $\delta k$  is greater than 360, and a quotient of the tuning rate ( $\Delta k/\tau$ ) and the laser line width  $\delta k$  is less than 40 MHz:

wherein an interferometer with a sample arm and a reference arm is provided, the reference arm having a reference plane set at any one of the following first to fourth

positions (note by the body: referred to as "Correction E-2" including this underlined portion and the following underlined portions) with respect to a retina or a cornea in the A-scan, the light source having a maximum laser line width corresponding to a position of the reference plane with respect to the retina or the cornea in the A-scan,

wherein when the reference plane is set at a first position between the retina and the cornea, the light source is designed to have a laser line width of  $\delta k < 162 \text{ m}^{-1}$ ,

wherein when the reference plane is set at a second position behind the retina, the light source is designed to have a laser line width of  $\delta k < 93 \text{ m}^{-1}$ ,

wherein when the reference plane is set at a third position in front of the cornea, the light source is designed to have a laser line width of  $\delta k < 81 \text{ m}^{-1}$ ,

wherein when the reference plane is set at a fourth position behind the retina and a minimum space of 64 mm is set between the reference plane and an optical element that lies closest to an eye, the light source is designed to have a laser line width of  $\delta k < 47 \text{ m}^{-1}$ .

[Claim 8]

The device for swept source optical coherence domain reflectometry for the eyes according to Claim 7, wherein the measurement beam diameter  $D$  is smaller than 3 mm".

"[Claim 14]

The device for swept source optical coherence domain reflectometry for the eyes according to any one of Claims 1, 2, and 4-12, wherein the measurement beam has a wavelength of 600 nm to 1150 nm".

#### No. 4 Outline of the reasons for revocation (advance notice of decision)

The gist of the reasons for revocation (advance notice of decision) is as follows.

Reason 1 for revocation (clarity) The patent of the case was made against a patent application whose the citations according to Claims 1-21 of the scope of claims do not satisfy the requirement stipulated in Article 36(6)(ii) of the Patent Act.

Reason 2 for revocation (ministerial ordinance requirement) The patent of the case was made against a patent application whose detailed description of the invention does not satisfy the requirement stipulated in Article 36(4)(i) of the Patent Act.

Reason 3 for revocation (requirements for support) The patent of the case was made against a patent application whose the descriptions according to Claims 1-21 of the scope of claims do not satisfy the requirement stipulated in Article 36(6)(i) of the Patent Act.

Reason 4 for revocation (enablement requirement) The patent of the case was made against a patent application whose detailed description of the invention does not satisfy the requirement stipulated in Article 36(4) of the Patent Act.

No. 5 Judgment by the body

1 Regarding Reason 1 for revocation

(1) Regarding the measurement beam diameter D

A Notified specific content

In (1) A of Reason 1 for revocation of the notice of reasons for revocation, it is pointed out that

"regarding the measurement beam 'diameter D' in the scope of claims, the Specification merely describes that 'a beam shaping and coupling unit 2 serves both to direct the beam of the laser 1 onto the sample 3 (illustrated schematically here as an eye), and to feed the light backscattered by the sample 3 to a detector 4, D in this figure being the diameter of the measurement beam when it impinges on the sample (here the cornea of the eye)'. On the other hand, the physical measurement beam 'diameter D' may take at least three types of definitions of FWHM,  $D_{63}$ , and  $D_{86}$ .

Therefore, it is unclear under what definition the measurement beam 'diameter D' of the scope of claims was specified". On the basis of opinions of the Patentee against that, in (1) C of Reason 1 for revocation in the notice of reasons for revocation (advance notice of decision), the following judgment was shown.

"Although the Patentee explains that 'Evidence A No. 20 explains that the term "the diameter D" of the measurement beam means diameter  $D_{86}$  for the ideal Gaussian profile, and by interpreting "the diameter D" of the measurement beam described in Claim 1 while taking the explanation into consideration on the basis of the common general technical knowledge (compare with one ideal Gaussian radius) at the time of filing, the description of "the diameter D" of the measurement beam is clear,' Evidence A No. 20 is a preliminary written opinion related to a patent opposition case by the European Patent Office, and not a technical document indicating an ordinary technical content about the 'diameter D' of the measurement beam used in 'the device for swept source optical coherence domain reflectometry,' so that it cannot be understood that the 'diameter D' is a value that defines  $D_{86}$ , on the basis of the description of Evidence A No. 20.

Further, in Evidence A No. 20, although there is a description of 'Standard (ISO11146-1,2,3:2005),' Standard (ISO11146-1,2,3:2005) is the international standard relating to 'Lasers and laser-related equipment - Test methods for laser beam widths, divergence angles and beam propagation ratios,' and according to that, it is described that  $D_{4\sigma}$  is used for the beam width (corresponding to 'the diameter D' of the measurement beam in the Invention). As mentioned above, the 'diameter D' of the beam may take the definitions of FWHM,  $D_{63}$ , and there is no evidence that it is common to use the definition

of  $D_{86}$  as the 'diameter D' of the measurement beam used for a device for swept source optical coherence domain reflectometry, among the definitions of FWHM,  $D_{63}$ , and  $D_{86}$ .

Consequently, concerning the 'diameter D' of 'the measurement beam of the diameter D' used in 'a device for swept source optical coherence domain reflectometry,' there is no evidence for taking  $D_{86}$  as its definition from the description that 'D being the diameter of the measurement beam when it impinges on the sample (here the cornea of the eye)' of the Specification, and it cannot be understood that the 'diameter D' is a value defined taking  $D_{86}$  as the definition on the basis of the description of Evidence A No. 20.

Therefore, since it cannot be said that there is a technical ground for considering the 'diameter D' of the measurement beam in the Invention as a value taking  $D_{86}$  as a definition, it is still not clear under what definition it was specified".

## B Allegation of the Patentee

(A) Against the judgment above, the Patentee alleges as follows in the written opinion submitted on November 2, 2020 (hereinafter, referred to as "the written opinion"), by attaching Evidence B No. 17 to Evidence B No. 23 described in (B) below.

"It is common to use  $D_{86}$  as the definition for the 'diameter D' of the measurement beam, and documents showing the grounds for this include Evidence B No. 17 to Evidence B No. 23. In all documents, it is stated that the intensity of  $1/e^2$  shown in the drawing presented by the opponent as Evidence A No. 23 is defined as the beam diameter".

"Therefore, Evidence B No. 17 to Evidence B No. 23 were thought to support that the Patentee, in the written opinion dated May 14, 2020, states the opinion agreeing with the view of the opposition department of the European Patent Office that 'in a viewpoint of a person skilled in the art, the term diameter D in the Patent should be assumed to mean diameter  $D_{86}$  for an ideal Gaussian profile".

## (B) Regarding Evidence B

Evidence B No. 17: Beam diameter, [online], Wikipedia, [search on October 22, 2020], URL: [https://en.wikipedia.org/w/index.php?title=Beam\\_diameter&oldid=955406649](https://en.wikipedia.org/w/index.php?title=Beam_diameter&oldid=955406649)

Evidence B No. 18: Wolfgang Drexler, et al., "Optical Coherence Tomography, Technology and Applications", Springer, pp. 0262-0263, 0413-0415, 1032

Evidence B No. 19: Rainer A. Leitgeb, "Current Technologies for High-Speed and Functional Imaging with Optical Coherence Tomography", Advances in Imaging and Electron Physics, Volume 168 (2011), Elsevier Inc., pp. 109, 121, 142

Evidence B No. 20: Ralf Menzel, "Photonics Linear and Nonlinear Interactions of Laser Light and Matter", Springer, pp. 29, 56, 371

Evidence B No. 21: Pedrotti, et al., "Optik Eine Einfuhrung" (u with an umlaut is described as u), Prentice Hall

Evidence B No. 22: BAHAA E.A SALEH, et al., "FUNDAMENTALS OF PHOTONICS", John Wiley & Sons, p. 85

Evidence B No. 23: "Understanding Laser Beam Parameters Leads to Better System Performance and Can Save Money", [online], [search on October 22. 2020], URL: [https://www.coherent.com/assets/pdf/Understanding-Beam-Parameters\\_FORMFIRST.pdf](https://www.coherent.com/assets/pdf/Understanding-Beam-Parameters_FORMFIRST.pdf), pp. 1-5 (hereinafter, "Evidence B No. 17" to "Evidence B No. 23" are referred to as "B17" to "B23")

## C Judgment

### (A) Regarding issue date

Although the Patentee submitted B17 to B23 as documents showing that it is common to use  $D_{86}$  as the definition for the diameter D of the measurement beam, since the issue date or publication date cannot be confirmed for B17-B18 and B20-23 other than B19, it cannot be said that B17-B18 and B20-23 were issued or published before the priority date of the Invention. Further, although it can be said that the issue date of B19 is in 2011, it is after the priority date of the Invention.

Therefore, B17-23 submitted by the Patentee cannot be grounds for indicating that it is common to use  $D_{86}$  as the definition for the diameter D of the measurement beam used in the device for swept source optical coherence domain reflectometry, before the priority date of the Invention.

Also, although for B18 and B20-B22, the Patentee, in the written opinion, stated that "the first edition of the document of Evidence B No. 18 was issued on September 25, 2008, the first edition of the document of Evidence B No. 20 was issued in 2001, the first edition of the document of Evidence B No. 21 was issued in 2009, and the first edition of the document of Evidence B No. 22 was issued in 1991. Information on the issuing of the first edition of each of the above documents can be easily obtained from information on the title, author, and publisher of the document on the Internet," it can be said that the same sentence is written even if "print" is different, but it cannot be said that the same sentence is described if "edition" is different. Accordingly, it is not possible to confirm whether the described matters of B18 and B20-B22 attached were issued on the date alleged by the Patentee.

### (B) Regarding $D_{86}$

$D_{86}$  increases an area in a circle shape from the center of gravity of a beam profile (a

graph with distance on the horizontal axis and beam intensity on the vertical axis), and calculates a diameter of the circle when the total beam power in the area reaches 86%, whereas  $1/e^2$  is defined as a distance between two points that is  $1/e^2$  of a peak value of the beam intensity, so that the two are different.

Therefore, although B17-23 describe that the intensity of  $1/e^2$  is used as the beam diameter as stated by the Patentee, since the intensity of  $1/e^2$  and  $D_{86}$  are different, even if the issue dates or publication dates of B17-18 and B20-23 were before the priority date of the Invention, these cannot be grounds for indicating that it is common to use  $D_{86}$  as the definition for the diameter  $D$  of the measurement beam used in the device for swept source optical coherence domain reflectometry, before the priority date of the Invention.

(C) Regarding  $1/e^2$

Since B17-23 describe that the intensity of  $1/e^2$  is used as the beam diameter as stated by the Patentee, it will be examined whether or not it is common to use the intensity of  $1/e^2$  as the beam diameter.

As pointed out in A above, in the international standard (ISO11146-1,2,3:2005) relating to "Lasers and laser-related equipment - Test methods for laser beam widths, divergence angles, and beam propagation ratios," it is described that  $D4\sigma$  is used for the beam width (corresponding to "the diameter  $D$ " of the measurement beam in the Invention).  $D4\sigma$  takes a distance of 4 times the standard deviation  $\sigma$  in the beam profile, and is the most accurate beam width, and thus it is adopted as an international standard.

Therefore, as stated by the Patentee, although the intensity of  $1/e^2$  may be used as the beam diameter, there is no technical ground for using  $1/e^2$  as the definition instead of  $D4\sigma$  adopted as an international standard, for the diameter  $D$  of the measurement beam used in the device for swept source optical coherence domain reflectometry.

(D) However, as described as "For an ideal single-mode Gaussian beam, the  $D4\sigma$ ,  $D_{86}$ , and  $1/e^2$  width measurements would give the same value." in lines 12-13 of the item " $1/e^2$ " of B17 above, mathematically, in the case of a complete Gaussian distribution in a single mode (lasers rarely have a complete Gaussian distribution), the widths of  $D4\sigma$ ,  $1/e^2$ , and  $D_{86}$  are the same.

However, even with reference to the Specification, it cannot be said that "the light source" of the Invention has a complete Gaussian distribution in a single mode, and furthermore, even with reference to the experiment report submitted by the Patentee as B2, it cannot be said that the light source a complete Gaussian distribution in a single mode.

Therefore, the widths of  $D4\sigma$ ,  $1/e^2$ ,  $D_{86}$  do not have the same value, and thus those cannot be equated as the diameter  $D$  of the measurement beam.

(D) Summary

Hence, there is no technical ground for using  $1/e^2$  as the definition for the diameter  $D$  of the measurement beam used in the device for swept source optical coherence domain reflectometry, among  $D4\sigma$ , FWHM,  $D_{86}$ , and  $D_{63}$ , and it cannot be understood as the value taking  $D_{86}$  as the definition from the description that "D being the diameter of the measurement beam when it impinges on the sample (here the cornea of the eye)" of the Specification, regarding "the diameter D" of "the measurement beam of the diameter D" used in "the device for swept source optical coherence domain reflectometry" of the Invention. Therefore, it is still unclear.

(2) Regarding tuning time  $\tau$

A Notified specific content

In (1) C of Reason 1 for revocation of the notice of reasons for revocation, it is pointed out that

"Regarding ' $\tau$ ' performing the tuning of the light source in the scope of claims, it is merely described as 'tuning time  $\tau$ ' in the Specification, and there is no description relating to a specific definition.

From the description of 'the tuning time of the light source,' the length of a time required for a single wavelength scanning, a period of a part of the single wavelength scanning (for example, a period from the start of increasing a wave number to the end of increasing the wave number, or a period from the start of decreasing the wave number to the end of decreasing the wave number), is assumed but it is not clear which time length is meant, and whether or not the term 'tuning time' is specified as meaning the reciprocal of the sweep rate; that is, the scan rate of the laser wavelength". On the basis of opinions of the Patentee against that, in (1) C of Reason 1 for revocation in the notice of reasons for revocation (advance notice of decision), the following judgment was shown.

"Although the Patentee has explained that 'the tuning time  $\tau$  defines the time for a single tuning of a spectral tuning range  $\Delta k$  (the tuning means tuning in only one direction),' in general, the tuning of a wave number (namely, scanning or sweeping of a wave number) is performed iteratively or periodically, and it is not clearly described whether 'tuning in only one direction' mentioned above means the time of a length of a period from the start of increasing the wave number to the end of increasing the wave number (up sweep), or a period from the start of decreasing the wave number to the end of decreasing the wave

number (down sweep), or another time.

Furthermore, for the pointed out matter that 'it is not clear whether or not the term "tuning time" is specified as meaning the reciprocal of the sweep rate; that is, the scan rate of the laser wavelength,' it is not clarified that 'tuning time' means the reciprocal of the sweep rate; that is, the scan rate of the laser wavelength.

Therefore, the content pointed out above has not been solved, and the definition of 'tuning time  $\tau$ ' is still unclear".

## B The Patentee's allegation

Against the judgment above, the Patentee, in the written opinion, alleges as follows, with the following Evidence B No. 13 attached.

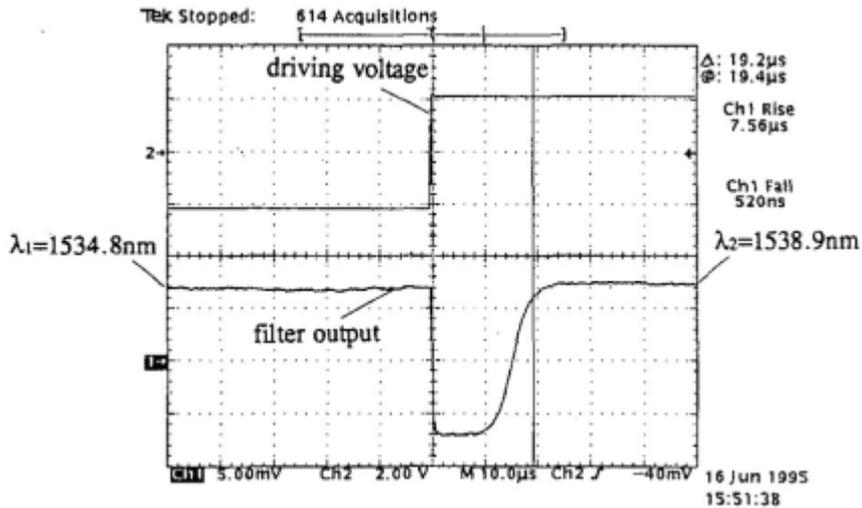
"As a measuring method of tuning time, it is described that 'the wavelength tuning time is measured from the filter response to the step transition of a rectangular driving voltage' in lines 31-33 in the right column on page 90 of Evidence B No. 13. Also, in FIG. 3(b) on page 91 of Evidence B No. 13, it is shown that the switching time (tuning time) from the rise of the rectangular driving voltage to the response of the filter is 19  $\mu$ s. Further, it is clear from other submitted documents that the laser of Evidence B No. 13 can be used as a light source for OCT. Therefore, it is considered clear that the tuning time  $\tau$  means the wavelength switching time (the period from the start of increasing a wave number to the end of increasing the wave number)".

Evidence B No. 13: Yufei Bao, et al., "High-speed liquid crystal fiber Fabry-Perot tunable filter", OFC (Optical Fiber Communication), Technical Digest, 1996, pp.90-91 (hereinafter, referred to as "B13")

## C Judgment

### (A) Regarding B13

B13 describes the following drawing and its explanation as Fig. 3 (b).



"WA1 Fig.3. Two-wavelength switching between 1534.8nm and 1538.9nm by applying  $\pm 63\text{V}$  of 900Hz at  $35^\circ\text{C}$ . Oscilloscope time scale: (a)  $200\mu\text{s}/\text{div}$ , and (b)  $10\mu\text{s}/\text{div}$ . The total switching time is  $19\mu\text{s}$ ."

Then, it is described in lines 12-20 in the left column on page 91 that "To demonstrate the fast wavelength switching of the LC-FFP-TF, two different wavelengths were input to the filter simultaneously, and the tuning time between the two wavelengths was measured. Figure 3 shows a total tuning time of  $19\mu\text{s}$  over 4.3-nm wavelength tuning between 1534.8 nm at  $-2.86\text{ V}/\mu\text{m}$  and 1538.9 nm at  $+2.86\text{ V}/\mu\text{m}$  at  $35^\circ\text{C}$ . The asymmetry in rise and fall responses of the LC-FFP-TF was observed. The rise, delay, and fall times were measured to be  $\sim 7.5\mu\text{s}$ ,  $\sim 12\mu\text{s}$ , and  $\sim 0.5\mu\text{s}$ , respectively."

Although the Patentee explains that "the tuning time  $\tau$  means the wavelength switching time (the period from the start of increasing a wave number to the end of increasing)" on the basis of the description of B13, if it is "the period from the start of increasing a wave number to the end of increasing," it can be also said to be a "rise". Further, if "the wavelength switching time" is "the total switching time" or "the total tuning time," it is the total time of "rise," "delay," and "fall". However, it is unclear which one "the tuning time" refers to.

(B) Regarding other Evidence B

The Patentee also explains the following about the description of the Evidence B other than Evidence B No. 13.

"In Evidence B No. 13, ...a wavelength sweep range is 1250 nm-1360 nm and a sweep repetition rate is 58 kHz, ..., a tuning time is  $1/58000=17\mu\text{s}$ ....

Since Evidence B No. 4 and Evidence B No. 5 describe that...the sweep rate is 58 kHz, ...the tuning time is  $1/58000=17\mu\text{s}$ ...

Since Evidence B No. 6 describes that...the maximum sweep rate is 290 kHz,...the tuning time is  $1/290000=3.4 \mu\text{s}$ ...

Since Evidence B No. 7 describes that...the sweeping time is 40  $\mu\text{s}$ ,...the tuning time is 40  $\mu\text{s}$ ".

With reference to the above description, "the tuning time" is the time of one cycle of sweeping the wavelength sweep range, which is different from any interpretation of (A) above.

### (C) Summary

Accordingly, even with reference to the written opinion, the definition is not decided whether "tuning time  $\tau$ " in the Invention is "rise" time from the start of increasing the wave number to the end of increasing the wave number in FIG. 3(b) above, or is the total time of "rise," "delay," and "fall," or further, is one cycle of sweeping the wavelength sweep range, and the definition of "tuning time  $\tau$ " is still unclear.

### (3) Summary

Therefore, the Patent has been granted on a patent application which does not satisfy the requirement stipulated in Article 36(6)(ii) of the Patent Act, and thus the patents according to Inventions 1-21 fall under Article 113(4) of the Patent Act and should be revoked.

## 2 Regarding Reason 2 for revocation

### (1) Notified specific content

In (1) of Reason 2 for revocation of the notice of reasons for revocation, it is pointed out that

"Although it is specified that 'tuning of the light source is performed in  $\tau < 44 \text{ sec}/(D \times k_0)$  about a centroid wave number  $k_0$ ' in the inventions according to Claims 1 and 7, since in the detailed description of the invention, it is not described under what technical significance the formula ' $44 \text{ sec}/(D \times k_0)$ ' was derived, and how ' $44 \text{ sec}$ ' was obtained, it is not possible to understand the technical significance of the formula ' $44 \text{ sec}/(D \times k_0)$ '." On the basis of opinions of the Patentee against that, in (3) of Reason 2 for revocation in the notice of reasons for revocation (advance notice of decision), the following judgment was shown.

"It was well known for a person skilled in the art at the time of the priority date that sweep speed (scan rate) is increased for increasing the measurement speed of a device for swept source optical coherence domain reflectometry, and if the tuning time  $\tau$  is related to the

reciprocal of the sweep rate (scan rate) (as described in (2) of '1 Regarding Reason 1 for revocation' above, although the definition of the tuning time  $\tau$  is not decided and it is unclear whether or not the premise holds), it is understandable to reduce the adjustment time  $\tau$  in order to increase the measurement speed.

However, concerning the matter that the tuning time  $\tau$  is made to be less than ' $44 \text{ sec}/(D \times k_0)$ ,' since it is not described under what technical significance the formula ' $44 \text{ sec}/(D \times k_0)$ ' was derived, and how ' $44 \text{ sec}$ ' was obtained, it is not possible to understand the technical significance of the formula ' $44 \text{ sec}/(D \times k_0)$ ' as described above.

Against this, although the Patentee explains that 'the tuning time  $\tau < 44 \text{ sec}/(D \times k_0)$  technically significant in that the tuning time of the laser is adapted to a reasonable measurement beam profile of the sample,' the relationship between ' $44 \text{ sec}/(D \times k_0)$ ' and 'being adapted to a reasonable measurement beam profile of the sample' is unclear. That is, it cannot be said that dividing the value of 44 seconds by the product of the measurement beam diameter  $D$  and the centroid wave number  $k_0$  is technically significant in 'being adapted to a reasonable measurement beam profile of the sample'.

## (2) The Patentee's allegation

Against the judgment above, the Patentee, in the written opinion, alleges as follows.

"Tuning of the light source is performed in  $\tau < 44 \text{ sec}/(D \times k_0)$  about a centroid wave number  $k_0$  so that the lateral sample displacements possible during the tuning time of the laser can predominantly amount only to fractions of the smallest possible measurement beam diameter in the sample (it is guaranteed that measurement is performed on the same speckle grain during the tuning time  $\tau$ ), and this means that no laser beam width remains in the eye within the tuning time. Thereby, as described in the specification, the measurement is robust against the usual axial and lateral patient movements, which typically lie in the region of 1 mm/s (see Paragraph [0037] of the Specification). Therefore, the Invention is technically significant in that the lateral sample displacements possible during the tuning time of the laser can predominantly amount only to fractions of the smallest possible measurement beam diameter in the sample (it is guaranteed that measurement is performed on the same speckle grain during the tuning time  $\tau$ ).

Further, although there is no description about the matter that tuning of the light source is performed in  $\tau < 44 \text{ sec}/(D \times k_0)$  about a centroid wave number  $k_0$  so that it is guaranteed that the measurement mentioned above is performed on the same speckle grain during the tuning time  $\tau$ , this is related to that the lateral sample displacements possible during the tuning time of the laser can predominantly amount only to fractions

of the smallest possible measurement beam diameter in the sample, as described in the specification. Then, a means for bringing technical significance; that is, a means (or condition) for meeting the inventor's need to ensure accurate measurements with the unconsciously moving eye (that is, saccade) was derived intuitively by focusing on the measurement diameter (D) and the wavelength ( $k_0$ ) which affect the size of the speckle grains on the basis of experience, knowledge, and understanding related to swept-source optical coherence domain reflectometry measurement using a laser light source of the inventor. As described in Paragraph [0016] of the Specification, the point of consideration that is the basis of 'intuition,' is that it depends on how long the laser tuning time should be whether the lateral sample displacements possible during the tuning time of the laser can predominantly amount only to fractions of the smallest possible measurement beam diameter in the sample (the measurement is unaffected by sample displacement). On the basis of the point of consideration, the inventors made a device having parameters ( $\Delta k=112000 \text{ m}^{-1}$ ,  $D=2 \text{ mm}$ , wavelength  $\lambda=1060 \text{ nm}$ , tuning time  $\tau=500 \text{ }\mu\text{s}$ ) disclosed in the Specification as one embodiment. Furthermore, although speckle grains are not explicitly stated in the Specification, the Specification discloses 'the smallest possible measurement beam diameter in the sample' in the description above, and this actually means that it is close to or equal to the size of the speckle grains. The reason is that the sweep light source OCT uses a non-lateral decomposition detector (that is, speckle grains smaller than the smallest beam diameter in the sample cannot be decomposed by a single detector). Therefore, making measurements with the same speckle grain and ensuring that the lateral sample displacements possible during the tuning time of the laser can predominantly amount only to fractions of the smallest possible measurement beam diameter in the sample are related. Therefore, it is thought that the Specification describes the technical significance of the Patent of ensuring that the lateral sample displacements possible during the tuning time of the laser can predominantly amount only to fractions of the smallest possible measurement beam diameter in the sample, and also describes the matters necessary for understanding the technical significance thereof (that is, the matter that tuning of the light source is performed in  $\tau < 44 \text{ sec}/(D \times k_0)$  about a centroid wave number  $k_0$ , and in the embodiment, the matter that a laser line width of  $\Delta k=112000 \text{ m}^{-1}$ ,  $D=2 \text{ mm}$ , wavelength  $\lambda=1060 \text{ nm}$ , tuning time  $\tau=500 \text{ }\mu\text{s}$ , and  $\delta k < 168 \text{ m}^{-1}$  is  $93 \text{ m}^{-1}$ ,  $81 \text{ m}^{-1}$ ,  $162 \text{ m}^{-1}$ , and  $47 \text{ m}^{-1}$ ."

### (3) Judgment

#### A Regarding $\tau$ and D

As described in "Regarding Reason 1 for revocation" of 1 above, since the

definitions of tuning time  $\tau$  and the measurement beam diameter D are unclear, in the Specification, the technical significance of  $\tau < 44 \text{ sec}/(D \times k_0)$  cannot be clearly understood.

#### B Detailed description of the invention

Although in Article 24-2 of the Regulations under the Patent Act, regarding the detailed description of the invention, it is prescribed that "the description specified by Order of the Ministry of Economy, Trade and Industry in Article 36(4)(i) of the Patent Act must be done by describing the problem to be solved by the invention and solution thereof, and a matter which is necessary for those who have ordinary skill in a field of the technology to understand the technical significance of the invention," in the explanation of the Patentee, the relationship between the speckle grains and the tuning time  $\tau$  is stated, and such a relationship between the speckle grains and the tuning time  $\tau$  is not described at all in the detailed description of the invention of the Specification.

In addition, although in the explanation of the Patentee, it is stated that "the smallest possible measurement beam diameter in the sample' is disclosed, and this actually means that it is close to or equal to the size of the speckle grains," in the Invention, it is specified in Inventions 2 and 8 that "the measurement beam diameter D is smaller than 3 mm". Although it can be said that the "largest" measurement beam diameter is disclosed also in the detailed description of the invention as "it is particularly advantageous for the device for SS-OCDR on the eye when the measurement beam diameter D is smaller than 3 mm in the region of the sample entrance" ([0026]), it cannot be said that the "smallest" measurement beam diameter is disclosed.

Therefore, even if there is some relationship between  $\tau < 44 \text{ sec}/(D \times k_0)$  and speckle grains with respect to the tuning time  $\tau$ , since the detailed description of the invention of the Specification does not describe at all the relationship between the speckle grain and the tuning time  $\tau$ , it cannot be said that the detailed description of the invention of the Specification satisfies the requirement stipulated in Article 24-2 of the Regulations under the Patent Act.

#### C Examination of the formula ( $\tau < 44 \text{ sec}/(D \times k_0)$ )

As described in A above, since the definition of the tuning time  $\tau$  and the measurement beam diameter D is unclear, the technical significance of  $\tau < 44 \text{ sec}/(D \times k_0)$  cannot be clearly understood in the Specification. However, on the basis of common general technical knowledge at the time of the priority date for the Invention, it will be examined for the time being whether or not the technical significance of the formula of  $\tau < 44 \text{ sec}/(D \times k_0)$  can be understood.

It was well known before the priority date that speckle grains are generated when a laser beam is coherent, and for example, in the document (TAKADA, Naoto and others "Diffusing surface one point displacement measurement using the interference of speckle light" Laser research, August in 2004) investigated by the body, it is described that "when the diffusing surface is irradiated with a light wave with excellent coherence such as laser light, light and dark mottled patterns called speckles are observed in the scattered light as a diffraction field and an image as an imaging field formed by an imaging optical system. Assuming that the average size of the light and darkness of the speckle is S, S changes depending on a diameter of a light beam irradiating the diffusing surface and a diameter of a diaphragm on the observation side. This dependence is considered to be equivalent to a formula that gives a diffraction angle of a light wave due to an aperture and the size of a focal point obtained by a focusing lens. When an effective diameter of the focusing lens is D and a focal length is F, a focal diameter 2a of the obtained Gaussian beam has the wavelength of light  $\lambda$ ,

$$\text{it is given by } 2a=4\lambda/\pi\cdot F/D \text{ (1)}$$

Replacing this relationship with the properties of speckle, D corresponds to this size S, 2a corresponds to the diameter of the light beam that irradiates the diffusing surface, and F corresponds to a distance from the diffusion surface to the screen when observing speckle in the diffraction field". (Underlines were given by the body.) In the above Formula (1), since D corresponds to the size S of the speckle grain, the size S of the speckle grain is expressed as  $S=4\lambda/\pi\cdot F/2a$  (hereinafter, referred to as "S-formula").

Comparing the above S-formula with  $44 \text{ sec}/(D\times k_0)$  that is the formula of the Invention, since the definition of D in the formula of the Invention is unclear, it cannot be compared, but even if 2a corresponds to D and  $\lambda$  corresponds to  $2\pi / k_0$ , since the above S-formula has length dimensions, and  $44 \text{ sec}/(D\times k_0)$  of the Invention is multiplied by 44 sec, it has time dimensions.

Then, from the length dimension formula, it is not clear under what technical significance or experiment it was "multiplied by 44 sec" to make it time dimensions.

In this respect, although the Patentee alleges that "was derived intuitively by focusing on the measurement diameter (D) and the wavelength (k0) that affect the size of the speckle grains on the basis of experience, knowledge, and understanding related to swept-source optical coherence domain reflectometry measurement using a laser light source of the inventor," even a person skilled in the art cannot understand that  $\tau<44 \text{ sec}/(D\times k_0)$  is "derived by intuition".

Even if it can be derived from experiments that  $\tau<44 \text{ sec}/(D\times k_0)$ , since the specification does not describe the experimental results (especially for "44 sec") for

deriving the formula, the technical significance of  $\tau < 44 \text{ sec}/(D \times k_0)$  cannot be understood.

#### D Summary

Since the definition of the tuning time  $\tau$  and the measurement beam diameter  $D$  are unclear, the technical significance of  $\tau < 44 \text{ sec}/(D \times k_0)$  cannot be clearly understood in the specification.

The Patentee has described the relationship between the speckle grain and the tuning time  $\tau$ , but it is not described at all in the detailed description of the invention in the specification, and even considering common general technical knowledge at the time of the priority date for the Invention, it cannot be understood that it becomes " $44 \text{ sec}/(D \times k_0)$ ". Therefore, it cannot be said that the detailed description of the invention describes the matters necessary to understand the technical significance of an invention, about the Invention, and it is not described in accordance with the provisions of Order of the Ministry of Economy, Trade and Industry (Article 24-2 of the Regulations under the Patent Act) delegated by Article 36(4)(i) of the Patent Act.

#### (4) Summary

Therefore, the Patent has been granted on a patent application whose the detailed description of the invention does not satisfy the requirement stipulated in Article 36(4)(i) of the Patent Act, and thus the patents according to Inventions 1-21 fall under Article 113(2) of the Patent Act and should be revoked.

### 3 Regarding Reason 4 for revocation

In view of the case, Reason 4 for revocation is examined first.

#### (1) Notified specific content

In Reason 4 for revocation of the notice of reasons for revocation, it is pointed out that

"The Specification does not describe the embodiment in which an A-scan was actually performed on a human eye using a light source in which  $\delta k$  is less than  $168 \text{ m}^{-1}$ , further less than  $93 \text{ m}^{-1}$ ,  $81 \text{ m}^{-1}$ ,  $47 \text{ m}^{-1}$ ,  $\tau$  is less than  $44 \text{ sec}/(D \times k_0)$ ,  $\Delta k$  is  $18000 \text{ m}^{-1}$  or more, and a wavelength is  $600 \text{ nm}$  to  $1150 \text{ nm}$ , and there is no ground that such a light sources could be normally used by a person skilled in the art at the time of the priority date. Thus, the detailed description of the invention is not clear and sufficient to enable a person skilled in the art to carry out the inventions according to Claims 1 and 7.

Further, on page 21106, the lowermost line to page 21107, line 2 of Evidence A No. 2, it is shown that 'In general as lasers move to higher sweep speeds there is an

increase in instantaneous line width, and a decrease in coherence length resulting in reduced measurement depth,' which means that the sweep speeds and an instantaneous line width ( $\delta k$ ) are in a trade-off relationship. Thus, making  $\delta k$  'less than  $168 \text{ m}^{-1}$ , further less than  $93 \text{ m}^{-1}$ ,  $81 \text{ m}^{-1}$ ,  $47 \text{ m}^{-1}$ ,' and making  $\tau$  'less than  $44 \text{ sec}/(D \times k_0)$ ' if the tuning time  $\tau$  of the Invention (as described in (2) of Reason 1 for revocation, the definition of the tuning time  $\tau$  is unclear) corresponds to the reciprocal to the sweep rate, both specify that both should be small, so that it can be said that it is difficult to realize".

Evidence A No. 2: Changho Chong, et al., "Spectral narrowing effect by quasi-phase continuous tuning in high-speed wavelength-swept light source", Optical Society of America, Optics Express, Vol. 16, No. 25, December 8, 2008, pp. 21105-21118  
Against that, the Patentee submitted the following experimental report as Evidence B No. 2 (hereinafter, referred to as "B2").

## Experimental Report

1. Date of the experiment: June 4th, 2008
2. Place of the experiment: CARL ZEISS MEDITEC AG, Germany, 07745 Jena, Göschwitzer Str. 51/52, Laboratory for Biometry
3. Person who conduct the experiment: Ralf Ebersbach, engineer for software and electronics design
4. Objectives of the experiment  
To confirm that the device later described in the embodiment of Japanese Patent No. 6523349 provide a laser line width  $\delta k$  within the range  $22 \text{ m}^{-1}$  to  $50 \text{ m}^{-1}$ .

### 5. Details of the experiment

The swept laser module (model number s3-1060, serial number SSA8AT) manufactured by Micron Optics, Inc., 1852 Century Place, N.E., Atlanta, GA 30345 USA, according to the specifications ordered by Carl Zeiss Meditec AG was tested. The purpose of the test was to measure laser spectral line width. The test method was measurement of laser fringe amplitude fall off at output of an interferometer with adjustable optical path difference.

### 6. Results of the experiment

Laser fringes amplitudes at output of an interferometer were measured at multiple positions in the range 0mm to 100mm optical path difference. Within the fringe amplitude fall-off curve obtained from these measurements the point with 50% amplitude compared to the maximum is searched. With this result and with the center wavelength of the laser of 1060nm, the laser spectral line width  $\delta\lambda$  can be calculated to be 8.26pm (refer to Annex 1 below). One can also calculate the laser line width  $\delta k$  in terms of wave number to be  $46 \text{ m}^{-1}$  ( $\delta k = 2\pi/\lambda^2 \cdot \delta\lambda = 2\pi/(1060\text{nm})^2 \cdot 0.0826\text{nm}$ ) if the spectral line width  $\delta\lambda$  is 8.26 pm (0.0826 nm).

Thus, it was confirmed that the tested device is within the range of the laser line width  $\delta k$  of  $22 \text{ m}^{-1}$  to  $50 \text{ m}^{-1}$  as later described in the embodiment of Japanese Patent No. 6523349.

Dated this 13th day of May, 2020



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(Signature)	Name:	Ralf Ebersbach
	Title:	R&D Systems Engineering, Zeiss Ophthalmic Devices Zeiss Expert Ladder - Senior

**Annex 1: How to calculate spectral line width from fringe amplitude fall off data.**

The coherence length of a laser limits the depth range for OCT measurements because OCT technology uses interference between coherent light beams to achieve high sensitivity. It is therefore reasonable to define the coherence length as the optical path length differences in the interferometer for which fringe amplitude changes down to 50% (or by -3dB) relative to maximum amplitude. It is important to note, that the distance between both -3dB-Points of the sensitivity fall-off curve is the coherence length ( $s>0$  and  $s<0$  or in other words both FWHM points).

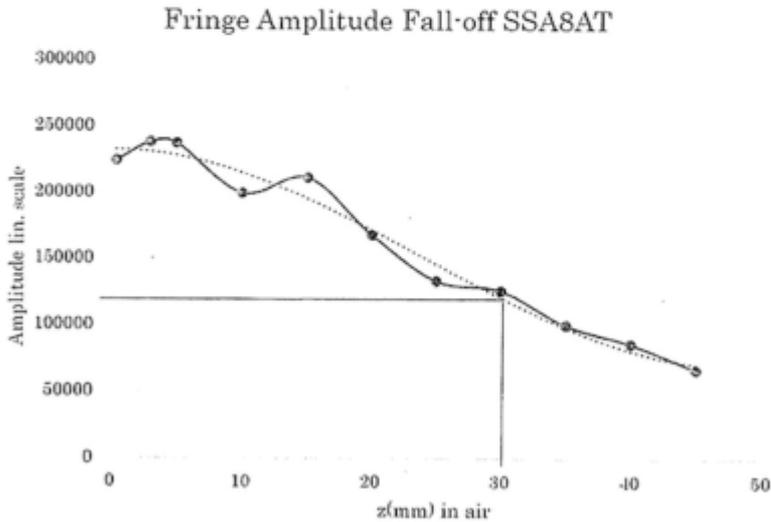
Since backscattered light travels twice through the samples it is common to use depth  $z = s/2$  instead of optical path differences. Then the so-called round-trip coherence length  $l_c$  is related to the laser spectral line width  $\Delta\lambda$  by this equation (Fercher et al. Rep. Prog. Phys. 66 (2003), page 268, equation 4.9)

$$l_c = \frac{2 \ln 2 \bar{\lambda}^2}{\pi \Delta\lambda}$$

and therefore, the spectral line width can be calculated with

$$\Delta\lambda = \frac{2 \ln 2 \bar{\lambda}^2}{\pi l_c}$$

with  $\bar{\lambda}$  the central wavelength of the laser and  $\Delta\lambda$  the spectral line width as named by Fercher (that corresponds to  $\delta\lambda$  in the language of Japanese Patent No. 6523349).



In detail, changing the depth position  $z$  of a mirror in the interferometer sample arm from DC to 30mm/air causes a change in fringe amplitudes from 0 to -3dB (24000 to 12000DN). The distance of both -3dB reflector positions would be the round-trip coherence length  $l_c=60$ mm. That corresponds to a laser spectral line width of 8.26pm with laser central wavelength of 1060nm.

Then, on the basis of opinions of the Patentee against that, the following judgment was shown as Reason 4 for revocation in the notice of reasons for revocation (advance notice of decision).

A Regarding a light source in which  $\delta k$  is  $46 \text{ m}^{-1}$

(A) In "5. Details of the experiment" and "6. Results of the experiment" of B2, with reference to the translation submitted by the Patentee, it is described as follows.

"5. Details of the experiment

The swept laser module (model number s3-1060, serial number SSA8AT)

manufactured by Micron Optics, Inc., 1852 Century Place, N.E., Atlanta, GA 30345 USA, according to the specifications ordered by Carl Zeiss Meditec AG was tested. The purpose of the test was to measure laser spectral line width. The test method was measurement of laser fringe amplitude fall off at output of an interferometer with adjustable optical path difference.

## 6. Results of the experiment

Laser fringes amplitudes at output of an interferometer were measured at multiple positions in the range 0mm to 100mm optical path difference. Within the fringe amplitude fall-off curve obtained from these measurements the point with 50% amplitude compared to the maximum is searched. With this result and with the center wavelength of the laser of 1060nm, the laser spectral line width  $\delta\lambda$  can be calculated to be 8.26pm (refer to Annex I below). One can also calculate the laser line width  $\delta\lambda$  in terms of wave number to be  $46 \text{ m}^{-1}$  ( $\delta k = 2\pi/\lambda^2 \cdot \delta\lambda = 2\pi/(1060 \text{ nm})^2 \cdot 0.0826 \text{ nm}$ ) if the spectral line width  $\delta\lambda$  is 8.26pm(0.0826nm)." (Underlines were given by the body)

(B) Referring to this, since the light source in which the laser line width  $\delta k$  can be calculated to be  $46 \text{ m}^{-1}$  is "a sweep laser module manufactured by Micron Optics according to specifications ordered by Carl Zeiss Meditec Akchen Gezel Shaft (hereinafter, referred to as 'Carl Zeiss')" for the purpose of the "test," even if the light source in which the laser line width  $\delta k$  can be calculated to be  $46 \text{ m}^{-1}$  is a special one manufactured by Micron Optics as a so-called prototype under the order of Carl Zeiss, it is not possible to confirm that a person skilled in the art could normally obtain it as a commercial product, etc. at the time of the priority date.

Further, referring to the specification, since no specific method of manufacturing the special light source in which the laser line width  $\delta k$  is  $46 \text{ m}^{-1}$  is described, even if a person skilled in the art refers to the specification, the laser line width  $\delta k$  is  $46 \text{ m}^{-1}$  cannot be manufactured and cannot normally be obtained.

Therefore, since "the light source in which the laser line width  $\delta k$  can be calculated to be  $46 \text{ m}^{-1}$ " described in the experimental report was not normally available to a person skilled in the art at the time of the priority date, it cannot be determined that "the tunable laser light source" of the Invention was normally available to a person skilled in the art at the time of the priority date.

### (C) Summary

Therefore, since "the tunable laser light source" of the Invention was normally available to a person skilled in the art at the time of the priority date, it cannot be said that a person skilled in the art can make "a device for swept source optical coherence domain

reflectometry" "having" that, and can use the device, and it cannot be said that the detailed description of the invention is not clear and sufficient to enable a person skilled in the art to carry out the Invention.

B Regarding the light source in which  $\delta k$  is 22-50  $m^{-1}$

(A) In "6. Results of the experiment" of B2, it is also described that "accordingly, it was confirmed that the device tested was within a laser line width  $\delta k$  of 22  $m^{-1}$  to 50  $m^{-1}$ , as described in the embodiment of Japanese Patent No. 6523349".

(B) However, only "the light source in which the laser line width  $\delta k$  can be calculated to be 46  $m^{-1}$ " is described, but it is described that a sweep laser module "within a laser line width  $\delta k$  of 22  $m^{-1}$  to 50  $m^{-1}$ " was manufactured. Also, at the time of the priority date, there was no common general technical knowledge that if a light source in which line width  $\delta k$  can be calculated to be 46  $m^{-1}$  can be manufactured, a light source in which a laser line width  $\delta k$  can be calculated to be "less than 22-46"  $m^{-1}$  can also be manufactured.

Thus, even if "the light source in which the laser line width  $\delta k$  can be calculated to be 46  $m^{-1}$ " was normally available to a person skilled in the art at the time of the priority date (as mentioned in A above, it was not available), it cannot be determined that a light source in which a laser line width  $\delta k$  can be calculated to be "less than 22-46"  $m^{-1}$  was normally available to a person skilled in the art at the time of the priority date.

(C) Summary

Therefore, since "the tunable laser light source" of the Invention including a laser line width of "less than 22- 46"  $m^{-1}$  was not normally available to a person skilled in the art at the time of the priority date, it cannot be said that a person skilled in the art can make "a device for swept source optical coherence domain reflectometry" "having" that, and can use the device, and it cannot be said that the detailed description of the invention is not clear and sufficient to enable a person skilled in the art to carry out the Invention.

C Regarding variables other than  $\delta k$

(A) Although "the tunable laser light source" of the Invention is specified to satisfy " $\tau < 44 \text{ sec}/(D \times k_0)$ " and " $\Delta k > 18000 \text{ m}^{-1}$ " in addition to  $\delta k$ , since the experimental report of Evidence B No. 2 does not describe the values of " $\tau$ ," "D," " $k_0$ ," and " $\Delta k$ ," it is unclear under what values the laser line width  $\delta k$  became 46  $m^{-1}$ .

Especially, as described above, if the tuning time  $\tau$  of the Invention corresponds to the reciprocal of the sweep rate, the sweep rate ( $\tau$ ) and the instantaneous line width ( $\delta k$ ) are in a trade-off relationship, so that considering that  $\delta k$  is a fairly small value of 46  $m^{-1}$ , there is no ground for determining that  $\tau$  is "less than 44  $\text{sec}/(D \times k_0)$ ".

Accordingly, in the experimental report of B2, it is not shown that "the light source

in which the laser line width  $\delta k$  can be calculated to be  $46 \text{ m}^{-1}$  satisfies " $\tau < 44 \text{ sec}/(D \times k_0)$ " and " $\Delta k > 18000 \text{ m}^{-1}$ ," and even if "the light source in which the laser line width  $\delta k$  can be calculated to be  $46 \text{ m}^{-1}$ " was normally available to a person skilled in the art at the time of the priority date (as mentioned in A above, it was not available), it cannot be said that a tunable laser light source simultaneously satisfying " $\tau < 44 \text{ sec}/(D \times k_0)$ " and " $\Delta k > 18000 \text{ m}^{-1}$ " was normally available.

(B) Summary

Therefore, even if  $\delta k$  satisfies the scope specified in the Invention, since "the tunable laser light source" of the Invention was normally available to a person skilled in the art at the time of the priority date in the point of " $\tau < 44 \text{ sec}/(D \times k_0)$ " and " $\Delta k > 18000 \text{ m}^{-1}$ ," it cannot be said that a person skilled in the art can make "a device for swept source optical coherence domain reflectometry" "having" that, and can use the device, and it cannot be said that the detailed description of the invention is not clear and sufficient to enable a person skilled in the art to carry out the Invention.

D Relationship between the detailed description of the experimental report

As described in A-C above, the experimental report of Evidence B No. 2 does not support that "the tunable laser light source" of the Invention was normally available to a person skilled in the art at the time of the priority date, and thus the experimental report of Evidence B No. 2 cannot make up for the lack of the detailed description of the invention in the Specification.

(2) The Patentee's allegation

A Against the judgment of (1) A and B above, with the following Evidence B No. 3 to Evidence B No. 7 attached, the Patentee states in the written opinion that "there is a large number of documents describing SS laser light sources that satisfy various laser line widths and various tuning times in sweep light source technology. These documents are attached as Evidence B No. 3 to Evidence B No. 7".

Further, with the following Evidence B No. 8 attached, the Patentee states that "Furthermore, the publication from Medical Device Online News is presented here as Evidence B No. 8. This is a regular newsletter that provides an overview of participants in relevant markets as manufacturers and suppliers. Here, Micron Optics is listed as 'a source and a part supplier'. The list of these suppliers is clear with 11 manufacturers and does not require any ingenuity to contact all 11 companies for laser light sources as needed. In particular, adopting Micron Optics as a supplier was a professional task".

Furthermore, with the following Evidence B No. 9 to Evidence B No. 16 attached,

the Patentee states that

"Micron Optics is well known in the field of SS laser light sources through numerous publications in the field. It's not a matter of knowing the details of the scientific publication, but such knowledge is due to the fact that Kevin Hsu, as an employee of Micron Optics, regularly publishes articles in the field of SS laser light sources. Documents published by Kevin Hsu, an employee of Micron Optics, regarding SS laser light sources and documents related to technology using SS laser light sources by Kevin Hsu are attached as Evidence B No. 9 to Evidence B No. 16. These documents demonstrate that Micron Optics or its employees are developing lasers that have a very strong presence in the field and have short tuning times".

Then, comprehensively considering Evidence B No. 3 to Evidence B No. 16, the Patentee alleges that

"therefore, a person skilled in the art presents many sweep light sources with various line widths and various tuning times available, and at least one system as an available example that satisfies the conditions of the light source of the Patent, and can ask any light source supplier whether or not the light source supplier can satisfy the conditions of the light source of the Invention. Then, when there are multiple sweep light source suppliers specializing in light sources for high-speed, short-range imaging, and the suppliers have obtained an opportunity to realize the Patent regarding the measurement of eye length, a person skilled in the art who understood the specification may be able to find out at least one supplier (for example, Micron Optics). However, I think that any other manufacturer that specializes in the measurement of eye length even if it is not short-range and high-speed imaging, and corresponds to wavelengths suitable for the eye, has a potential to provide a light source that satisfies the conditions of the Patent.

Therefore, it can be understood that a person skilled in the art can decide specifications and request a manufacturer with the specifications to obtain a prototype of the SS laser light source, from 'fiber ring laser' described as being particularly suitable for implementation, for example, based on the common general technical knowledge at the time of filing such as Evidence B No. 3 to Evidence B No. 16".

B Against the judgment of (1) C above, the Patentee, in the written opinion, alleges that "a light source with  $\tau$  less than  $44 \text{ sec}/(D \times k_0)$  and having a laser line width of  $\delta k < 168 \text{ m}^{-1}$  or in which  $\delta k$  is  $46 \text{ m}^{-1}$  as described in the experimental report (Evidence B No. 2) could be implemented at the time of priority, and it is considered that it could be implemented that a specific value of 'a frequency of  $\Delta k / (\tau \times \delta k)$ ,' that is 'a value obtained by dividing the tuning rate  $\Delta k / \tau$  by the laser line width  $\delta k$  is greater than 18 kHz' and

'smaller than 40 MHz,' and that 'the bandwidth of the at least one receiver is greater than  $2 \times \Delta k / (\tau \times \delta k)$  and less than 80 MHz'.

Further, the light source having the laser line in which  $\delta k$  is  $46 \text{ m}^{-1}$  could implement the matter that 'a ratio of a tuning range  $\Delta k$  and the laser line width  $\delta k$  is greater than 360' at a test level, and was normally available to a person skilled in the art at the time of the priority date. Thus, it is considered that the matter that 'a ratio of a tuning range  $\Delta k$  and the laser line width  $\delta k$  is greater than 360' can be implemented".

#### C Evidence B attached

Evidence B No. 3: United States Patent No. 7414779 Specification

Evidence B No. 4: R. Huber, et al., "Fourier Domain Mode Locked Lasers for OCT imaging at up to 290 kHz sweep rates", Optical Society of America, 2005

Evidence B No. 5: R. Huber, et al., "OCT imaging at up to 290 kHz sweep rates", SPIE-OSA, Vol. 5861, 2005, pp. 58611B-1 to 58611B-6

Evidence B No. 6: R. Huber r, et al., "Fourier Domain Mode Locked Lasers for Swept Source OCT Imaging at up to 290 kHz Scan Rates", Proc. of SPIE, Vol. 6079, 2006, pp. 60790U-1 to 60790U-6

Evidence B No. 7: United States Patent Application Publication No. 2007/0013917 Specification

Evidence B No. 8: "Optical Coherence Tomography Market to Top \$800 Million By 2012", January 14, 2008, [online], MED DEVICE ONLINE, [searched on October 22, 2020], URL: <https://www.meddeviceonline.com/doc/optical-coherence-tomography-market-to-top-80-0001>

Evidence B No. 9: R. Huber, et al., "Amplified, frequency swept lasers for frequency domain reflectometry and OCT imaging: design and scaling principles", OPTICS EXPRESS, Vol. 13, No. 9, May 2, 2005, pp. 3513-3528

Evidence B No. 10: Sanjay Asrani, MD, et al., "Detailed Visualization of the Anterior Segment Using Fourier-Domain Optical Coherence Tomography", NIH Public Access, American Medical Association, June 2008

Evidence B No. 11: L. Dong, et al., "Efficient Single-frequency Fibre Lasers with Novel Photosensitive Er/Yb Optical Fibers", Optoelectronics Research Centre University of Southampton

Evidence B No. 12: S. Yamashita, et al., "Single-frequency, single-polarization operation of tunable miniature erbium: ytterbium fiber Fabry-Perot lasers by use of self-injection locking", OPTICS LETTERS, Vol. 23, No. 15, Optical Society of America, August 1, 1998, pp. 1200-1202

Evidence B No. 13 (reproduced): Yufei Bao, et al., "High-speed liquid crystal fiber Fabry-Perot tunable filter", OFC (Optical Fiber Communication), Technical Digest, 1996, pp. 90-91

Evidence B No. 14: Jun Zhang, et al., "Full range polarization-sensitive Fourier domain optical coherence tomography", OPTICS LETTERS, Vol. 12, No. 24, Optical Society of America, November 29, 2004, pp. 6033-6039

Evidence B No. 15: Michael A. Choma, et al., "Swept source optical coherence tomography using an all-fiber 1300-nm ring laser source", Journal of Biomedical Optics 10(4), July/August 2005, pp. 044009-1 to 044009-6

Evidence B No. 16: Jun Zhang, et al., "Swept laser source at 1  $\mu\text{m}$  for Fourier domain optical coherence tomography", APPLIED PHYSICS LETTERS 89, American Institute of Physics, 2006, pp. 073901-1 to 073901-3

(Hereinafter, "Evidence B No. 3 to "Evidence B No. 16" are referred to as "B3" to "B16".)

### (3) Judgment

A Regarding the light source in which  $\delta k$  is  $46 \text{ m}^{-1}$

(A) Regarding B3-B7

a Regarding B3

In lines 12-17 of column 6 of B3, it is described that "The aspects and embodiments of the invention disclosed herein relate to frequency swept; i.e., time varying wave sources. In particular, a frequency swept laser source is a wave source that changes the frequency or wavelength over time as a periodic function  $f(t)$ , such as those depicted in FIGS. 1a-c", and in lines 15-18 of column 10 thereof, it is described that "Additional dispersion management is not necessary because the zero dispersion point of the fiber is at 1313 nm. Such a system operates with a wavelength sweep range between 1250 nm and 1360 nm". The wavelength of the laser light source of B3 is 1250 nm-1360 nm, and is different from the light source having "a wavelength of 600 nm-1150 nm" of the Invention.

b Regarding B4-B6

B4-B6 are documents written by the same author and having the same title and the same drawings, in which almost the same sentences are described and the disclosed technical contents are the same.

In Introduction of B4, it is described that

"The development of high speed, frequency swept laser sources with narrow dynamic linewidths (long instantaneous coherence lengths) is crucial for swept source OCT. [1-7] OCT using swept source / Fourier domain detection [4,8-11] enables increased

sensitivity and imaging speeds compared to time domain techniques [12]. In this paper, we demonstrate the new technique called "Fourier Domain Mode Locking" (FDML) for designing high speed, frequency swept lasers, which overcomes many of the limitations of standard laser designs. FDML achieves a quasi-stationary operating regime of the laser, enables superior performance in linewidth, sweep speed, and output power. Record frequency sweep speeds of up to 290 kHz, with a tuning range of 145 nm at 1300 nm are demonstrated. Output powers up to 35 mW are obtained directly from the laser without amplification. The instantaneous linewidth was estimated to be  $< 0.01$  nm by measuring the instantaneous coherence length. OCT imaging is demonstrated with the FDML laser at a sweep rate of 58 kHz."

In Introduction of B5, it is described that

"The development of high speed, frequency swept laser sources with narrow dynamic linewidths (long instantaneous coherence lengths) has widespread applications from high speed spectroscopy, sensing, and metrology applications [1-4] as well as more recently for swept source OCT. [5-14] OCT using swept source / Fourier domain detection [9,15-18] enables increased sensitivity and imaging speeds compared to time domain techniques [19] and therefore opens new applications and acquisition protocols. [20-25] In this paper, we demonstrate the new technique "Fourier Domain Mode Locking" (FDML) for designing high speed, frequency swept lasers, which overcomes many of the limitations of standard laser designs. FDML achieves a quasi-stationary operating regime of the laser and enables superior performance in linewidth, sweep speed, and output power. Record frequency sweep speeds of up to 290 kHz, with a tuning range of 145 nm at 1300 nm are demonstrated. Output powers up to 35 mW are obtained directly from the laser without amplification. The instantaneous linewidth was estimated to be as small as 0.01 nm by measuring the instantaneous coherence length. OCT imaging is demonstrated with the FDML laser at a sweep rate of 58 kHz."

In Abstract of B6, it is described that

"A new type of laser operation, Fourier Domain Mode Locking (FDML), is demonstrated for high performance, frequency swept light sources. FDML achieves superior sweep speeds, coherence lengths, and bandwidths compared to standard bulk or fiber lasers. At 1300 nm a sweep range up to 145 nm, up to 4 cm delay length, and sweep rates up to 290kHz were achieved. This light source is demonstrated for swept source OCT imaging."

Therefore, the wavelengths of the laser light sources of B4-B6 are those within a tuning (sweep) range of 145 nm at 1300 nm; that is, 1155 to 1445 nm, and are different from the light source having "a wavelength of 600 nm-1150 nm" of the Invention.

c Regarding B7

In B7, regarding the wavelength, it is merely described in [0009] that "A 40 nm wavelength range at 1550 nm center wavelength corresponds to a distance resolution of about 25  $\mu\text{m}$ .", in [0029] that "Due to the limited number of detectors (typically at most 2048) in any array based spectrometer, the resolution is usually not better than roughly 0.05 nm, giving a maximum measurement depth of 12 mm for a center wavelength of 1550 nm." This is different from the light source having "a wavelength of 600 nm-1150 nm" of the Invention.

The Patentee, in the written opinion, explains that "when 0.1 GHz is converted to wavelength, it becomes 2.998m" (it is not clear what kind of conversion was done), from the description of [0033] that "For example, the line width may be as narrow as 0.1 GHz, approximately corresponding to a coherence length of 2 m." However, the wavelength of "2,998 m" is quite different from "a wavelength of 600 nm-1150 nm" of the Invention.

d Summary of B3-B7

Then, the light sources of B3-B7 are different from "the light source" "having a wavelength of 600 nm to 1150 nm" of the Invention on that premise.

In addition, since B3-B7 do not specify the measurement beam diameter  $D$ ,  $44 \text{ sec}/(D \times k_0)$  cannot be calculated, and even if it can be calculated, as described in (1) of Reason 1 for revocation, the definition of the tuning time  $\tau$  and the measurement beam diameter  $D$  is unclear, so that it is unclear whether or not the condition of " $\tau < 44 \text{ sec}/(D \times k_0)$ " under the Invention is satisfied.

Then, although B3-B7 may correspond to the documents in the explanation by the Patentee that "there is a large number of documents describing SS laser light sources that satisfy various laser line widths and various tuning times in sweep light source technology," it is not ground for determining whether or not "the tunable laser light source" of the Invention was normally available to a person skilled in the art at the time of the priority date.

(B) Regarding B8

B8 was issued before the priority date of the Invention, and in lines 21-28 thereof, it is described that

"At least 18 companies are actively developing and/or manufacturing OCT systems, with many more supplying the key optical sources, detectors, and related photonics components that enable the various OCT products and applications. As this technology

continues to penetrate new markets, opportunities exist for photonics companies in optical sources, detection, and delivery systems. OCT systems manufacturers profiled in the report include Carl Zeiss Meditec, Heidelberg Engineering, OPKO (Ophthalmic Technologies), Optopol, Optovue, Topcon Medical Systems, Biotigen, GlucoLight, Fox Hollow (ev3), Lightlab Imaging, Lantis Laser, Michelson Diagnostics, Glucolight, Tomophase, Santec, Thorlabs, Volcano/CardioSpectra, and Imalux. Source and components providers are also profiled, including Cambridge Technology, Denselight, Exalos, Femtolasers, Goodrich, Inphenix, Micron Optics, Multiwave Photonics, NP Photonics, Optiphase, and Superlum."

Referring to this, 18 companies are listed as OCT systems manufacturers, and 11 companies are listed as source and component providers, and as one of the 11 companies, Micron Optics, which manufactured the sweep laser module according to the specifications ordered by the Patentee, is merely listed. From B8, it is not possible to confirm that "the tunable laser light source" of the Invention was normally available to a person skilled in the art as "a commercial product, etc." at the time of the priority date.

(C) Regarding B9-B16

a Regarding the description of Evidence B

(a) B9 is a document entitled "Amplified, frequency swept lasers for frequency domain reflectometry and OCT imaging: design and scaling principles" which was issued before the priority date of the Invention, and K. Hsu (Micron Optics Inc.) is mentioned as one of the authors.

(b) B10 is a document entitled "Detailed Visualization of the Anterior Segment Using Fourier-Domain Optical Coherence Tomography" which was issued before the priority date of the Invention, and in a lower margin note on page 1, it is described that "Additional Contribution: Kevin Hsu, PhD, MicronOptics Inc. loaned the high-speed swept laser source, and biotigen Inc. supplied the base software package for acquisition and display."

(c) B11 is a document entitled "Efficient Single-frequency Fibre Lasers with Novel Photosensitive Er/Yb Optical Fibers" whose issue date is unknown, and K. Hsu (Micron Optics Inc.) is mentioned as one of the authors.

(d) B12 is a document entitled "Single-frequency, single-polarization operation of tunable miniature erbium: ytterbium fiber Fabry-Perot lasers by use of self-injection locking"

which was issued before the priority date of the Invention, and K. Hsu (Micron Optics Inc.) is mentioned as one of the authors.

(e) B13 is a document entitled "High-speed liquid crystal fiber Fabry-Perot tunable filter" which was issued before the priority date of the Invention, and K. Hsu (Micron Optics Inc.) is mentioned as one of the authors.

(f) B14 is a document entitled "Full range polarization-sensitive Fourier domain optical coherence tomography" which was issued before the priority date of the Invention, and in "Acknowledgments" on page 6039, it is described that "Loan of the 1.31  $\mu\text{m}$  swept source from Micron Optics, Inc. and discussions with Kevin Hsu are also gratefully acknowledged."

(g) B15 is a document entitled "Swept source optical coherence tomography using an all-fiber 1300 nm ring laser source" which was issued before the priority date of the Invention, and Kevin Hsu (Micron Optics, Incorporated) is mentioned as one of the authors.

(h) B16 is a document entitled "Swept laser source at 1  $\mu\text{m}$  for Fourier domain optical coherence tomography," and Kevin Hsu (Micron Optics Inc.) is mentioned as one of the authors.

b Facts that can be grasped

From the descriptions of B9, B10 and B12-B16, the following matters can be grasped as facts at the time of the priority date of the Invention.

Kevin Hsu is a member of Micron Optics Inc. and was involved in the development of sweep laser light sources. In particular, from the description of B14 that "discussions with Kevin Hsu are also gratefully acknowledged," it can be said that he is a person who has extremely specialized knowledge about the technology related to the sweep laser light source.

c Judgment

As described in the experimental report of B2, although it is true that Micron Optics Inc. is a company that manufactures sweep laser modules according to the specifications ordered by the Patentee, and that Kevin Hsu, who has extremely specialized knowledge of the technology related to sweep laser light sources, belonged to the company, it is not possible to confirm that "the tunable laser light source" of the Invention

was normally available to a person skilled in the art as "a commercial product, etc." at the time of the priority date, with this matter.

(D) Comprehensive judgment

As described in (A)-(C) above, it is not able to confirm that "the tunable laser light source" of the Invention was normally available to a person skilled in the art as "a commercial product, etc." at the time of the priority date, with B3-B16.

Rather, from the descriptions of B9-B16, even if "the tunable laser light source" of the Invention is manufactured as "a sweep laser module (model number s3-1060, serial number SSA8AT)" in the experimental report of B2, it confirms that it can only be manufactured by someone with extremely specialized knowledge of SS light sources, such as Kevin Hsu. Therefore, it cannot be said that a person in the art who had ordinary knowledge in the field and was not required to have extremely specialized knowledge at the time of the priority date of this case could have manufactured "the tunable laser light source" of the Invention, without requiring more trial and error than expected, complicated and advanced experiments, etc.

Although the Patentee alleges that "it can be understood that a person skilled in the art can decide specifications and request a manufacturer with the specifications to obtain a prototype of the SS laser light source, based on the common general technical knowledge at the time of filing such as Evidence B No. 3 to Evidence B No. 16," it cannot be said that "the prototype" is on the market, and it cannot be said that "the prototype" that can be manufactured only by a person who has extremely specialized knowledge about SS light sources was normally available to a person skilled in the art by deciding the specifications and requesting a manufacturer with the specifications".

(E) Summary

Therefore, even if the experimental report of B2 describes "the light source in which the laser line width  $\delta k$  can be calculated to be  $46 \text{ m}^{-1}$ ," "the tunable laser light source" of the Invention was normally available to a person skilled in the art at the time of the priority date, so that it cannot be said that a person skilled in the art can make "a device for swept source optical coherence domain reflectometry" "having" that, and can use the device, and it cannot be said that the detailed description of the invention is clear and sufficient to enable a person skilled in the art to carry out Inventions 1 and 7.

B Regarding the light source in which  $\delta k$  is  $22\text{-}50 \text{ m}^{-1}$

Against the indication that "even if 'the light source in which the laser line width

$\delta k$  can be calculated to be  $46 \text{ m}^{-1}$  was normally available to a person skilled in the art at the time of the priority date (as mentioned in A above, it was not available), it cannot be determined that a light source in which a laser line width  $\delta k$  can be calculated to be 'less than  $22\text{-}46 \text{ m}^{-1}$  was normally available to a person skilled in the art at the time of the priority date" in (1) B above, the Patentee has only made an allegation to (1) A above, and has not specifically argued about a light source whose laser line width  $\delta k$  can be calculated to be "22 to less than  $46 \text{ m}^{-1}$ ."

Therefore, since "the tunable laser light source" of the Invention including a laser line width of "22 to less than  $46 \text{ m}^{-1}$  was not normally available to a person skilled in the art at the time of the priority date, it cannot be said that a person skilled in the art can make "a device for swept source optical coherence domain reflectometry" "having" that, and can use the device, and it cannot be said that the detailed description of the invention is clear and sufficient to enable a person skilled in the art to carry out the Invention.

#### C Regarding variables other than $\delta k$

As described in (2) B above, the Patentee merely states "...it is considered that it could be implemented...it is considered that...," and has not argued with concrete grounds.

Therefore, as described in (1) above, even if "the light source in which the laser line width  $\delta k$  can be calculated to be  $46 \text{ m}^{-1}$ " was normally available to a person skilled in the art at the time of the priority date (as mentioned in A above, it was not available), it cannot be said that a tunable laser light source simultaneously satisfying " $\tau < 44 \text{ sec}/(D \times k_0)$ " and " $\Delta k > 18000 \text{ m}^{-1}$ " was normally available.

Therefore, even if  $\delta k$  satisfies the scope specified in the Invention, since "the tunable laser light source" of the Invention was not normally available to a person skilled in the art at the time of the priority date in the point of " $\tau < 44 \text{ sec}/(D \times k_0)$ " and " $\Delta k > 18000 \text{ m}^{-1}$ ," it cannot be said that a person skilled in the art can make "a device for swept source optical coherence domain reflectometry" "having" that, and can use the device, and it cannot be said that the detailed description of the invention is clear and sufficient to enable a person skilled in the art to carry out Inventions 1 and 7.

#### D Relationship between the detailed description of the experimental report

As described in A-C above, B3-B16 do not support that "the tunable laser light source" of the Invention was normally available to a person skilled in the art at the time of the priority date, and thus the experimental report of B2 cannot make up for the lack of the detailed description of the invention in the Specification.

## E Summary

As described in A-D, since "the tunable laser light source" of the Invention was not normally available to a person skilled in the art at the time of the priority date, it cannot be said that a person skilled in the art can make "a device for swept source optical coherence domain reflectometry" "having" that, and can use the device, and it cannot be said that the detailed description of the invention is clear and sufficient to enable a person skilled in the art to carry out Invention.

Therefore, the Patent has been granted on a patent application whose the detailed description of the invention does not satisfy the requirement stipulated in Article 36(4)(i) of the Patent Act, and thus the patents according to Inventions 1-21 fall under Article 113(4) of the Patent Act and should be revoked.

### 4 Regarding Reason 3 for revocation

#### (1) Description of the Specification

The Specification does not describe the embodiment in which an A-scan was actually performed on a human eye using a light source in which  $\delta k$  is less than  $168 \text{ m}^{-1}$ , further less than  $93 \text{ m}^{-1}$ ,  $81 \text{ m}^{-1}$ ,  $47 \text{ m}^{-1}$ ,  $\tau$  is less than  $44 \text{ sec}/(D \times k_0)$ ,  $\Delta k$  is  $18000 \text{ m}^{-1}$  or more, and a wavelength is 600 nm to 1150 nm.

Although in [0067] of the Specification, it is described that "with the preferred values of tuning range  $\Delta k=112000 \text{ m}^{-1}$ ,  $D=2 \text{ mm}$ , wavelength  $\lambda=1060 \text{ nm}$ , and tuning time  $\tau=500 \mu\text{s}$ , it is possible for the first time to determine the overall eye length and the position of the crystalline lens in one measuring operation with an OCDR resolution/measuring accuracy of  $< 30 \mu\text{m}$ . It is ensured here that the measurement result is not corrupted by involuntary eye movements," this description is that "with the preferred values...it is possible...", and it is not clear whether or not it actually indicates the result of actually performing an A scan on a human eye, and the value of  $\delta k$  is not described.

#### (2) Regarding Inventions 1 and 7

##### A Notified specific content

In (2) of Reason 3 for revocation of the notice of reasons for revocation, it is pointed out that

"Since the specification does not describe the embodiment in which an A-scan was actually performed on a human eye using a light source in which  $\delta k$  is less than  $168 \text{ m}^{-1}$ , further less than  $93 \text{ m}^{-1}$ ,  $81 \text{ m}^{-1}$ ,  $47 \text{ m}^{-1}$ ,  $\tau$  is less than  $44 \text{ sec}/(D \times k_0)$ ,  $\Delta k$  is  $18000 \text{ m}^{-1}$  or more, and a wavelength is 600 nm to 1150 nm, it cannot be said that the inventions

according to Claims 1 and 7 are those supported by the Specification.

Then, even considering a common general technical knowledge at the time of the priority date, there is no fact that some light sources are less than  $94.4\text{m}^{-1}$ . Even in the case of  $94.4\text{m}^{-1}$ , the wavelength does not satisfy 600 nm to 1150 nm, so that it is not possible to confirm that a light source in which  $\delta k$  is less than  $168\text{m}^{-1}$ , further less than  $93\text{m}^{-1}$ ,  $81\text{m}^{-1}$ ,  $47\text{m}^{-1}$ ,  $\tau$  is less than  $44\text{sec}/(D \times k_0)$ ,  $\Delta k$  is  $18000\text{m}^{-1}$  or more, and a wavelength is 600 nm to 1150 nm, existed at the time of the priority date. Even if such a light source existed and it is not described as an embodiment in the specification, there is no ground that it was normally available to a person skilled in the art at the time of the priority date.

Then, it cannot be said that a light source 'wherein the light source has a laser line width of  $\delta k < 168\text{m}^{-1}$ ; wherein tuning of the light source is performed in  $\tau < 44\text{sec}/(D \times k_0)$  about a centroid wave number  $k_0$ ; wherein the light source has a spectral tuning range  $\Delta k$  about a centroid wave number  $k_0$  of at least  $\Delta k > 18000\text{m}^{-1}$ ; wherein the light source has a wavelength of 600 nm to 1150 nm' in the invention according to Claim 1, and a light source 'wherein the light source has a laser line width of  $\delta k < 168\text{m}^{-1}$ ; wherein tuning of the light source is performed in  $\tau < 44\text{sec}/(D \times k_0)$  about a centroid wave number  $k_0$ ; wherein the light source has a spectral tuning range  $\Delta k$  about a centroid wave number  $k_0$  of at least  $\Delta k > 18000\text{m}^{-1}$ ,' and having 'a laser line width of  $\delta k < 93\text{m}^{-1}$ ,' ' $\delta k < 81\text{m}^{-1}$ ,' and ' $\delta k < 47\text{m}^{-1}$ ' in Claim 7 are supported by the detailed description of the invention, even in light of a common general technical knowledge at the time of the priority date". On the basis of opinions of the Patentee against that, in (2) C of Reason 3 for revocation in the notice of reasons for revocation (advance notice of decision), the following judgment was shown.

"Although FIG. 2c and FIG. 2d are described in [0066] of the Specification as 'FIG. 2c shows an A-scan that was measured with the aid of an arrangement according to FIG. 2 (with reference arm),' for the light source, it is merely described in [0067] that 'with the preferred values of tuning range  $\Delta k = 112000\text{m}^{-1}$ ,  $D = 2\text{mm}$ , wavelength  $\lambda = 1060\text{nm}$  and tuning time  $\tau = 500\text{ }\mu\text{s}$ , it is possible for the first time to determine the overall eye length and the position of the crystalline lens in one measuring operation with an OCDR resolution/measuring accuracy of  $< 30\text{ }\mu\text{m}$ ,' and it is still unclear what kind of light source was actually used in the device shown in FIG. 2. Even if an enlarged view of FIG. 2c and FIG. 2d, which is the result of the A-scan is presented as Evidence B No. 1 (Note by the body: Regarding FIG. 2d, it seems that the graph was drawn again, and it does not look like an enlarged version of FIG. 2d of the gazette containing the patent.), there is no evidence that an A-scan was actually performed on a human eye using a light

source in which  $\delta k$  is less than  $168 \text{ m}^{-1}$ , further less than  $93 \text{ m}^{-1}$ ,  $81 \text{ m}^{-1}$ ,  $47 \text{ m}^{-1}$ ,  $\tau$  is less than  $44 \text{ sec}/(D \times k_0)$ ,  $\Delta k$  is  $18000 \text{ m}^{-1}$  or more, and a wavelength is  $600 \text{ nm}$  to  $1150 \text{ nm}$ .

Then, as described above, it is not possible to confirm that a light source in which  $\delta k$  is less than  $168 \text{ m}^{-1}$ , further less than  $93 \text{ m}^{-1}$ ,  $81 \text{ m}^{-1}$ ,  $47 \text{ m}^{-1}$ ,  $\tau$  is less than  $44 \text{ sec}/(D \times k_0)$ ,  $\Delta k$  is  $18000 \text{ m}^{-1}$  or more, and a wavelength is  $600 \text{ nm}$  to  $1150 \text{ nm}$ , existed at the time of the priority date. Even if such a light source existed and it is not described as an embodiment in the specification, there is no fact that a person skilled in the art could normally obtain it as a commercial product, etc. or could manufacture at the time of the priority date, so that there is no ground that it was normally available to a person skilled in the art at the time of the priority date.

Therefore, since there is no evidence that an A-scan was actually performed on a human eye using a light source in which  $\delta k$  is less than  $168 \text{ m}^{-1}$ , further less than  $93 \text{ m}^{-1}$ ,  $81 \text{ m}^{-1}$ ,  $47 \text{ m}^{-1}$ ,  $\tau$  is less than  $44 \text{ sec}/(D \times k_0)$ ,  $\Delta k$  is  $18000 \text{ m}^{-1}$  or more, and a wavelength is  $600 \text{ nm}$  to  $1150 \text{ nm}$ , it cannot be said that Inventions 1 and 7 are those supported in the detailed description of the invention".

#### B The Patentee's allegation

Against the judgment above, as described in "(2) The Patentee's allegation" in Reason 2 for revocation, the Patentee, in the written opinion, states about the relationship between the speckle grains and the tuning time  $\tau$  and alleges as follows.

"On the basis of the point of consideration, the inventors made a device having parameters ( $\Delta k=112000 \text{ m}^{-1}$ ,  $D=2 \text{ mm}$ , wavelength  $\lambda=1060 \text{ nm}$ , tuning time  $\tau=500 \mu\text{s}$ ) disclosed in the specification as one embodiment. This corresponds to the embodiment of time  $\tau < 44 \text{ sec}/(D \times k_0)$  described in Paragraph [0067] of the specification. That is, a centroid wave number  $k_0=2\pi/1060 \times 10^{-9} \text{ m}=0.005925 \times 10^9 \text{ m}^{-1}$  can be obtained from wavelength  $\lambda=1060 \text{ nm}$  described in Paragraph [0067], the maximum value  $44 \text{ sec}/(D \times k_0)=44 \text{ sec}/(2 \times 10^{-3} \text{ m} \times 0.005925 \times 10^9 \text{ m}^{-1})=3713 \times 10^{-6} \text{ sec}=3713 \mu\text{sec}$  of time  $\tau$  can be obtained from  $D=2 \text{ mm}$  and  $k_0=0.005925 \times 10^9 \text{ m}^{-1}$ . Tuning time  $\tau=500 \mu\text{s}$  is smaller than the maximum value  $3713 \mu\text{sec}$  of time  $\tau$ , and thus satisfies the condition of  $\tau < 44 \text{ sec}/(D \times k_0)$ . Further, for a laser line width of  $\delta k < 168 \text{ m}^{-1}$ , the specification describes embodiments of  $93 \text{ m}^{-1}$ ,  $81 \text{ m}^{-1}$ ,  $162 \text{ m}^{-1}$ , and  $47 \text{ m}^{-1}$ . Therefore, the specification describes embodiments corresponding to means for solving the problem".

#### C Judgment

First, the allegation made by the Patentee regarding the relationship between the speckle grains and the tuning time  $\tau$  in the written opinion is not described in the

specification at all, as described in (3) B of Reason 2 for revocation, and it cannot be said that the relationship between the speckle grains and the adjustment time  $\tau$  itself is supported, so that the allegation does not solve the indication of A above.

Although the Patentee alleges the description of [0067] of the specification described (1) above as "the inventors made a device having parameters ( $\Delta k=112000 \text{ m}^{-1}$ ,  $D= \text{mm}$ , wavelength  $\lambda=1060 \text{ nm}$ , tuning time  $\tau=500 \mu\text{s}$ ) disclosed in the specification as one embodiment," the description of [0067] is that

"with the preferred values of tuning range  $\Delta k=112000 \text{ m}^{-1}$ ,  $D=2 \text{ mm}$ , wavelength  $\lambda=1060 \text{ nm}$  and tuning time  $\tau=500 \mu\text{s}$ , it is possible for the first time to determine the overall eye length and the position of the crystalline lens in one measuring operation with an OCDR resolution/measuring accuracy of  $< 30 \mu\text{m}$ , It is ensured here that the measurement result is not corrupted by involuntary eye movements," and it is "with the preferred values...it is possible...," and thus it cannot be said that the result of actually manufacturing the device with the values of these parameters and actually performing the A scan on the human eye with the device is shown.

Furthermore, the Patentee alleges that "the specification describes the embodiments of  $93 \text{ m}^{-1}$ ,  $81 \text{ m}^{-1}$ ,  $162 \text{ m}^{-1}$ , and  $47 \text{ m}^{-1}$ ," the specification describes that "[0038] [FIG. 3] depicts various solutions for arranging the reference plane for the measurement". "[0068]

It has emerged that the maximum laser line width  $\delta k$  depends on the measurement regime. The laser line width must be smaller than  $162 \text{ m}^{-1}$  in the case of measuring the autocorrelation function; that is to say, with a blocked reference arm. [0069]

If use is made of an arrangement with a reference arm, it is possible by suitable definition of the reference plane in the sample to ensure that: 1. the signals from the cornea, lens, and retina are detected with sufficient strength, and that 2. mirror artifacts can be suppressed or identified and eliminated by computation. FIG. 3 shows this schematically for various positions of the reference plane, which can be set via the wavelength differences between the reference and sample light paths. [0070]

In FIG. 3a, the reference plane was set behind the retina (R), the result being a maximum laser line width of  $93 \text{ m}^{-1}$  (signal drop of 80 dB over a total measuring range of 54 mm, represented schematically as a curve). R', C' denote the mirror artifacts here and below.

[0071]

In FIG. 3b, the reference plane is set in front of the cornea (C), the result being a maximum laser line width of  $81 \text{ m}^{-1}$  (possible signal drop of 60 dB over a total measuring range of 54 mm, since the cornea reflects better than the retina).

[0072]

In FIG. 3c, the reference plane was set between the cornea (C) and retina (R), the result being a maximum laser line width of  $162 \text{ m}^{-1}$ .

As in FIG. 3a, in FIG. 3d, the reference plane was set behind the retina (R); given a target signal drop of only 20 dB over a total measuring range of 54 mm, the result is a maximum laser line width of  $47 \text{ m}^{-1}$ . This is the preferred laser line width  $\delta k$ . It is necessary here to implement a minimum space of 64 mm between the reference planes and the optical element that lies closest to the eye and is traversed by the measurement beam". However, as described as "the laser line width must be smaller than  $162 \text{ m}^{-1}$  in the case of measuring the autocorrelation function," these merely mention that a laser light source with such a laser line width is needed, and it cannot be said that a device is actually manufactured with a laser light source with a laser line width smaller than  $162 \text{ m}^{-1}$ , and the result of actually performing the A scan on a human eye with the device is shown. Similarly, concerning the maximum laser line width of  $93 \text{ m}^{-1}$ , the maximum laser line width of  $81 \text{ m}^{-1}$ , and the maximum laser line width of  $93 \text{ m}^{-1}$ , it cannot be said that a device is actually manufactured with a laser light source with those laser line widths, and the result of actually performing the A scan on a human eye with the device is shown.

Therefore, since there is no evidence that an A-scan was actually performed on a human eye using a light source in which  $\delta k$  is less than  $168 \text{ m}^{-1}$ , further less than  $93 \text{ m}^{-1}$ ,  $81 \text{ m}^{-1}$ ,  $47 \text{ m}^{-1}$ ,  $\tau$  is less than  $44 \text{ sec}/(D \times k_0)$ ,  $\Delta k$  is  $18000 \text{ m}^{-1}$  or more, and a wavelength is 600 nm to 1150 nm, it cannot be said that Inventions 1 and 7 are those supported in the detailed description of the invention.

(3) Regarding Inventions 1, 4, and 6

A Notified specific content

In (3) of Reason 3 for revocation the notice of reasons for revocation, it is pointed out as follows.

(A) Regarding Invention 1, concerning "digitizing backscattered light detected by the receiver during a single tuning at a rate of more than  $\Delta k/(\tau \times \delta k)$ ," a specific embodiment relating to at a rate of  $\Delta k/(\tau \times \delta k)$  is not described in the specification. Here, "a rate" is corrected to "a frequency" as described in No. 2 above. Furthermore, concerning the indication that it is specified that "a ratio of a tuning range  $\Delta k$  and the laser line width  $\delta k$  is greater than 360" in Claim 3 before correction, whereas the specification does not

describe specific embodiments that satisfy it, since the correction made it a specific matter of Invention 1, it was the content pointed out for Invention 1.

(B) Regarding Invention 4, although it is specified that "a value obtained by dividing the tuning rate  $\Delta k/\tau$  by the laser line width  $\delta k$  is greater than 18 kHz," the specification does not describe specific embodiments that satisfy it. Further, as described in No. 2 above, to Invention 1, "a quotient of the tuning rate ( $\Delta k/\tau$ ) and the laser line width  $\delta k$  is less than 40 MHz" is added by the correction, and "a value obtained by dividing the tuning rate  $\Delta k/\tau$  by the laser line width  $\delta k$ " and "a value obtained by dividing the tuning rate  $\Delta k/\tau$  by the laser line width  $\delta k$ " have the same meaning, so that the above-mentioned matters added to Invention 1 by the correction shall be examined together with the above-mentioned indication in Invention 4.

(C) Regarding Invention 6, although it is specified that "the bandwidth of the at least one receiver is greater than  $2 \times \Delta k / (\tau \times \delta k)$  and less than 80 MHz," the specification does not describe specific embodiments that satisfy it.

Then, on the basis of opinions of the Patentee against that, in (3) C of Reason 3 for revocation in the notice of reasons for revocation (advance notice of decision), the following judgment was shown.

"A (A)-(C) above will be collectively judged.

As described in (3) of 'Regarding Reason 4 of revocation' of 1 above, it is not possible to confirm that a light source having a laser line width in which  $\tau$  is less than  $44 \text{ sec}/(D \times k_0)$ , and  $\delta k < 168 \text{ m}^{-1}$ , or  $\delta k$  is  $46 \text{ m}^{-1}$  could be implemented at the time of the priority date, and there is no embodiment about the matter that a specific value of 'a frequency of  $\Delta k / (\tau \times \delta k)$ ', that is 'a value obtained by dividing the tuning rate  $\Delta k / \tau$  by the laser line width  $\delta k$  is larger than 18 kHz,' and 'smaller than 40 MHz,' and 'the bandwidth of the at least one receiver is greater than  $2 \times \Delta k / (\tau \times \delta k)$  and less than 80 MHz,' so that there is still no support for these.

Further, concerning the matter that 'a ratio of a tuning range  $\Delta k$  and the laser line width  $\delta k$  is greater than 360,' even if a light source having a laser line width in which  $\delta k$  is  $46 \text{ m}^{-1}$  could be implemented at a test level at the time of the priority date, it cannot be said that it was normally available to a person skilled in the art at the time of the priority date, it cannot be confirmed that 'a ratio of a tuning range  $\Delta k$  and the laser line width  $\delta k$  is greater than 360' without embodiments.

Therefore, since the indications of (A)-(C) are not solved by the Patentee's allegation, it cannot be said that Inventions 1, 4, and 6 are those supported in the detailed description of the invention."

## B The Patentee's allegation

The patentee does not argue at all against the above-mentioned judgment.

## C Judgment

It is as judged in A above.

### (4) Summary

As described above, even referring to the written opinion, a figure alleged to be an enlarged view of FIG. 2c and FIG. 2d of B1, and the experimental report of B2, and B3-B16 submitted by the Patentee, it cannot be said that the detailed description of the invention describes Inventions 1, 4, 6 and 7, and Inventions 2, 5, 8-18, 20 and 21 which are dependent on those.

Therefore, the Patent has been granted on a patent application whose Inventions 1-21 do not satisfy the requirement stipulated in Article 36(6)(i) of the Patent Act, and thus the patents according to Inventions 1-21 fall under Article 113(4) of the Patent Act and should be revoked.

### No. 6 Closing

As described above, the Patent has been granted on a patent application whose Inventions 1-21 do not satisfy the requirement stipulated in Article 36(6)(i) of the Patent Act, and a patent application whose detailed description of the invention does not satisfy the requirement stipulated in Article 36(4)(i) of the Patent Act.

Therefore, the patents according to Claims 1, 2, 4-18, 20 and 21 fall under Article 113(4) of the Patent Act and should be revoked.

Further, as described above, the patents according to Claims 3 and 19 were deleted by the correction. Therefore, concerning opposition to a granted patent by the Opponent, there is no claim to be a subject of the opposition to a granted patent with respect to Claims 3 and 19, so that it should be dismissed in accordance with the provisions of Article 135 of the Patent Act which is applied *mutatis mutandis* pursuant to Article 120-8(i) of the Patent Act.

Therefore, the decision shall be made as described in the conclusion.

February 3, 2021

Chief administrative judge: MORI, Ryosuke  
Administrative judge: MISAKI, Hitoshi  
Administrative judge: WATADO, Masayoshi