UNITED STATES PATENT AND TRADEMARK OFFICE

IN THE UNITED STATES PATENT TRIAL AND APPEAL BOARD

HAAG-STREIT AG
Petitioner

v.

EIDOLON OPTICAL, LLC
Patent Owner

CASE IPR: 2018-_____

U.S. PATENT NO.6,547,394 B2

PETITION FOR *INTER PARTES* REVIEW

Mail Stop *Patent Board*
Patent Trial and Appeal Board
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P.O. Box 1450
Alexandria, VA 22313-1450

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LIST OF EXHIBITS

Ex. 1020 UK Patent Application No. GB 2 077 946A

I. INTRODUCTION

Haag-Streit AG ("Petitioner") hereby petitions for *inter partes* review of claims 1, 5, 6, 8-10, 14-16 and 19 (the "challenged claims") of U.S. Patent No. 6,547,394 ("the '394 Patent") (Ex. 1001) under 35 U.S.C. §§ 311–319 and 37 C.F.R. § 42. According to the assignment information contained in the records of the United States Patent & Trademark Office (the "USPTO"), the '394 Patent is assigned to, and therefore owned by, Eidolon Optical, LLC (the "Patent Owner"). For the reasons provided in detail below, the challenged claims should be found unpatentable and canceled.

II. MANDATORY NOTICES (37 C.F.R. § 42.8)

A. Real Parties-In-Interest (37 C.F.R. § 42.8(b)(1))

The real parties-in-interest in this matter are Petitioner Haag-Streit AG and its parent companies, Haag-Streit Holdings AG and Metall Zug AG.

B. Related Matters (37 C.F.R. § 42.8(b)(2))

As of the filing date of this Petition, Petitioner is unaware of any matters involving the '394 Patent currently pending in any United States court or administrative agency

C. Lead and Backup Counsel (37 C.F.R. § 42.8(b)(3))

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D. Service Information (37 C.F.R. § 42.8(b)(4))

Please address all correspondence to Lead Counsel at the mailing address shown above. Petitioner also consents to electronic service by email.

III. GROUNDS FOR STANDING (37 C.F.R. § 42.104(a))

Petitioner hereby certifies that: (1) the '394 Patent issued on April 15, 2003 and so is eligible for *inter partes* review; (2) Petitioner has not been served with a complaint alleging infringement of any of the claims of the '394 patent and so is therefore not barred or estopped from requesting *inter partes* review of the '394 Patent on the grounds identified herein; and (3) Petitioner has not filed a complaint challenging the validity of the '394 Patent. This Petition is being filed in accordance with 37 C.F.R. § 42.106(a).

IV. IDENTIFICATION OF CHALLENGES

Petitioner asks that the Board review the accompanying prior art and analysis thereof, and the supporting evidence, institute a trial for *Inter Partes* Review of claims 1, 5, 6, 8-10, 14-16 and 19 of the '394 Patent, and cancel those claims as invalid under 35 U.S.C. § 102 or 35 U.S.C. § 103. More specifically, Petitioner requests cancellation of claims 1, 5, 6, 8, 9, 10, 14, 15, 16 and 19 of the '394 Patent on the following grounds:

Challenge #1: Claims 1, 5, 6, 8-10, 14-16 and 19 of the '394 Patent are anticipated under pre-AIA 35 U.S.C. § 102(e)(2) by United States Letters Patent No. 6,211,626 to Lys *et al.* ("*Lys*"; Ex. 1003). *Lys* issued on April 3, 2001 from an application filed on December 17, 1998, and that application claims priority to an

earlier provisional application filed in the United States on December 17, 1997. Because the earliest effective filing date of the '394 Patent in the United States is October 20, 1998, *Lys* is prior art to the '394 Patent under pre-AIA 35 U.S.C. § 102(e)(2).

Challenge #2: Claims 6, 10 and 14 of the '394 Patent are obvious under pre-AIA 35 U.S.C. § 103(a) over *Lys* (Ex. 1003) in view of the general knowledge in the art.

V. BACKGROUND

A. Technology

Eye examinations are routinely made with a device known as an ophthalmoscope. The ophthalmoscope includes a light source providing light of a predetermined wavelength or wavelengths. Different parts of the eye, including the cornea, which includes epithelial tissue, the lens and the interior surface of the eye opposite the lens, known as the fundus, can be illuminated to determine the health of the eye. The fundus includes the retina, the optic disc, the macula, the fovea, and the posterior pole.

Ophthalmoscopes include different types of illumination devices such as an incandescent bulb, including those having a tungsten filament, a halogen bulb, a laser illumination device, and a light emitting diode. Ophthalmoscopes often include

interference filters located between the illumination device and the eye to transmit light of a certain wavelength, particularly when the illumination device provides a white light. Since different parts of the eye are more clearly seen when examined with light of a certain wavelength, the interference filter provides the desired wavelength. For instance, certain parts of the eye are more easily seen when a fluorescein dye is applied to the eye and examined with a blue light.

B. The '394 Patent

According to the specification, the '394 Patent relates to "a device which is used to illuminate a patient's eye that has been administered with a fluorescent dye for the purpose of examining the eye for epithelial defects. The invention in its simplest form utilizes four components: a battery, an electrical resistor, an electrical switch and a blue light emitting diode." Ex. 1001 at 1:48-53.

C. Prosecution History

The '394 Patent issued from United States Patent Application No. 09/768,731 ("the '731 Application"), which was filed on January 24, 2001. The '731 Application is a continuation-in-part application of prior United States Patent Application No. 09/175,796, which was filed on October 20, 1998, and subsequently abandoned.

The prosecution history of the '394 Patent (Ex. 1004) is relatively brief, with the claims being allowed after the applicant's response to the first Office Action.

Ex. 1004 at 82-86. Original claims 1-3, 8, 11-16, 18 and 20 (which correspond exactly to claims 1-3, 8, 11-16, 18 and 20 of the '394 Patent) were rejected under 35 U.S.C. § 102(e) over U.S. Patent No. 6,340,868. *Id.* at 69-72. The remaining claims were objected to as being dependent upon a rejected base claim, but were deemed to be allowable if rewritten in independent form including all of the limitations of the base claims and any intervening claims. *Id*.

In response to this rejection, the applicant did not amend the claims, but instead argued that the cited reference patent had an effective filing date after the priority date of the '731 Application. *Id.* at 78-81. In support of this argument, applicant asserted that

> Under 35 U.S.C. § 120 (see also M.P.E.P. 201.11), Applicant is at least entitled to a priority date of October 21, 1997 for the use of Fluorescein and a blue LED to examine an eye. Accordingly, the effective filing date of the present '731 Application for use of Fluorescein and a blue LED to examine the eye is October 21, 1997. All elements or step elements, respectively, of claims 1 and 15, listed in detail below, were taught and disclosed in [US Provisional Patent Application No. 60/063,131]. The invention of claims 1 and 15 in the '731 Application are therefore entitled to a prior date of at least October 21, 1997, which is prior to the filing date of [the cited reference].

Id. at 79. The examiner subsequently withdrew the rejection of the cited reference, and allowed all of the pending claims as originally filed. *Id.* at 82.

VI. PERSON OF ORDINARY SKILL IN THE ART

A United States patent is to be read and understood from the perspective of a person of ordinary skill in the relevant art (technical field) at the time the invention was made. Here, the relevant date is October 20, 1998, *i.e.* when the inventor named on the '394 Patent filed the original patent application to the subject matter now claimed in the '394 Patent and to which priority is claimed.

A person of ordinary skill in the art ("POSA") is a hypothetical person presumed to know the relevant prior art. *See*, *e.g.*, *Gnosis S.p.A. v. South Alabama Med. Sci. Found.*, IPR2013-00116, Final Written Decision (Paper 68) at 9. Such a person is of ordinary creativity, not merely an automaton, and is capable of combining the teachings of the prior art. *See id*., citing *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 420-21 (2007). The factors that may be used to determine the level of skill of a person of ordinary skill in the art may include the education level of those working in the field, the sophistication of the technology, the types of problems encountered in the art, prior art solutions to those problems and the speed at which innovations in the art are made and implemented.

In this case, the '394 Patent is directed to "a device which is used to illuminate a patient's eye that has been administered with a fluorescent dye for the purpose of examining the eye for epithelial defects." Petitioner therefore submits that a person of ordinary skill should have at least some familiarity with the

practical aspects of ophthalmologic instruments. Ex. 1002 at ¶¶ 33. Accordingly, Petitioner submits that a person of ordinary skill in the art of the '394 Patent as of October 20, 1998, would have had at least a bachelor of science or engineering degree in electrical or mechanical engineering, physics, optics, or a related field, and either an advanced degree (such as a masters) in such a subject or an equivalent amount of work experience, *i.e.* 2-3 years, in an area relating to ophthalmic instrument design and/or fabrication or a related technical field. *Id.* at ¶ 33-34.

VII. CLAIM CONSTRUCTION

The following constructions of certain claim terms are proposed by Petitioner using the "broadest reasonable interpretation" standard currently applicable for *inter partes* review. *See* 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs. v. Lee*, 579 U.S. ___, ___, 136 S. Ct. 2131, ____ (2016). If, however, the "plain and ordinary meaning" standard was applicable, Petitioner would still propose the same constructions for the same reasons as provided below.

1. "*ophthalmic illuminator*" (claims 1, 5, 6, 8-10, 14-16 and 19)

This term appears in the preamble of all of the challenged claims. The specification of the '394 Patent does not expressly define this term, but does disclose that "[t]he subject of this invention is a device which is used to illuminate a patient's eye that has been administered with a fluorescent dye for the purpose of examining the eye for epithelial defects." Ex. 1001 at 1:48-51. Petitioner therefore proposes that the claim term *ophthalmic illuminator* be construed to mean "*a device for illuminating a patient's eye for ophthalmic examination.*" Ex. 1002 at ¶ 43.

VIII. IDENTIFICATION OF HOW EACH CHALLENGED CLAIM OF THE '394 PATENT IS UNPATENTABLE

As discussed in detail below, the challenged claims are unpatentable over the prior art.

A. Challenge #1: Claims 1, 5, 6, 8-10, 14-16 and 19 are anticipated under pre-AIA 35 U.S.C. § 102(e)(2) by *Lys*

Lys (Ex. 1003) issued on April 3, 2001 from U.S. Patent Application No. 09/213,659 ("the '659 application), which was filed on December 17, 1998. The '659 application claims the benefit of the filing date of a number of earlier-filed provisional patent applications filed in the United States, including U.S. Provisional Patent Application No. 60/071,281, which was filed on December 17,

1997, and is also a continuation-in-part of prior U.S. Patent Application No. 08/920,156, which was filed on August 26, 1997. Because the earliest effective filing date of the '394 Patent in the United States is October 20, 1998, *Lys* is prior art to the '394 Patent under pre-AIA 35 U.S.C. § 102(e)(2).

"'Anticipation'" in patent terms means that the claimed invention is not new; that is, the invention as claimed was already known." *Ericson Inc. v. Intellectual Ventures LLC*, ___ F.3d ___, ___ (Fed. Cir. 2018). A finding of anticipation requires that every limitation of the claim is present in a single prior art reference. *See, e.g.*, *Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1341 (Fed. Cir. 2016); *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009).

Lys anticipates each of claims 1, 5, 6, 8-10, 14-16 and 19 of the '394 Patent. That is, "each and every element" of claims 1, 5, 6, 8-10, 14-16 and 19 of the '394 Patent is identically disclosed by *Lys*, "arranged or combined in the same way as in the claim." *Ericson Inc. v. Intellectual Ventures LLC*, ___ F.3d ___, ___ (Fed. Cir. 2018) (citing *Blue Calypso*, 815 F.3d at 1341).

1. Claim 1

a. The preamble

The preamble of claim 1 of the '394 Patent recites "[a]n ophthalmic illuminator . . .." Ex 1001 at 4:12. To the extent that this preamble is deemed a

limitation, a point Petitioner expressly does not concede, this limitation is expressly disclosed by *Lys*. Ex 1002 at ¶ 43.

More specifically, *Lys* discloses methods and apparatus for "providing light of a selectable color using light sources, such as light-emitting diodes (LEDs)." Ex. 1003 at 1:29-31. Among the specific uses exemplified by *Lys* for this apparatus is as an ophthalmic illuminator. Ex. 1002 at ¶ 43. In particular, *Lys* teaches that "[a]s a further example of the methods described herein, the LED system can be used to illuminate the retina for ophthalmological examination." Ex. 1003 at 68:33-35.

Accordingly, to the extent the preamble is limiting, this limitation is identically disclosed by *Lys*.

b. *a battery*

The first element of the ophthalmic illuminator of claim 1 is *a battery*. Ex 1001 at col. 4:13. *Lys* identically discloses this element. Ex 1002 at ¶ 45.

Lys discloses methods and apparatus for "providing light of a selectable color using light sources, such as light-emitting diodes (LEDs)." Ex. 1003 at 1:29-31. One such apparatus is presented in FIG. 24 of *Lys*. Ex. 1002 at ¶ 45. Referring to that FIG. 24, *Lys* teaches

> [A] modular LED unit **4000**, is provided for illumination within an environment. Modular unit **4000** comprises a light module **4002**, similar to item **120** discussed in connection with FIG. 1, and a

> processor **4004**, similar to item **16** discussed in connection with FIG. 1. . .. **The modular unit 4000 may also include a power module 4010**, as discussed in connection with FIG. 9, **for providing an electrical current from** a power source, for example, an electrical outlet or **a battery**, to the light module **4002**.

Ex. 1003 at 31:64-32:33 (emphasis added).

Lys therefore identically teaches the *battery* limitation of claim 1.

c. ***an electrical resistor in circuit with the battery***

The second element of claim 1 is *an electrical resistor in circuit with the battery*. Ex. 1001 at 4:14. *Lys* identically discloses this element, and in the same arrangement as recited in the claim. Ex. 1002 at ¶¶ 47-49.

As noted above with respect to the *battery* element, *Lys* discloses methods and apparatus for "providing light of a selectable color using light sources, such as light-emitting diodes (LEDs)." Ex. 1003 at 1:29-31. Referring to the apparatus depicted in FIG. 24, *Lys* teaches

> [A] modular LED unit **4000**, is provided for illumination within an environment. Modular unit 4000 comprises a light module **4002**, similar to item **120** discussed in connection with FIG. 1, and a processor **4004**, similar to item 16 discussed in connection with FIG. 1. The light module **4002** may include, as illustrated in FIG. 25, an LED **4006** having a plurality of color-emitting semiconductor dies **4008** for generating a range of radiation within a spectrum, for example, a range of frequencies within the visible spectrum. Each color-emitting die **4008** preferably represents a primary color and is capable of individually generating a primary color of varying intensity. . .. **The processor 4004, on the other hand, may be provided for controlling an amount of electrical current supplied to each of the semiconductor die 4008.** Depending on the amount of

> electrical current supplied to each die, a primary color of a certain intensity may be emitted therefrom. Accordingly, by controlling the intensity of the primary color produced from each die, the processor **4004**, in essence, can control the particular color illuminated from the LED **4006**.

Ex. 1003 at 31:64-32:18 (emphasis supplied). Since *Lys's* processor **4004** controls the amount of electrical current supplied by the power module **4010** to the light module **4002**, it is an electrical resistor. Ex. 1002 at ¶ 47.

Moreover, because *Lys's* processor **4004** controls the amount of electrical current supplied by the power module **4010** to the light module **4002** and the power module **4010** provides electrical current from a battery to the light module **4002**, the battery and processor **4004** (*i.e.* the claimed *resistor*) are necessarily a part of the same circuit. Ex. 1002 at ¶ 48.

Lys therefore identically teaches the *electrical resistor in circuit with the battery* limitation of claim 1.

d. *an electrical switch in circuit with the resistor*

The third element of claim 1 is *an electrical switch in circuit with the resistor*. Ex. 1001 at 4:15. *Lys* identically discloses this element, and in the same arrangement as recited in the claim. Ex. 1002 at ¶¶ 52-54.

As noted above with respect to the *battery* and *resistor* elements, *Lys* discloses methods and apparatus for "providing light of a selectable color using

light sources, such as light-emitting diodes (LEDs)." Ex. 1003 at 1:29-31.

Referring to the apparatus depicted in FIG. 24, *Lys* teaches

> [A] modular LED unit **4000**, is provided for illumination within an environment. Modular unit **4000** comprises a light module **4002**, similar to item **120** discussed in connection with FIG. 1, and a processor **4004**, similar to item **16** discussed in connection with FIG. 1. . ..

Ex. 1003 at 31:64-32:1.

Lys further teaches, with respect to all of the embodiments disclosed therein, that

> The microprocessors that provide the digital control functions of the LEDs of the present invention may be responsive to any electrical signal; that is, external signals may be used to direct the microprocessors to control the LEDs in a desired manner. . .. **Input signals can range from simple on-off or intensity signals, such as that from a light switch** or dial, or from a remote control, ...

Ex. 1003 at 16:50-67 (emphasis added). Moreover, because *Lys's* processor (*i.e.* the claimed *electrical resistor*) responds to signals from a light switch (which is well known by those skilled in the art to be a type of *electrical switch*), the processor (*electrical resistor*) and light switch (*electrical switch*) are necessarily a part of the same circuit. Ex. 1002 at ¶ 53.

Lys therefore identically teaches the *electrical switch in circuit with the resistor* limitation of claim 1.

e. *at least one light emitting diode . . .*

The fourth element of claim 1 is *at least one light emitting diode, in circuit with the switch, for generating blue light energy in response to activation of the switch*. Ex. 1001 at 4:16-18. *Lys* identically discloses this element, and in the same arrangement as recited in the claim. Ex. 1002 at ¶¶ 55-65.

i. *at least one light emitting diode, in circuit with the switch . . .*

The first feature of this element is *at least one light emitting diode, in circuit with the switch.* Ex. 1001 at 4:16. *Lys* identically discloses this feature. Ex. 1002 at ¶¶ 57-60.

Lys expressly discloses an apparatus for "providing light of a selectable color using light sources, such as light-emitting diodes (LEDs)." Ex. 1003 at 1:29-31. Referring to FIG. 24, *Lys* teaches that

> Modular unit 4000 comprises a light module **4002**, similar to item **120** discussed in connection with FIG. 1, and a processor **4004**, similar to item 16 discussed in connection with FIG. 1. **The light module 4002 may include**, as illustrated in FIG. 25, **an LED 4006** having a plurality of color-emitting semiconductor dies **4008** for generating a range of radiation within a spectrum, for example, a range of frequencies within the visible spectrum.

Ex. 1003 at 31:64-32:6 (emphasis added).

Lys further teaches that "[t]he processor **4004** . . . may be provided for controlling an amount of electrical current supplied to each of the semiconductor

die **4008**" and that "[i]nput signals [to the processor] can range from simple on-off or intensity signals, such as that from a light switch." Ex. 1003 at 16:50-76; 32:10-13. And based on this relationship, *i.e.* the switch controls the processor and the processor controls the amount of electrical current to the LED, the LED and the light switch must be a part of the same electrical circuit. Ex. 1002 at ¶ 59.

ii. *at least one light emitting diode . . . for generating blue light energy in response to activation of the switch*

The second feature of this limitation is that the *at least one light emitting diode . . . generat[es] blue light energy in response to activation of the switch.* Ex. 1001 at 4:16-18. *Lys* identically discloses this feature too. Ex. 1002 at ¶¶ 61-65.

> Referring again to FIG. 24, *Lys* teaches that
>
> The light module **4002** may include, as illustrated in FIG. 25, an LED **4006** having a plurality of color-emitting semiconductor dies **4008** for generating a range of radiation within a spectrum, for example, a range of frequencies within the visible spectrum. Each color-emitting die **4008** preferably represents a primary color and is capable of individually generating a primary color of varying intensity. . . .

Ex. 1003 at 32:1-8. It is well known to those skilled in the art that blue is a primary color. Ex. 1002 at ¶ 62. Indeed, *Lys* expressly teaches that

> LED system **120** includes a set **121** of red LEDs, a set **140** of blue LEDs, and a set **160** of green LEDs. The LEDs may be conventional LEDs, such those obtainable from the Nichia America Corporation. These LEDs are primary colors . . .."

Ex. 1003 at 10:58-61. Accordingly, *Lys's* teaching that the LEDs in the disclosed device can generate "a primary color," this necessarily means that the LEDs can generate blue light. Ex. 1002 at ¶ 62.

Moreover, such generation of light by the LEDs can only come from the electrical current supplied by the processor, which is controlled, in turn, by the switch as described above. Ex. 1002 at ¶ 64. The generation of blue light by *Lys's* LEDs is therefore in response to the switch being turned "on" (*i.e.* activated).

Lys therefore identically discloses the *at least one light emitting diode, in circuit with the switch, for generating blue light energy in response to activation of the switch* limitation of claim 1.

f. *a fluorescein dye administered to a patent's eye . . .*

The final element of claim 1 of the '394 patent is *a fluorescein dye administered to a patent's* [sic, *patient's*] *eye, the dye being responsive to the energy to fluoresce.* Ex. 1001 at 4:19-20. *Lys* identically discloses this limitation. Ex. 1002 at ¶¶ 66-68.

Lys expressly discloses an apparatus for "providing light of a selectable color using light sources, such as light-emitting diodes (LEDs)." Ex. 1003 at 1:29-31. *Lys* teaches that "the LED system can be combined with fluoroscein [sic] dye applied topically to the surface of the eye for ophthalmological evaluation." Ex.

1003 at 69:24-27. It is known by those skilled in the art that fluorescein dye fluoresces when illuminated with blue light. Ex. 1002 at ¶ 67.

Lys therefore identically discloses the *fluorescein dye administered to a patient's eye, the dye being responsive to the energy to fluoresce* limitation of claim 1.

2. Claim 5

Claim 5 depends directly from claim 1, and therefore contains all of the limitations of claim 1 as if recited fully therein. Accordingly, each of these limitations is expressly disclosed by *Lys* for the same reasons as provided with respect to claim 1 above in section **VIII.A.1.** (which is herein incorporated in its entirety by reference). Ex. 1002 at ¶ 69.

In addition to the elements recited in claim 1, claim 5 also requires two additional elements, *viz.,* (1) *a housing for integrating the battery, switch, resistor and diode into an integral package, the diode being positioned to generate blue light energy away from the package*; and (2) *a magnifier lens coupled to the housing for providing a magnified image of the patient's eye to a user of the illuminator*. Ex. 1001 at 4:31-37.

a. *a housing . . .*

The first element of claim 5 is *a housing for integrating the battery, switch, resistor and diode* of the claimed device. Ex. 1001 at 4:31-33. *Lys* identically discloses this limitation.

Lys discloses "[a] light module, comprising: an LED system for generating a range of colors within a color spectrum; a processor for controlling the amount of electrical current supplied to the plurality of light emitting diodes . . . [and] a housing within which the LED system is positioned . . .." Ex. 1003 at 76:63-77:3. *Lys* further discloses that this LED system also includes a power module (which may be a battery, as discussed above). Ex. 1003 at 78:3-4.

In addition, in FIGS. 19, 29 and 93B, *Lys* exemplifies self-contained, portable, hand-held illumination devices as illustrative embodiments of the disclosed and claimed LED-based light source. Ex. 1002 at ¶ 73. All of these devices are clearly depicted with the diode being positioned to generate light away from the housing containing the various elements as required by claim 5. *Id.*

Moreover, because these exemplary devices are all shown to be self-contained, one skilled in the art would understand that the housing would necessarily contain at least, *inter alia*, the LED(s), processor, power module and switch. Ex. 1002 at ¶ 74. Indeed, *Lys* expressly discloses such an arrangement by teaching that

> The foregoing embodiments may reside in any number of different housings. Turning now to FIG. 19, there is shown an exploded view of an illumination unit of the present invention comprising a substantially cylindrical body section **602**, a light module **604**, a conductive sleeve **608**, a power module **612**, a second conductive sleeve **614**, and an enclosure plate **618**. It is to be assumed here that the light module **604** and the power module **612** contain the electrical structure and software of light module **100** and power module **200**, described above, or other embodiments of the light module **100** or other power modules disclosed herein. . .. Power module **612** has a power terminal side holding a terminal **638** for connection to a source of DC power.

Ex. 1003 at 29:53-30:16.

Lys therefore identically discloses the *housing for integrating the battery, switch, resistor and diode into an integral package, the diode being positioned to generate blue light energy away from the package* limitation of claim 5.

b. *a magnifier lens . . .*

The second element of claim 5 is *a magnifier lens coupled to the housing for providing a magnified image of the patient's eye to a user of the illuminator*. Ex. 1001 at 4:34-37. *Lys* identically discloses this element as well. Ex. 1002 at ¶¶ 76-78.

Lys discloses that "in an embodiment of the present invention, a LED-based illumination source is used for projection [of] images or patterns. This system may utilize an LED light source with a series of lenses and/or diffusers, . . . and a final shaping lens. Only the light source, the . . . object [being imaged], and a surface to

receive the projection are necessary for this embodiment." Ex. 1003 at 75:26-34. Moreover, because *Lys* discloses that the image can be projected onto a large surface such as a wall or screen, one skilled in the art would understand that this projection would necessarily involve increasing the size (magnification) of the image. Ex. 1003 at 75:35-38; Ex. 1002 at ¶ 77.

Lys therefore identically discloses the *magnifier lens* limitation of claim 5.

3. Claim 6

Claim 6 depends from claim 5 of the '394 patent (which depends, in turn, from claim 1), and therefore contains all of the limitations of claims 1 and 5 as if recited fully therein. Accordingly, each of these limitations is expressly disclosed by *Lys* for the same reasons as provided with respect to claims 1 and 5 above in sections **VIII.A.1.** and **VIII.A.2.** (which are herein incorporated in their entirety by reference). Ex. 1002 at ¶ 79.

Claim 6 also includes a *wherein* clause, *viz.* that *the magnifier lens has a magnification between 1.5x and 15x*. Ex. 1001 at 4:38-39. *Lys* inherently discloses this limitation. Ex. 1002 at ¶¶ 80-82.

It is known by those POSAs that ophthalmoscopy, as performed by a trained professional complying with generally accepted practices and procedures, involves magnification of the eye broadly between about 10 and 55 diopters (about 3.5 times to 14.75 times), and conventionally about 14 to 30 diopters (about 4.5

times to 8.5 times). Ex. 1002 at ¶ 81. Because *Lys* discloses an LED system for illuminating the eye as a part of an ophthalmic examination and for projecting an image of that object, a POSA would understand that the magnification by the lens would necessarily be between about 3.5 times and about 14.75 times and preferably about 4.5 times to about 8.5 times. *Id*.

Lys therefore discloses *the magnifier lens has a magnification between 1.5x and 15x* of claim 6.

4. Claim 8

Claim 8 depends from claim 1, and therefore contains all of the limitations of claim 1 as if recited fully therein. Accordingly, each of these limitations is expressly disclosed by *Lys* for the same reasons as provided with respect to claim 1 above in section **VIII.A.1.** (which is herein incorporated in its entirety by reference). Ex. 1002 at ¶ 83.

Claim 8 also includes a *wherein* clause*, viz.* that *the dye comprises Sodium Fluorescein*. Ex. 1001 at 4:47-48. *Lys* identically discloses this limitation. Ex. 1002 at ¶¶ 84-86.

Lys teaches that "the [disclosed] LED system can be combined with fluoroscein [sic] dye applied topically to the surface of the eye for ophthalmological evaluation." Ex. 1003 at 69:24-27. It is known by those skilled in the art that sodium fluorescein is the only fluorescein compound that is used for

ophthalmic examinations. Ex. 1002 ¶ 85. Accordingly, one skilled in the art would understand *Lys's* disclosure of "fluoroscein [sic] dye applied topically to the surface of the eye for ophthalmological evaluation" to mean sodium fluorescein. *Id.*

Lys therefore teaches that *the dye comprises Sodium Fluorescein* as required by claim 8.

5. Claim 9

Claim 9 depends from claim 1, and therefore contains all of the limitations of claim 1 as if recited fully therein. Accordingly, each of these limitations is expressly disclosed by *Lys* for the same reasons as provided with respect to claim 1 above in section **VIII.A.1.** (which is herein incorporated in its entirety by reference). Ex. 1002 at ¶ 87.

Claim 9 also includes a *wherein* clause*, viz.* that *the diode comprises Gallium nitride*. Ex. 1001 at 4:49-50. *Lys* identically discloses this limitation. Ex. 1002 at ¶¶ 88-90.

Lys expressly discloses the use of blue LEDs in the various embodiments of the disclosed LED system. Ex. 1002 at ¶ 89. For example, *Lys* teaches that

> LED system **120** includes a set **121** of red LEDs, a set **140** of blue LEDs, and a set **160** of green LEDs. The LEDs may be conventional LEDs, such those obtainable from the Nichia America Corporation. These LEDs are primary colors . . .."

Ex. 1003 at 10:58-61. It is known by those skilled in the art that blue LEDs obtained from Nichia America Corporation in 1997 (when *Lys* was filed) were powered by GaN (gallium nitride). Ex. 1002 at ¶ 89.

Lys therefore inherently discloses that *the diode comprises Gallium nitride* as required by claim 9.

6. Claim 10

Claim 10 depends from claim 1, and therefore contains all of the limitations of claim 1 as if recited fully therein. Accordingly, each of these limitations is expressly disclosed by *Lys* for the same reasons as provided with respect to claim 1 above in section **VIII.A.1.** (which is herein incorporated in its entirety by reference). Ex. 1002 at ¶ 91.

Claim 10 also includes a *wherein* clause*, viz.* that *the diode comprises Silicon Carbide*. Ex. 1001 at 4:51-52. *Lys* inherently discloses this limitation. Ex. 1002 at ¶¶ 92-94.

Lys expressly discloses the use of blue LEDs in the various embodiments of the disclosed LED system. Ex. 1002 at ¶ 93; Ex. 1003 at 10:58-61. It is known by those skilled in the art that blue LEDs were powered by GaN (gallium nitride) or SiC (silicon carbide). Ex. 1002 at ¶ 93. Accordingly, one skilled in the art would immediately envisage an LED powered by SiC upon reading *Lys's* disclosure of blue LEDs. *Id.*

Lys therefore inherently discloses that *the diode comprises Silicon Carbide* as required by claim 10.

7. Claim 14

Claim 14 depends directly from claim 1, and therefore contains all of the limitations of claim 1 as if recited fully therein. Accordingly, each of these limitations is expressly disclosed by *Lys* for the same reasons as provided with respect to claim 1 above in section **VIII.A.1.** (which is herein incorporated in its entirety by reference). Ex. 1002 at ¶ 95.

In addition to the elements recited in claim 1, claim 14 also requires *a focusing lens constructed and arranged with at least one of the diodes to focus the blue light energy onto the patient's eye*. Ex. 1001 at 4:64-67. *Lys* discloses this element. Ex. 1002 at ¶¶ 96-98.

In describing the uses of the disclosed LED system, *Lys* teaches that the light produced by the system can be "directed" towards a specific target tissue or area within the body. Ex. 1003 at 69:16-35. One skilled in the art would understand that "directing" the light produced by the LEDs in *Lys's* system towards a specific target tissue would necessarily involve the use of a lens. Ex. 1002 at ¶ 97.

Lys therefore discloses the *focusing lens constructed and arranged with at least one of the diodes to focus the blue light energy onto the patient's eye.*

8. Claim 15

a. The preamble

The preamble of claim 15 of the '394 Patent recites "[a] method for illuminating a patient's eye for ophthalmic examination." Ex 1001 at 5:1-2. To the extent that this preamble is deemed a limitation, a point Petitioner expressly does not concede, this limitation is expressly disclosed by *Lys*. Ex 1002 at ¶¶ 99-101.

Lys discloses apparatus for "providing light of a selectable color using light sources, such as light-emitting diodes (LEDs)." Ex. 1003 at 1:29-31. Among the specific uses exemplified by *Lys* for this apparatus is as an ophthalmic illuminator. Ex. 1002 at ¶ 100. In particular, *Lys* teaches that "[a]s a further example of the methods described herein, the LED system can be used to illuminate the retina for ophthalmological examination." Ex. 1003 at 68:33-35.

Accordingly, to the extent the preamble is limiting, this limitation is identically disclosed by *Lys*.

b. *administering a fluorescein dye to the patient's eye*

The first step of the method claimed in claim 15 is *administering a fluorescein dye to the patient's eye.* Ex. 1001 at 5:2-3. *Lys* identically discloses this step. Ex. 1002 at ¶¶ 102-104.

Lys discloses apparatus for "providing light of a selectable color using light sources, such as light-emitting diodes (LEDs)." Ex. 1003 at 1:29-31. *Lys*

expressly teaches that "th[is] LED system can be combined with fluoroscein [sic] dye applied topically to the surface of the eye for ophthalmological evaluation." Ex. 1003 at 69:24-27.

Lys therefore teaches the claimed step of *administering a fluorescein dye to the patient's eye* as recited in claim 15.

c. *illuminating the eye with blue light energy generated by one or more light emitting diodes . . .*

The second step of the claimed method is *illuminating the eye with blue light energy generated by one or more light emitting diodes, the dye being responsive to the blue light energy to fluoresce.* Ex. 1001 at 5:3-6. *Lys* identically discloses this step too. Ex. 1002 at ¶¶ 105-109.

Lys discloses apparatus for "providing light of a selectable color using light sources, such as light-emitting diodes (LEDs)." Ex. 1003 at 1:29-31. Referring to FIG. 24, *Lys* teaches that

> The light module **4002** may include, as illustrated in FIG. 25, an LED **4006** having a plurality of color-emitting semiconductor dies **4008** for generating a range of radiation within a spectrum, for example, a range of frequencies within the visible spectrum. Each color-emitting die **4008** preferably represents a primary color and is capable of individually generating a primary color of varying intensity. . ..

Ex. 1003 at 32:1-8. It is well known to those skilled in the art that blue is a primary color. Ex. 1002 at ¶ 106. Moreover, *Lys* expressly teaches that

> LED system **120** includes a set **121** of red LEDs, a set **140** of blue LEDs, and a set **160** of green LEDs. The LEDs may be conventional LEDs, such those obtainable from the Nichia America Corporation. These LEDs are primary colors . . .."

Ex. 1003 at 10:58-61.

As noted with respect to step (b) above, *Lys* also discloses administering a fluorescein dye to a patient's eye for ophthalmic examination, *i.e.* "the LED system can be combined with fluoroscein [sic] dye applied topically to the surface of the eye for ophthalmological evaluation." Ex. 1003 at 69:24-27. It is known by those skilled in the art that fluorescein dyes fluoresce when irradiated or illuminated with blue light. Ex. 1002 at ¶ 108.

Lys therefore discloses the step of *illuminating the eye with blue light energy generated by one or more light emitting diodes, the dye being responsive to the blue light energy to fluoresce* as required by claim 15.

d. *viewing the patient's eye, and viewing the eye while the dye fluoresces*

The third and fourth steps of the claimed method require *viewing the patient's eye* and *viewing the eye while the dye fluoresces.* Ex. 1001 at 5:6-7. The '394 Patent does not, however, specify whether these steps are performed simultaneously or separately. Ex. 1002 at ¶ 110. Nevertheless, irrespective of that ambiguity, *Lys* identically discloses both of these steps. Ex. 1002 at ¶¶ 111-112.

Lys discloses administering a fluorescein dye to a patient's eye for ophthalmic examination, *i.e. Lys* teaches that "the LED system can be combined with fluoroscein [sic] dye applied topically to the surface of the eye for ophthalmological evaluation." Ex. 1003 at 69:24-27. As noted above with respect to step (c), it is known by those skilled in the art that fluorescein dyes fluoresce when irradiated or illuminated with blue light. Ex. 1002 at ¶ 111. Accordingly, one skilled in the art would understand *Lys* to disclose examining the patient's eye while the fluorescein dye fluoresces since the LED system includes LEDs that generate blue light. *Id.*

Lys therefore discloses the step(s) of *viewing the patient's eye, and viewing the eye while the dye fluoresces* as required by claimed 15.

9. Claim 16

Claim 16 depends directly from claim 15, and therefore contains all of the limitations of claim 15 as if recited fully therein. Accordingly, each of these limitations is expressly disclosed by *Lys* for the same reasons as provided with respect to claim 15 above in section **VIII.A.8.** (which is herein incorporated in its entirety by reference). Ex. 1002 at ¶ 113.

Claim 16 also includes a *wherein* clause, *viz.* that *the step of administering a fluorescein dye comprises administering Sodium Fluorescein to the eye.* Ex. 1001 at 5:8-10. This limitation, *i.e.* that the *fluorescein dye* is *Sodium Fluorescein* is the

same as the limitation recited in claim 8. Accordingly, this limitation is expressly disclosed by *Lys* for the same reasons as provided with respect to claim 8 above in section **IX.A.4.** (which is herein incorporated in its entirety by reference). Ex. 1002 at ¶ 114.

Lys therefore identically discloses the limitation recited in claim 16 of the '394 patent.

10. Claim 19

Claim 19 depends directly from claim 15, and therefore contains all of the limitations of claim 15 as if recited fully therein. Accordingly, each of these limitations is expressly disclosed by *Lys* for the same reasons as provided with respect to claim 15 above in section **VIII.A.8.** (which is herein incorporated in its entirety by reference). Ex. 1002 at ¶ 116.

Claim 19 also includes a *wherein* clause, *viz.* that *the step of viewing comprises viewing through a magnifying lens coupled with a housing that supports the diodes.* Ex. 1001 at 5:8-10. This limitation, *i.e.* the *magnifying lens coupled with a housing that supports the diodes*, is the same as the limitation recited in claim 5. Accordingly, this limitation is expressly disclosed by *Lys* for the same reasons as provided with respect to claim 5 above in section **IX.A.2.** (which is herein incorporated in its entirety by reference). Ex. 1002 at ¶ 117.

Lys therefore identically discloses the limitation recited in claim 19 of the '394 patent.

B. Challenge #2: Claims 6, 10 and 14 are obvious under pre-AIA 35 U.S.C. 103(a) over *Lys* in view of the general knowledge in the art

"Obviousness" is when the claimed subject matter is not identically described, but would have been obvious, as a whole, to a person of ordinary skill in the art. 35 U.S.C. § 103(a); *see KSR Int'l, Inc. v. Teleflex, Inc*., 550 U.S. 398, 406–07 (2007). A proper obviousness analysis requires the following steps: (1) determining the scope and content of the prior art; (2) ascertaining the difference(s) between the prior art and the claimed invention; (3) resolving the level of ordinary skill in the art; and (4) evaluating the objective evidence relevant to obviousness, if any. *See*, *e.g.*, *Graham v. John Deere Co*., 383 U.S. 1, 17-18 (1966); *KSR*, 550 U.S. at 404.

When obviousness is based on information from a combination of sources, a relevant factor is whether a person of ordinary skill in the art would have been motivated to select and combine this information, and with a reasonable expectation of achieving the desired result. *See, e.g.*, *Merck & Cie v. Gnosis S.p.A.*, 808 F.3d 829, 833 (Fed. Cir. 2015), *cert. denied*, 137 S. Ct. 297 (2016).

To the extent that one or more of claims 6, 10 and 14 are not inherently anticipated by *Lys*, the subject matter claimed in those claims 6, 10 and 14 of the

'394 Patent would have been obvious to one of ordinary skill in the art at the time the claimed invention was made over *Lys* in view of the general knowledge in the art. Ex. 1002 at ¶ 119

1. Claim 6

As noted in section **VIII.A.1.** above, claim 6 of the '394 Patent depends directly from claim 1 and therefore contains all of the limitations of claim 1 as if recited fully therein. And, as also noted above, each of these limitations is expressly disclosed by *Lys* for the same reasons as provided with respect to claim 1 above in section **VIII.A.1.** (which is herein incorporated in its entirety by reference). Ex. 1002 at ¶ 120.

Claim 6 also includes a *wherein* clause, *viz.* that *the magnifier lens has a magnification between 1.5x and 15x*. Ex. 1001 at 4:38-39. *Lys* does not expressly disclose this limitation. Ex. 1002 at ¶ 121.

It was, however, known by those POSAs at the time the invention claimed in the '394 Patent was that ophthalmoscopy, as performed by a trained professional complying with generally accepted practices and procedures, involves magnification of the eye broadly between about 10 and 55 diopters (about 3.5 times to 14.75 times), and preferably about 14 to 30 diopters (about 4.5 times to 8.5 times). Ex. 1002 at ¶ 122.

As noted in section **VI.** above, a person of ordinary skill in the relevant art as of October 20, 1998, would have had at least a bachelor of science or engineering degree in electrical or mechanical engineering, physics, optics, or a related field, and either an advanced degree (such as a masters) in such a subject or an equivalent amount of work experience, *i.e.* 2-3 years, in an area relating to ophthalmic instrument design and/or fabrication or a related technical field.

Because *Lys* discloses an LED system for illuminating the eye as a part of an ophthalmic examination and for projecting an image of that object, a person of ordinary skill in the relevant art would have been motivated to use a magnification of between 2 and 15 times for the magnifier lens since that was the standard at the relevant time (and remains so today). Ex. 1002 at ¶ 124.

Finally, there is no evidence in the prosecution history of any secondary considerations that would overcome this very strong evidence that Claim 6 would have been obvious over *Lys* in view of the general knowledge in the art. Ex. 1002 at ¶ 125.

2. Claim 10

As noted above in section **VIII.A.6.**, claim 10 depends from claim 1, and therefore contains all of the limitations of claim 1 as if recited fully therein. And, as also noted in section **VIII.A.6.**, each of these limitations is expressly disclosed by *Lys* for the same reasons as provided with respect to claim 1 above in section

VIII.A.1. (which is herein incorporated in its entirety by reference). Ex. 1002 at ¶ 126.

Claim 10 also includes a *wherein* clause*, viz.* that *the diode comprises Silicon Carbide*. Ex. 1001 at 4:51-52. *Lys* does not expressly disclose this limitation. Ex. 1002 at ¶ 127.

More specifically, *Lys* expressly discloses the use of blue LEDs in the various embodiments of the disclosed LED system, but does not disclose that such blue LEDs contain silicon carbide. Ex. 1002 at ¶ 128; Ex. 1003 at 10:58-61. *Lys* does, however, exemplify blue LEDs containing gallium nitride. Ex. 1003 at 10:58-61.

Moreover, it was known at the relevant time by those POSAs that blue LEDs were powered by GaN (gallium nitride) or SiC (silicon carbide). Ex. 1002 at ¶ 129.

As noted in section **VI.** above, a person of ordinary skill in the relevant art as of October 20, 1998, would have had at least a bachelor of science or engineering degree in electrical or mechanical engineering, physics, optics, or a related field, and either an advanced degree (such as a masters) in such a subject or an equivalent amount of work experience, *i.e.* 2-3 years, in an area relating to ophthalmic instrument design and/or fabrication or a related technical field.

Because silicon carbide is known to be cheaper and easier to use than gallium nitride, a person of ordinary skill in the relevant art would have been motivated to use silicon carbide as the blue LED light source in *Lys's* illumination system. Ex. 1002 at ¶ 131.

Finally, there is no evidence in the prosecution history of any secondary considerations that would overcome this very strong evidence that Claim 6 would have been obvious over *Lys* in view of the general knowledge in the art. Ex. 1002 at ¶ 132.

3. Claim 14

As noted in section **VIII.A.7.**, Claim 14 depends directly from claim 1, and therefore contains all of the limitations of claim 1 as if recited fully therein. And, as described above, each of these limitations is expressly disclosed by *Lys* for the same reasons as provided with respect to claim 1 above in section **VIII.A.1.** (which is herein incorporated in its entirety by reference). Ex. 1002 at ¶ 133.

Claim 14, however, also requires *a focusing lens constructed and arranged with at least one of the diodes to focus the blue light energy onto the patient's eye*. Ex. 1001 at 4:64-67. *Lys* does not expressly disclose this element. *Lys* does, however, teach that the light produced by the system can be "directed" towards a specific target tissue or area within the body. Ex. 1003 at 69:16-35. Ex. 1002 at ¶¶ 134-135.

As noted in section **VI.** above, a person of ordinary skill in the relevant art as of October 20, 1998, would have had at least a bachelor of science or engineering degree in electrical or mechanical engineering, physics, optics, or a related field, and either an advanced degree (such as a masters) in such a subject or an equivalent amount of work experience, *i.e.* 2-3 years, in an area relating to ophthalmic instrument design and/or fabrication or a related technical field.

Because one skilled in the art would understand that "directing" the light produced by the LEDs in *Lys's* system towards a specific target tissue would be improved by using a lens to focus the light (as shown, for example, by UK Patent Application No. GB 2 077 946A (Ex. 1020), one skilled in the art would have been motivated to adding such a lens to *Lys's* illumination system. Ex. 1002 at ¶ 137.

Finally, there is no evidence in the prosecution history of any secondary considerations that would overcome this very strong evidence that Claim 14 would have been obvious over *Lys* in view of the general knowledge in the art. Ex. 1002 at ¶ 138.

IX. INSTITUTION SHOULD NOT BE DENIED BASED ON §325(d)

The reference being relied upon in Challenge #1, U.S. Patent No. 6,211,626 to Lys *et al.* ("*Lys*"; Ex. 1003) issued from U.S. Patent Application No. 09/213,659

("the '659 Application"). The '659 Application is the parent of U.S. Patent No. 6,340,868 ("the '868 Patent").

As noted in section **V.C.** above, the '868 Patent was cited by the examiner during prosecution of the '731 Application as anticipating pending claims 1-3, 8, 11-16, 18 and 20 (now claims 1-3, 8, 11-16, 18 and 20 of the '394 Patent). Ex. 1004 at 69-72. The examiner subsequently withdrew this rejection (and allowed claims 1-3, 8, 11-16, 18 and 20) when the Patent Owner asserted that it was entitled to a priority date of October 21, 1997. *Id.* at 78-81.

Contrary to the Patent Owner's assertion, however, the '394 Patent states on its cover page in the Related U.S. Application Data section that it is a "Continuation-in-part of application No. 09/175,796, filed on Oct 20, 1998, now abandoned." There is no reference to an earlier-filed application, nor is any cross-reference to an earlier filed application found in the specification of the '394 Patent. Ex. 1001 at 1:4-7. Moreover, the Combined Declaration and Power of Attorney signed by the inventor on January 24, 2001, which includes a Claim for Benefit of Earlier U.S./PCT Application(s) under 35 U.S.C 120, only claims the benefit of the Application No. 09/175,796, filed on Oct 20, 1998, and makes no reference to any earlier-filed application.

Accordingly, the Board should not deny institution under 35 U.S.C. § 325(d) in this case. More specifically, although the Board may, in its discretion, deny

institution under 35 U.S.C. § 325(d) if "the same or substantially the same prior art or arguments previously were presented to the Office," that is not the situation here. Rather, *Lys* is being used in the instant Petition as prior art under pre-AIA 35 U.S.C. § 102(e)(2) based on the '394 Patent only being entitled to a filing date of October 20, 1998. This argument was not raised by the examiner during prosecution of the '394 Patent.

X. CONCLUSION

For the reasons given above, Petitioner requests that the Board institute an *Inter Partes* Review of claims 1, 5, 6, 8-10, 14-16 and 19 of the '394 Patent on each of the grounds specified in this petition.

Respectfully submitted,

Dated: June 25, 2018

By: /Donald R. McPhail/
Donald R. McPhail (Reg. No. 35,811)

CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. § 42.24(d), the undersigned certifies that the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 6,547,394 contains 9064 words (as measured by the word-processing software used to prepare this paper).

Respectfully submitted,

Dated: June 25, 2018

By: /Donald R. McPhail/
Donald R. McPhail (Reg. No. 35,811)

CERTIFICATE OF SERVICE

The undersigned hereby certifies that, on June 25, 2018, the undersigned caused a true and correct copy of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 6,547,394 and supporting exhibits to be served via Express Mail on the Patent Owner at the following correspondence address of record (as listed on PAIR):

LATHROP GAGE LLP
2440 Junction Place
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Boulder CO 80301

By: /Donald R. McPhail/
Donald R. McPhail (Reg. No. 35,811)