United States Court of Appeals for the Federal Circuit

KARL STORZ ENDOSCOPY-AMERICA, INC.,

Plaintiff-Appellant

– v. –

STERIS INSTRUMENT MANAGEMENT SERVICES, INC.,

Defendant-Appellee

On Appeal from the United States District Court for the Northern District of Alabama in No. 2:12-cv-02716-RDP, R. David Proctor, Judge

NON-CONFIDENTIAL BRIEF FOR PLAINTIFF-APPELLANT

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NOVEMBER 14, 2022

CLAIM LANGUAGE AT ISSUE

Claim Language of U.S. Patent No. 7,530,945 recites

1. A method for assembling an endoscope having a tubular shaft, an optical system having several components, said components of said optical system are contained in an interior of said tubular shaft, said components of said optical systems are at least partially surrounded by a tube made of both a transparent and a shrunk material, said method comprising the following steps

    a) introducing said components into a tube of transparent and shrinkable material to form a unit,

    b) shrinking said shrinkable material of said tube for fixing the position of said components contained within said tube relative to one another,

    c) checking a position of said components relative to one another through said transparent shrunk material, of said shrunk tube and

    d) introducing said unit composed of said shrunk tube and said components contained therein into said tubular shaft.

Appx39 at 6:21-38.

Claim Language of U.S. Patent No. RE47044 recites

1. An endoscope, comprising:

a tubular shaft, having an inside face,

an optical system having several components, said components of said optical system are contained in an interior of said tubular shaft,

said components comprising at least two of the following: a lens, a spacer, a diaphragm, a prism and a filter, said components directly surrounded by a support piece made of a shrunk material, wherein

said shrunk material is a transparent material,

said support piece made of said transparent material has a shape of a tube, and

said tube containing said components of said optical system has been shrunk prior to inserting said tube into said interior of said tubular shaft, for allowing a visual check of a position of said components relative to one another, and

a gap located between an outside surface of said tube of shrunk material and said inside face of said tubular shaft.

Appx47 at 6:27-47

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number	2022-1078
Short Case Caption	Karl Storz Endoscopy-America, Inc. v. STERIS Instrument Management Services, Inc.
Filing Party/Entity	Karl Storz Endoscopy-America, Inc.

Instructions: Complete each section of the form. In answering items 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance. **Please enter only one item per box; attach additional pages as needed and check the relevant box**. Counsel must immediately file an amended Certificate of Interest if information changes. Fed. Cir. R. 47.4(b).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 11/14/2022

Signature: /s/ William A. Meunier

Name: William A. Meunier

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☑ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☐ None/Not Applicable
Karl Storz Endoscopy-America, Inc.		Karl Storz GmbH & Co. KG

☐ Additional pages attached

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

☐ None/Not Applicable ☐ Additional pages attached

Paul D. Duplessis Whitmyer IP Group LLC	Benjamin N. Luehrs formerly of Whitmyer IP Group LLC	Benjamin C. White formerly of St. Onge Steward Johnston & Reens LLC
John G. Dana Gordon, Dana & Gilmore LLC	Brannon J. Maner formerly of Gordon, Dana & Gilmore, LLC	Samuel F. Davenport Mintz Levin
Laura L. Petrasky Mintz Levin	Katharine Foote Mintz Levin	

5. Related Cases. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b).

☑ None/Not Applicable ☐ Additional pages attached

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

☑ None/Not Applicable ☐ Additional pages attached

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STATEMENT REGARDING CONFIDENTIAL MATERIAL

The material omitted on pages 23-24 and 47 describes customer feedback and customer experiences using reconstructed endoscopes. The confidential material in the brief is highlighted in yellow.

TABLE OF AUTHORITIES

Page(s)

Federal Cases

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Treatises

STATEMENT OF RELATED CASES

No appeal in this case was previously before this Court or any other court.

Counsel for Appellant is aware of one case in another court that may be directly affected by this Court's decision in the pending appeal, specifically the pending case from which this appeal is taken, Karl Storz Endoscopy-America, Inc. v. Steris Instrument Management Services, Inc., Case No. 2:12-CV02716 in the United States District Court for the Northern District of Alabama.

In this underlying district court case, Appellant/plaintiff Karl Storz Endoscopy-America, Inc. ("Karl Storz") alleged that Appellee Steris Instrument Management Services ("IMS") infringed Karl Storz's U.S. Patent Nos. RE47,044 Patent ("the '044 Patent") and 7,530,945 Patent ("the '945 Patent").

On February 2, 2022, IMS moved for summary judgment, requesting that the district court find that IMS's actions were permissible repair. On May 19, 2022, the district court granted the motion.

In response to the district court's grant of summary judgment of repair, IMS filed a motion for attorneys' fees against Karl Storz, arguing (among other things) that Karl Storz should be sanctioned because its assertion that IMS's actions were infringing reconstruction rather than permissible repair was exceptionally meritless.

Karl Storz then timely filed this appeal, and the district court subsequently stayed IMS's sanctions motion pending the outcome of this appeal.

This Court's decision in this Karl Storz appeal may directly affect the outcome of IMS's pending sanctions motion and the underlying district court case pending in the Northern District of Alabama.

STATEMENT OF JURISDICTION

Because this action arose under the patent laws of the United States, 35 U.S.C. §§ 101 *et seq.*, the district court had jurisdiction under 38 U.S.C. §§ 1331 and 1338. A Memorandum and Order was entered in this action on May 19, 2022, and the Final Judgment was entered on June 2, 2022. *See* Appx82-83 at Doc. Nos. 215, 216, and 221. Pursuant to 28 U.S.C. § 2107, Appellant timely filed its notice of appeal on June 17, 2022. *See* Appx84 at Doc. No. 229, Appx4668-4670 (Notice of Appeal). This Court has jurisdiction under 28 U.S.C. § 1295(a).

INTRODUCTION

Appellant Karl Storz appeals the district court's summary judgment decision finding that Appellee IMS met its burden of proving its permissible repair defense as a matter of law. The district court's grant of summary judgment should be reversed because the court misinterpreted and misapplied the applicable repair law, resulting in the court improperly ignoring evidence that at the very least creates

genuine disputes of material fact as to whether IMS's infringing activities were impermissible reconstruction rather than permissible repair.

Karl Storz manufactures and sells surgical endoscopes that include an inventive optical relay assembly housed within an inflexible tubular shaft. It owns and asserts two patents in this case, one a method patent for the process of assembling the inventive optical relay within the tubular shaft, the other an apparatus patent covering the inventive optical relay assembly and tubular shaft.

The evidence on summary judgment showed that Appellee IMS makes a new optical assembly for use in a used Karl Storz endoscope, using different parts and a different design, and resulting in endoscopes that, in the words of the district court, "are inferior to and different from [Karl Storz's] originally manufactured endoscopes." Appx22 (SJ Order). Despite using inferior and different parts and designs that admittedly do not meet Karl Storz's standards, IMS advertises its endoscopes as "Certified Pre-Owned" Karl Storz endoscopes, with only Karl Storz branding—but no IMS branding—on the inferior endoscopes.

The district court found on summary judgment that IMS's manufacturing of these new and different optical assemblies and endoscopes was permissible repair, not infringing reconstruction. The district court's decision is legal error and should be reversed for at least three independent reasons:

1. Not Readily Replaceable Parts: This Court's precedents establish that while the replacement of "readily replaceable" parts may be repair, the replacement of parts that are **not** readably replaceable is **impermissible reconstruction**. *E.g.*, *Husky Injection Molding Sys. v. R&D Tool & Eng'g Co.*, 291 F.3d 780, 787 (Fed. Cir. 2002). But the district court ignored this distinction, determining that the replacement of any part—readily replaceable or not—was permissible repair.

Under the correct application of this readily replaceable test, IMS was not entitled to summary judgment on its affirmative defense of repair. IMS did not even assert the Karl Storz optical relay assembly was readily replaceable, much less establish that there was no genuine dispute concerning this material fact. For this reason alone, IMS did not meet its burden and the summary judgment ruling should be reversed.

Moreover, at the very least, Karl Storz identified evidence sufficient for a jury to determine that the Karl Storz optical assembly is **not** readily replaceable. For example, Karl Storz does not sell or provide replacement optical assemblies because Karl Storz's endoscopes are subject to strict FDA regulations requiring them to be permanently sealed in a particular manner. The optical assembly cannot be accessed and replaced without first breaking this FDA-validated permanent seal. Accordingly, IMS must build its own inferior optical assemblies and breaks the FDA-validated permanent seal before it can replace the Karl Storz optical relay

assembly with its own. For this reason alone, a jury could reasonably determine that the optical relay assembly is not readily replaceable and, therefore, summary judgment applying the repair defense is inappropriate.

2. Novel and Distinguishing: The district court found that "without question, the way the optical relay is assembled is the novel and distinguishing part of the invention." Appx23-24 (SJ Order). The district court nonetheless ignored that IMS is performing this entire novel assembly and replacing the entire claimed novel optic relay assembly, relying on *Aro I* to conclude that the novelty of the optic assembly "does not affect the repair versus reconstruction analysis." Appx24 (SJ Order).

But under the Supreme Court's decision in *Quanta*, *Aro I* does not apply here because *Aro I* applies only to claims "**in which the combination itself is the only inventive aspect of the patent**." *Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617, 635 (2008) (emphases added) (discussing *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336 (1916) (*Aro I*)). The Supreme Court explained that *Aro I* does not apply where something other than just the combination of well-known elements is inventive, such as where, like here, the designs of one or more elements in the combination are themselves inventive. *Id*.

Thus, the district court's reliance on *Aro I* was incorrect because the district court found that some of the elements in Karl Storz's claims—the claimed optical

relay assembly—were themselves new: "without question, the way the optical relay is assembled is the novel and distinguishing part of the invention." Appx23-24.

Accordingly, Karl Storz's patents are not the type of "combination patents" to which *Aro I* is limited, and under *Quanta*, the extent to which IMS performed and replaced the novel aspect of Karl Storz's invention is highly relevant evidence showing that IMS's actions constituted infringing reconstruction, not permissible repair.

3. <u>Essentially New Article</u>: The right to repair does "not include the right to construct an essentially new article on the template of the original, for the right to make the article remains with the patentee." *Jazz Photo Corp. v. Int'l Trade Comm'n*, 264 F.3d 1094, 1102 (Fed. Cir. 2001). Accordingly, if IMS did "in fact make a new article," its actions are infringing reconstruction and not permissible repair. *Id*. at 1103.

Karl Storz provided evidence creating at least a genuine dispute as to whether IMS created a "new article," and summary judgment of repair was improper and should be reversed. For example, the district court acknowledged that IMS replaced every claimed element (but for the tubular shaft in which the inventive optical relay assembly is placed) with new and different parts, finding that the IMS

endoscopes had "a different shrink wrap enclosing the optical relay, and different lenses and spacers in the optical relay." Appx21.

In addition to the replacement of all of these elements with new and different parts (including the entirety of the inventive optical relay assembly), the evidence shows that the resulting IMS endoscopes are substantially different from the Karl Storz endoscope template on which they were built. In the words of the district court:

> Evidence in the summary judgment record supports a reasonable inference that IMS endoscopes are inferior and different from [Karl Storz's] originally manufactured endoscopes. Some IMS endoscopes have rod lenses of different diameters and optical prescriptions, produce inferior images, have smaller fields of view, are more fragile, have welds prone to deterioration, and can be eight centimeters longer than [Karl Storz's] endoscopes.

Appx26-27.

Accordingly, there is at least a genuine dispute of fact as to whether IMS created an essentially new article, and summary judgment finding repair as matter of law was improper.

STATEMENT OF THE ISSUES ON APPEAL

1. Whether the district court's summary judgment of repair should be reversed where IMS had the burden of establishing that there was no material dispute that the Karl Storz parts it replaced were "readily replaceable," but IMS did

not assert that those parts were readily replaceable, and Karl Storz identified substantial evidence showing that the parts were not readily replaceable.

2. Whether the district court's summary judgment of repair should be reversed where Karl Storz's evidence of impermissible reconstruction included IMS performing and replacing the entire "novel and distinguishing part of the invention," but the district court ignored this evidence in direct contravention of the Supreme Court's decision in *Quanta*, 553 U.S. at 635.

3. Whether the district court's summary judgment of repair should be reversed where the right to repair does "not include the right to construct an essentially new article," and Karl Storz provided substantial evidence on which a jury could reasonably conclude that IMS's actions created an essentially new article.

STATEMENT OF THE CASE

I. The Asserted Endoscope Optical System Patents

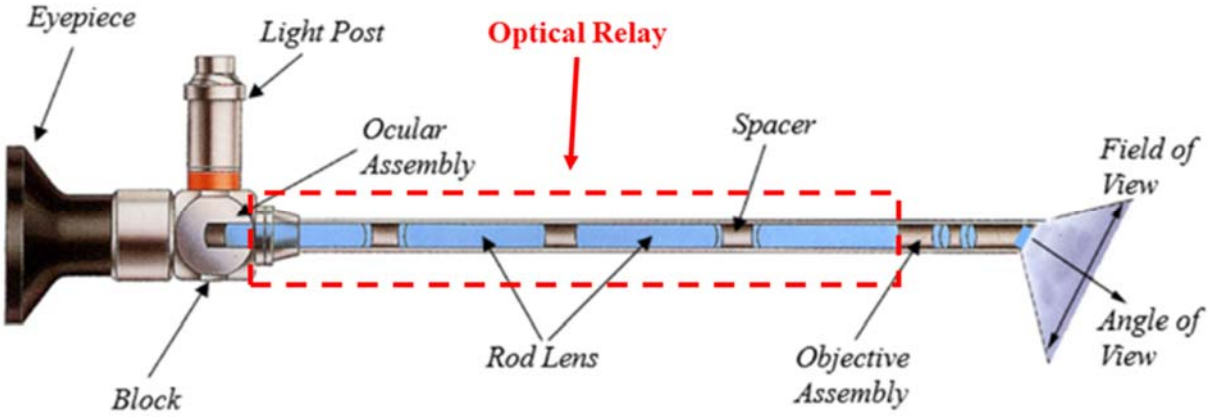
Karl Storz's asserted '044 and '945 Patents share the same substantive specification and are directed towards the structure and assembly of an "optical system" in an endoscope. *See* Appx47-49 ('044 Patent) at 6:28-9:7; Appx39 ('945 Patent) at 6:21-59.

The novel optical system comprises a tube composed of a transparent and shrinkable material. *E.g.*, Appx47 ('044 Patent at 6:37-39; Appx39 ('945 Patent) at 6:28-29. This transparent and shrinkable tube contains components, such as lenses and spacers, and together this transparent tube, spacers, and lenses are alternately called an optical relay, optical assembly, or optical relay assembly. *E.g.*, Appx47 ('044 Patent) at 6:33-36; Appx37 ('945 Patent) at 1:13-17; Appx39 at 6:28-29.

A. The Basic Parts of an Endoscope

An endoscope is "an instrument that can be at least partially inserted into a cavity to visually examine that cavity." Appx273. Endoscopes are used during surgical procedures, such as an ureteroscopy, to provide the surgeon an image of an internal organ. Appx496-497, ¶¶ 30-31.

As illustrated below, an endoscope typically comprises a tubular shaft, eyepiece, light post, ocular lens, objective lens assembly, optic illumination fibers, and an optical relay. Appx2232-2233, ¶¶ 1, 6.



See Appx2233, ¶ 6 (annotations added).

The endoscope's optical relay comprises a series of lenses and spacers residing inside a tubular shaft, as annotated above. *See, e.g.*, Appx2232-2233, ¶¶ 2, 6; Appx2235, ¶17; Appx2236-2237, ¶¶ 25, 32. The optical relay "performs the endoscope's primary function of transmitting an optical image from one end of the endoscope to the other." Appx23 (SJ Order); *see also* Appx2232, ¶ 2. As a result, the user can look through an eyepiece attached to the proximal end of the endoscope to see the image from the distal end. Appx2232-2233, ¶¶ 1, 6.

B. Drawbacks of Prior Art Endoscope Optical Relay Systems

For an optical relay assembly to accurately transmit an image, its lenses and spacers must be precisely and accurately positioned within the relay: "For a good image quality, it is not only necessary for these [lenses and spacers] to be precisely oriented relative to one another and fixed axially along an optical axis; it is also necessary for their relative rotation positions to be unchangeable." Appx45 ('044 Patent) at 2:32-35). Accordingly, in "the course of assembly, it is expedient to check the optical image qualities of such a lens system so that, if appropriate, systems with optical misalignments can be eliminated." *Id.* at 2:35-38.

When manufacturing endoscopes using typical prior art optical relay assemblies, however, optical alignment could only be checked after the entire endoscope was assembled. *Id.* at 2:39-46; Appx37 ('945 Patent) at 2:22-28. Because the optical relay in an assembled endoscope is sealed inside the tubular

shaft, a single flipped or reversed lens could require the destruction of the entire endoscope to fix the optical relay. Appx45 (’044 Patent) at 2:39-44; Appx37 (’945 Patent) at 2:22-26. This made manufacturing difficult and expensive: “If optical errors are found, it is then very expensive to correct these, and in most cases the endoscope has to be completely dismantled.” Appx45 (’044 Patent) at 2:40-43.

C. Karl Storz’s Patented Solution

The inventors solved the foregoing drawbacks by providing a novel optical relay assembly that allows the optical assembly to be visually checked and (if necessary) corrected prior to insertion into the endoscope. Appx45 (’044 Patent) at 2:44-3:6.

This inventive optical assembly included a tube made of transparent and shrinkable material, sometimes referred to as shrink-wrap. The lenses and spacers of the optical assembly are positioned within this transparent and shrinkable tube. For example, the below Figure 1 from the Asserted Patents shows components 16 (namely, lenses 18, 18’, 18’’ and spacers 20, 21) inside “a tube 12 made of transparent and shrinkable material 14.” Appx46 (’044 Patent) at 4:51-59; Appx42, Fig. 1.

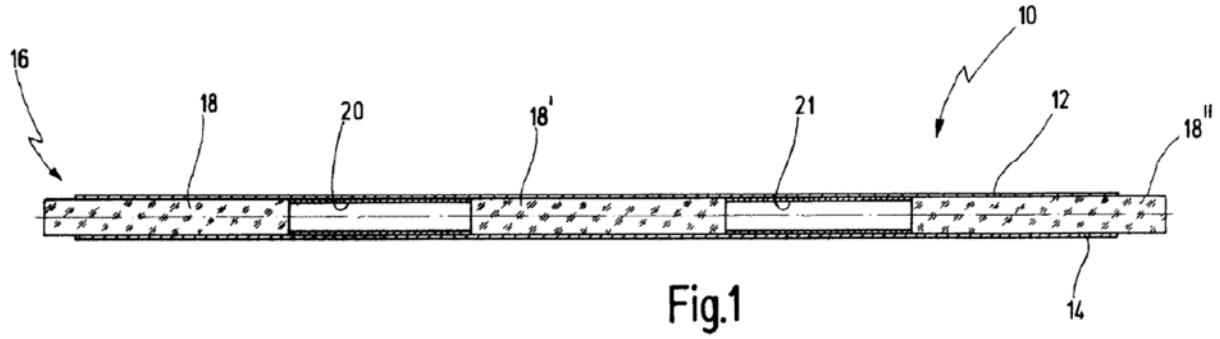


Fig.1

"By virtue of the transparency of the material 14, it is possible to check the desired correct fit of these components 16 to one another from the outside, for example to check whether the opposing end faces of the two rod lenses 18 and 18' bear exactly on the spacer 20." Appx46 ('044 Patent) at 4:65-5:2.

After this visual check, the shrinkable material is heated, causing it to shrink around the lenses and spacers and thereby "fix the position of the components in relation to another." Appx45 ('044 Patent) at 2:19-20; Appx47 at 5:3-33. "By virtue of the transparency of the material 14 which is still present even after the shrinkage, it is possible once again to check, from the outside, the correct fit of the individual components 16 [i.e., the individual lenses and spacers] relative to one another." Appx47 ('044 Patent) at 5:34-37).

"The shrunk unit 10' is then inserted into a tubular shaft 42 of the endoscope 40, as shown in FIG. 3." *Id*. at 5:38-39.

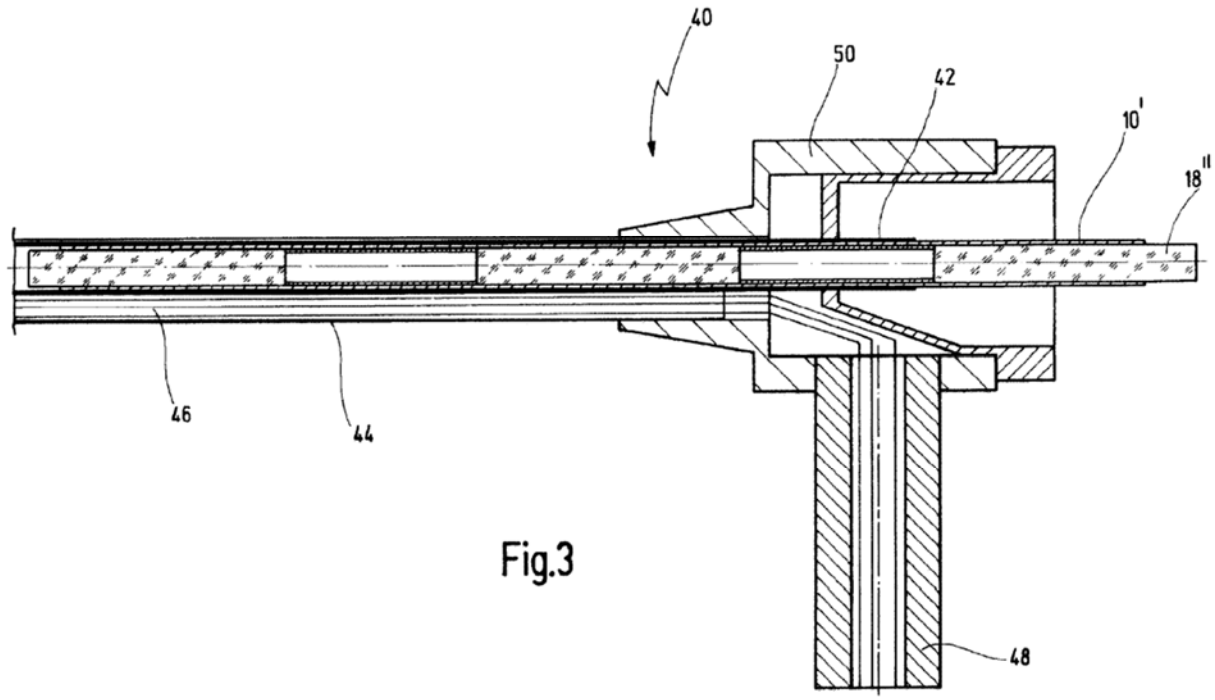


Fig.3

Id. at Fig. 3.

> The district court summarized the invention as follows:
>
> In simpler terms, [Karl Storz's] rigid endoscopes have a unique "tube within a tube" construction. The outer tube is the rigid body of the endoscope. The inner tube is enclosed with a transparent and shrinkable material, which the parties sometimes refer to as "shrink wrap." The inner tube contains lenses of different diameters and prescriptions separated by spacers of different sizes. So in the most general sense, the inner tube is a shrink-wrapped row of lenses and spacers. This inner tube can be assembled and inspected separately from the rest of the endoscope and can be removed from the endoscope as one unit. Again, the inner tube is the optical relay assembly.

Appx6 (SJ Order).

D. Karl Storz's Representative Claims

Consistent with the foregoing, Karl Storz's representative asserted claims are not directed to and do not claim all elements of an endoscope, but instead recite

the inventive optic assembly and the rigid tube into which it is placed. *See* Appx39 ('945 Patent, claim 1) at 6:21-38. The district court found that "without question, the way the optical relay assembly is assembled is the novel and distinguishing part of the invention." Appx23-24 (SJ Order).

For example, in the '945 Patent, method claim 1 is representative and describes a method of assembling the inventive optical relay assembly, including placing the optical relay components into a transparent tube, shrinking the transparent tube, checking the position of the components, and inserting the optical relay into a tubular shaft:

> 1. A method for assembling an endoscope having a tubular shaft, an optical system having several components, said components of said optical system are contained in an interior of said tubular shaft, said components of said optical systems are at least partially surrounded by a tube made of both a transparent and a shrunk material, said method comprising the following steps:
>
> a) introducing said components into a tube of transparent and shrinkable material to form a unit,
>
> b) shrinking said shrinkable material of said tube for fixing the position of said components contained within said tube relative to one another,
>
> c) checking a position of said components relative to one another through said transparent shrunk material, of said shrunk tube, and
>
> d) introducing said unit composed of said shrunk tube and said components contained therein into said tubular shaft.

Appx39 ('945 Patent) at 6:21-38.

Similarly, in the ’044 Patent, apparatus claim 1 is representative and describes an inventive optical system (the foregoing optical assembly or optical relay) and the tube in which that inventive optical system is placed:

> 1. An endoscope, comprising:
>
> a tubular shaft, having an inside face,
>
> an optical system having several components, said components of said optical system are contained in an interior of said tubular shaft,
>
> said components comprising at least two of the following: a lens, a spacer, a diaphragm, a prism, and a filter, said components directly surrounded by a support piece made of a shrunk material, wherein
>
> said shrunk material is a transparent material,
>
> said support piece made of said transparent material has a shape of a tube, and
>
> said tube containing said components of said optical system has been shrunk prior to inserting said tube into said interior of said tubular shaft, for allowing a visual check of a position of said components relative to one another, and
>
> a gap located between an outside surface of said tube of shrunk material and said inside face of said tubular shaft.

Appx47 (’044 Patent) 6:28-48.

II. Karl Storz Endoscopes

A. Karl Storz’s Endoscope Business and Products Are Subject To FDA Regulations

Karl Storz is an Original Equipment Manufacturer (OEM) of rigid endoscopes. *See* Appx3997 at 36:14-15. As an OEM, Karl Storz’s rigid endoscopes are subject to FDA regulations. Appx4303 at 183:8-12; Appx3854 at 60:6-12. Among other things, these requirements necessitate that the endoscopes

are permanently sealed in a certain manner and to certain standards. Appx9 (SJ Order) ("[Karl Storz] seals its rigid endoscopes with epoxies and welds that have been validated by the FDA."); Appx3854 at 59:24-61:4 ("Q. . . . what is the issue with opening the scope and then resealing it? . . . all that stuff has been validated [by the FDA] for sterilization and reprocessing. It goes through a certain amount of cycles. Once that's opened up and you put it back together, it's unclear what epoxy is being used, what weld's being used, what materials are being used . . . ."). This FDA-validated permanent seal is to assure that the endoscope seals can withstand the repeated sterilization processes that must occur between each use, which subject endoscopes to water vapor at a high temperature and pressure. Appx9 (SJ Order) ("Keeping the rigid endoscope closed also serves to withstand autoclaving."); Appx1283 at 44:21-45:8; Appx3854 at 60:7-61:4.

Pursuant to these regulations, Karl Storz endoscopes are not designed or manufactured to be taken apart to access the inner optical assembly—"once [the endoscope] is sealed it's meant to be sealed forever." Appx3854 at 59:24-25; Appx3971 at 38:21-24 (each Karl Storz rigid endoscope is "is not meant to be taken apart …It's permanently put together."); *see also* Appx3854 at 60:1-61:4. As such, Karl Storz permanently "seals its rigid endoscopes with epoxies and welds that have been validated by the FDA." Appx9 (SJ Order); *see also* Appx3854 at 59:24-61:4; Appx3856 at 68:5-19.

B. Karl Storz's Repair Business

Karl Storz offers non-invasive exterior "repairs" of its endoscopes, such as cleaning, polishing, and replacing exterior accessories. Appx2391 at 75:16-77:9; Appx3857 at 70:9-71:3. But given the importance of maintaining the endoscope's permanent seal, Karl Storz has not and does not perform invasive reconstructions of its rigid endoscopes; for example, Karl Storz does not break the endoscope seal to access and replace its optic assembly. Appx2398 at 103:6-7; Appx3854 at 59:14-61:4. In fact, no known OEM performs invasive reconstructions of rigid endoscopes. Appx2398 at 104:9-20. Invasive reconstruction would require breaking open the seal, which Karl Storz cannot do without permanently damaging the endoscope. Appx3854 at 59:13-61:4.

III. IMS's Endoscopes

IMS is an independent service organization that makes new optical assemblies for use in used Karl Storz endoscopes, using different parts and a different design, resulting in endoscopes that, in the words of the district court, "are inferior to and different from [Karl Storz's] originally manufactured endoscopes." Appx26. Despite using inferior and different parts and designs that admittedly do not meet Karl Storz's standards, IMS advertises its endoscopes as "Certified Pre-Owned" Karl Storz endoscopes, with only Karl Storz branding—but

no IMS branding—on the exceedingly inferior endoscopes. Appx660-661, ¶¶ 346-47; Appx662-663, ¶ 350; Appx3888 at 196:6-18; *see also* Appx4424 at 45:15-18.

A. IMS's Extensive Rebuild Steps

IMS purports to "repair" the optical relays of Karl Storz's rigid endoscopes. Appx7 (SJ Order); *see generally* Appx3638-3653. In fact, in order to perform such "repairs," IMS builds an entirely new, different, and inferior optical relay assembly. *See, e.g.,* Appx2234-2237, ¶¶ 15-34 (IMS builds a new optical relay assembly); Appx26-27 (SJ Order) (IMS builds a different and inferior endoscope); Appx520-521, ¶¶ 77; Appx659-661, ¶¶ 345-46; Appx662, ¶ 349 (IMS builds a more fragile optical relay with a limited field of view).

As part of the lengthy and invasive process, IMS must first break open the permanent seal of the Karl Storz endoscope. Before even attempting to break the seal, IMS must use a HydroFlux welder to compromise the seal bonds. Appx1666 at 68:5-1; *see also* Appx510, ¶ 57; Appx2235, ¶ 16. After using the welder, IMS places the endoscope in a jig to hold the endoscope firm while a technician uses a specialized tool to break open the seal. Appx1666 at 68:12-15; *see also* Appx510, ¶ 57; Appx2235, ¶ 16. Then, IMS heats the glue over the screws, removes the glue, and then removes screws holding the ocular base in place. Appx510, ¶ 57; Appx1666 at 68:16-69:20; *see also* Appx2235, ¶ 16. If IMS still cannot open the

seal after performing these steps, it will "machine" the eyepiece off. Appx1671 at 86:2-4; *see also* Appx510, ¶ 57.

Once the inner cavity is accessible, IMS removes the Karl Storz optical relay assembly and cuts and discards the transparent tube surrounding the lenses and spacers. Appx2235, ¶ 18; Appx510-511, ¶ 58. IMS then inspects the rods and spacers, places satisfactory rods and spacers into inventory, and discards the remaining rods and spacers. Appx2235, ¶¶ 19-21. IMS discards nearly half the lenses. *Id*., ¶ 22.

Practicing the claims of the Asserted Patents, IMS makes an entirely new and different optical relay. Defendant's sub-assembly department randomly selects lenses from an inventory of *new* IMS cylindrical lenses and salvaged Karl Storz dog-bone lenses. Appx1685 at 143:17-144:2; Appx2236, ¶¶ 30-31; Appx512, ¶ 61; Appx520-521, ¶ 77. Like the claims in the '044 and '945 Patents, a technician loads the lenses and spacers into a **new** tube of transparent shrinkable material. Appx1695-1696 at 185:18-186:2 (stating that "tubing" is a new material in inventory); Appx2236, ¶ 32 ("slides the components into a metal loading tube covered in shrink wrap"); Appx551, ¶ 131 (discussing how IMS changed its new shrunk material); *cf.*, Appx39 ('945 Patent, claim 1) at 6:28-29, ("introducing said components into a tube of transparent and shrinkable material to form a unit"). Typically, 60-100% of the replacement lenses are IMS cylindrical lenses and 0-

40% are Karl Storz dog-bone lenses, resulting in at least some IMS optical assemblies that have **no Karl Storz parts**, original or otherwise. *Compare* Appx1655 at 22:17-24 (stating that an optical relay has ten lenses), *with* Appx8 (SJ Order); Appx2236, ¶ 31 ("typically, about two to four [Karl Storz] lenses are used per endoscope, though a repaired endoscope may have all replacement lenses").

Like the claims in the '044 and '945 Patents, a technician then shrinks the new transparent tube by applying heat to the tube. Appx2236, ¶ 33; *see also* Appx2237-2238, ¶ 36 (not disputing the shrinking step of Claim 1 of the '945 Patent); *cf.,* Appx39 ('945 Patent, claim 1) at 6:30-33 ("shrinking said shrinkable material of said tube for fixing the position of said components contained within said tube relative to one another"). Like the claims in the '044 and '945 Patents, a technician visually inspects the new optical relay by "looking through the relay." *See e.g.*, Appx518-519, ¶ 74; Appx548-549, ¶ 127; Appx581-582, ¶ 186 (work instruction stating "inspect system for debris by looking through the relay or use optical testing device" after heat shrink step); Appx516-519, ¶¶ 70-74; Appx548-552, ¶¶ 125-132; *cf.*, Appx39 ('945 Patent, claim 1) 6:33-36 ("checking a position of said components relative to one another through said transparent shrunk material, of said shrunk tube"). Like the claims in the '044 and '945 Patents, a technician also introduces the new optical relay into the tubular shaft. Appx2236, ¶

25; *cf.*, Appx39 ('945 Patent, claim 1) 6:36-38 ("introducing said unit composed of said shrunk tube and said components contained therein into said tubular shaft").

Once IMS has made the new optical relay, it is inserted and the endoscope is closed by attempting to recreate the seal. Appx523, ¶ 82. IMS first assembles the eyepiece and ocular base over the optical relay. Appx2236, ¶ 25. Once assembled, the technician performs optical alignments. Appx2236, ¶ 26. The endoscope and eyepiece are then placed in an oven to remove any moisture. Appx2236, ¶ 27. The technician then applies glue over the threads of the endoscope and secures the eyepiece to the threads. Appx2236, ¶ 28.

B. IMS's Rebuild Creates a New, Different, and Inferior Article

The rebuilding process results in a new, inferior optical relay and endoscope. *See e.g.*, Appx2234-2236, ¶¶ 15-33 (IMS builds a new optical relay assembly); Appx26-27 (SJ Order) (IMS builds an "inferior [] and different" endoscope); Appx520-521, ¶ 77; Appx659-662, ¶¶ 345-46, 349 (IMS builds a more fragile optical relay with a limited field of view). The rebuilt optical relay is comprised of new lenses and spacers, and is encased in a new transparent tube, which has undergone a new shrinking process. Appx8 (SJ Order) ("The lenses and spacers that an IMS technician uses to assemble a replacement optical relay are either new or recycled from previously repaired [Karl Storz] endoscopes."); Appx2235, ¶¶ 18 (cutting and removing old shrink wrap), 21-22 (discarding old lenses), 31-33 (new

lenses) (new shrinking process); Appx1685 at 144:3-13 (new spacers), Appx1695-1696 at 185:18-186:2 (new spacers, new lenses, and new shrink wrap); Appx551, ¶ 131 (new shrink wrap).

The new lenses are cylindrical-shaped. Appx1685 at 143:17-144:2; Appx512, ¶ 61. However, the unique design of Karl Storz optical relays necessitates dog-bone shaped lenses to allow the endoscope to flex. Appx520-522, ¶¶ 77-79. Cylindrical-shaped lenses reduce the amount of flex the endoscope can perform and produces a more fragile endoscope. Appx521-522, ¶ 79; Appx657, ¶ 340. Thus, a "user who sends a [Karl Storz] endoscope to IMS 'would therefore get back an endoscope significantly more delicate than the one [Karl Storz] initially sold them.'" Appx9 (SJ Order) (citation omitted); *see also* Appx520-521, ¶ 77).

The new lenses also create a poor image and field of view. The mix-and-match of cylindrical and dog-bone shaped lenses changes the optics, and IMS documents show that its cylindrical lenses produce endoscopes having poorer images compared to Karl Storz endoscopes. Appx9 (SJ Order); *See* Appx659-661, ¶¶ 344-46; *see also* Appx3849 at 39:4-40:11; Appx3851 at 49:2-6. Evidence also shows that IMS endoscopes have a narrower field of view. Appx9 (SJ Order); Appx662, ¶ 349; *see* Appx3999 at 42:15-44:9; Appx4000 at 46:24-47:3.

Furthermore, in addition to receiving a new optical relay, the endoscope also receives a new, subpar seal. As noted by the district court, IMS seals are not validated by the FDA and unsurprisingly, the sealing process creates many quality issues:

> Indeed, [Karl Storz] seals its rigid endoscopes with epoxies and welds that have been validated by the FDA. (Doc. # 186-2 at 16). Apparently, IMS does not use that technique because the director of [Karl Storz's] scope inspections at hospitals has seen [Karl Storz] endoscopes repaired by third-parties with pitted, flaking, and discolored seals. (*Id.* at 12). . . . The record contains evidence of an IMS endoscope with rusting, pitting, and cracking at the laser weld within two weeks of use, an IMS endoscope eight centimeters longer than a [Karl Storz] endoscope, and an IMS "welding jig that may produce scope shafts slightly longer than specification." (*Id.*).

Appx10 (SJ Order).

Physicians believing they are using Karl Storz endoscopes can unknowingly instead use these new, different, and inferior IMS endoscopes, which can lead to compromised and customer feedback/experiences. *See* Appx522, ¶ 80; Appx658-659, ¶ 343 (physicians believing they are using Karl Storz endoscopes for procedures when they are actually using IMS endoscopes). As such, customers unwittingly expect the function and handling of the new endoscopes to be the same as the function and handling of original endoscopes. *See* Appx3888 at 196:6-18 ("[T]he surgeon who's the end user, has absolutely no idea and so, throughout the years, we have heard complaints about the quality of our scopes, only to find out that they were altered by an independent service organization or third party.");

Appx658-659, ¶¶ 343-44 (unsatisfied customers requesting Karl Storz to evaluate new IMS endoscopes).

Surgeons are not expecting endoscopes that have "different diameters and optical prescriptions, produce inferior images, have smaller fields of view, are more fragile [i.e., tolerate less flex], have welds prone to deterioration, and can be eight centimeters longer than Karl Storz's endoscopes." Appx26-27 (SJ Order); *see also* Appx520-522, ¶¶ 77, 79-80; Appx659-662, ¶¶ 344-46, 349. The changes have resulted in serious problems, such as customer feedback/ experiences in customer feedback/ experiences or customer feedback/ experiences customer feedback/ experiences. Appx4011 at 93:1-8 ("I think you're aware of the situation at customer feedback/ experiences customer feedback/ experiences where the scope . . . all of a sudden started to customer feedback/ experiences, right, inside the customer feedback/ experiences room. . . that would represent an example of materials used by somebody other than Karl Storz that . . . had not gone through testing to be proven to be safe and efficacious."); Appx658, ¶ 342 ("customer feedback/ experiences where scope customer feedback/ experiences on customer feedback/ experiences' during a procedure'") ("customer feedback/ experiences where 'something customer feedback/ experiences of the customer feedback/ experiences of scope'"), Appx659, ¶ 344; Appx662, ¶ 349 (customer feedback/ experiences due to a customer feedback/ experiences endoscope and customer feedback/ experiences due to limited field of view).

SUMMARY OF THE ARGUMENT

There are at least three independent bases for reversing the district court's grant of summary judgment. Each is a separate and independent reason that the

district court committed legal error by ignoring and giving no weight to the evidence showing that when infringing the asserted patents, IMS wholly replaces the entire claimed optical relay assembly:

(1) IMS did not establish that the replaced optical relay assembly was readily replaceable;

(2) the replaced optical assembly was, in the words of the district court, "the novel and distinguishing part of the invention;" and

(3) by replacing the optical assembly, IMS created "an essentially new article."

First, to prevail on its summary judgment arguments, IMS had the burden of establishing there was no genuine dispute that the replaced Karl Storz optical relay assembly was readily replaceable. But IMS did not even assert the replaced Karl Storz optical assembly was readily replaceable, much less establish that there was no genuine dispute concerning this material fact. Moreover, at the very least, Karl Storz identified evidence sufficient for a jury to determine that the Karl Storz optical relay assembly is **not** readily replaceable. Thus, at the very least, there was a genuine question of fact preventing the entry of summary judgment of repair here, and the district court's summary judgment order should be reversed.

Second, the district court found that "without question, the way the optical relay is assembled is the novel and distinguishing part of the invention." Appx23-

24 (SJ Order). It was also undisputed on summary judgment that IMS performed this novel assembly method in its entirety and, in doing so, replaced the entire novel optical relay assembly. The district court nonetheless gave this substantial evidence of reconstruction no weight and, in doing so, committed reversible error by directly contravening the Supreme Court's decision in *Quanta*, 553 U.S. at 635.

Third, the right to repair does "not include the right to construct an essentially new article on the template of the original, for the right to make the article remains with the patentee." *Jazz Photo*, 264 F.3d at 1102. But Karl Storz provided evidence creating at least a genuine dispute as to whether IMS created "an essentially new article." For example, the district court acknowledged that IMS replaced every claimed element but the tubular shaft with new and different parts, finding that the IMS endoscopes had "a different shrink wrap enclosing the optical relay, and different lenses and spacers in the optical relay." Appx21 (SJ Order). And the district court further admitted that "the summary judgment record supports a reasonable inference that IMS endoscopes are inferior and different from [Karl Storz's] originally manufactured endoscopes." Appx26 (SJ Order). Accordingly, there is at least a genuine dispute of fact as to whether IMS created an essentially new article, and summary judgment finding repair as matter of law was improper.

ARGUMENT

I. The Standard of Review For The District Court's Grant Of Summary Judgment On The Affirmative Defense Of Repair

Repair is an affirmative defense for which accused infringer IMS bears the burden of proof. *Jazz Photo*, 264 F.3d at 1101-02; *Dana Corp. v. Am. Precision Co.*, 827 F.2d 755, 758 (Fed. Cir. 1987). The defense arises from the implied license given to each purchaser of a patented article, which includes a right to repair the purchased article. *Bottom Line Mgmt. v. Pan Man, Inc.*, 228 F.3d 1352, 1354 (Fed. Cir. 2000), *citing Aro I*, 365 U.S. at 346. But this right to repair is limited—a purchaser cannot go beyond repairing the article to reconstructing it because a buyer's implied license "does not include the right to make a new device or to reconstruct one which has been spent." *Hewlett-Packard Co. v. Repeat-O-Type Stencil Mfg. Corp.*, 123 F.3d 1445, 1451 (Fed. Cir. 1997); *Jazz Photo*, 264 F.3d at 1102; *Lummus Indus. v. D.M. & E. Corp.*, 862 F.2d 267, 272 (Fed. Cir. 1988).

Although the law is clear that the owner of patented device has the right to repair it, but not the right to reconstruct it, "distinguishing between the two concepts is more easily said than done." *Wahpeton Canvas Co. v. Bremer*, 893 F. Supp. 863, (N.D. Iowa 1995). In the words of the Federal Circuit, "the Supreme Court and this court have struggled for years to appropriately distinguish between

repair of a patented machine and reconstruction." *Husky*, 291 F.3d at 785-86.

Commenters have concurred:

> In many instances, it is rather difficult to draw a line of distinction between permissible repair and non-permissible reconstruction. The distinction between repair and reconstruction, while clearly defined at the extreme ends, **presents a problem of factual determination at the boundary where legitimate repair ends and illegitimate reconstruction begins**.

6 Ernest B. Lipscomb III, Lipscomb's Walker on Patents § 22.9, 438-39 (3d ed. 1984) (emphases added); *see also* Donald S. Chisum, 5 Chisum on Patents, § 16.03[3], at 16-159 (1997) ("The line between permissible repair and impermissible reconstruction is difficult one to draw . . . .").

Accordingly, this Court cautions that there is no "bright-line test" for what constitutes repair versus reconstruction, and that the inquiry is unique to each set of underlying facts and circumstances:

> It is impracticable, as well as unwise, to attempt to lay down any rule on this subject, owing to the number and infinite variety of patented inventions. **Each case, as it arises, must be decided in the light of all the facts and circumstances presented, and with an intelligent comprehension of the scope, nature, and purpose of the patented invention, and the fair and reasonable intention of the parties.** Having clearly in mind the specification and claims of the patent, together with the condition of decay or deconstruction of the patented device or machine, the question whether its restoration to a sound state was legitimate repair, or a substantial reconstruction or reproduction of the patented invention, should be determined less by definitions or technical rules than by the exercise of sound common sense and an intelligent judgment.

FMC Corp. v. Up-Right Inc., 21 F.3d 1073, 1078 (Fed. Cir. 1994) (emphases added).

Thus, although the ultimate question of whether an accused infringing act constitutes permissible repair is a question of law, it must be answered based on all underlying facts and the totality of the circumstances, and the legal question of repair cannot be answered until all material questions of fact are resolved: "Questions of law are not answerable in a vacuum. Only after the necessary fact pattern exists can the legal question be answered." *Dana*, 827 F.2d at 758; *Bottom Line*, 228 F.3d at 1355; *Aktiebolag v. E.J. Co.*, 121 F.3d 669, 674 (Fed. Cir. 1997). Only when "there is no genuine issue of material fact, or when after a trial the facts have been found, [is] the question of whether the defendant's conduct constituted permissible repair . . . answerable as question of law." *Dana*, 827 F.2d at 758.

Because the district court decided the affirmative defense of repair on summary judgment and did not allow this issue to proceed to trial, IMS's burden was to establish that (1) there was no material dispute of underlying fact and (2) based on the established undisputed facts, IMS's acts were permissible repair as a matter of law. *Dana*, 827 F.2d at 758; *Aktiebolag*, 121 F.3d at 672. This Court reviews each of those questions *de novo*, without deference. *Husky*, 291 F.3d at 784; *Aktiebolag*, 121 F.3d at 674.

Moreover, all justifiable factual inferences must be drawn in favor of Karl Storz, the party opposing summary judgment. *Pall Corp. v. PTI Techs., Inc.*, 259 F.3d 1383, 1389 (Fed. Cir. 2001); *Aktiebolag*, 121 F.3d at 672. And "[a]ll doubt respecting the presence or absence of material factual issues must be resolved in the favor of the party opposing summary judgment," here Karl Storz. *Dana Corp.*, 827 F.2d at 758. Summary judgment is thus appropriate only where no "reasonable jury could return a verdict for the nonmoving party." *Hewlett-Packard*, 123 F.3d at 1450, (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)).

II. The District Court Committed Reversible Legal Error By Ignoring That The Karl Storz Optical Relays Are Not "Readily Replaceable" Parts

Although this Court warns that the repair defense must be decided based on "**all** facts and circumstances presented" and there is **no** "bright-line rule" as to what constitutes permissible repair versus impermissible reconstruction, the district court committed reversible legal error by ignoring these warnings. *E.g.*, *FMC*, 21 F.3d at 1078. Contrary to the required repair doctrine analysis, the district court reached its erroneous summary judgment decision by:

- failing to consider "all facts" and instead focusing on just a few select factual assertions in a vacuum, improperly ignoring other relevant facts supporting a finding that IMS's infringing actions were in fact impermissible reconstruction; and

- applying to these limited facts an incorrect "bright-line rule" that is contrary to this Court's controlling precedent.
- For example, the district court determined that IMS's manufacturing process replaced parts of the Karl Storz endoscopes (one fact given unduly weight over the others) and determined that as a matter of law, any replacement of parts is always "repair" as a matter of law (a bright-line rule that this Court has explicitly rejected).

Appx21-22, Appx24 (SJ Order).

But contrary to the erroneous bright-line rule adopted by the district court, the replacement of parts is not always permissible repair. Rather, this Court holds that while the replacement of "readily replaceable" parts may be repair, the replacement of parts that are **not** readably replaceable is **impermissible reconstruction**. *E.g.*, *Husky*, 291 F.3d at 787; *Aktiebolag*, 121 F.3d at 674.

Thus, by concentrating on the fact that IMS replaced the Karl Storz optical assembly, the district court ignored another material and contravening factual inquiry: whether that optical assembly was "readily replaceable." IMS did not even assert the Karl Storz optical assembly was readily replaceable, much less establish that there was no genuine dispute concerning this material fact. For this reason alone, IMS did not meet its burden and the summary judgment ruling should be reversed.

Moreover, at the very least, Karl Storz identified evidence sufficient for a jury to determine that the Karl Storz optical assembly is **not** readily replaceable. This, too, means, that the district court's entry of summary judgment of "repair" was legal error and should be reversed.

A. Whether The Replacement Of A Part Is Permissible Repair Depends On Whether The Part Is "Readily Replaceable"

The Federal Circuit explains that when determining whether the replacement of claimed parts of a patented combination constitutes permitted repair or infringing reconstruction, there is a spectrum of such parts, with readily replaceable parts on one end of the spectrum and parts not manufactured or intended to be readily replaceable on the other end. *See*, *e.g.*, *Husky*, 291 F.3d at 787. According to the Federal Circuit, replacing a part from the readily replaceable end of the spectrum would be repair; replacing a part from the non-readily replaceable end of the spectrum would be reconstruction; and determining where on the spectrum the line exists between readily replaceable and not readily replaceable could pose "difficult questions." *Id*.

For example, the readily replaceable end of the spectrum is illustrated in this Court's decision in *Kendall Co. v. Progressive Medical Tech., Inc.*, 85 F.3d 1570 (Fed. Cir. 1996). Kendall's asserted patent was directed to a medical device for applying compressive pressure to a patient's limbs, the device comprising "three basic components: a controller-pneumatic pump for supply pressurized fluid; a

pair of pressure sleeves that wrap around a patient's limbs; and connecting tubes." *Id*. at 1571. The claimed pressure sleeves were readily replaceable: Kendall sold these devices to customers knowing that they intended to replace the claimed pressure sleeves after each use by a single patient in order to reduce the risk of contamination; Kendall sold replacement sleeves to its customers; and Kendall marked its replacement sleeves as "FOR SINGLE PATIENT USE ONLY. DO NOT REUSE." 85 F.3d at 1571. Thus, when Kendall asserted that its customers who bought replacement sleeves from other manufacturers were infringing the Kendall patent, the Court disagreed. Following the Supreme Court's *Aro I* decision, the Court found that the replacement of the sleeves was permissible repair and not infringement. *Id*. at 1574, *quoting Aro I*, 365 U.S. at 345.

But this Court stresses that *Aro I* and its progeny are concerned with readily replaceable parts and do not stand for the proposition that the repair defense is applicable where the claimed part being replaced is **not** readily replaceable. *Husky*, 291 F.3d at 787. The Federal Circuit identifies its *Aktiebolag* decision as illustrative as this other, non-readily replaceable end of the spectrum. *Id*. In *Aktiebolag*, the patents-in-suit were directed to a drill that included a shank and a drill tip. *Aktiebolag*, 121 F.3d at 670. The accused infringer replaced worn or damaged drill tips with new tips. *Id*. at 671. The Federal Circuit found that this replacement of a part in a patented device was not permissible repair, but

infringing reconstruction. *Id.* at 673. In doing so, the Court contrasted the replaced tips with readily replaceable parts, noting that the "drill tip was not manufactured to be a replaceable part . . . it was not intended or expected to have a life of temporary duration in comparison to the drill shank;" and "the tip was not attached to the shank in a manner to be easily detachable." *Id.* at 674.

When using *Aktiebolag* as an example of a clearly not readily replaceable part (and infringing reconstruction), the *Husky* Court also noted that where to draw the line between readily replaceable and not readily replaceable parts may involve "difficult questions." *Husky*, 291 F.3d at 787. The *Husky* Court did not need to address this question, however, because "there is no question that the particular parts [at issue in Husky] were readily 'replaceable' parts." *Id.* at 788.

B. Reversal Is Required Because IMS Did Not Assert, And The District Court Did Not Consider Or Find, That The Replaced Karl Storz Optical Assembly Is "Readily Replaceable"

In contrast to the *Husky* decision, this is not a case where there is "no question" that the replaced Karl Storz optical assembly is readily replaceable. To the contrary, although IMS bore the burden of proof of establishing that there is no material dispute that the Karl Storz optical assembly is readily replaceable, IMS did not even assert, much less definitively establish beyond dispute, that the optical assembly was readily replaceable. Likewise, the district court did not address this issue and granted summary judgment of permissible repair without even

considering whether the Karl Storz optical assembly was a readily replaceable part. For these reasons alone, the summary judgment grant of permissible repair should be reversed.

Moreover, at the very least, Karl Storz identified evidence sufficient to create a material dispute concerning whether its optical assembly was readily replaceable. Indeed, the weight of the evidence clearly establishes that the optical assembly was not readily replaceable (and therefore, that the repair defense does not apply here). *See e.g.*, Appx510-511, ¶¶ 57-58 (the endoscope seal must be opened to replace the optical relay assembly); Appx3854 at 59:24-61:4 (explaining that the seal of an endoscope cannot be opened without compromising the FDA certified seal); Appx8 (SJ Order) (Karl Storz does not sell replacement parts); Appx2398 at 103:6-7; 104:9-20 (No OEM, including Karl Storz, repairs its endoscopes); Appx2234-2236, ¶¶ 15-33 (the nature and quantity of the steps needed to replace the optical relay are extensive).

For example, Karl Storz sells, and its customers buy, an FDA-validated and regulated endoscope. Appx3854 at 60:3-12; Appx3866 at 107:3-6. The mere fact that IMS cannot replace the optical assembly without first breaking the FDA-validated permanent seal establishes on its own that the optical assembly is not "readily replaceable." Appx510-511, ¶¶ 57-58; Appx3854 at 60:3-12; Appx3866 at 107:3-6; *see also* Appx1666-1667 at 68:5-70:19; Appx2235, ¶ 16. As shown above

(and on summary judgment), Karl Storz's endoscopes are subject to strict FDA regulations requiring them to be permanently sealed in a particular manner so that the seal can withstand repeated sterilization processes. Appx3854 at 59:24-61:4 (explaining that the "when we go through our [FDA certification] . . . [the] scope, epoxies, welds, all that stuff has been validated for sterilization and reprocessing. Once that's opened up and you put it back together, it's unclear what epoxy is being used, what weld's being used, what materials are being used, therefore, it could potentially be compromised during reprocessing and sterilization."); Appx9 (SJ Order) ("Keeping the rigid endoscope closed also serves to withstand autoclaving."); Appx1283 at 44:21-45:8 ("Autoclaving . . . is a means of sterilization."). Thus, the evidence shows that the seal used by Karl Storz has been cleared and verified by the FDA and is intended to be permanent—"once [the endoscope] is sealed it's meant to be sealed forever." Appx3854 at 59:24-25; *see also* Appx3971 at 38:21-24 (each Karl Storz rigid endoscope is "is not meant to be taken apart …It's permanently put together."). If the seal is broken, any subsequent seal is not FDA cleared and it is unknown whether the new seal will hold-up to sterilization and reprocessing. *See* Appx3854 at 59:24-61:4. But it is undisputed that for IMS to replace the optical assembly in a Karl Storz endoscope, IMS must first break this seal and replace it with one that is not FDA cleared or regulated, posing a health risk to the public. Appx510, ¶¶ 57-58 (breaking the seal);

Appx2235, ¶ 16 (breaking the seal); Appx3854 at 60:3-61:4 (replacement seals are not validated by FDA); Appx4303 at 183:8-12 (IMS seals are not cleared by the FDA). For this reason alone, a jury could reasonably determine that the optical assembly is not readily replaceable and, therefore, summary judgment applying the repair defense is inappropriate.

But additional evidence also supports a finding that the Karl Storz optical assembly is not readily replaceable. For example, Karl Storz does not replace or sell replacement optical assemblies for its endoscopes, and neither does any other OEM of endoscopes. Appx8 (SJ Order) ("Nor does [Karl Storz] sell component parts"); Appx525, ¶ 85; Appx2398 at 103:6-7, 104:9-20; Appx2406 at 134:13-14. This is because any replacement of the optical assembly would require breaking the permanent seal, which would permanently damage and make spent the FDA-cleared endoscope. Appx3854 at 59:13-60:5; Appx2234-2235, ¶¶ 15-16.

Further evidence that the Karl Storz optical assembly is not readily replaceable are the extensive steps that IMS must perform in order to replace the assembly—like the drill tip in *Aktiebolag*, the optical assembly is not "easily detachable." *Aktiebolag*, 121 F.3d at 674. As described above, IMS uses invasive techniques, including breaking the permanent bonds of the sealed endoscope with a HydroFlux welder to access the optical relay. Appx2235, ¶ 16; Appx1666 at 68:5-11). The technician then removes the optical relay, cutting and discarding the

transparent tube surrounding the lenses and spacers. Appx2235, ¶ 18; Appx510-511, ¶ 58. After inspecting the rods and spacers, the satisfactory ones are reserved, and the rest are discarded. Appx2235, ¶¶ 19-21. IMS then reconstructs a replacement optical relay with mostly IMS cylindrical lenses and spacers instead of Karl Storz dog bone lenses and spacers, into a new tube of transparent shrinkable material. Appx2236, ¶¶ 31-32; Appx512, ¶ 61; Appx520-521, ¶ 77; Appx1685 at 143:17-144:2, Appx1695-1696 at 185:18-186:2; Appx8 (SJ Order). The technician then shrinks the new transparent tube by applying heat, visually inspects the new optical relay, and introduces the new optical relay into the tubular shaft. Appx2236, ¶¶ 25, 33; Appx518, ¶ 74; Appx548-549, ¶ 127; Appx581-582, ¶186 (work instruction stating "inspect system for debris by looking through the relay or use optical testing device" after heat shrink step); *see also* Appx2237-2238, ¶ 36; Appx516-519, ¶¶ 70-74; Appx548-552, ¶¶ 125-132. Once IMS reconstructs the optical relay, it attempts to recreate the hermetic seal. Appx523, ¶ 82.

In *Aktiebolag*, the Court noted that, like here, the defendant did not

> just attach a new part for a worn part, but rather must go through several steps to replace, configure and integrate the tip onto the shank. It has to break the worn or damaged tip from the shank by heating it to 1300 degrees Fahrenheit. It brazes to the shank a new rectangular block of carbide and grinds and machines it to the proper diameter and creates the point. Thereafter, the tip is honed and sharpened, grinding the rake surfaces and the center of the point and honing the edges. These actions are effectively a re-creation of the patented invention after it is spent.

121 F.3d at 673. Thus, like in *Aktiebolag*, the extensive steps undertaken by IMS also establish that the Karl Storz optical relay is not a readily replaceable part.

For these reasons, IMS did not meet its burden of showing that there is no material dispute that the Karl Storz is a readily replaceable part. IMS did not assert or argue that the optical assembly was readily replaceable and, at the very least, Karl Storz identified sufficient evidence allowing a reasonable jury to find that the optical assembly is not readily replaceable. Therefore, summary judgment finding repair as a matter of law was wrong and should be reversed.

III. The District Court Committed Reversible Error By Ignoring That The Asserted Patents Are Not "Combination Patents" And That IMS Replaced The Entirety Of The "Novel and Distinguishing Aspect Of The Invention"

It is undisputed that when IMS replaces the Karl Storz optical assembly, it performs or replaces almost the entirety of the claimed invention; specifically, IMS performs all claimed steps in the '945 Patent and replaces all claimed parts, except the tubular shaft, in both the '044 and '945 Patents. *See infra* Section IV (showing IMS replaces all claimed parts); Appx542-545, ¶¶ 112-118 ("introducing said components into a tube of transparent and shrinkable material to form a unit"), 119-124 ("shrinking said shrinkable material of said tube for fixing the position of said components contained within said tube relative to one another"), 70-74, 125-132 ("checking a position of said components relative to one another through said transparent shrunk material, of said shrunk tube"), 133-134 ("introducing said unit

composed of said shrunk tube and said components contained therein into said tubular shaft"); *see also* Appx2236, ¶¶ 30-32 ("introducing said components into a tube of transparent and shrinkable material to form a unit"); *Id*., ¶ 33 ("shrinking said shrinkable material of said tube for fixing the position of said components contained within said tube relative to one another"); *Id*., ¶ 25 ("introducing said unit composed of said shrunk tube and said components contained therein into said tubular shaft"); Appx551, ¶ 131 (discussing how IMS changed its new shrunk material); *cf*., Appx39 ('945 Patent, claim 1) at 6:28-29, ("introducing said components into a tube of transparent and shrinkable material to form a unit"). In addition, the district court determined that what is replaced and performed by IMS is "the novel and distinguishing part of the invention." Appx23-24 (SJ Order). But in determining that IMS's actions were repair as a matter of law, the district court gave no weight to the extent and inventive nature of the parts replaced by IMS. In doing so, the district court directly contravened the Supreme Court's decision in *Quanta*, 553 U.S. at 635, thereby committing reversible legal error.

A. The Supreme Court's *Quanta* Decision Confirms That *Aro I* Does Not Apply To Karl Storz's Claims And Inventive Optic Assembly

The district court found that "without question, the way the optical relay is assembled is the novel and distinguishing part of the invention." Appx23-24 (SJ Order). But the district court ignored that IMS is performing this entire novel assembly and replacing the entire claimed novel optic relay assembly, relying on

Aro I to conclude that the novelty of the optic assembly "does not affect the repair versus reconstruction analysis." Appx24 (SJ Order).

But although *Aro I* is frequently cited for its statement that there is no protection for just the "'essential' element, 'gist,' or 'heart' of the invention," this statement is explicitly limited to "a combination patent" and does not apply here. *See Aro I*, 365 U.S. at 345 (stating that the "Court has made it clear in the two *Mercoid* cases that there is no legally recognizable or protected 'essential' element, 'gist,' or 'heart' of the invention **in a combination patent**" (emphasis added)).

The Supreme Court recently drove home the limited applicability of the *Aro I* decision in its *Quanta* decision. In *Quanta*, the Supreme Court rejected an attempt to broadly apply *Aro I*, stating that "*Aro*'s warning that no element can be viewed as central to or equivalent to the invention is **specific to the context in which the combination itself is the only inventive aspect of the patent**." 553 U.S. at 635 (emphases added). The Supreme Court explained that *Aro I* does not apply where something other than just the combination of well-known elements is inventive, such as where the design of one or more elements in the combination are themselves inventive. *Id*. ("In this case, the inventive part of the patent is not the fact that memory and buses are combined with a microprocessor or chipset; rather, it is included in the design of the Intel products themselves and the way these products access the memory or bus.").

Thus, the Supreme Court's *Quanta* decision compels a finding that *Aro I* does not apply here because the district court did not find, and IMS did not establish as a matter of law, that Karl Storz's claims are inventive only because they are "a new combination of existing parts." *Quanta*, 553 U.S. at 635. To the contrary, the district court found that some of the elements in the claims—the claimed optical assembly—were themselves new: "without question, the way the optical relay is assembled is the novel and distinguishing part of the invention." Appx23-24 (SJ Order). Accordingly, Karl Storz's patents are not the type of "combination patents" to which *Aro I* is limited. *See id*.

B. IMS Impermissibly Reconstructed Endoscopes Because IMS Admittedly Performed and Replaced The Entire "Novel and Distinguishing Part of the Invention"

Thus, under *Quanta*, the extent to which IMS performed and replaced the novel aspect of Karl Storz's invention is highly relevant to whether IMS's action constituted permissible repair or impermissible reconstruction. Accordingly, summary judgment of repair was improper because the evidence establishes that IMS performed and replaced the entire "novel and distinguishing part of the invention."

First, the district court determined that the "optical relay . . . performs the endoscope's primary function of transmitting an optical image from one end of the endoscope to the other" and stated that "**the way the optical relay is assembled is**

the novel and distinguishing part of the invention." Appx23-24 (SJ Order) (emphasis added).

Second, not only does IMS perform all steps in the '945 Patent and replace all named parts, except the tubular shaft, in both the '044 and '945 Patents, but IMS rebuilds and replaces the entire inventive aspect of the '044 and '945 Patents. Indeed, it is undisputed on summary judgment that IMS rebuilds and replaces the entire optical relay. Appx4627 (stating that "it is immaterial that IMS replaces the entire optical relay").

Accordingly, it was contrary to *Quanta* and reversible legal error for the district court to ignore that IMS performed and replaced the entire "novel and distinguishing part of the invention." But that is exactly what the district court did here in finding that IMS's actions were permissible repair as a matter of law.

IV. Reversal Is Required Because There Is At Least A Material Dispute of Fact As To Whether IMS Makes An Essentially New Article

The right to repair does "not include the right to construct an essentially new article on the template of the original, for the right to make the article remains with the patentee." *Jazz*, 264 F.3d at 1102. Accordingly, if IMS's actions did "in fact make a new article," its actions are infringing reconstruction and not permissible repair. *Id*. at 1103; *Bottom Line*, 228 F.3d at 1355. Here, Karl Storz provided evidence creating at least a genuine dispute as to whether IMS created an

"essentially new article," and summary judgment of repair was therefore improper and should be reversed.

For example, in representative claim 1 from the '044 Patent, IMS replaces all of the bolded elements, which comprise every claimed element except the "tubular shaft":

> 1. An endoscope, comprising:
>
> a tubular shaft, having an inside face,
>
> **an optical system having several components, said components of said optical system are contained in an interior of said tubular shaft,**
>
> **said components comprising at least two of the following: a lens, a spacer, a diaphragm, a prism and a filter, said components directly surrounded by a support piece made of a shrunk material, wherein**
>
> **said shrunk material is a transparent material,**
>
> **said support piece made of said transparent material has a shape of a tube, and**
>
> **said tube containing said components of said optical system has been shrunk prior to inserting said tube into said interior of said tubular shaft, for allowing a visual check of a position of said components relative to one another, and**
>
> **a gap located between an outside surface of said tube of shrunk material and said inside face of said tubular shaft**.

Appx47 ('044 Patent, claim 1) at 6:27-48; Appx2237, ¶ 35 (inserting tube into said tubular shaft), Appx2236, ¶¶ 30-31 (new lenses), *Id*. ¶ 32 (tube containing components), *Id*. ¶ 33 (tube is shrunk prior to inserting tube into tubular shaft); Appx1685 at 143:17-144:2 (new lenses), 144:3-13 (new spacers), Appx1695-1696 at 185:18-186:2 (new tube, i.e., shrink wrap and new spacers); Appx517-518, ¶ 73;

Appx548-552, ¶¶ 125-132 (visual check) Appx551, ¶ 131 (new tube), Appx572-577, ¶¶ 170-178 (said shrunk material is a transparent material), Appx577-580, ¶¶ 179-183 (said support piece made of said transparent material has a shape of a tube), Appx580-588, ¶¶ 184-196 (said tube containing said components of said optical system has been shrunk prior to inserting said tube into said interior of said tubular shaft, for allowing a visual check of a position of said components relative to one another) (allowing a visual check), Appx588-590, ¶¶197-201 (a gap located between an outside surface of said tube of shrunk material and said inside face of said tubular shaft); *see also* Appx7-8 (SJ Order).

The district court acknowledged that IMS replaced every claimed element but the tubular shaft with new and different parts, finding that the IMS endoscopes had "a different shrink wrap enclosing the optical relay, and different lenses and spacers in the optical relay." Appx21 (SJ Order).

In addition to the replacement of all of these elements with new and different parts (including the entirety of the inventive optical assembly), the evidence shows that the resulting IMS endoscopes are quite different from the Karl Storz endoscope template on which they were built. Appx26-27 (SJ Order); Appx659-662, ¶¶ 345-46, 349 (In comparison to Karl Storz endoscopes, IMS endoscopes have an inferior image quality, limited field of view, and may be eight centimeters

longer.). For example, although IMS advertises its endoscopes as "Certified Pre-Owned" Karl Storz endoscopes:

- Karl Storz's endoscopes are FDA cleared, but IMS's are not (*compare* Appx3854 at 59:24-61:4; Appx3856 at 68:1-18 *with* Appx4303 at 183:8-12);
- IMS's endoscopes do not meet Karl Storz's manufacturing specifications (Appx9-10 (SJ Order); Appx 26-27; *see also* Appx660-661, ¶ 346);
- Where all Karl Storz endoscopes feature dog-bone shaped rod lenses that provide a higher degree of flex without breaking the lens, IMS's endoscopes feature inferior cylindrical lens which lead to easier breakage and inferior image quality (Appx520-522, ¶¶ 77-79; Appx659-660, ¶¶ 344-45; *see also* Appx3849 at 39:1-13; Appx3999 at 42:15-44:9, Appx4000 at 46:24-47:3);
- IMS's endoscopes have a smaller field of view than Karl Storz's endoscopes (Appx659, ¶ 344; Appx662, ¶ 349);
- IMS does not seal its endoscopes according to Karl Storz's specifications, leading to inferior pitted, flaking, and discolored seals (Appx9 (SJ Order); *see also* Appx660-661, ¶ 346);
- IMS apparently uses an inferior laser weld which leads to rusting, pitting, and cracking within two weeks of use (Appx9-10 (SJ Order); *see also* Appx660-661, ¶ 346); and

- IMS's endoscopes are eight centimeters longer than Karl Storz endoscopes (Appx10 (SJ Order); *see also* Appx660-661, ¶ 346).

All of the vast differences can and do cause health hazards when a surgeon is expected to be using a Karl Storz endoscope and is instead using a much different and inferior new IMS endoscope. *See e.g.,* Appx659, ¶ 344; Appx662, ¶ 349 (customer feedback/ experiences due to limited field of view). For example, a surgeon would only see the Karl Storz branding on the IMS endoscope, and would therefore be unaware that the endoscope he or she was actually using tolerated less flex and could easily break during use. Appx520-522 at ¶¶ 77-79; Appx659-660, ¶ 345 (IMS endoscopes tolerate less flex), Appx662, ¶ 350 (IMS does not mark endoscopes with IMS branding); Appx4424 at 45:15-18("Q. Does IMS mark endoscopes to indicate that they repaired the – the endo-scope? A. Not on -- not on the device."); *see also* Appx3999-4000 at 45:14-46:2 ("The scope itself is labeled Karl Storz, the physician doesn't know the difference, right."); Appx3888 at 196:6-18. IMS endoscopes have customer feedback/ experiences on customer feedback/ experiences in the customer feedback/ experiences Appx658, ¶ 342. A customer feedback/ experiences was customer feedback/ experiences because the customer feedback/ experiences could not see what was required, not realizing that the inferior IMS endoscope has a comparatively limited field of view. Appx662, ¶ 349; Appx3999 at 42:15-44:9.

And the district court acknowledged all of the critical differences between the Karl Storz endoscope and the new IMS endoscopes, finding:

> Evidence in the summary judgment record supports a reasonable inference that IMS endoscopes are inferior and different from [Karl Storz's] originally manufactured endoscopes. Some IMS endoscopes have rod lenses of different diameters and optical prescriptions, produce inferior images, have smaller fields of view, are more fragile, have welds prone to deterioration, and can be eight centimeters longer that [Karl Storz's] endoscopes.

Appx26-27 (SJ Order).

However, despite IMS replacing the entire inventive optical assembly with new and different parts, resulting in an admittedly different and inferior endoscope, the district court inexplicably found there was no genuine issue of material fact "because IMS has the right to modify the endoscopes beyond [Karl Storz's] specifications **as long as IMS does not in fact make a new article**." Appx27 (SJ Order) (emphasis added).

But the district court's circular reasoning misses the point—all of the foregoing is evidence that IMS **did** in fact make a new article. And, if IMS did make an essentially new article, by law its actions are not permissible repair. The district court therefore should have let Karl Storz present to a jury its evidence showing that IMS created an essentially new article, and summary judgment of repair was improper.

CONCLUSION

For the foregoing reasons, the Court should reverse the district court's summary judgment finding permissible repair.

Dated: November 14, 2022

Respectfully submitted,

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ADDENDUM

ADDENDUM TABLE OF CONTENTS

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U.S. DISTRICT COURT
N.D. OF ALABAMA

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

KARL STORZ ENDOSCOPY-AMERICA, INC.,	}	
Plaintiff,	}	
v.	}	**Case No.: 2:12-CV-02716-RDP**
STERIS INSTRUMENT MANAGEMENT SERVICES, INC.,	}	
Defendant.	}	

FINAL JUDGMENT

This matter is before the court on the Joint Motion filed by Plaintiff Karl Storz Endoscopy-America Inc. ("KSEA") and Defendant Steris Instrument Management Services, Inc. ("IMS") to dismiss IMS's Counterclaims pursuant to Fed. R. Civ. P. 41(a)(2). (Doc. # 219).

On May 19, 2022, the court issued a Memorandum Opinion (Doc. # 215) and Order (Doc. # 216) in which the court granted Defendant's motion for summary judgment, entered final judgment in Defendant's favor on all claims against it, and closed this case. However, the court's Memorandum Opinion and Order did not address Defendant's four counterclaims: (1) declaration of non-infringement of the '945 Patent; (2) declaration of invalidity of the '945 Patent; (3) declaration of non-infringement of the '044 Patent; and (4) declaration of invalidity of the '044 Patent. (Doc. # 94 at 13-21).

In its June 1, 2022 Response to the court's Order Regarding the Status of Defendants' Counterclaims, Defendant IMS states that it "agrees that the Court's entry of final judgment in favor of IMS on Counts One and Two in Plaintiff's Second Amended Complaint (Doc. # 216) renders its First and Third Counterclaims for a declaratory judgment of non-infringement moot."

(Doc. # 218 at 1). Further, because there appears to be some concern about whether the issue of patent invalidity may arise if the court's Memorandum Opinion and Order on Defendant's motion for summary judgment is reversed on appeal, "in the interests of efficiency and judicial economy, IMS and Plaintiff Karl Storz Endoscopy America Inc. ("KSEA") [] agreed to dismiss IMS's invalidity counterclaims without prejudice and with leave for IMS to re-file its counterclaims in the event that this matter is remanded after appeal." (*Id.* at 2).

Therefore, by agreement of the parties, it is **ORDERED** as follows:

1. The Joint Motion (Doc. # 219) is **GRANTED**.
2. IMS's First Counterclaim for a declaration of non-infringement of U.S. Patent No. 7,530,945 ("the '945 Patent") and IMS's Third Counterclaim for a declaration of non-infringement of RE47,044 ("the '044 Patent") are **DISMISSED AS MOOT**.
3. IMS's Second Counterclaim for a declaration of invalidity of the '945 Patent and IMS's Fourth Counterclaim for a declaration of invalidity of the '044 Patent are hereby **DISMISSED WITHOUT PREJUDICE**.
4. IMS is further granted leave to re-file its First through Fourth Counterclaims in the event that this matter is remanded after an appeal.

DONE and **ORDERED** this June 2, 2022.

R. DAVID PROCTOR
UNITED STATES DISTRICT JUDGE

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2022 May-19 AM 10:51
U.S. DISTRICT COURT
N.D. OF ALABAMA

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

KARL STORZ ENDOSCOPY-AMERICA, INC.,	}	
Plaintiff,	}	
v.	}	**Case No.: 2:12-CV-02716-RDP**
STERIS INSTRUMENT MANAGEMENT SERVICES, INC.,	}	
Defendant.	}	

MEMORANDUM OPINION

This patent infringement case is before the court on six motions: Plaintiff's Motion for Partial Summary Judgment as to certain infringement claims and patent validity (Doc. # 172); Defendant's Motion for Summary Judgment based on the affirmative defense of repair (Doc. # 174); the parties' *Daubert* motions to exclude expert witness testimony at trial (Docs. # 173, 175); and Plaintiff's Motion for Sanctions based on alleged spoliation of evidence (Doc. # 171). The Motions have been fully briefed (Docs. # 176, 177, 178, 179, 180, 190, 191, 192, 196, 197, 202-1, 202-2, 212, 213, 214) and are under submission. After careful review, and for the reasons discussed below, Defendant's Motion for Summary Judgment (Doc. # 174) is due to be granted and all other Motions (Docs. # 171, 172, 173, 175, 210) are due to be denied.

I. Background[1]

This case concerns endoscopes. An endoscope is a tubular device used by medical professionals to see inside body cavities. (Doc. # 104 at 2). Endoscopes have various components. The outermost body of a rigid endoscope is an inflexible tubular shaft. (Doc. # 169-1 at 1, ¶ 1). The shaft houses an inner tube called the optical relay assembly. (*Id.* at 1, ¶¶ 1-2). The optical relay assembly is a series of lenses and spacers arranged in a specific order. (*Id.* at 1, ¶ 2). The purpose of the optical relay assembly is to pass the image from one end of the endoscope to the other. (*Id.*). The user can look through an eyepiece attached to the proximal end of the endoscope to see the image from the distal end. (*Id.* at 1-2, ¶¶ 1, 6).

Plaintiff Karl Storz Endoscopy-America, Inc. ("KSEA") manufactures and services endoscopes. It owns two patents at issue in this case: U.S. Patent No. 7,530,945, entitled "Endoscope and Method for Assembling Components of an Optical System" ("the '945 Patent"), and U.S. Reissued Patent No. RE46,044, also entitled "Endoscope and Method for Assembling Components of an Optical System" ("the '044 Patent"). (Docs. # 93-1, 93-2). The '945 Patent is a method patent covering a process of assembling endoscopes and the '044 Patent is a machine patent covering the endoscopes themselves. (*See id.*). The patents are substantially similar; that is, they cover the same devices and the method of assembling those devices. (*See id.*). Through the patents, KSEA claims right to the process of creating an endoscope with an interior tube (the optical relay assembly), which is encased in transparent shrinkable material that encloses and fixes

[1] The facts set out in this opinion are gleaned from the parties' submissions and the court's own examination of the evidentiary record. All reasonable doubts about the facts have been resolved in favor of the nonmoving party. *See Info. Sys. & Networks Corp. v. City of Atlanta*, 281 F.3d 1220, 1224 (11th Cir. 2002). These are the "facts" for summary judgment purposes only. They may not be the actual facts that could be established through live testimony at trial. *See Cox v. Adm'r U.S. Steel & Carnegie Pension Fund*, 17 F.3d 1386, 1400 (11th Cir. 1994).

the optical components (lenses and spacers) and allows for a visual check of the alignment of the optical components before assembly of the entire endoscope. (Docs. # 93-1 at 7; 93-2 at 7).

Without the claimed invention, the quality check of the optical relay assembly in an endoscope is normally performed after the endoscope is completely assembled. (*Id.*). "If optical errors are found, it is then very expensive to correct these, and in most cases the endoscope has to be completely dismantled." (*Id.*). The invention solves this issue because "it is now possible to produce [an optical relay assembly] outside the endoscope and to check this unit visually" through the transparent shrinkable material. (*Id.*).

The '945 Patent has seven claim limitations. (Doc. #93-1 at 9). Claim 1 is representative of the claimed method:

> 1. A method for assembling an endoscope having a tubular shaft, an optical system having several components, said components of said optical system are contained in an interior of said tubular shaft, said components of said optical systems are at least partially surrounded by a tube made of both a transparent[2] and a shrunk material, said method comprising the following steps
>
> a) introducing said components into a tube of transparent and shrinkable material to form a unit,
>
> b) shrinking said shrinkable material of said tube for fixing the position of said components contained within said tube relative to one another,
>
> c) checking a position of said components relative to one another through said transparent shrunk material, of said shrunk tube and
>
> d) introducing said unit comprised of said shrunk tube and said components contained therein into said tubular shaft.

(*Id.*).

[2] Pursuant to *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996), Judge Bowdre, who previously was assigned this case, construed "transparent," as the term is used in the patents, to mean "allowing the transmission of light such that the assembler of an endoscope can visually check the alignment of the component parts of the endoscope." (Doc. # 112 at 2). Judge Bowdre declined to construe any other disputed terms, finding that no other terms required construction. (*Id.* at 3).

The '044 Patent has 32 claim limitations. (Doc. # 93-2 at 9-11). Claim 1 is representative of the claimed device:

> 1. An endoscope, comprising:
>
> A tubular shaft, having an inside face,
>
> An optical system having several components, said components of said optical system are contained in an interior of said tubular shaft,
>
> said components comprising at least two of the following: a lens, a spacer, a diaphragm, a prism and a filter, said components directly surrounded by a support piece made of a shrunk material, wherein
>
> said shrunk material is a transparent material,
>
> said support piece made of said transparent material has a shape of a tube, and
>
> said tube containing said components of said optical system has been shrunk prior to inserting said tube into said interior of said tubular shaft, for allowing a visual check of a position of said components relative to one another, and
>
> a gap located between an outside surface of said tube of shrunk material and said inside face of said tubular shaft.

(*Id.* at 9). Claims 8, 15, and 23 describe substantially similar endoscopes. (*Id.* at 10). Claims 2, 9, 16, and 24 limit the claimed endoscopes to those with optical components enclosed by transparent material. (*Id.*).

In simpler terms, KSEA rigid endoscopes have a unique "tube within a tube" construction. The outer tube is the rigid body of the endoscope. The inner tube is enclosed with a transparent and shrinkable material, which the parties sometimes refer to as "shrink wrap." The inner tube contains lenses of different diameters and prescriptions separated by spacers of different sizes. So, in the most general sense, the inner tube is a shrink-wrapped row of lenses and spacers. This inner tube can be assembled and inspected separately from the rest of the endoscope and can be removed from the endoscope as one unit. Again, the inner tube is the optical relay assembly.

Defendant STERIS Instrument Management Service, Inc. ("IMS") repairs[3] endoscopes. IMS is KSEA's primary competitor in servicing rigid endoscopes. (Doc. # 169-1 at 2, ¶ 7). A common repair that IMS makes related to KSEA rigid endoscopes is to fix a broken rod lens caused by an operator torquing the endoscope during surgical procedures or some other misuse. (*Id.* at 3, ¶¶ 12-13). Generally speaking, when called upon to repair an endoscope with a damaged rod lens or an optical relay that is not functioning properly for any reason, IMS will replace the optical relay. (*Id.* at 3-4, ¶¶ 15, 24). More specifically, the parties stipulated to the following facts regarding IMS's repair process:

1. When IMS receives a rigid endoscope for repair, a technician first evaluates the endoscope to determine the extent of repairs necessary. (*Id.* at 3, ¶ 9).
2. If this evaluation reveals that the endoscope is not providing an acceptable optical image, then the technician will remove and inspect the optical relay. (*Id.* at 3, ¶ 15).
3. To access the optical relay, "the technician opens the endoscope by heating the adhesive sealing the eyepiece utilizing the flame from a HydroFlux Welder, placing the endoscope in a jig, breaking the seal with a specialized tool, and then removing the eyepiece and the screws that hold the ocular base in place." (*Id.* at 4, ¶ 16).
4. The technician slides the optical relay out of the tubular shaft and cuts open the shrink wrap. (*Id.* at 4, ¶¶ 17-18).
5. The technician discards any damaged lenses and spacers and places any reusable lenses and spacers in inventory. (*Id.* at 4, ¶¶ 20-21).

[3] At this point, the court uses the word "repair" in the common language sense, not (at least yet) in any technical or legal sense.

6. The technician slides a replacement optical relay -- assembled by a separate IMS sub-assembly department (more on that below) -- into the tubular shaft. (*Id.* at 4-5, ¶¶ 24-25).
7. The technician "assembles the eyepiece and ocular base over the optical relay" and "performs optical alignments." (*Id.* at 5, ¶¶ 25-26).
8. "The endoscope and eyepiece are then placed in an oven to remove any moisture." (*Id.* at 5, ¶ 27).
9. Finally, the technician seals the endoscope by "appl[ying] glue over the threads of the endoscope and secures the eyepiece to the threads." (*Id.* at 5, ¶ 28).

The parties also stipulated about how a technician in the IMS sub-assembly department assembles replacement optical relays for KSEA rigid endoscopes:

1. The technician lines up a sequence of lenses and spacers in "a tray with a V-shaped notch to hold the components in place." (*Id.* at 5, ¶ 32).
2. The technician slides and pulls the line of components through a loading tube that covers the components in shrink wrap. (*Id.*).
3. The technician heats the sub-assembly to seal the shrink wrap and cuts off any excess. (*Id.* at 5, ¶ 33).

The lenses and spacers that an IMS technician uses to assemble a replacement optical relay are either new or recycled from previously repaired KSEA endoscopes. (*Id.* at 5, ¶ 30). "Typically, about two to four [recycled] rod lenses are used per endoscope, though a repaired endoscope may have all replacement lenses." (*Id.* at 5, ¶ 31). But, IMS does not track the number of recycled lenses used in each endoscope. (*Id.*). Nor does KSEA sell component parts like rod lenses and spacers. (*See* Docs. # 166-8 at 40, ¶ 85; 197 at 26).

Endoscopes repaired by IMS do not meet KSEA's original manufacturing specifications, primarily because IMS uses different lenses. (Doc. # 166-8 at 174-75, ¶¶ 345-46). The rod lenses in KSEA rigid endoscopes are dog-bone shaped, which, according to KSEA's expert on medical imaging devices, Albert Juergens, "allow a higher degree of flex in the endoscope shaft without breaking the lens." (*Id.* at 35, ¶ 77). But, IMS assembles replacement optical relays with both dog-bone and cylindrical lenses. (*Id.* at 174, ¶ 345). Mixing and matching the two types of lenses can negatively affect image quality. (*Id.*). Cylindrical lenses break easier than dog-bone lenses. (*Id.* at 35, ¶ 77). So, a user who sends a KSEA endoscope to IMS "would therefore get back an endoscope significantly more delicate than the one [KSEA] initially sold them." (*Id.* at 35, ¶ 77). And, whether because of the lenses used or some other reason, at least one IMS endoscope was discovered to have a limited field of view. (*Id.* at 174, 177, ¶¶ 344, 349).

IMS does not seal the endoscopes according to KSEA's specifications. KSEA's rigid endoscopes are not designed to be opened as doing so may allow moisture to enter the shaft. (Docs. # 166-30 at 50-52; 186-2 at 16). Keeping the rigid endoscope closed also serves to withstand autoclaving. (*Id.*). Indeed, KSEA seals its rigid endoscopes with epoxies and welds that have been validated by the FDA. (Doc. # 186-2 at 16). Apparently, IMS does not do use that technique because the director of KSEA's scope inspections at hospitals has seen KSEA endoscopes repaired by third-parties with pitted, flaking, and discolored seals. (*Id.* at 12). To be sure, Juergens stated in his export report that IMS "acknowledges that it does not meet KSEA's standards even though it advertises its endoscopes as 'Certified Pre-Owned.'" (Doc. # 166-8 at 175, ¶ 346).[4] The record contains evidence of an IMS endoscope with rusting, pitting, and cracking at the laser weld within

[4] The entire summary judgment record is more expansive than the court's preceding recitation of the facts may suggest. But the facts presented are all the summary judgment facts relevant to IMS's Motion for Summary Judgment, and, because the Motion is due to be granted, the remaining Motions relying on other parts of the summary judgment record are due to be denied.

two weeks of use, an IMS endoscope eight centimeters longer than a KSEA endoscope, and an IMS "welding jig that may produce scope shafts slightly longer than specification." (*Id.*).

In its Second Amended Complaint, KSEA alleged two instances of patent infringement. It contends that IMS infringes both the '945 Patent and the '044 Patent. (Doc. # 93 at 8-13). KSEA asserts that IMS produces infringing endoscopes through infringing methods during its repair process by fixing the position of optical components in a tube made out of a transparent shrunk material, checking the position of optical components through the transparent shrunk material, and introducing the shrunk tube into the tubular shaft of the endoscope. (*See id.*). Among other damages, KSEA seeks lost profits from IMS's endoscope repair sales. (*Id.* at 10, 12, ¶¶ 32, 41).

IMS filed counterclaims for declarations that it does not infringe either patent and that both patents are invalid. (Doc. #94 at 13-21). IMS raised as one of its many defenses that its methods involve a permissible repair of the patented endoscopes. (*Id.* at 11, ¶ 52).

II. Summary Judgment Standard

Under Federal Rule of Civil Procedure 56, summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). The party asking for summary judgment always bears the initial responsibility of informing the court of the basis for its motion and identifying those portions of the pleadings or filings which it believes demonstrate the absence of a genuine issue of material fact. *Id.* at 323. Once the moving party has met its burden, Rule 56 requires the non-moving party to go beyond the pleadings and -- by pointing to affidavits, or depositions, answers to interrogatories, and/or admissions on file -- designate specific facts showing that there is a genuine issue for trial. *Id.* at 324.

The substantive law will identify which facts are material and which are irrelevant. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). All reasonable doubts about the facts and all justifiable inferences are resolved in favor of the non-movant. *See Allen v. Bd. of Pub. Educ. for Bibb Cty.*, 495 F.3d 1306, 1314 (11th Cir. 2007); *Fitzpatrick v. City of Atlanta*, 2 F.3d 1112, 1115 (11th Cir. 1993). A dispute is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson*, 477 U.S. at 248. If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted. *See id.* at 249.

When faced with a "properly supported motion for summary judgment, [the nonmoving party] must come forward with specific factual evidence, presenting more than mere allegations." *Gargiulo v. G.M. Sales, Inc.*, 131 F.3d 995, 999 (11th Cir. 1997). "[A] party opposing a properly supported motion for summary judgment 'may not rest upon the mere allegations or denials of his pleading, but . . . must set forth specific facts showing that there is a genuine issue for trial.'" *Anderson*, 477 U.S. at 248 (citations omitted).

Summary judgment is mandated "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp.*, 477 U.S. at 322. If the moving party bears the burden of proof at trial, then it can only meet its initial burden on summary judgment by coming forward with positive evidence demonstrating the absence of a genuine issue of material fact: *i.e.*, facts that would entitle it to a directed verdict if not controverted at trial. *See Fitzpatrick*, 2 F.3d at 1115. Once the moving party makes such a showing, the burden shifts to the non-moving party to produce significant, probative evidence demonstrating a genuine issue for trial. *See id.*

"[A]t the summary judgment stage the judge's function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Anderson*, 477 U.S. at 249. "Essentially, the inquiry is 'whether the evidence presents a sufficient disagreement to require submission to the jury or whether it is so one-sided that one party must prevail as a matter of law.'" *Sawyer v. Sw. Airlines Co.*, 243 F. Supp. 2d 1257, 1262 (D. Kan. 2003) (quoting *Anderson*, 477 U.S. at 251-52); *see also LaRoche v. Denny's, Inc.*, 62 F. Supp. 2d 1366, 1371 (S.D. Fla. 1999) ("The law is clear . . . that suspicion, perception, opinion, and belief cannot be used to defeat a motion for summary judgment.").

The Eleventh Circuit has interpreted *Celotex* to require that, as to issues on which the nonmovant would bear the burden of proof at trial:

> [a] moving party is not required to support its motion with affidavits or other similar material negating the opponent's claim in order to discharge this initial responsibility. Instead, the moving party simply may show [ ]—that is, point[ ] out to the district court—that there is an absence of evidence to support the non-moving party's case. Alternatively, the moving party may support its motion for summary judgment with affirmative evidence demonstrating that the non-moving party will be unable to prove its case at trial.

Fitzpatrick, 2 F.3d at 1115 (quoting *U.S. v. Four Parcels of Real Property*, 941 F.2d 1428, 1437 (11th Cir. 1991)). And, where the moving party has met this initial burden by showing that there is an absence of evidence supporting the nonmoving party's case, the nonmoving party must

> respond in one of two ways. First, he or she may show that the record in fact contains supporting evidence, sufficient to withstand a directed verdict motion, which was "overlooked or ignored" by the moving party, who has thus failed to meet the initial burden of showing an absence of evidence. Second, he or she may come forward with additional evidence sufficient to withstand a directed verdict motion at trial based on the alleged evidentiary deficiency.

Id. (internal citations omitted).

If the moving party bears the burden of proof at trial, then it can only meet its initial burden on summary judgment by coming forward with positive evidence demonstrating the absence of a

genuine issue of material fact; *i.e.* facts that would entitle it to a directed verdict if not controverted at trial. *See Fitzpatrick*, 2 F.3d at 1115. Once the moving party makes such a showing, the burden shifts to the non-moving party to produce significant, probative evidence demonstrating a genuine issue for trial.

III. Analysis

IMS argues that it is entitled to summary judgment on KSEA's two claims of patent infringement pursuant to the affirmative defense of repair. (*See* Doc. # 174). IMS contends that it does not utilize infringing methods to reconstruct infringing devices. Rather, according to IMS, as a matter of law, it permissibly repairs KSEA endoscopes as a matter of law. IMS asserts that KSEA exhausted its patent rights in any endoscopes sold and that IMS consequently has the right to repair the endoscopes. For the reasons explained below, the court concludes that (1) the undisputed evidence in the Rule 56 record would entitle IMS to a directed verdict at trial based on the repair defense, and (2) KSEA has failed to show there is a genuine issue of material fact for a jury to decide as to that defense. Therefore, IMS's Motion for Summary Judgment is due to be granted.

A. The Extent of Patent Rights

A patent grants to the patentee "the right to exclude others from making, using, offering for sale, or selling the [patented] invention." 35 U.S.C. § 154(a)(1). Patent infringement therefore occurs when a party "without authority makes, uses, offers to sell, or sells any patented invention . . . during the term of the patent." 35 U.S.C. § 271(a).

But, a patentee's right to exclude is not unlimited. "For over 160 years, the doctrine of patent exhaustion has imposed a limit on that right to exclude." *Impression Prod., Inc. v. Lexmark Int'l, Inc.*, 137 S. Ct. 1523, 1531 (2017). The doctrine of patent exhaustion "provides that the initial authorized sale of a patented item terminates all patent rights to that item." *Quanta Computer, Inc.*

v. LG Elecs., Inc., 553 U.S. 617, 625 (2008). This is so because "[t]he Patent Act promotes the progress of science and the useful arts by granting to inventors a limited monopoly that allows them to secure the financial rewards for their inventions. . . . But once a patentee sells an item, it has enjoyed all the rights secured by that limited monopoly." *Impression Prod.*, 137 S. Ct. at 1531-32 (quotation and alteration marks omitted). Accordingly, "[w]hen a patentee chooses to sell an item, that product is no longer within the limits of the monopoly and instead becomes the private, individual property of the purchaser, with the rights and benefits that come along with ownership." *Id.* at 1531 (quotation omitted).

B. The Right to Repair

A purchaser's right to repair is one of the rights under the doctrine of patent exhaustion that limits the patentee's rights to exclude. *Id.* at 1532. The purchaser of a patented article has "the right to preserve the useful life of the original article," *Jazz Photo Corp. v. Int'l Trade Comm'n*, 264 F.3d 1094, 1102 (Fed. Cir. 2001), and the right "to enable it to function properly," *Bottom Line Mgmt., Inc. v. Pan Man, Inc.*, 228 F.3d 1352, 1354 (Fed. Cir. 2000). Simply stated, making a "repair" is permissible, but undertaking a "reconstruction" is not. *Jazz Photo*, 264 F.3d at 1102. Impermissible "reconstruction" of a patented device is "reconstruction of the entity as to in fact make a new article, . . . after the entity, viewed as a whole, has become spent." *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 346 (1961) (quotation and citation omitted).

Repair is an affirmative defense to a patent infringement claim. *Jazz Photo*, 264 F.3d at 1101. So, a defendant raising the repair defense has the burden of proof at trial of establishing that its activities constitute permissible repair and not impermissible reconstruction. *See id.* at 1102 ("The burden of establishing an affirmative defense is on the party raising the defense. The Commission correctly held that the respondents had the burden of establishing this defense by a

preponderance of the evidence, including the burden of coming forward with evidence to show that the activities performed in processing the used cameras constituted permissible repair.").

The distinction between what constitutes permissible repair as opposed to impermissible reconstruction is a judicially created and in some instances may be a fact intensive inquiry. *See Aktiebolag v. E.J. Co.*, 121 F.3d 669, 674 (Fed. Cir. 1997) ("[T]here is no bright-line test for determining whether reconstruction or repair has occurred."). The seminal Supreme Court case on repair versus reconstruction is *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336 (1961). In *Aro*, the patent at issue covered a combination of a fabric convertible top and associated metal support structure for an automobile. The fabric itself was an unpatented component of the larger patented system. The patentee alleged that the petitioner infringed the patent by selling replacement fabrics designed to fit within the patented system. The Supreme Court disagreed, finding that "the replacement of the fabric involved in this case must be characterized as permissible 'repair,' not 'reconstruction,'" because "[m]ere replacement of individual unpatented parts, one at a time, whether of the same part repeatedly or different parts successively, is no more than the lawful right of the owner to repair his property." *Aro*, 365 U.S. at 346. An impermissible "reconstruction," on the other hand, is "such a true reconstruction of the entity as to in fact make a new article, . . . after the entity, viewed as a whole, has become spent." *Id.* (quotation and citation omitted).

Three years following its *Aro* opinion, the Supreme Court decided *Wilbur-Ellis Co. v. Kuther*, 377 U.S. 422 (1964). In *Wilbur-Ellis*, the alleged infringers resized six of the 35 elements of patented fish-canning machines so that the machines could pack fish into five-ounce instead of one-pound cans, as the machines were originally constructed to do. The Supreme Court found permissible repair, not impermissible reconstruction, because (1) the fish-canning machines "were

not spent; they had years of usefulness remaining though they needed cleaning and repair"; (2) "the size of cans serviced by the machine was no part of the invention; nor were characteristics of size, location, shape and construction of the six elements in question patented"; and (3) although the alleged infringers "were doing more than repair in the customary sense[,] . . . what they did was kin to repair for it bore on the useful capacity of the old [patented] combination." *Wilbur-Ellis*, 377 U.S. at 424-25.

There is also Federal Circuit precedent in this area. In *General Electric Co. v. United States*, 572 F.2d 745 (Ct. Cl. 1978), the U.S. Navy replaced patented gun mounts on its vessels by, among other things, disassembling the gun mounts into their smallest component parts and reassembling the gun mounts with either new components or reused components from other disassembled gun mounts. The Navy did not track whether any components from a specific disassembled gun mount were used in the reassembled version of the same gun mount, so some reassembled gun mounts did not contain any of their original components. The Court of Claims found that completely disassembling the gun mounts and reassembling them with mixed-and-matched used and new parts was permissible repair. *Gen. Elec.*, 572 F.2d at 786. The reassembled gun mounts were not new articles "even though the gun mounts were disassembled in order to be overhauled, and even though, in some or most or all instances, the reassembled elements were not returned to the same gun mount or the same ship." *Id.* at 784. Like the fish-canning machines in *Wilbur-Ellis*, the gun mounts were not "spent" because they had years of usefulness remaining despite the need for maintenance. *Id.* at 785. The Court of Claims concluded that overhauling the gun mounts was perhaps even more convincingly a permissible repair than refurbishing the fish-canning machines in *Wilbur-Ellis* because the Navy used only the patentee's components in reassembling the gun mounts and did not adapt the gun mounts to different uses. *Id.* at 785-86. And, as the Court of

Claims also reasoned, "[i]f it is permissible, as it is, to introduce wholly new components, acquired from another supplier, into the renovation of a device embodying a patented combination, . . . it is very hard to say that [the Navy's activities] amounted to reconstruction when . . . the Navy worked with, substantially, all [patentee]-supplied elements and did not introduce new elements acquired from others than [the patentee]." *Id.* at 786 (citations omitted).

Similarly, in *Dana Corp. v. Am. Precision Co.*, 827 F.2d 755 (Fed. Cir. 1987), the alleged infringers rebuilt patented truck clutches by disassembling the clutches into their component parts, replacing worn or defective parts with either new or salvaged parts, and reassembling the clutches. The alleged infringers maintained an inventory of salvaged components from disassemblies that could be reused in later assemblies. If they ran out of salvaged inventory, they simply ordered new parts. The Federal Circuit decided that this process was a permissible repair. *Dana*, 827 F.2d at 760. In doing so, it determined that the patentee contemplated repair of the patented trucks' clutches and that the complete disassembly of the clutches was not "voluntary destruction of the patented clutch" followed by a "second creation." *Id.* at 759-60.

In *Jazz Photo*, the Federal Circuit sanctioned the following process as a permissible repair of a patented disposable film camera: removing the cardboard cover encasing the camera; opening the plastic camera body, usually by cutting at least one weld; replacing the winding wheel or modifying the film cartridge; resetting the film counter; replacing the battery in flash cameras; winding new film out of a canister onto a spool or into a roll; resealing the plastic body with tape or glue; and applying a new cardboard cover. *Jazz Photo*, 264 F.3d at 1101, 1105. This process made the camera reusable even though the patentee intended for the camera to be discarded after using up one film roll. Still, it was deemed a permissible repair because "the patentee's unilateral intent, without more, does not bar reuse of the patented article, or convert repair into

reconstruction." *Id.* at 1106. The Federal Circuit did not consider "inserting new film and film container, resetting the film counter, and resealing the broken case" a "second creation" of the patented article. *Id.*

The *Jazz Photo* court called the "right to preserve its fitness for use" the "common thread in precedent" for what constitutes permissible repair of a patented article. 264 F.3d at 1106 (quotation omitted). Determining whether a party preserves an article's fitness for use requires "consideration of the remaining useful capacity of the article, and the nature and role of the replaced parts in achieving that useful capacity." *Id.* By breaking open the camera and replacing the film, the alleged infringers in *Jazz Photo* extended the useful life of the camera, and the refurbished cameras otherwise remained as originally sold. *Id.* at 1107. Therefore, the cameras were repaired – not reconstructed. *Id.*

On the other end of the spectrum, "'Reconstruction' . . . requires a more extensive rebuilding of the patented entity than is exemplified in *Aro Manufacturing*, *Wilbur-Ellis*, *General Electric*, and *Dana Corp*." *Id.* at 1104. For example, in *Aktiebolag v. E.J. Co.*, 121 F.3d 669, 670 (Fed. Cir. 1997), the patented invention was a drill formed by a shank and a unique tip geometry. The drill tip required occasional resharpening as it became dulled with use over time. *Aktiebolag*, 121 F.3d at 671. But the defendant, a third-party drill repair service, went beyond just merely resharpening the drill tip. *Id.* It also offered "retipping" services, through which it removed the worn tip from the drill shank, brazed a rectangular piece of new carbide onto the drill shank, and then carved the carbide into the unique tip geometry from the patented drill. In other words, the defendant reconstructed (*i.e.*, recreated) the drill tip. *Id.* at 671-72.

In finding that the retipping service was impermissible reconstruction, the Federal Circuit first reviewed the Supreme Court's "expansive view of what constitutes a permissible repair"

established in *Aro*. *Id.* at 672. Under *Aro*, even if the retipping service "cost almost as much as the drill or if the replacement of the tip is difficult and time consuming, as in this case, these factors are not dispositive of reconstruction." *Id.* Also under *Aro*, "the fact that [the alleged infringer] may be replacing the novel features of the . . . patented invention is also not dispositive of reconstruction." *Id.* at 673.

The Federal Circuit identified several factors a court should consider in determining whether a defendant made a new article: "the nature of the actions by the defendant"; "the nature of the device and how it is designed (namely, whether one of the components of the patented combination has a shorter useful life than the whole)"; "whether a market has developed to manufacture or service the part at issue"; and "objective evidence of the intent of the patentee." *Id.* at 672. Guided generally by those factors, the Federal Circuit found that the drill is "spent" when the tip can no longer be resharpened and must be retipped. *Id.* Because the defendant's actions were "effectively a re-creation," the nature of defendant's work was not repair. *Id.* The drill did not have a "useful life much longer than that of certain parts which wear out quickly" because the drill tip was not manufactured to be a replaceable part, the drill tip was not expected to have a useful life different than that of the drill shank, and the drill tip was not easily detachable from the drill shank. *Id.* at 673-74. Considering also that the patentee never intended for its drills to be retipped and that no substantial market for drill retipping existed, the Federal Circuit found that the defendant "reconstruct[ed] an otherwise spent device." *Id.* at 674.

Similarly, in *Lummus Indus., Inc. v. D.M. & E. Corp.*, 862 F.2d 267, 269 (Fed. Cir. 1988), the patent claims covered an apparatus for cutting textile fiber bundles that utilized an assembly of reels. In *Lummus*, the defendants manufactured and sold cutter reels that were usable only in the patented device. A jury returned a verdict of infringement. Part of the instruction the district

court gave the jury stated: "the replacement of a component which is not worn out with an accessory component which is a material part of the invention constitutes patent infringement, because it is reconstruction of the patented machine." *Lummus*, 862 F.2d at 270. The Federal Circuit found this portion of the instruction to be a correct statement of law. *Id.*

The district court also instructed the jury on the parties' respective positions: "the plaintiff contends . . . that [the cutter reel] is the heart of the invention and that to make the reel, manufacture it and to sell it new violates the very heart of the patent. The defendants say and contend that it's repair, that they bought the overall machine, and that this is only a part and that to make [it] new and to replace it is nothing more than repair." *Lummus*, 862 F.2d at 271. The Federal Circuit rejected the defendants' argument that that instruction "misinformed the jury that manufacture and sale of the reel cannot be 'repair' if the component is a sufficiently important element of the combination" because *Aro* "eschewed the suggestion that the legal distinction between 'reconstruction' and 'repair' should be affected by whether the element of the combination that has been replaced is an 'essential' or 'distinguishing' part of the invention." *Id.* (quoting *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 217 (1980)). So, the Federal Circuit affirmed the jury verdict of infringement. *Id.* at 273.

Finally, in *Husky Injection Molding Sys. Ltd. v. R & D Tool Eng'g Co.*, the Federal Circuit provided an obvious, yet still helpful, example of impermissible reconstruction: "if a patent is obtained on an automobile, the replacement of the spark plugs would constitute permissible repair, but few would argue that the retention of the spark plugs and the replacement of the remainder of the car at a single stroke was permissible activity akin to repair." 291 F.3d 780, 786 (Fed. Cir. 2002).

C. Analysis of IMS's Affirmative Defense

Here, the Rule 56 evidence, examined in the light most favorable to KSEA and assessed in view of the relevant case law, makes clear that IMS repairs rather than reconstructs KSEA's endoscopes. To recap, the parties stipulated that an IMS technician does the following to replace an optical relay: breaks the adhesive sealing the eyepiece to the endoscope; slides the optical relay out of the endoscope; cuts open the shrink wrap enclosing the optical relay; places any undamaged lenses and spacers into inventory for reuse and discards the rest; inserts a replacement optical relay that a technician from a different department assembles by shrink wrapping a series of new or recycled lenses and spacers; and reseals the eyepiece to the endoscope with glue. (Doc. # 169-1 at 4-5, ¶¶ 16-21, 24-33). The end result is an endoscope comprised of all of the same materials except for a different adhesive seal between the eyepiece and the endoscope formed by glue over threads, a different shrink wrap enclosing the optical relay, and different lenses and spacers in the optical relay. The endoscope remains as originally sold in all other respects. All of the individual components that are replaced are unpatented. The lenses and spacers are removable as one unit by design, making it much easier for an IMS technician to replace those components. And, replacing the optical relay can keep the endoscope functioning over its expected 25-year or longer lifespan. (*See* Doc. # 169-1 at 2, ¶ 8). IMS does not in any manner make a "second creation" of an endoscope. *See Jazz Photo*, 264 F.3d at 1106. Rather, IMS replaces individual unpatented parts to preserve the useful life of the endoscope, and this process fits comfortably within the right to repair.

When an optical relay fails to pass a clear image because, for example, a rod lens has cracked, the endoscope, "*viewed as a whole*," is not "spent" as that term is used in Supreme Court parlance. *See Aro*, 365 U.S. at 346 (emphasis added). Instead, the endoscope can function properly

again with a replacement optical relay. So, when IMS replaces the optical relay, it "preserve[s] [the endoscope's] fitness for use," which is the "common thread in precedent" for what constitutes permissible repair. *See Jazz Photo*, 264 F.3d at 1106.

For the most part, IMS's activities are similar to the activities found to be permissible repair in *Jazz Photo*. Here and in *Jazz Photo*, the alleged infringers break a permanent seal on a patented device's outer body to replace internal components. But IMS's activities are even less akin to reconstruction than those in *Jazz Photo*. That is so because, unlike the repairers in *Jazz Photo*, IMS does not repurpose the patented device. The repairs in *Jazz Photo* modified a single-use camera into a reusable camera, whereas here the endoscope's functionality remains precisely the same after IMS's repair. *See also Wilbur-Ellis*, 377 U.S. at 424-25 (determining that repurposing a patented machine was permissible repair). Again, this shows that IMS is only exercising its right to preserve the endoscope's useful life.

Likewise, IMS's activities are similar to (and, indeed, even less substantial) than the activities found to be permissible repair in *Gen. Elec.* There, some of the reassembled gun mounts contained none of their original components. 572 F.3d at 786. But here, an endoscope with an optical relay replaced by IMS contains all of its original parts except for adhesive, shrink wrap, lenses, and spacers. This demonstrates repair, not reconstruction.

This case is distinguishable from *Aktiebolag*. There, the patented drill was spent as a whole when the drill tip was no longer operable and could not be resharpened. At that point, the drill could not drill. And, the only way to enable the drill to function properly was to reform the drill tip from a piece of carbide brazed on the drill shank. This was "effectively a re-creation." *Aktiebolag*, 121 F.3d at 673. But here, an endoscope that is otherwise operational but contains a

failed optical relay is not spent as a whole and does not need to be reconstructed or recreated. Instead, the endoscope can be repaired by replacing unpatented components within it.

KSEA argues that whether IMS's activities constitute a reconstruction is a jury question. In support of its contention, KSEA presents a general assertion and a more contextual argument. First, KSEA asserts that the repair doctrine is a narrow defense that is not appropriate to be decided on summary judgment and that it does not apply to claims for infringement of method patents. (*See* Doc. # 197 at 20-22, 42-43). But, that general assertion is off the target. A repair defense can be decided on summary judgment. *See Aktiebolag v. E.J. Co.*, 121 F.3d 669, 672 (Fed. Cir. 1997) ("We review the district court's grant of summary judgment *de novo* . . . . Summary judgment is appropriate where there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. . . . Whether defendant's actions constitute a permissible repair or an infringing reconstruction is a question of law which we also review *de novo*."); *see, e.g.*, *Dana Corp. v. Am. Precision Co.*, 827 F.2d 755, 760 (Fed. Cir. 1987) (affirming district court's grant of summary judgment for the defendant based on the repair defense). And, the repair defense applies to method patents. *See Jazz Photo Corp. v. Int'l Trade Comm'n*, 264 F.3d 1094, 1108 (Fed. Cir. 2001) ("The defense of repair is applicable to process claims, [and] to apparatus claims . . . .").

Second, KSEA makes the more specific contention that replacing the entire optical relay is effectively reconstructing a new endoscope. (*See* Doc. # 197 at 7, 22-24). According to KSEA, the "optical relay is what makes the endoscope an endoscope," such that when the optical relay no longer works, the endoscope is "spent" as a whole, and replacing the optical relay therefore effectively reconstructs a new endoscope. (*Id.*). Admittedly, the optical relay is an essential assembly of components that performs the endoscope's primary function of transmitting an optical image from one end of the endoscope to the other. And, without question, the way the optical relay

is assembled is the novel and distinguishing part of the invention. But, as the Supreme Court in *Aro* noted, "whether the element of the combination that has been replaced is an 'essential' or 'distinguishing' part of the invention" does not affect the repair versus reconstruction analysis. *Dawson*, 448 U.S. at 217 (quoting *Aro*, 365 U.S. at 344). Otherwise, one element of the patented combination would be "ascrib[ed] . . . the status of patented invention in itself." *Aro*, 365 U.S. at 344-45. And "replacing the novel features of the . . . patented invention is also not dispositive of reconstruction." *Aktiebolag*, 121 F.3d at 673. So, the importance of the optical relay and its novel features does not dictate a finding that a reconstruction occurs.

To be clear, unlike the convertible-top fabric in *Aro*, the optical relay is not a single unpatented component of a patented combination. Instead, the optical relay itself is comprised of unpatented rod lenses and spacers. And IMS does not simply replace one broken rod lens when it repairs an endoscope by, for example, cutting open the original shrink wrap, replacing one rod lens, and resealing the original shrink wrap. Rather, IMS replaces the entire optical relay with its own shrink-wrapped optical relay.

The optical relay is a series of unpatented rod lenses and spacers held together by unpatented shrink wrap. So, by replacing the entire optical relay, IMS effectively replaces "different parts successively," which it has the right to do. *See Aro*, 365 U.S. at 346. Moreover, replacing and/or refurbishing multiple unpatented components at the same time, like IMS does when it inserts a new optical relay, is permissible repair. *See Wilbur-Ellis*, 377 U.S. at 424-25 (resizing six elements of a patented machine was repair); *Gen. Elec.*, 572 F.2d at 785-86 (reassembling gun mounts with multiple replacement parts was repair); *Dana*, 827 F.2d at 759-60 (reassembling truck clutches with multiple replacement parts was repair).

KSEA's focus on the importance of the optical relay is misplaced, particularly when the Supreme Court's logic in *Aro* is analyzed. To be clear, a party in KSEA's shoes could make this same argument with respect to a single unpatented rod lens. After all, according to KSEA, (1) "without the optical relay [the endoscope] cannot relay the image from inside the cavity, and it is broken (or otherwise spent) as a whole" (Doc. # 197 at 23) and (2) replacing the optical relay reconstructs the endoscope. (*Id.* at 22-24). However, by that logic, a single broken rod lens renders the entire endoscope spent, because then the endoscope could not relay the image, and replacing the single rod lens would reconstruct the endoscope. Of course, replacing one lens is a far cry from reconstructing an endoscope, which helps to explain why the Supreme Court's rationale removes the significance of worn components from the repair doctrine analysis.

Next, KSEA contends that IMS completely deconstructs an endoscope to replace its optical relay; therefore, the argument goes, replacing the optical relay and putting the endoscope back together must be a reconstruction. (Doc. # 197 at 7, 23-24). This is part and parcel to KSEA's assertion that, "[r]econstruction follows when something has been voluntarily broken." (*Id.* at 23) (citing *Am. Cotton-Tie Co. v. Simmons*, 106 U.S. 89, 94 (1882)). However, that is simply not a correct statement of law and the contention is actually at odds with *Cotton-Tie*. The *Cotton-Tie* decision involved patented cotton bale ties consisting of a band for wrapping around a cotton bale and a buckle for fastening the ends of the band together. Users cut and discarded the bale ties to access the cotton. The defendants salvaged those discarded ties and used their components to construct ties that the Supreme Court found to infringe the patents. *Cotton-Tie*, 106 U.S. at 94-95. But, contrary to KSEA's suggestion, the Supreme Court did not find infringement *because* the old ties were cut. Rather, the defendants sold a substantially similar product that just so happened to be made from salvaged components that had been voluntarily broken. *See id.*

Moreover, and again contrary to KSEA's position, deconstructing a patented article to replace its component parts does not demonstrate reconstruction. *See Gen. Elec.*, 572 F.2d at 786 (finding repair when the defendant disassembled and reassembled gun mounts); *Dana*, 827 F.2d at 760 (finding repair when the defendant disassembled and reassembled truck clutches); *Jazz Photo*, 264 F.3d at 1101, 1105 (finding repair when the defendant opened a camera casing by breaking at least one weld). Although the method by which a defendant breaks open a patented article is relevant to the "nature of the actions by the defendant" factor, *Aktiebolag*, 121 F.3d at 673, the standard for determining reconstruction centers on whether a defendant made "such a true reconstruction of the entity as to in fact make a new article . . . after the entity, viewed as a whole, has become spent," *Aro*, 365 U.S. at 346 (quotation and citation omitted). So, tearing apart a device does not equal reconstruction unless it is followed by the creation of "a new article." Therefore, the fact that IMS breaks permanent bonds on the endoscope to access the optical relay does not create a genuine issue of fact regarding repair versus reconstruction. *See Jazz Photo*, 264 F.3d at 1101, 1105 (finding a repair occurred even though the alleged infringer cut open a plastic body of a disposable camera by usually cutting at least one weld).

KSEA also argues that IMS reconstructs the endoscopes because, after IMS replaces the optical relay and reseals the bonds, the endoscopes are not built to KSEA's specifications. (*See* Doc. # 197 at 25-28, 28-31).[5] Evidence in the summary judgment record supports a reasonable inference that IMS endoscopes are inferior to and different from KSEA's originally manufactured endoscopes. Some IMS endoscopes have rod lenses of different diameters and optical prescriptions, produce inferior images, have smaller fields of view, are more fragile, have welds

[5] KSEA makes similar arguments about IMS endoscopes allegedly violating FDA regulations and posing a danger to the public. (Doc. # 197 at 28, 30-31). Those matters are not relevant to the repair versus reconstruction issue.

prone to deterioration, and can be eight centimeters longer than KSEA's endoscopes. (*See* Doc. # 166-8 at 35, 174-75, 177, ¶¶ 77, 344-46, 349). But, this evidence does not establish a genuine issue of material fact precluding summary judgment because IMS has the right to modify the endoscopes beyond KSEA's specifications as long as IMS does not in fact make a new article. *See Surfco Hawaii v. Fin Control Sys. Pty, Ltd.*, 264 F.3d 1062, 1066 (Fed. Cir. 2001) ("The right of repair follows from the exhaustion of a patentee's right to control the disposition of a patented article after it has been sold. The owner may use, repair, and modify the device as long as there is not reconstruction of the entity as to in fact make a new article. . . . Although extension of the useful life of an article is the usual reason for modification or replacement of component parts, it is not the only reason allowed by law.") (quotation omitted) (citing *Aro*, 365 U.S. at 346). Moreover, IMS's use of mixed-and-matched recycled and new lenses and spacers in its optical relays does not demonstrate reconstruction because "it is permissible . . . to introduce wholly new components, acquired from another supplier, into the renovation of a device embodying a patented combination." *Gen. Elec.*, 572 F.2d at 786. And, a repairer can use both recycled and new parts. *See id.*; *Dana*, 827 F.2d at 760.

Finally, KSEA argues that the repair doctrine is limited to the replacement of what KSEA calls "consumable" parts -- parts that are temporary or designed to be replaced -- and that the optical relay is not a consumable part. (Doc. # 197 at 26-28, 34-36). This argument fails for at least two reasons. First, no precedent establishes such a limitation. KSEA claims that *Jazz Photo*, *Gen. Elec.*, and *Dana* involved only "consumable" parts, such that the repair doctrine is limited to the same kind of parts. (*Id.* at 34-36). The disposable camera film roll in *Jazz Photo* was the kind of part that KSEA calls "consumable," but nothing in *Jazz Photo* suggests that the Federal Circuit found permissible repair *because* the film roll was consumable, or that the Federal Circuit would

not have found permissible repair if a more permanent part of the camera is replaced. Moreover, whether the gun mount parts in *General Electric* or truck clutch parts in *Dana* were temporary or designed to be replaced did not matter; rather, what mattered was that the defendants replaced worn parts to extend the useful life of a patented article. Here, IMS replaces worn parts to extend the useful life of the endoscope, and whether the optical relay is "consumable" is inapposite.

Second, KSEA points only to facts that are immaterial to the repair doctrine -- the permanent seals on the endoscope and KSEA's sale conditions -- to show that the optical relay is not "consumable." KSEA contends that, because an optical relay can last indefinitely, KSEA permanently seals its endoscopes and requires purchasers to agree that the whole endoscope must be replaced if it produces a poor image. (Doc. # 197 at 27 (citing Doc. # 186-8 at 11, 31)). But, as explained above, the permanent seals on the endoscope, and IMS breaking them, does not demonstrate reconstruction. *Jazz Photo*, 264 F.3d at 1101, 1105. And, the Supreme Court has expressly rejected the notion that a patentee can preserve any of its patent rights through a post-sale restriction: "[P]atent exhaustion is uniform and automatic. Once a patentee decides to sell . . . that sale exhausts its patent rights, regardless of any post-sale restrictions the patentee purports to impose, either directly or through a license." *Impression Prod*, 137 S. Ct. at 1535.

In summary, because KSEA exhausted its patent rights in any rigid endoscope that it sold, IMS has the right to repair such endoscope by opening the endoscope, removing the optical relay, replacing it with an optical relay assembled by shrink wrapping new and recycled lenses and spacers, and resealing the endoscope. Therefore, there is no genuine dispute of material fact as to IMS's affirmative defense of repair and IMS is entitled to judgment as a matter of law as to the patent infringement claims.

D. The Convoyed Sale Doctrine Is Inapplicable

As a consequence of dismissing the infringement claims, the issue regarding convoyed sales that takes up the remainder of the briefing on IMS's Motion for Summary Judgment becomes inapposite. A "convoyed sale" is the sale of an unpatented product that is sufficiently associated with a patented product. *Am. Seating Co. v. USSC Grp., Inc.*, 514 F.3d 1262, 1268 (Fed. Cir. 2008). If a patented product and an unpatented product "together [are] considered to be components of a single assembly or parts of a complete machine, or they together constituted a functional unit," then the patentee theoretically would have sold both the patented product and the unpatented product had infringement not occurred. *Id.* (quotation omitted). Convoyed sales are thus recoverable as lost profits from a patent infringement claim. *Id.*

Here, KSEA claims that IMS's repairs of KSEA's unpatented flexible endoscopes are convoyed sales recoverable as lost profits from the infringement claims. (*See* Docs. # 93 at 10, 12, ¶¶ 32, 41; 168-2 at 9-12). KSEA's damages expert opined that "it is more likely than not that [KSEA] would have sold the [flexible endoscope repairs] [but for] the infringement" because "rigid and flexible repair sales are typical components of a service contract and/or pricing arrangement with customers, and are used in the same procedures . . . ." (Doc. # 168-2 at 10, ¶ 20) (emphasis in original). But, there is no patent infringement in this case so infringement cannot possibly be the but-for cause of convoyed sales. And the loss of flexible endoscope repair sales cannot support any standalone claim because the flexible endoscopes are not patented.

E. Other Pending Motions

Because the court has determined that IMS's Motion for Summary Judgment is due to be granted, the other pending motions are consequently due to be denied as moot. The repair defense defeats all of KSEA's claims against IMS, so there are no remaining claims on which KSEA may

be entitled to partial summary judgment. And, as there is no need for a trial, the parties' respective *Daubert* motions are moot. KSEA has moved for the sanction of an adverse inference against IMS -- that IMS performs the "checking" step of claim 1 of the '945 Patent -- but that inference would have no bearing on the application of the repair defense. Therefore, that motion is also moot.

IV. Conclusion

For all the foregoing reasons, the court concludes that IMS's Motion for Summary Judgment (Doc. # 174) is due to be granted. Because final judgment will be entered in favor of IMS as to the only two claims in this case, KSEA's Motion for Partial Summary Judgment (Doc. # 172) is due to be denied. Because the requested sanction has no bearing on IMS's Motion for Summary Judgment, KSEA's Motion for Sanctions (Doc. # 171) is due to be denied as moot. The parties' *Daubert* motions (Docs. # 173, 175) are due to be denied as also moot. An Order consistent with this Memorandum Opinion will be entered.

DONE and **ORDERED** this May 18, 2022.

R. DAVID PROCTOR
UNITED STATES DISTRICT JUDGE

FILED
2022 May-19 AM 10:56
U.S. DISTRICT COURT
N.D. OF ALABAMA

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

KARL STORZ ENDOSCOPY-AMERICA, INC.,	}	
Plaintiff,	}	
v.	}	**Case No.: 2:12-CV-02716-RDP**
STERIS INSTRUMENT MANAGEMENT SERVICES, INC.,	}	
Defendant.	}	

ORDER

This case is before the court on Plaintiff's Motion for Partial Summary Judgment (Doc. # 172), Defendant's Motion for Summary Judgment (Doc. # 174), the parties' *Daubert* motions (Docs. # 173, 175), Plaintiff's Motion for Sanctions (Doc. # 171), and the parties' joint Motion for Oral Argument (Doc. # 210). In accordance with the Memorandum Opinion entered contemporaneously herewith, Defendant's Motion for Summary Judgment (Doc. # 174) is **GRANTED**. Accordingly, it is **ORDERED** that final judgment be entered under Rule 56 in favor of Defendant on Counts One and Two in Plaintiff's Second Amended Complaint (Doc. # 93). In addition, Plaintiff's Motion for Partial Summary Judgment (Doc. # 172), Plaintiff's Motion for Sanctions (Doc. # 171), and the joint Motion for Oral Argument (Doc. # 210) are **DENIED**. And the *Daubert* motions (Docs. # 173, 175) are **MOOT**.

Costs are taxed against Plaintiff.

The Clerk of Court is **DIRECTED** to close this case.

DONE and **ORDERED** this May 18, 2022.

R. DAVID PROCTOR
UNITED STATES DISTRICT JUDGE

US007530945B2

(12) **United States Patent**
Rudischhauser et al.

(10) **Patent No.: US 7,530,945 B2**
(45) **Date of Patent: May 12, 2009**

(54) **ENDOSCOPE AND METHOD FOR ASSEMBLING COMPONENTS OF AN OPTICAL SYSTEM**

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(73) Assignee: **Karl Storz GmbH & Co. KG** (DE)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 645 days.

(21) Appl. No.: **11/206,562**

(22) Filed: **Aug. 18, 2005**

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Related U.S. Application Data

(63) Continuation of application No. PCT/EP2004/000765, filed on Jan. 29, 2004.

(30) **Foreign Application Priority Data**

Feb. 18, 2003 (DE) 103 07 904

(51) **Int. Cl.**
A61B 1/00 (2006.01)

(52) **U.S. Cl.** **600/128**; 600/121; 600/130; 600/138; 600/139; 600/160; 600/161; 600/182; 359/434; 359/435; 359/849

(58) **Field of Classification Search** 600/121, 600/128, 130, 138–139, 160, 182; 359/434–435, 359/894

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,148,550	A	4/1979	MacAnally	350/54
4,148,551	A *	4/1979	MacAnally	359/435
4,750,476	A *	6/1988	Forkner et al.	600/161
4,822,154	A	4/1989	Oxford et al.	350/572
4,966,439	A	10/1990	Althaus et al.	350/253
5,419,313	A	5/1995	Lemke	128/6
5,480,302	A *	1/1996	Fife	433/116
6,201,649	B1 *	3/2001	Rudischhauser et al.	359/808
6,305,536	B1 *	10/2001	Tanaka	206/316.2
6,398,723	B1	6/2002	Kehr et al.	600/160
6,471,640	B1	10/2002	Frische et al.	600/138
7,385,772	B2 *	6/2008	Forkey et al.	359/819

(Continued)

FOREIGN PATENT DOCUMENTS

DE	28 12 369	11/1978

(Continued)

OTHER PUBLICATIONS

International Search Report (PCT, May 13, 2004, 7 pages).

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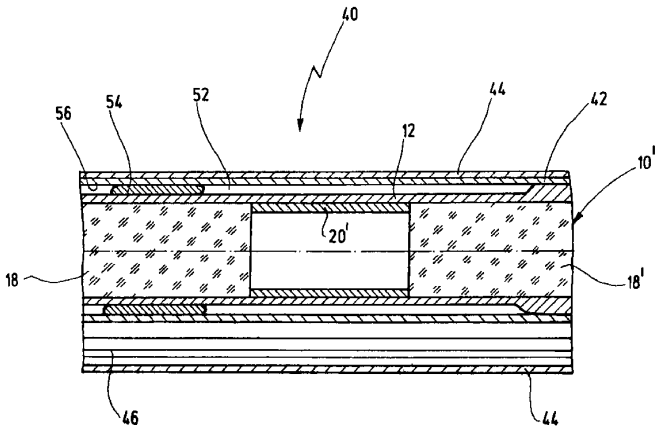
(57) **ABSTRACT**

An endoscope has a tubular shaft whose interior contains components, in particular lenses, spacers, diaphragms, prisms and filters of an optical system, said components being at least partially surrounded by a support piece made of shrunk material. It is proposed that the components be surrounded by a transparent and tube-sleeve-shaped shrunk material which has been shrunk before the components are introduced into the tubular shaft.

7 Claims, 3 Drawing Sheets



U.S. PATENT DOCUMENTS

2002/0007111 A1 1/2002 Deckert et al. 600/177

FOREIGN PATENT DOCUMENTS

DE	37 38 451	5/1988
DE	39 12 720	10/1990
DE	197 32 991	2/1999
DE	199 12 656	11/2000
DE	102 53 559	6/2004
EP	3 337 142	10/1989

* cited by examiner

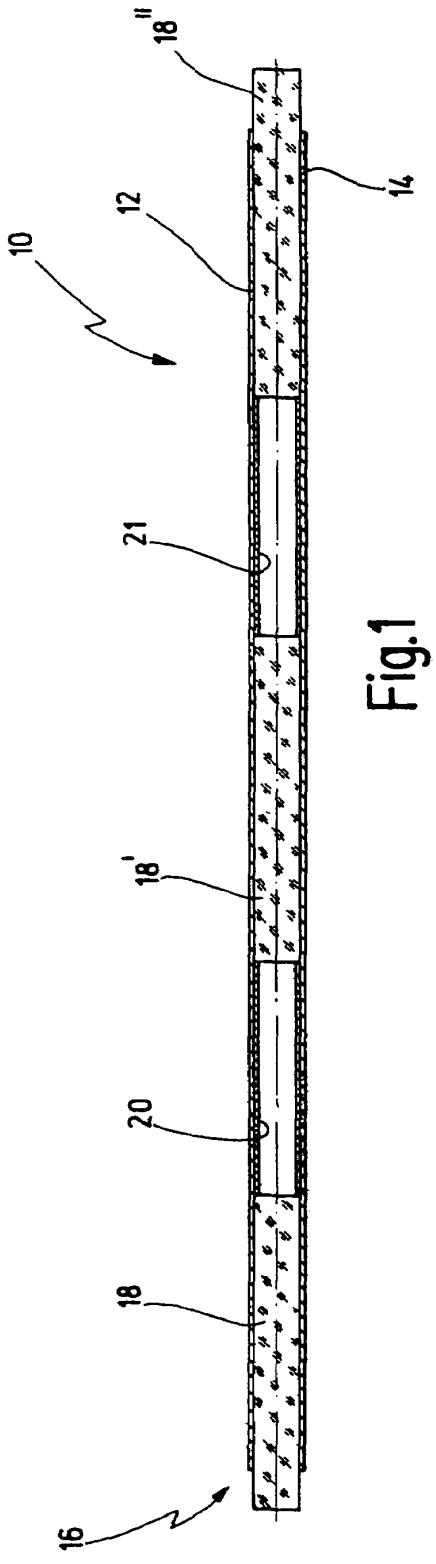


Fig.1

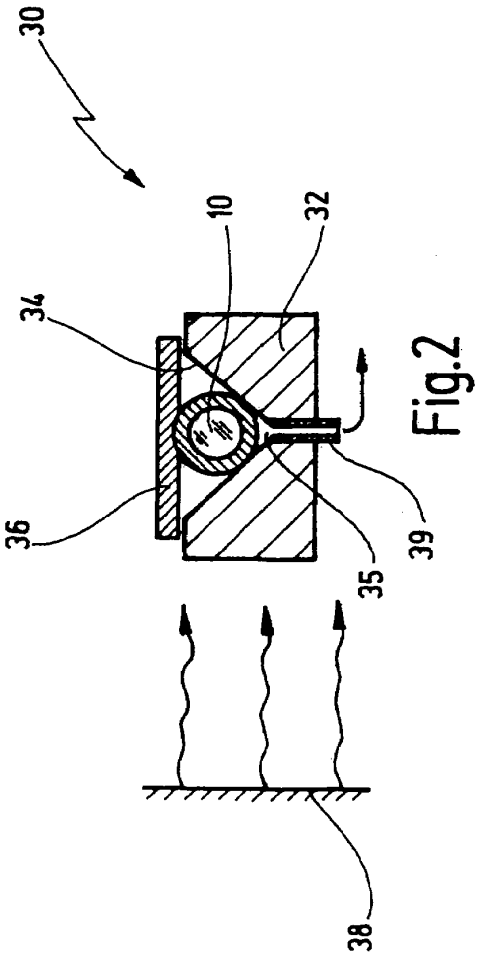


Fig.2

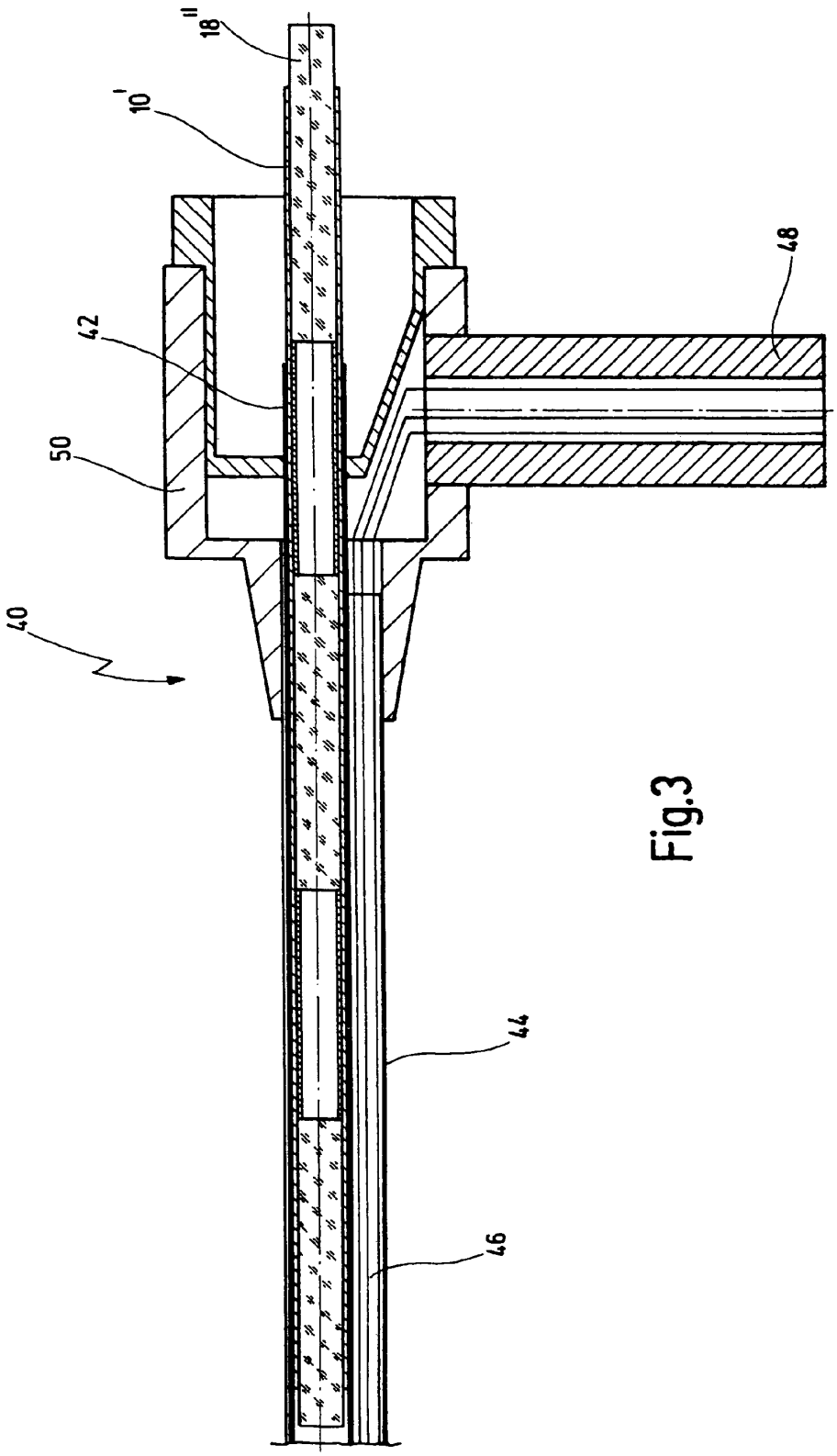


Fig.3

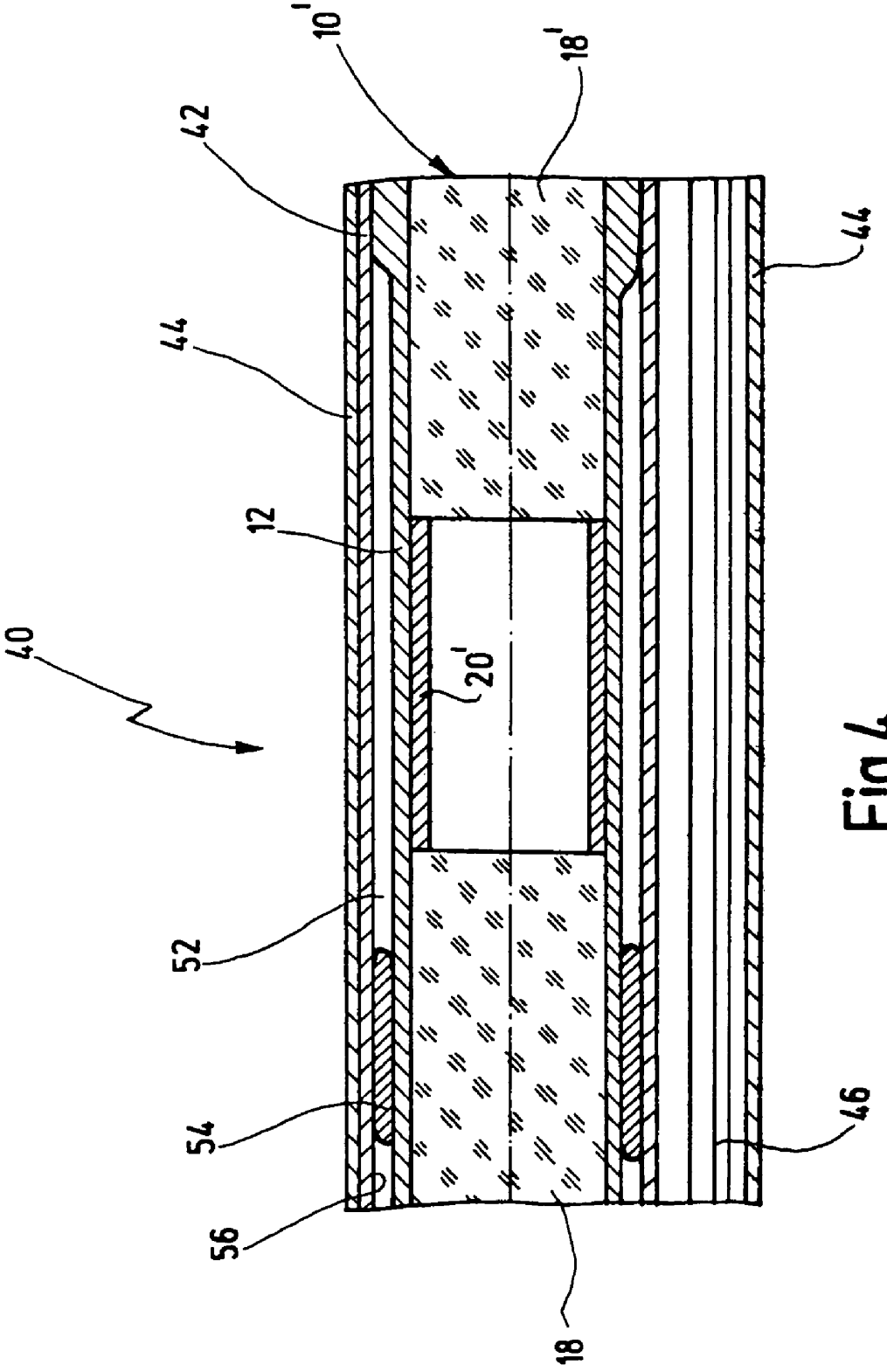


Fig.4

ENDOSCOPE AND METHOD FOR ASSEMBLING COMPONENTS OF AN OPTICAL SYSTEM

This application is a continuation of pending international application PCT/EP 2004/000765 filed on Jan. 29, 2004 which designates the United States and which claims priority of German patent application No. 103 07 904.1 filed on Feb. 18, 2003.

BACKGROUND OF THE INVENTION

The invention relates to an endoscope, with a tubular shaft whose interior contains components, in particular lenses, spacers, diaphragms, prisms and filters of an optical system, said components being at least partially surrounded by a support piece made of shrunk material.

The invention also relates to a method for assembling components, in particular lenses, spacers, diaphragms and filters of an optical system in the interior of a tubular shaft of an endoscope, said components being surrounded by a support piece made of shrunk material.

Such an endoscope and such a method are known from document DE 197 32 991 C2.

In the method disclosed in the latter document, the shrinkable material is used to fix the components of the optical system in the tubular shaft. To do this, the components are introduced into a support piece made of shrinkable material at least partially surrounding said components, and this unit is then pushed into the tubular shaft. The dimensions are such that a small gap remains between the outside face of the support piece and the inside face of the tubular shaft. As the material shrinks, it expands slightly in the radial direction and fills the gap, so that in this way the unit is fixed on the inside face of the tubular shaft.

DE 39 12 720 C2 also discloses the use of a plastic shrinkable tube for positioning the elements of a relay lens system of an endoscope. The material is chosen such that it does not transmit light, i.e. is opaque. This is intended to ensure that light does not pass from the light guide into the area of the relay lens system or into the area of the objective lens and there cause reflections or glare. The lenses of the lens system can first be placed in a correct position. The shrinkable tube is then shrunk by application of heat so that it holds the lenses, without a lens fixture in the conventional sense being needed.

This construction is intended to make it possible to produce endoscopes extremely inexpensively, and provision is therefore also made to produce the lenses from plastic.

In the document DE 39 12 720 C2 mentioned earlier, the aim is to fix the expensive components of the optical system to the inside face of a metal tubular shaft by using the shrink properties of the material surrounding these components.

It is an object of the present invention is to further optimize an endoscope and a method for assembling components in such a way that, by using shrinkable materials, it is possible to fix the optical components relative to one another in a way which can also be checked.

SUMMARY OF THE INVENTION

According to the invention, the object in respect of an endoscope is achieved by the fact that the components are surrounded by a transparent and tube-shaped shrunk material which has been shrunk before the components are introduced into the tubular shaft.

According to the invention, the object in respect of a method is achieved by the following steps, namely introducing the components into a transparent and tube-shaped shrinkable material to form a unit, shrinking the material to fix the position of the components relative to one another, checking the position of the components relative to one another through the transparent shrunk material, and introducing the unit composed of shrunk tube-shaped material, and the components contained therein, into the tubular shaft.

The optical system of an endoscope is made up of a succession of different optical components. A particularly good image quality can be obtained using what are referred to as rod lenses. For this purpose, several rod lenses separated from one another by spacers are arranged in series, and other components such as diaphragms, filters or cover glasses or prisms can additionally be provided.

For a good image quality, it is not only necessary for these parts to be precisely oriented relative to one another and fixed axially along an optical axis; it is also necessary for their relative rotation positions to be unchangeable. In the course of assembly, it is expedient to check the optical image qualities of such a lens system so that, if appropriate, systems with optical misalignments can be eliminated.

The quality check of the optical system is normally made only after complete assembly of the endoscope. If optical errors are found, it is then very expensive to correct these, and in most cases the endoscope has to be completely dismantled.

With the present invention, it is now possible to produce a unit composed of the optical components and the tube outside the endoscope and to check this unit visually. For this purpose, a transparent shrinkable material is used which in many respects affords advantages over the opaque materials known from the prior art. On the one hand, the position of the components relative to one another can be visually checked at the time the individual components are introduced into the material before it has been shrunk. In particular, it is possible to establish whether, for example, individual filter components or diaphragms have turned relative to one another, or whether, for example, a gap is or is not present between a spacer and a rod lens.

It is also possible to check the correct arrangement of the lens components, lenses, spacers and, if appropriate, diaphragms, filters and/or prisms.

After this unit has been shrunk, a check can once again be made, namely as to whether the shrinking has caused any relative changes to take place. During shrinkage, the material surrounding the optical elements moves. By provision of the transparent material, it is now possible for the first time to perform a visual check even after the shrinking process. Of course, checks are also already possible in the direction of the optical axis that is to say through the optical elements. Thus, such a preliminary check can be made even before the optical system is fitted in the shaft. After introduction of the shrunk unit and final positioning of this unit in the shaft, a final check can then also be made.

In this way, the reliability of the assembly and the assembly as such, can also be simplified and improved.

In a further embodiment of the invention, all the components are surrounded by a single tube of transparent and shrunk material.

This measure has the advantage that all the components are introduced into a single tube-shaped body and this unit can be handled as such after shrinking, for example can be simply inserted as a unit into the tubular shaft of the endoscope. This unit can be introduced into the endoscope shaft in the appropriate position of rotation or can be brought to the correct position of rotation after introduction. If, for example, a front closure forms a prism with a lateral angle of view, the posi-

tion, that is to say lateral angle of view, can be chosen to the left, to the right, upward or downward.

In a further embodiment of the invention, the components are fixed to the inside face of the tubular shaft via the tube-shaped shrunk material.

There are a great many ways of doing this, for example by adhesive fixation where the adhesive can be applied before introduction of the unit, or can be introduced for fixing after introduction through radial bores in the tubular shaft.

In a further embodiment of the invention, the tube is fixed to the inside face of the tubular shaft by radial expansion of the shrunk material.

This measure has the advantage that the effect, known from DE 197 32 991 C2, can now additionally be used to fix the already "pre-shrunk" unit to the inside face of the tubular shaft by a further shrinking process. This entails a further axial shrinkage with slight radial expansion.

The extent of the shrinking process can be controlled by the nature and duration of the shrink treatment. In a first preliminary shrinking process, the shrink phenomenon is utilized so that the components introduced into the tube can be fixed relative to one another. After insertion of this unit into the tubular shaft, a further shrinking process is carried out, its sole purpose being to fill the gap between the outside face of the unit, composed of pre-shrunk shrinkable tube and the components contained therein, and the inside face of the tubular shaft into which this unit is inserted, in order thereby to fix this unit on this inside face of the tubular shaft as it experiences a slight expansion in the radial direction during this further shrinking. For this purpose, certain preliminary treatments of the shrinkable tube can be envisaged, for example one or more beads in the form of rings or partial rings lying within the cross section. These geometric departures from the otherwise cylindrical shape of the shrinkable tube entail radial expansion of the geometry of the shrinkable tube upon its axial shrinkage, without expansion of the material as such.

In one embodiment of the method, the unit composed of components and of transparent shrinkable material is inserted, before shrinkage, into a retaining device in which the unit lies in an oriented position.

This measure has the advantage that the retaining device can provide additional measures for keeping the unit correctly aligned. It is also possible, after insertion in the retaining device, to check the unit for correct fit before the shrink process is instigated.

The unit inserted in the retaining device can be additionally fixed by a partial vacuum.

In a further embodiment of the method, the unit is inserted into a groove of the retaining device.

This is particularly advantageous if long endoscope shafts are to be fitted and in particular if there is a risk of the force of gravity causing bending or bulging.

In a further embodiment, the unit inserted into the retaining device is weighed down by application of an object.

This measure has the advantage that not only is a support provided in the direction of gravity by way of insertion, but bending in the sense of lifting up can be prevented by application of the object before shrinkage.

In a further embodiment, the object is applied with a partial form fit onto the unit.

This measure is of advantage if a great many small individual parts are assembled which have a tendency to change their position in the event of movements, for example during shrinkage.

It will be appreciated that the features mentioned above and those still to be explained below can be used not only in the respectively cited combination, but also in other combinations or singly, without departing from the scope of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is described and explained in greater detail below on the basis of a number of selected illustrative embodiments and with reference to the attached drawings, in which:

FIG. **1** shows a longitudinal section through a unit composed of a tube of transparent and shrinkable material and of optical components, namely rod lenses and spacers, before shrinkage,

FIG. **2** shows a cross section of a retaining device in which the unit shown in FIG. **1** is inserted, specifically upon shrinkage,

FIG. **3** shows a longitudinal section through an endoscope during assembly, into which endoscope the unit shown in FIG. **1**, after it has been shrunk in the retaining device **3** shown in FIG. **2**, is inserted into the tubular shaft, and

FIG. **4** shows, on a greatly enlarged scale, a partial longitudinal section through a shaft of an endoscope in whose tubular shaft a unit according to the invention is inserted, the left-hand half showing the unit fixed on the inside face of the tubular shaft by adhesive contacts, and the right-hand side showing it being fixed by means of further shrinkage.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENT

In FIG. **1**, a unit, designated in its entirety by reference number **10**, comprises a tube **12** made of transparent and shrinkable material **14**. A plurality of components **16** of an optical system are introduced into the tube **12**, specifically, as viewed from left to right, a rod lens **18**, whose external diameter corresponds approximately to the clear internal diameter of the tube **12**, a tubular and stiff spacer **20**, a further rod lens **18'**, a further spacer **21**, and a further rod lens **18"**.

This unit **10** is shown only by way of example, and other components such as filters, diaphragms or the like can of course also be included. It is also possible to provide closure windows at the ends or, in the case of an angled side view, suitable prisms.

By virtue of the transparency of the material **14**, it is possible to check the desired correct fit of these components **16** relative to one another from the outside, for example to check whether the opposing end faces of the two rod lenses **18** and **18'** bear exactly on the spacer **20**.

For the shrinking process, the unit **10** is inserted into a retaining device **30**, as is shown in FIG. **2**.

The retaining device **30** has an elongate body **32** whose length corresponds to least to the length of the unit **10**.

Cut out on the top face of the body **32** there is a longitudinally extending groove **34** which is configured in such a way that the unit **10** can be inserted into this groove, the unit **10** protruding slightly above the upper edge of the retaining device.

A roughly plate-shaped object **36** is placed onto this protruding area and bears with an at least partial form fit on the top face of the unit **10**, as it were pressing said unit **10** into the groove **34**.

In this way, the unit **10** is inserted and fixed in the retaining device **30** in such a way that a uniform shrinking of the material **14** of the tube **12** is possible, but with the unit still being fixed in position.

Alternatively or in addition, the position can be fixed by use of a partial vacuum. For this purpose, at least one opening **35** is provided in the bottom of the groove **34** and can be connected via an attachment piece **39** to a partial vacuum source (not shown here).

As is known per se, in the actual shrinking process, energy is supplied from an energy source **38** and causes the material **14** of the tube **12** to shrink.

One energy source is, for example, heat, if the material is designed such that it shrinks when heated. It is of course also possible to heat the retaining device **30** itself or to cause heated fluid to flow onto the retaining device.

After the shrinkage, the object **36** is taken off and the now shrunk unit **10'** is removed from the retaining device **30**.

By virtue of the transparency of the material **14** which is still present even after the shrinkage, it is possible once again to check, from the outside, the correct fit of the individual components **16** relative to one another.

The shrunk unit **10'** is then inserted into a tubular shaft **42** of an endoscope **40**, as is shown in FIG. **3**.

The endoscope **40** shown in FIG. **3** is represented highly schematically and, in addition to the tubular shaft **42** also referred to as inner tube, it also comprises an outer tube **44** of greater diameter which is mounted in a housing **50**. The tubular shaft **42** is received in the interior of the outer tube **44**.

As is normally the case, a light guide **46** is arranged in an approximately crescent-shaped space between tubular shaft **42** and outer tube **44**, said light guide **46** leading to a laterally angled light guide attachment **48**. In the illustrative embodiment shown, the light guide **46** is composed of a bundle of light-conducting glass fibers. The state shown in FIG. **3** is a state of partial assembly in which the eyepiece cup is still to be applied to the right-hand end, and, if appropriate, closure components or the like to the left-hand end.

FIG. **4** shows a cross section, on a greatly enlarged scale, through the shaft of an endoscope **40**, and, for the sake of clarity of the drawing, a slightly shorter spacer **20'** is shown here separating the two rod lenses **18** and **18'** from one another.

From the cross-sectional view in FIG. **4** it will be evident that the unit **10'** is inserted after shrinkage into the tubular shaft **42** received in the outer tube **44**. The external diameter is chosen in such a way that a small gap **52** is present between the outside face of the shrunk tube **12** and the inside face **56** of the tubular shaft **42**.

In FIG. **4**, for the sake of clarity of the drawing, this gap **52** is shown much larger than it really is.

The width of the gap is chosen such that the shrunk unit **10'** can be pushed into the tubular shaft **42** easily, or at any rate with minimal resistance.

FIG. **4** shows, on the left-hand side, that the unit **10'** is fixed on the inside face **56** of the tubular shaft **42** via an adhesive **54**. The adhesive **54** can either be introduced through openings (not shown here) from the outside or can be applied to the shrunk unit **10'** before the latter is inserted into the tubular shaft **42**.

The right-hand end of FIG. **4** shows that the unit **10'** is fixed to the inside face **56** of the tubular shaft **52** by further shrinkage of the tube and associated radial expansion, in which case, as has already been mentioned, the shrinkable tube can be geometrically designed in such a way that, for example by provision of beads, incisions or other configurations which promote expansion at predetermined locations, this expansion takes place in a specific manner during the further shrinking process.

This possibility is chosen when the material **14** of the tube **12** permits two shrinking processes, namely a first or preliminary shrinking process for fixing the components to one another, for example in the retaining device **30** shown in FIG. **2**, and then, after insertion into the tubular shaft **42** as shown in FIG. **4**, a further shrinking and radial expansion for filling the gap **52**.

What is claimed is:

1. A method for assembling an endoscope having a tubular shaft, an optical system having several components, said components of said optical system are contained in an interior of said tubular shaft, said components of said optical systems are at least partially surrounded by a tube made of both a transparent and a shrunk material, said method comprising the following steps

a) introducing said components into a tube of transparent and shrinkable material to form a unit,

b) shrinking said shrinkable material of said tube for fixing the position of said components contained within said tube relative to one another,

c) checking a position of said components relative to one another through said transparent shrunk material, of said shrunk tube and

d) introducing said unit composed of said shrunk tube and said components contained therein into said tubular shaft.

2. The method of claim **1**, wherein said unit composed of said components within said transparent shrinkable tube is, prior to shrinkage, introduced into a retaining device, said unit lying in an oriented position within said retaining device.

3. The method of claim **2**, wherein a partial vacuum is applied to said unit when inserted into said retaining device.

4. The method of claim **3**, wherein said unit is inserted into a groove of said retaining device.

5. The method of claim **4**, wherein said unit inserted into said retaining device is weighed down by posing an object thereon.

6. The method of claim **5**, wherein said object applied to said unit at least partially fit onto said unit.

7. The method of claim **1**, wherein after performing step c) of introducing the unit within the tubular shaft said unit is fixed to the inside surface of said tubular shaft.

* * * * *

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(54) **ENDOSCOPE AND METHOD FOR ASSEMBLING COMPONENTS OF AN OPTICAL SYSTEM**

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Appl. No.: **12/413,891**
Filed: **Mar. 30, 2009**

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(58) **Field of Classification Search**

CPC A61B 1/00163; A61B 1/002; A61B 1/055; G02B 23/2476

(Continued)

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,730,175 A * 5/1973 Fukami et al. 600/176
4,148,550 A 4/1979 MacAnally

(Continued)

FOREIGN PATENT DOCUMENTS

DE 2812369 A1 11/1978
DE 3738451 A1 5/1988

(Continued)

OTHER PUBLICATIONS

Complaint against Integrated Medical Systems International Inc, filed by Karl Storz Endoscopy-America Inc. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Exhibit D, # 5 Exhibit E, # 6 Exhibit F)(SAC) (Entered: Aug. 16, 2012) 40 pages.

(Continued)

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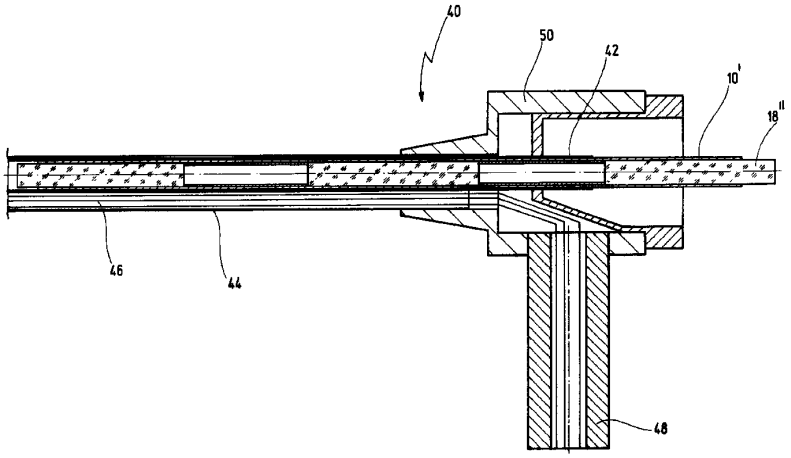
(57) **ABSTRACT**

An endoscope has a tubular shaft whose interior contains components, in particular lenses, spacers, diaphragms, prisms and filters of an optical system, said components being at least partially surrounded by a support piece made of shrunk material. It is proposed that the components be surrounded by a transparent and tube-sleeve-shaped shrunk material which has been shrunk before the components are introduced into the tubular shaft.

32 Claims, 3 Drawing Sheets



Related U.S. Application Data

continuation of application No. PCT/EP2004/000765, filed on Jan. 29, 2004.

(58) **Field of Classification Search**
USPC 600/121, 128, 130, 138–139, 160, 182; 359/434–435, 894
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,148,551	A	4/1979	MacAnally	A61B 1/002 359/435
4,737,380	A	4/1988	Shene	
4,750,476	A	6/1988	Forkner et al.	A61B 1/002 600/138
4,822,154	A	4/1989	Oxford et al.	
4,966,439	A	10/1990	Althaus et al.	
5,419,313	A	5/1995	Lemke	
5,437,000	A	7/1995	Dyott	
5,452,395	A *	9/1995	Schichman et al.	385/125
5,480,302	A	1/1996	Fife	
5,486,171	A *	1/1996	Chou	606/16
5,638,483	A *	6/1997	Konwitz	385/38
5,701,200	A	12/1997	Horton	
6,013,047	A *	1/2000	King	604/22
6,201,649	B1	3/2001	Rudischhauser et al.	
6,305,536	B1	10/2001	Tanaka	
6,366,726	B1 *	4/2002	Wach et al.	385/115
6,398,723	B1	6/2002	Kehr et al.	
6,471,640	B1	10/2002	Frische et al.	
7,385,772	B2	6/2008	Forkey et al.	
7,595,935	B2 *	9/2009	Lei et al.	359/665
2001/0034514	A1 *	10/2001	Parker	604/525
2002/0007111	A1	1/2002	Deckert et al.	
2006/0041187	A1 *	2/2006	Rudischhauser	A61B 1/00163 600/138

FOREIGN PATENT DOCUMENTS

DE	3912720 A1	10/1990	
DE	19732991 A1	2/1999	
DE	19912656 A1	11/2000	
DE	10253559 A1	6/2004	G02B 23/2446
DE	10307904 A1	10/2004	
EP	0337142 A1	10/1989	
WO	2004073508 A1	9/2004	

OTHER PUBLICATIONS

Corporate Disclosure Statement by Karl Storz Endoscopy-America Inc. filed by Karl Storz Endoscopy-America Inc (Maner, J) (Entered: Aug. 22, 2012) 2 pages.

Summons Issued as to Integrated Medical Systems International Inc.; delivered to Plaintiff. (SAC) (Entered: Aug. 22, 2012) 1 page

Return of Service by Karl Storz Endoscopy-America Inc (Dana, John) (Entered: Aug. 22, 2012) 1 page.

Motion for Limited Admission Motion for Pro Hac Vice of Dabney J. Carr IV by Integrated Medical Systems International Inc. (Bottcher, Christopher) (Entered: Sep. 21, 2012) 8 pages.

Motion to Dismiss and Memorandum in Support of Motion by Integrated Medical Systems International Inc. (Attachments: # 1 Exhibit 1—2010 Complaint, # 2 Exhibit 2—2011 Complaint, # 3 Exhibit 3—Jun. 30, 2011 Judge's Memo Opinion and Order, # 4 Exhibit 4—Dec. 27, 2011 Judge's Order)(Bottcher, Christopher) (Entered: Sep. 21, 2012) 127 pages.

Motion to Stay Pending Resolution of Inter Partes Reexamination by Integrated Medical Systems International Inc. (Attachments: # 1 Exhibit 1—Inter Partes Reexamination Filings Jun. 30, 2012, # 2 Exhibit 2—Electronic Acknowledgment for patent 7,530,945, # 3 Exhibit 3—Electronic Acknowledgment for patent 8,029.437, # 4 Exhibit 4—Reexamination Filings FY 2012)(Bottcher, Christopher) (Entered: Sep. 21, 2012) 233 pages.

Vacated—Order Setting Briefing Schedule re 6 Motion to Dismiss and Memorandum in Support of Motion filed by Integrated Medical Systems International Inc. The plaintiffs response will be due Oct. 15, 2012. Any reply brief, if necessary, will be due Oct. 29, 2012. Signed by Judge Karon O Bowdre on Sep. 24, 2012. (SAC) Modified on Oct. 12, 2012—Vacated—see order doc # 13 (ASL). (Entered: Sep. 24, 2012) 1 page.

Motion Set Briefing Schedule on Defendant's Motion to Stay Pending Resolution of Inter Partes Reexamination by Karl Storz Endoscopy-America Inc. (Dana, John) (Entered: Sep. 26, 2012) 4 pages.

Motion for Limited Admission Pro Hac Vice for Paul E. McGowan by Integrated Medical Systems International Inc. (Bottcher, Christopher) (Entered: Sep. 26, 2012) 5 pages.

Alnd Uniform Initial Order Governing All Further Proceedings, reminding parties of their obligations under Federal Rule of Civil Procedure 26 (f) and Local Rule LR26.1(d)—with appendices attached. Signed by Judge Karon O Bowdre on Oct. 2, 2012. (FNC) (Entered: Oct. 2, 2012) 20 pages.

Joint Motion to Stay re 6 Motion to Dismiss and Memorandum in Support of Motion, 7 Motion to Stay Pending Resolution of Inter Partes Reexamination by Integrated Medical Systems International Inc, Karl Storz Endoscopy-America Inc. (Attachments: # 1 Exhibit A—Order on Joint Motion) (Bottcher, Christopher) (Entered: Oct. 10, 2012) 8 pages.

Order granting 12 parties' joint motion to stay action and withdraw motion to dismiss, without prejudice; court Vacates Orders (doc 8 and docket entry Order dated Sep. 27, 2012) setting briefing schedules regarding motion to dismiss and motion to stay; parties shall submit Joint status report in ninety days or as soon as the USPTO rules. Signed by Judge Karon O Bowdre on Oct. 12, 2012 (ASL) (Entered: Oct. 12, 2012) 2 pages.

Status Report Joint Satus Report by Integrated Medical Systems International Inc, Karl Storz Endoscopy-America Inc. filed by Integrated Medical Systems International Inc, Karl Storz Endoscopy-America Inc (Bottcher, Christopher) (Entered: Jan. 8, 2013) 3 pages.

Status Report Joint Status Report by Integrated Medical Systems International Inc, Karl Storz Endoscopy-America Inc. filed by Integrated Medical Systems International Inc, Karl Storz Endoscopy-America Inc (Bottcher, Christopher) (Entered: Feb. 25, 2013) 3 pages.

Order The court Orders the parties to file another Joint Status Report by May 27, 2013 or at the conclusion of the reexamination proceedings for Claims 8-14 of the '437 Patent, whichever is sooner. Signed by Judge Karon O Bowdre on Feb. 26, 2013. (SAC) (Entered: Feb. 26, 2013) 1 page.

Joint Status Report Filed on May 28, 2013; 3 pages.

International Search Report, May 13, 2004, 7 pages.

* cited by examiner

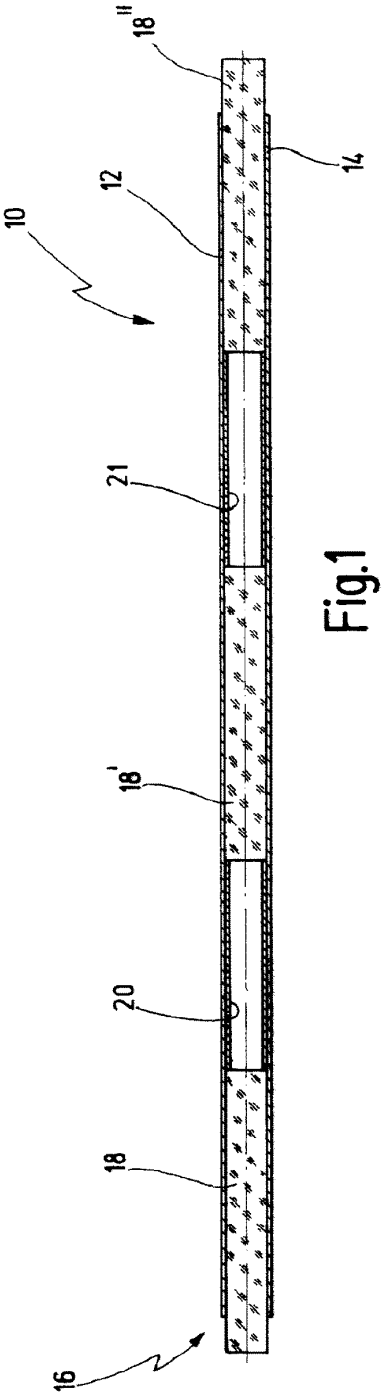


Fig.1

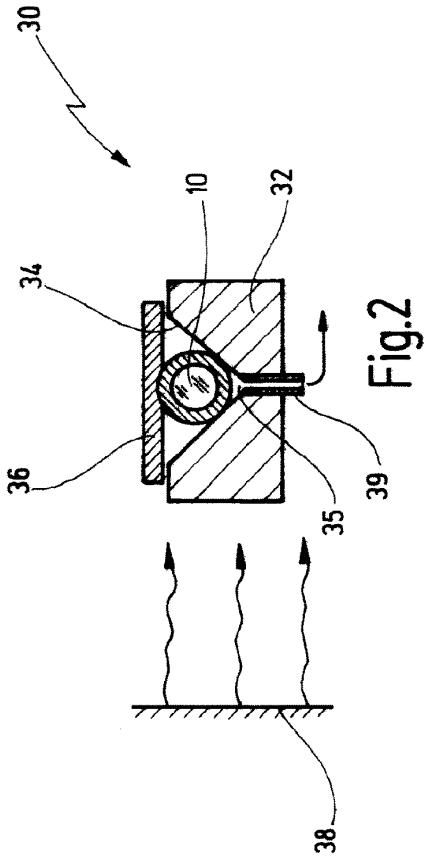


Fig.2

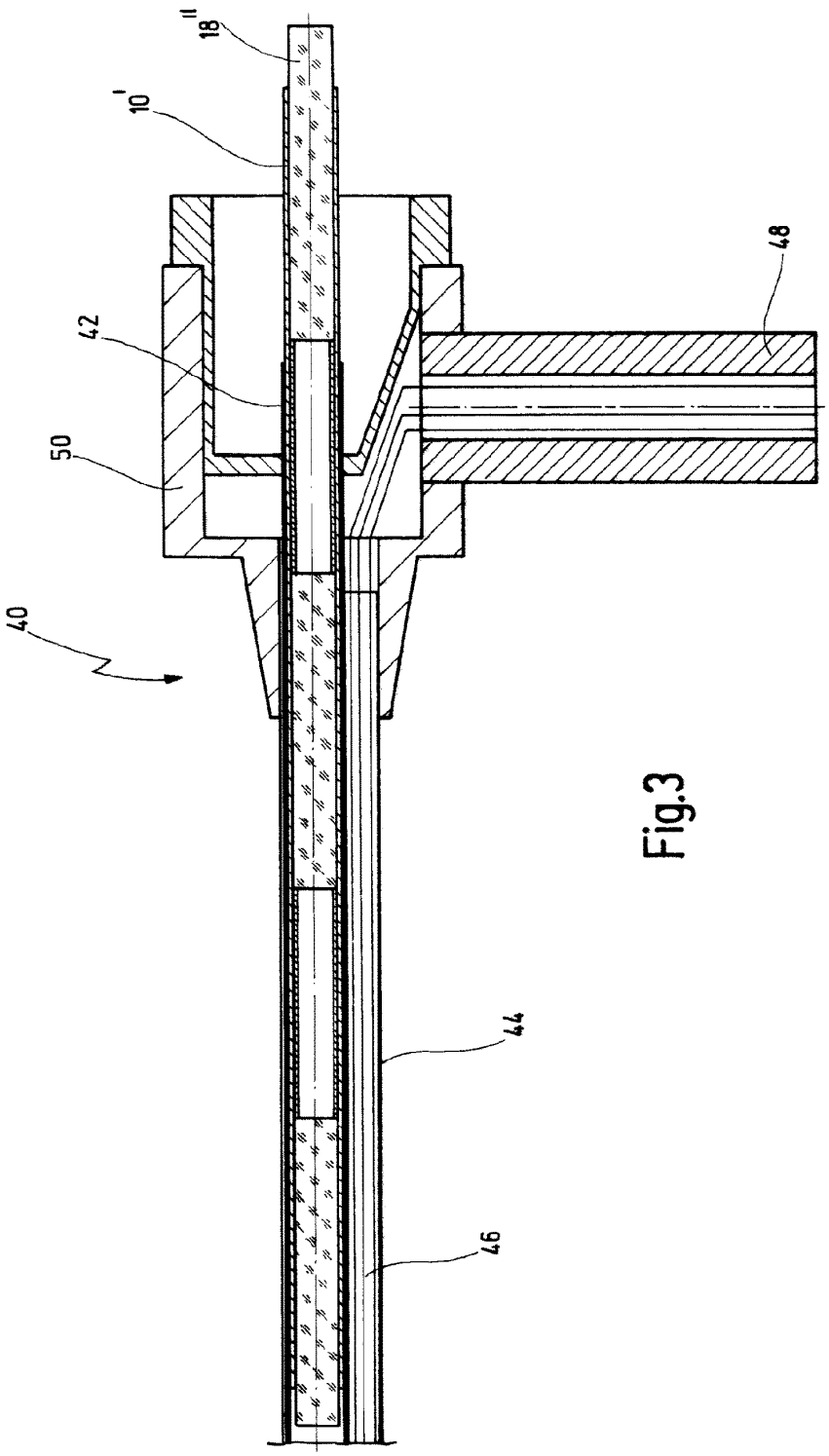


Fig.3

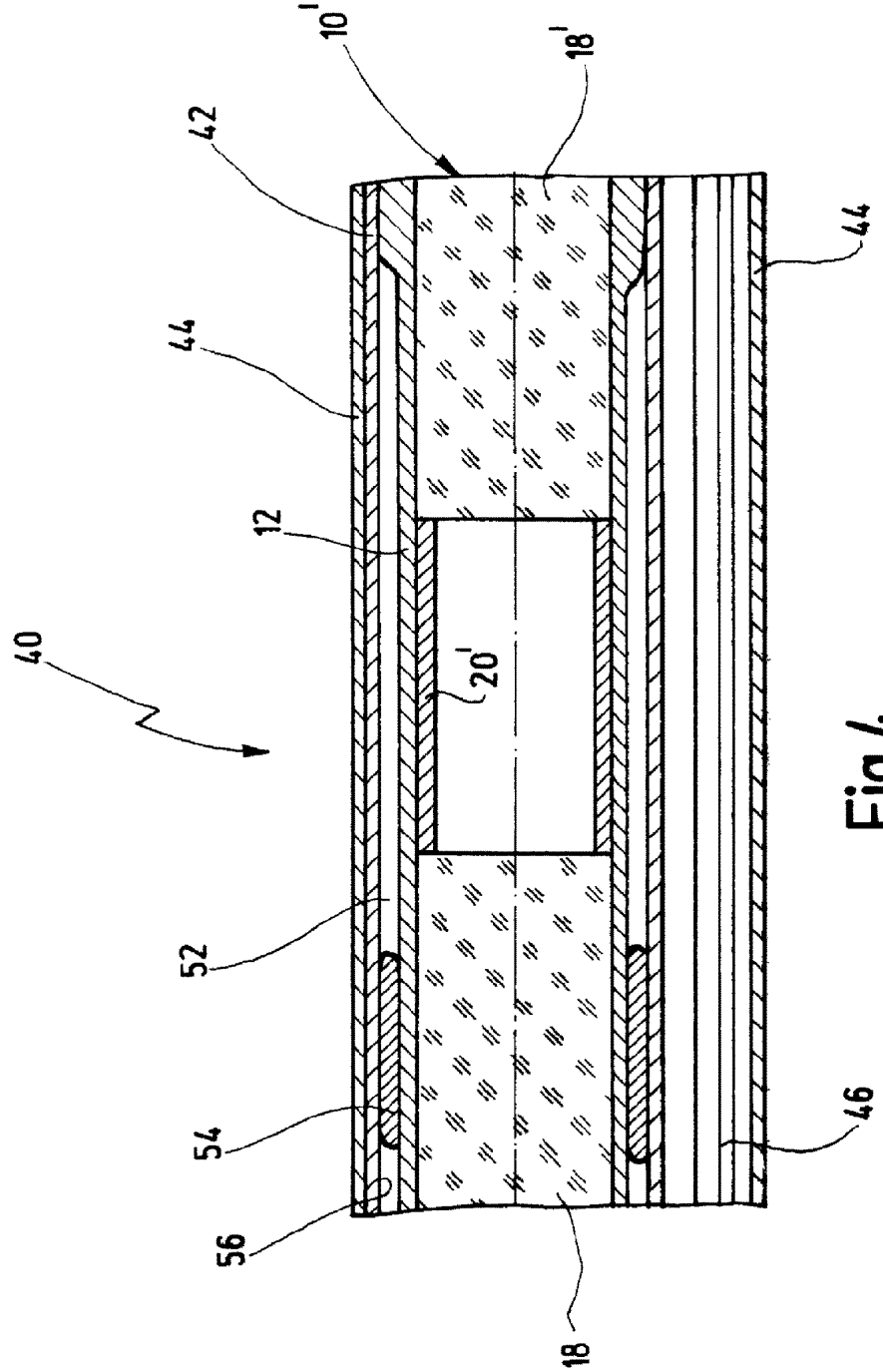


Fig.4

ENDOSCOPE AND METHOD FOR ASSEMBLING COMPONENTS OF AN OPTICAL SYSTEM

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue; a claim printed with strikethrough indicates that the claim was canceled, disclaimed, or held invalid by a prior post-patent action or proceeding.

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a division of U.S. patent application Ser. No. 11/206,562 filed Aug. 18, 2005, now U.S. Pat. No. 7,530,945 which in turn is a continuation of international application PCT/EP 2004/000765 filed on Jan. 29, 2004 which designates the United States and which claims priority of German patent application No. 103 07 904.1 filed on Feb. 18, 2003. All prior applications are herein incorporated by reference. *This is a Reissue Patent Application of U.S. Pat. No. 8,029,437, issued Oct. 4, 2011.*

BACKGROUND OF THE INVENTION

The invention relates to an endoscope, with a tubular shaft whose interior contains components, in particular lenses, spacers, diaphragms, prisms and filters of an optical system, said components being at least partially surrounded by a support piece made of shrunk material.

The invention also relates to a method for assembling components, in particular lenses, spacers, diaphragms and filters of an optical system in the interior of a tubular shaft of an endoscope, said components being surrounded by a support piece made of shrunk material.

Such an endoscope and such a method are known from document DE 197 32 991 C2.

In the method disclosed in the latter document, the shrinkable material is used to fix the components of the optical system in the tubular shaft. To do this, the components are introduced into a support piece made of shrinkable material at least partially surrounding said components, and this unit is then pushed into the tubular shaft. The dimensions are such that a small gap remains between the outside face of the support piece and the inside face of the tubular shaft. As the material shrinks, it expands slightly in the radial direction and fills the gap, so that in this way the unit is fixed on the inside face of the tubular shaft.

DE 39 12 720 C2 also discloses the use of a plastic shrinkable tube for positioning the elements of a relay lens system of an endoscope. The material is chosen such that it does not transmit light, i.e. is opaque. This is intended to ensure that light does not pass from the light guide into the area of the relay lens system or into the area of the objective lens and there cause reflections or glare. The lenses of the lens system can first be placed in a correct position. The shrinkable tube is then shrunk by application of heat so that it holds the lenses, without a lens fixture in the conventional sense being needed.

This construction is intended to make it possible to produce endoscopes extremely inexpensively, and provision is therefore also made to produce the lenses from plastic.

In the document DE 39 12 720 C2 mentioned earlier, the aim is to fix the expensive components of the optical system

to the inside face of a metal tubular shaft by using the shrink properties of the material surrounding these components.

It is an object of the present invention is to further optimize an endoscope and a method for assembling components in such a way that, by using shrinkable materials, it is possible to fix the optical components relative to one another in a way which can also be checked.

SUMMARY OF THE INVENTION

According to the invention, the object in respect of an endoscope is achieved by the fact that the components are surrounded by a transparent and tube-shaped shrunk material which has been shrunk before the components are introduced into the tubular shaft.

According to the invention, the object in respect of a method is achieved by the following steps, namely introducing the components into a transparent and tube-shaped shrinkable material to form a unit, shrinking the material to fix the position of the components relative to one another, checking the position of the components relative to one another through the transparent shrunk material, and introducing the unit composed of shrunk tube-shaped material, and the components contained therein, into the tubular shaft.

The optical system of an endoscope is made up of a succession of different optical components. A particularly good image quality can be obtained using what are referred to as rod lenses. For this purpose, several rod lenses separated from one another by spacers are arranged in series, and other components such as diaphragms, filters or cover glasses or prisms can additionally be provided.

For a good image quality, it is not only necessary for these parts to be precisely oriented relative to one another and fixed axially along an optical axis; it is also necessary for their relative rotation positions to be unchangeable. In the course of assembly, it is expedient to check the optical image qualities of such a lens system so that, if appropriate, systems with optical misalignments can be eliminated.

The quality check of the optical system is normally made only after complete assembly of the endoscope. If optical errors are found, it is then very expensive to correct these, and in most cases the endoscope has to be completely dismantled.

With the present invention, it is now possible to produce a unit composed of the optical components and the tube outside the endoscope and to check this unit visually. For this purpose, a transparent shrinkable material is used which in many respects affords advantages over the opaque materials known from the prior art. On the one hand, the position of the components relative to one another can be visually checked at the time the individual components are introduced into the material before it has been shrunk. In particular, it is possible to establish whether, for example, individual filter components or diaphragms have turned relative to one another, or whether, for example, a gap is or is not present between a spacer and a rod lens.

It is also possible to check the correct arrangement of the lens components, lenses, spacers and, if appropriate, diaphragms, filters and/or prisms.

After this unit has been shrunk, a check can once again be made, namely as to whether the shrinking has caused any relative changes to take place. During shrinkage, the material surrounding the optical elements moves. By provision of the transparent material, it is now possible for the first time to perform a visual check even after the shrinking process. Of course, checks are also already possible in the direction of the optical axis that is to say through the optical elements.

Thus, such a preliminary check can be made even before the optical system is fitted in the shaft. After introduction of the shrunk unit and final positioning of this unit in the shaft, a final check can then also be made.

In this way, the reliability of the assembly and the assembly as such, can also be simplified and improved.

In a further embodiment of the invention, all the components are surrounded by a single tube of transparent and shrunk material.

This measure has the advantage that all the components are introduced into a single tube-shaped body and this unit can be handled as such after shrinking, for example can be simply inserted as a unit into the tubular shaft of the endoscope. This unit can be introduced into the endoscope shaft in the appropriate position of rotation or can be brought to the correct position of rotation after introduction. If, for example, a front closure forms a prism with a lateral angle of view, the position, that is to say lateral angle of view, can be chosen to the left, to the right, upward or downward.

In a further embodiment of the invention, the components are fixed to the inside face of the tubular shaft via the tube-shaped shrunk material.

There are a great many ways of doing this, for example by adhesive fixation where the adhesive can be applied before introduction of the unit, or can be introduced for fixing after introduction through radial bores in the tubular shaft.

In a further embodiment of the invention, the tube is fixed to the inside face of the tubular shaft by radial expansion of the shrunk material.

This measure has the advantage that the effect, known from DE 197 32 991 C2, can now additionally be used to fix the already "pre-shrunk" unit to the inside face of the tubular shaft by a further shrinking process. This entails a further axial shrinkage with slight radial expansion.

The extent of the shrinking process can be controlled by the nature and duration of the shrink treatment. In a first preliminary shrinking process, the shrink phenomenon is utilized so that the components introduced into the tube can be fixed relative to one another. After insertion of this unit into the tubular shaft, a further shrinking process is carried out, its sole purpose being to fill the gap between the outside face of the unit, composed of pre-shrunk shrinkable tube and the components contained therein, and the inside face of the tubular shaft into which this unit is inserted, in order thereby to fix this unit on this inside face of the tubular shaft as it experiences a slight expansion in the radial direction during this further shrinking. For this purpose, certain preliminary treatments of the shrinkable tube can be envisaged, for example one or more beads in the form of rings or partial rings lying within the cross section. These geometric departures from the otherwise cylindrical shape of the shrinkable tube entail radial expansion of the geometry of the shrinkable tube upon its axial shrinkage, without expansion of the material as such.

In one embodiment of the method, the unit composed of components and of transparent shrinkable material is inserted, before shrinkage, into a retaining device in which the unit lies in an oriented position.

This measure has the advantage that the retaining device can provide additional measures for keeping the unit correctly aligned. It is also possible, after insertion in the retaining device, to check the unit for correct fit before the shrink process is instigated.

The unit inserted in the retaining device can be additionally fixed by a partial vacuum.

In a further embodiment of the method, the unit is inserted into a groove of the retaining device.

This is particularly advantageous if long endoscope shafts are to be fitted and in particular if there is a risk of the force of gravity causing bending or bulging.

In a further embodiment, the unit inserted into the retaining device is weighed down by application of an object.

This measure has the advantage that not only is a support provided in the direction of gravity by way of insertion, but bending in the sense of lifting up can be prevented by application of the object before shrinkage.

In a further embodiment, the object is applied with a partial form fit onto the unit.

This measure is of advantage if a great many small individual parts are assembled which have a tendency to change their position in the event of movements, for example during shrinkage.

It will be appreciated that the features mentioned above and those still to be explained below can be used not only in the respectively cited combination, but also in other combinations or singly, without departing from the scope of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is described and explained in greater detail below on the basis of a number of selected illustrative embodiments and with reference to the attached drawings, in which:

FIG. **1** shows a longitudinal section through a unit composed of a tube of transparent and shrinkable material and of optical components, namely rod lenses and spacers, before shrinkage,

FIG. **2** shows a cross section of a retaining device in which the unit shown in FIG. **1** is inserted, specifically upon shrinkage,

FIG. **3** shows a longitudinal section through an endoscope during assembly, into which endoscope the unit shown in FIG. **1**, after it has been shrunk in the retaining device **3** shown in FIG. **2**, is inserted into the tubular shaft, and

FIG. **4** shows, on a greatly enlarged scale, a partial longitudinal section through a shaft of an endoscope in whose tubular shaft a unit according to the invention is inserted, the left-hand half showing the unit fixed on the inside face of the tubular shaft by adhesive contacts, and the right-hand side showing it being fixed by means of further shrinkage.

DETAILED DESCRIPTION OF THE INVENTION

In FIG. **1**, a unit, designated in its entirety by reference number **10**, comprises a tube **12** made of transparent and shrinkable material **14**. A plurality of components **16** of an optical system are introduced into the tube **12**, specifically, as viewed from left to right, a rod lens **18**, whose external diameter corresponds approximately to the clear internal diameter of the tube **12**, a tubular and stiff spacer **20**, a further rod lens **18'**, a further spacer **21**, and a further rod lens **18"**.

This unit **10** is shown only by way of example, and other components such as filters, diaphragms or the like can of course also be included. It is also possible to provide closure windows at the ends or, in the case of an angled side view, suitable prisms.

By virtue of the transparency of the material **14**, it is possible to check the desired correct fit of these components **16** relative to one another from the outside, for example to

check whether the opposing end faces of the two rod lenses **18** and **18'** bear exactly on the spacer **20**.

For the shrinking process, the unit **10** is inserted into a retaining device **30**, as is shown in FIG. **2**.

The retaining device **30** has an elongate body **32** whose length corresponds to least to the length of the unit **10**.

Cut out on the top face of the body **32** there is a longitudinally extending groove **34** which is configured in such a way that the unit **10** can be inserted into this groove, the unit **10** protruding slightly above the upper edge of the retaining device.

A roughly plate-shaped object **36** is placed onto this protruding area and bears with an at least partial form fit on the top face of the unit **10**, as it were pressing said unit **10** into the groove **34**.

In this way, the unit **10** is inserted and fixed in the retaining device **30** in such a way that a uniform shrinking of the material **14** of the tube **12** is possible, but with the unit still being fixed in position.

Alternatively or in addition, the position can be fixed by use of a partial vacuum. For this purpose, at least one opening **35** is provided in the bottom of the groove **34** and can be connected via an attachment piece **39** to a partial vacuum source (not shown here).

As is known per se, in the actual shrinking process, energy is supplied from an energy source **38** and causes the material **14** of the tube **12** to shrink.

One energy source is, for example, heat, if the material is designed such that it shrinks when heated. It is of course also possible to heat the retaining device **30** itself or to cause heated fluid to flow onto the retaining device.

After the shrinkage, the object **36** is taken off and the now shrunk unit **10'** is removed from the retaining device **30**.

By virtue of the transparency of the material **14** which is still present even after the shrinkage, it is possible once again to check, from the outside, the correct fit of the individual components **16** relative to one another.

The shrunk unit **10'** is then inserted into a tubular shaft **42** of an endoscope **40**, as is shown in FIG. **3**.

The endoscope **40** shown in FIG. **3** is represented highly schematically and, in addition to the tubular shaft **42** also referred to as inner tube, it also comprises an outer tube **44** of greater diameter which is mounted in a housing **50**. The tubular shaft **42** is received in the interior of the outer tube **44**.

As is normally the case, a light guide **46** is arranged in an approximately crescent-shaped space between tubular shaft **42** and outer tube **44**, said light guide **46** leading to a laterally angled light guide attachment **48**. In the illustrative embodiment shown, the light guide **46** is composed of a bundle of light-conducting glass fibers. The state shown in FIG. **3** is a state of partial assembly in which the eyepiece cup is still to be applied to the right-hand end, and, if appropriate, closure components or the like to the left-hand end.

FIG. **4** shows a cross section, on a greatly enlarged scale, through the shaft of an endoscope **40**, and, for the sake of clarity of the drawing, a slightly shorter spacer **20'** is shown here separating the two rod lenses **18** and **18'** from one another.

From the cross-sectional view in FIG. **4** it will be evident that the unit **10'** is inserted after shrinkage into the tubular shaft **42** received in the outer tube **44**. The external diameter is chosen in such a way that a small gap **52** is present between the outside face of the shrunk tube **12** and the inside face **56** of the tubular shaft **42**.

In FIG. **4**, for the sake of clarity of the drawing, this gap **52** is shown much larger than it really is.

The width of the gap is chosen such that the shrunk unit **10'** can be pushed into the tubular shaft **42** easily, or at any rate with minimal resistance.

FIG. **4** shows, on the left-hand side, that the unit **10'** is fixed on the inside face **56** of the tubular shaft **42** via an adhesive **54**. The adhesive **54** can either be introduced through openings (not shown here) from the outside or can be applied to the shrunk unit **10'** before the latter is inserted into the tubular shaft **42**.

The right-hand end of FIG. **4** shows that the unit **10'** is fixed to the inside face **56** of the tubular shaft **52** by further shrinkage of the tube and associated radial expansion, in which case, as has already been mentioned, the shrinkable tube can be geometrically designed in such a way that, for example by provision of beads, incisions or other configurations which promote expansion at predetermined locations, this expansion takes place in a specific manner during the further shrinking process.

This possibility is chosen when the material **14** of the tube **12** permits two shrinking processes, namely a first or preliminary shrinking process for fixing the components to one another, for example in the retaining device **30** shown in FIG. **2**, and then, after insertion into the tubular shaft **42** as shown in FIG. **4**, a further shrinking and radial expansion for filling the gap **52**.

What is claimed is:

1. An endoscope, comprising:

a tubular shaft, having an inside face,

an optical system having several components, said components of said optical system are contained in an interior of said tubular shaft,

said components comprising at least two of the following: a lens, a spacer, a diaphragm, a prism and a filter, said components directly surrounded by a support piece made of a shrunk material, wherein

said shrunk material is a transparent material,

said support piece made of said transparent material has a shape of a tube, and

said tube containing said components of said optical system has been shrunk prior to inserting said tube into said interior of said tubular shaft, for allowing a visual check of a position of said components relative to one another, and

a gap located between an outside surface of said tube of shrunk material and said inside face of said tubular shaft.

2. The endoscope of claim **1**, wherein said components are surrounded by a single tube made of said transparent material.

3. The endoscope of claim **1**, wherein said shrunk transparent tube containing said components is fixed to the inside face of said tubular shaft.

4. The endoscope of claim **3**, wherein said tube being fixed to said inside face of said tubular shaft by a radial expansion of said shrunk material.

5. The endoscope of claim **4**, wherein said shrunk tube containing said components has in at least one area a configuration effecting a radial expansion during an axial shrinkage of said tube already inserted into said hollow shaft.

6. The endoscope of claim **5**, wherein said configuration being at least one of thickened parts, beads and incisions of said transparent material.

7. The endoscope of claim **1**, wherein said components comprise at least one of each of the following: a lens, a spacer, a diaphragm, a prism and a filter.

8. An endoscope, comprising:

a tubular shaft having an interior and an inside face;

an optical system including a plurality of components positioned in the interior of said shaft, the plurality of components comprising at least two of the following: a lens, a spacer, a diaphragm, a prism and a filter;

a support piece comprising a shrunk material enclosing said optical system to fit into the interior of said tubular shaft and providing support for said optical system, said shrunk material directly surrounding said plurality of components;

wherein said optical system is enclosed by and in contact with said shrunk material prior to insertion into said interior of said tubular shaft; and

wherein said shrunk material is either transparent or translucent such that visual inspection of said plurality of components relative to each other may be conducted prior to insertion into said interior of said tubular shaft, and

a gap located between an outside surface of said tube of shrunk material and said inside face of said tubular shaft.

9. The endoscope of claim 8, wherein said plurality of components is surrounded by a single tube made of said transparent or translucent material.

10. The endoscope of claim 8, wherein said shrunk transparent or translucent material containing said plurality of components is affixed to the inside face of said tubular shaft.

11. The endoscope of claim 10, wherein said shrunk transparent or translucent material is affixed to said inside face of said tubular shaft by a radial expansion of said shrunk transparent or translucent material.

12. The endoscope of claim 11, wherein said shrunk transparent or translucent material containing said plurality of components has in at least one area a configuration effecting a radial expansion during an axial shrinkage of said transparent or translucent material already inserted into the interior of said tubular shaft.

13. The endoscope of claim 11, wherein said configuration being at least one of thickened parts, beads and incisions of said transparent or translucent material.

14. The endoscope of claim 8, wherein said plurality of components comprise at least one of each of the following: a lens, a spacer, a diaphragm, a prism and a filter.

15. An endoscope, comprising:

a tubular shaft, having an inside face,

an optical system having several components, said components of said optical system are contained in an interior of said tubular shaft,

said components comprising at least two of the following: a lens, a spacer, a diaphragm, a prism and a filter, said components directly surrounded by a support piece made of a shrunk material, wherein

said support piece has a shape of a tube, and

said tube containing said components of said optical system has been shrunk prior to inserting said tube into said interior of said tubular shaft, and the material of the tube permits a visual check of a position of said components relative to one another through the material of the tube, and

a gap located between an outside surface of said tube of shrunk material and said inside face of said tubular shaft.

16. The endoscope of claim 15, wherein said tube is made of a transparent material.

17. The endoscope of claim 15, wherein said components are surrounded by a single tube.

18. The endoscope of claim 15, wherein said shrunk tube containing said components is fixed to the inside face of said tubular shaft.

19. The endoscope of claim 18, wherein said tube being fixed to said inside face of said tubular shaft by a radial expansion of said shrunk material.

20. The endoscope of claim 19, wherein said shrunk tube containing said components has in at least one area a configuration effecting a radial expansion during an axial shrinkage of said tube already inserted into said hollow shaft.

21. The endoscope of claim 20, wherein said configuration being at least one of thickened parts, beads and incisions of said transparent material.

22. The endoscope of claim 15, wherein said components comprise at least one of each of the following: a lens, a spacer, a diaphragm, a prism and a filter.

23. An endoscope, comprising:

a tubular shaft having an interior and an inside face;

an optical system including a plurality of components positioned in the interior of said shaft, the plurality of components comprising at least two of the following: a lens, a spacer, a diaphragm, a prism and a filter;

a support piece comprising a shrunk material enclosing said optical system to fit into the interior of said tubular shaft and providing support for said optical system, said shrunk material directly surrounding said plurality of components;

wherein said optical system is enclosed by and in contact with said shrunk material prior to insertion into said interior of said tubular shaft; and

wherein said shrunk material permits visual inspection of said plurality of components relative to each other through the shrunk material prior to insertion into said interior of said tubular shaft, and

a gap located between an outside surface of said shrunk material and said inside face of said tubular shaft.

24. The endoscope of claim 23, wherein said shrunk material is transparent.

25. The endoscope of claim 23, wherein said plurality of components is surrounded by a single piece of said shrunk material.

26. The endoscope of claim 23, wherein said shrunk material containing said plurality of components is affixed to the inside face of said tubular shaft.

27. The endoscope of claim 26, wherein said shrunk material is affixed to said inside face of said tubular shaft by a radial expansion of said shrunk material.

28. The endoscope of claim 27, wherein said shrunk material containing said plurality of components has in at least one area a configuration effecting a radial expansion during an axial shrinkage of said material already inserted into the interior of said tubular shaft.

29. The endoscope of claim 28, wherein said configuration being at least one of thickened parts, beads and incisions of said material.

30. The endoscope of claim 23, wherein said plurality of components comprise at least one of each of the following: a lens, a spacer, a diaphragm, a prism and a filter.

31. The endoscope of claim 15, wherein said components of said optical system include a rod lens having a first outer diameter along an entirety of a length of the rod lens, and a spacer having a second outer diameter along an entirety of a length of the spacer, and wherein the first outer diameter is substantially the same as the second outer diameter.

32. The endoscope of claim 23, wherein the plurality of components of said optical system include a rod lens having a first outer diameter along an entirety of a length of the rod lens, and a spacer having a second outer diameter along an entirety of a length of the spacer, and wherein the first outer diameter is substantially the same as the second outer diameter.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : RE47,044 E
APPLICATION NO. : 13/921884
DATED : September 18, 2018
INVENTOR(S) : Jürgen Rudischhauser et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Claims

Column 7, Claim 8, Line 15:
"wherein said shrunk material is either transparent or"
Should read:
--wherein said shrunk material is transparent--

Column 7, Claim 8, Line 16:
"translucent such that visual inspection of said plurality"
Should read:
--such that visual inspection of said plurality--

Column 7, Claim 9, Line 26:
"transparent or translucent material."
Should read:
--transparent material.--

Column 7, Claim 10, Line 28:
"transparent or translucent material containing said plurality"
Should read:
--transparent material containing said plurality--

Column 7, Claim 11, Line 32:
"transparent or translucent material is affixed to said inside"
Should read:
--transparent material is affixed to said inside--

Signed and Sealed this
Sixth Day of August, 2019

Andrei Iancu
Director of the United States Patent and Trademark Office

Column 7, Claim 11, Line 34:
"shrunk transparent or translucent material."
Should read:
--shrunk transparent material.--

Column 7, Claim 12, Line 36:
"transparent or translucent material containing said plurality"
Should read:
--transparent material containing said plurality--

Column 7, Claim 12, Line 39:
"transparent or translucent material already inserted into the"
Should read:
--transparent material already inserted into the--

Column 7, Claim 13, Line 43:
"of said transparent or translucent material."
Should read:
--of said transparent material.--

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF SERVICE

Case Number 2022-1978

Short Case Caption Karl Storz Endoscopy-America, Inc. v. STERIS Instrument Management Services, Inc.

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☐ Additional pages attached.

Date: 11/14/2022

Signature: /s/ William A. Meunier

Name: William A. Meunier

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

Case Number: 2022-1978

Short Case Caption: Karl Storz Endoscopy-America, Inc. v. STERIS Instrument Management Services, Inc.

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Name: William A. Meunier

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Case Number: 2022-1978

Short Case Caption: Karl Storz Endoscopy-America, Inc. v. STERIS Instrument Management Services, Inc.

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Signature: /s/ William A. Meunier

Name: William A. Meunier