2022-1978

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 DEFENDANT-APPELLEE

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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	2022-1978
Short Case Caption	Karl Storz Endoscopy-America, Inc. v. STERIS Instrument Management Services, Inc.
Filing Party/Entity	STERIS Instrument Management Services, 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: 07/05/2022

Signature: /s/ Dabney Jefferson Carr IV

Name: Dabney J. Carr IV

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
STERIS Instrument Management Services, Inc.		STERIS Corporation
		STERIS PLC

☐ 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

Robert R. Baugh Dentons Sirote PC	Alyse N. Windsor Dentons Sirote PC	

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 2 and 7 describes information regarding the pricing of Appellant's endoscopes which Appellant has marked as confidential pursuant to the Protective Order entered in this matter.

The material omitted on pages 5, 15, 16 and 39 describes the volume of repairs of rigid endoscopes performed by Appellee.

The material omitted on page 37 and 40 describes customer feedback and customer experiences using Karl Storz endoscopes which was omitted from the Appellant's Brief.

The confidential material is highlighted in yellow in the confidential brief.

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STATEMENT OF RELATED CASES

No other appeal in or from this action was previously before this or any other appellate court.

No case known to counsel is pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Appellant identifies the case from which this appeal is taken as a pending case that may be directly affected by this Court's decision in the pending appeal and references a motion for attorneys' fees filed by Appellee in the district court. The district court, however, terminated Appellee's motion for attorneys' fees with leave to renew following appeal, if appropriate, and so neither that motion nor the case from which this appeal is taken is pending.

INTRODUCTION

Karl Storz SE & Co. KG is a German manufacturer of medical equipment, including rigid (non-flexible) endoscopes which are the subject of the two patents-in-suit. Its wholly owned subsidiary, Appellant Karl Storz Endoscopy America ("Karl Storz"), sells Karl Storz endoscopes in the U.S. to hospitals and other health care providers. When those endoscopes become damaged or otherwise begin to suffer performance issues, the owners of Karl Storz endoscopes often come to Appellee STERIS Instrument Management Services, Inc. ("IMS") or one of many other Independent Service Organizations ("ISOs") for repairs. For decades, IMS has successfully repaired endoscopes for these customers, preserving the useful life of endoscopes, which can last for 25 years or more.

Karl Storz does not repair its customers' endoscopes. Instead, it forces its customers to trade in their damaged endoscopes for an as-new "E-Class" endoscope, at a Karl Storz pricing than a simple repair. IMS and the other ISOs are impediments to the Karl Storz "break-and-replace" business model, because after years of experience with IMS, these customers recognize the quality and value of IMS's repair services. Having thus failed to persuade its customers in the marketplace, Karl Storz now seeks to coerce them with its patents, accusing IMS, and by extension Karl Storz's own customers, of patent infringement by denying them the right of repair.

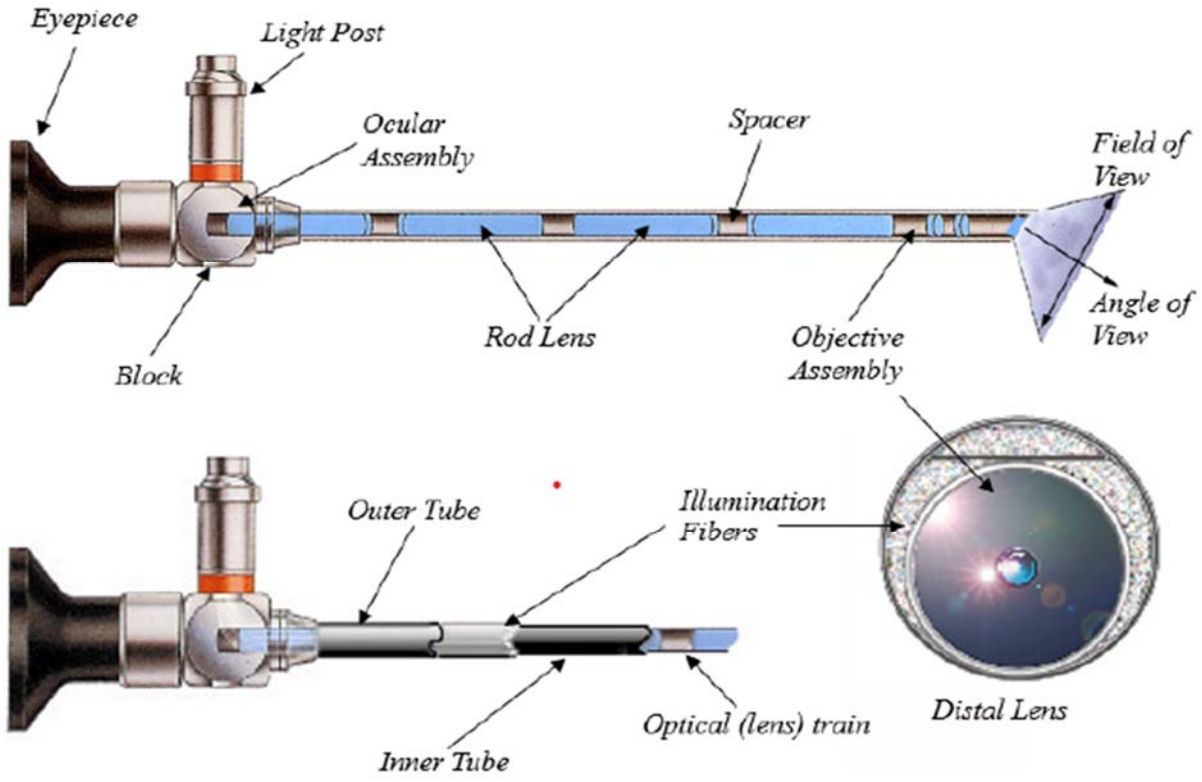
This Court has expressly considered and rejected every argument Karl Storz has advanced in support of its position. Under that precedent, permissible repair exists regardless of how important the broken part is, how difficult it is to repair, whether the patentee intends or wants it to be repaired, or whether the repair results in a device with different form or function. Frustrated by the reality of this legal landscape, Karl Storz attempts to create its own reality by misrepresenting the holding of various cases, fabricating supposed "tests" from whole cloth, and littering its appeal with irrelevant FDA regulations and unsubstantiated anecdotal complaints about the quality of repairs by unknown ISOs. Many of these arguments were not even raised with the District Court and thus are waived, though they fail not only procedurally, but also on the merits.

STATEMENT OF THE CASE

I. The Parts of an Endoscope

An endoscope is a medical device which allows a healthcare provider to look deep inside a patient's body. It transmits light into the body cavity and relays an image of what's inside back to an eyepiece or monitor. As shown below, the shaft of an endoscope includes both an inner and outer tubular shaft, with optical illumination fibers in between. Appx2232, ¶ 1, Appx2323, ¶ 6. The fiber optics between the inner and outer tubes illuminate the material at the distal end of the endoscope, and the optical relay (called the "optical (lens) train" in the figure below)

passes the optical image from the distal end of the endoscope to the proximal end (at the eyepiece). Appx2232, ¶¶ 1-3.



The optical relay is located inside the inner tubular shaft of the endoscope and is made up of a series of rod lenses that must be put in a specific order and orientation. Appx2232, ¶ 2. The rod lenses are grouped into pairs separated by a small spacer. *Id*. Each pair of rod lenses is separated by a larger spacer. In addition to the optical relay, the optical components of the endoscope include a separate objective lens assembly as well as an ocular lens. Appx2232, ¶ 1. The objective lens assembly is located at the distal end of the endoscope and includes a negative lens, a prism made up of at least three components, an objective lens made up of multiple

components, a spacer and two field lenses, all housed in a cartridge. Appx2232-2233, ¶ 4.

II. IMS's Repair of Karl Storz Endoscopes

The small glass rod lenses inside the inner tubular shaft depicted above are fragile and break easily if the endoscope is flexed, dropped or misused in some manner. Appx2474, ¶ 3. The parties stipulated that rod lenses are typically broken from torquing the endoscope during surgical procedures or some other misuse by the operator of the endoscope. Appx2234, ¶ 13. As a result, damage to these rod lenses is one of the most common reasons owners send their endoscopes to IMS for repair. Appx2234, ¶ 12, Appx2474, ¶ 3. Indeed, IMS replaces IMS repair sales of rod lenses a year in endoscopes made by a variety of original equipment manufacturers ("OEMs"), including Karl Storz. Appx2474, ¶ 4. The cost of those rod lenses and spacers are low in comparison to other components, and repair of the optical relay typically occurs far more frequently than most other repairs. Appx2474, ¶¶ 5-6. Between 2009 and 2020, IMS made more than IMS repair sales such repairs on over IMS repair sales Karl Storz endoscopes. Appx3295, ¶ 3; Appx3362; Appx2475, ¶ 10. Of those endoscopes, IMS repaired approximately 50% more than once and approximately 30% three or more times. Appx2475, ¶ 10. Because a thriving repair market exists for these devices, IMS also regularly receives Karl Storz rigid endoscopes for repair that have been previously repaired by other ISOs. Appx2475, ¶ 11.

The parties stipulated to all of the facts regarding the IMS repair process, and those facts are set forth in the district court's decision. Appx7-8; *see also* Appx2234-2236. In short, the technician opens the endoscope, slides the optical relay out of the inner tubular shaft as a single unit, slides in a replacement optical relay assembled from new and reused lenses and spacers, and re-seals the endoscope. Appx7-8. To create the replacement optical relay, an IMS technician lines up a sequence of new or recycled lenses and spacers, slides those components into a tube of shrink wrap; the assembly is heated and then stored for later use. Appx8, Appx2236, ¶¶ 32-33. As the district court concluded:

> 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.

Appx21. These are the only material facts relevant to the repair doctrine, and as mentioned above, they are not in dispute. Nothing Karl Storz attempts to characterize as additional "fact questions" have anything to do with the structure of the device or the process of repair, but rather are legal arguments based on these undisputed facts.

III. The Karl Storz Trade-In Program

Karl Storz makes and sells endoscopes but will not repair its customers' endoscopes when they break. Appx2383-2384 at 45:23-46:10.[1] If something as simple as a rod lens breaks, rather than offering to fix it, Karl Storz only allows its customers to trade in the damaged endoscope for an as-new, replacement endoscope (dubbed an "E-Class" endoscope). Appx2376 at 14:2-7. Not surprisingly, the cost of a Karl Storz E-Class endoscope is Karl Storz pricing than the cost of a repair, even with the trade-in of the customer's old endoscope. Appx3469 at 26:15-19; Appx2405 at 133:2-13. Through this lawsuit, Karl Storz is thus attempting to eliminate its customers' ability to have their endoscopes repaired by ISOs like IMS, and instead force them to buy a new endoscope every time even a single rod lens breaks.

IV. Patents-in-Suit and the Prior Art

The patents in suit claim a combination of unpatented elements. Specifically, the claims of the asserted patents recite an endoscope with the combination of a tubular shaft and an optical system within the shaft made up of several components (including rod lenses and spacers among other components), surrounded by a transparent shrunk material. See e.g., Appx39 ('945 patent, claim 1); Appx47-48 ('044 patent, claims. 1, 8, 15, 23). None of these elements are individually patented,

[1] Karl Storz will only address superficial issues such as external cleaning. Appx2391 at 75:13-76:9.

Appx21, and all of them are required to make up the patented combination. *See e.g.*, Appx600, ¶ 233, Appx601-602, ¶ 239, Appx607, ¶ 244 (identifying elements of patented combination). As Karl Storz's expert agreed, individual rod lenses or a plurality of rod lenses and spacers together do not infringe the asserted patents. Appx2292 at 202:10-20. Likewise, a plurality of rod lenses and spacers in shrink wrap or a shrink-wrapped optical relay alone does not infringe the asserted patents. Appx2292 at 202:21-203:7. Thus, as the district court noted, "[t]he optical relay is a series of unpatented rod lenses and spacers held together by unpatented shrink wrap." Appx22.

The '945 and '044 patents acknowledge that the prior art includes the use of shrinkable material surrounding the components of the optical relay. Appx37 ('945 patent) at 1:23-39 (in the prior art, "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."); Appx45 ('044 patent) at 1:39-55. According to the patents, however, the prior art only described the use of *opaque* shrink wrap. Appx37 ('945 patent) at 1:23-52; Appx45 ('044 patent) at 1:39-2:2. The patents claim to improve the prior art by using *transparent* shrink wrap. Appx37 ('945 patent) at 1:61-65; 2:26-32 ("a transparent shrinkable material is used which in many respects affords advantages over the

opaque materials known from the prior art."); Appx45 ('044 patent) at 2:3-8; 2:44-49. Karl Storz's expert agrees that the use of transparent shrink wrap rather than opaque shrink wrap is the sole inventive aspect of the patents. Appx499-501, ¶¶ 34-37.

SUMMARY OF THE ARGUMENT

The customers who purchase Karl Storz endoscopes have a broad right to repair those devices. The right includes replacing unpatented components regardless of how critical those pieces are to the overall device, how difficult or costly the repair may be, whether the resulting product has a new or different form or function than the original, and regardless of whether the patent owner wants or intends that the customer perform such repairs. Indeed, the right of repair includes the sequential replacement of parts in successive repairs, *even if that culminates in an entirely new device*, so long as no single instance of repair constitutes the full reconstruction.

The repair at issue in this case fits easily within the scope of permissible repair – it is not even close. It is not disputed that the individual components within the optical relay that IMS replaces are not themselves patented. It is not disputed that IMS salvages and recycles unbroken components within the optical relay. It is not disputed that IMS does not replace other components of the patented endoscopes as part of this repair. Indeed, the parties have stipulated all the material facts regarding the structure of Karl Storz's endoscopes and the steps of the IMS repair process.

In the face of this overwhelming headwind of law and facts, Karl Storz ignores precedent and invents non-existent legal tests. For example, Karl Storz argued in the district court that the repair doctrine was limited to "consumable" parts. The district court rightly rejected the argument, noting the legion of precedent finding permissible repair even for non-consumable elements and noting that no court had ever even used the word "consumable" when discussing the doctrine. On appeal, Karl Storz makes a new argument, finding a phrase that at least appears in a reported opinion ("readily replaceable") but again does not exist as an actual legal test. Karl Storz also argues for the first time on appeal that a Supreme Court case (*Quanta Computer Inc. v. LG Elecs, Inc.*, 553 U.S. 617 (2008)) that did not involve the repair doctrine, rewrote the repair doctrine in a way that no other litigant or court has noticed or applied in the 15 years since *Quanta* was decided.

The remainder of Karl Storz's brief is an exercise in falsehoods, distractions, and irrelevancies. Although irrelevant to the applicability of the repair doctrine, IMS performs quality repairs which have earned the loyalty of its customers over decades. Nevertheless, Karl Storz dedicates substantial effort to gratuitous, irrelevant, and unsubstantiated anecdotal complaints, which cannot be tied to IMS's repairs or the specific repair at issue in this case. Karl Storz also litters its brief with erroneous and irrelevant insinuations relating to FDA regulations, again apparently hoping to distract this Court from the actual issues at hand.

In the end, while cases may exist that test the boundaries of the repair doctrine, this is not such a case. The material facts are not disputed and the law is clear, and the Court should affirm the district court's decision, despite Karl Storz's attempts at distraction and concocted legal standards.

ARGUMENT

I. STANDARD OF REVIEW

Whether a defendant's actions constitute permissible repair is a question of law. *Fuji Photo Film Co. v. ITC*, 474 F.3d 1281, 1296 (Fed. Cir. 2007); *Aktiebolag v. E.J. Co.*, 121 F.3d 669, 672 (Fed. Cir. 1997). As a result, this Court has routinely upheld decisions resolving the issue of permissible repair on summary judgment. *See e.g., Husky Injection Molding v. R&D Tool & Eng'g Co.*, 291 F.3d 780, 782 (Fed. Cir. 2002) (affirming summary judgment of permissible repair); *Surfco Haw. v. Fin Control Sys. Pty. Ltd.*, 264 F.3d 1062, 1066 (Fed. Cir. 2001) (granting summary judgment of permissible repair as a matter of law); *Bottom Line Mgmt. v. Pan Man, Inc.*, 228 F.3d 1352, 1353 (Fed. Cir. 2000); *Kendall Co. v. Progressive Medical Tech., Inc.*, 85 F.3d 1570 (Fed. Cir. 1996) (affirming summary judgment of permissible repair); *Sage Prods. v. Devon Indus., Inc.*, 45 F.3d 1575, 1576 (Fed. Cir. 1995) (affirming summary judgment of permissible repair); *Dana Corp. v. Am. Precision Co.*, 827 F.2d 755, 760 (Fed. Cir. 1987) (affirming summary judgment of permissible repair). Here, the parties stipulated to the steps IMS performs when it

repairs the optical relays in Karl Storz endoscopes. Appx2234-2236, ¶¶ 15-33. As a result, no genuine issue of fact exists regarding the IMS repair process, and the only issue to resolve as a matter of law is whether that process enjoys protection under the repair doctrine.

II. PERMISSIBLE REPAIR IS NOT LIMITED TO "READILY REPLACEABLE" PARTS

A. Karl Storz's Customers Have the Legal Right to Repair Their Endoscopes

Karl Storz asserts that the right to repair is based on an implied license given to the purchaser of a patented article. Brief for Plaintiff-Appellant ("Opening Br.") at 27. That statement, however, ignores the Supreme Court's decision in *Impression Prods. v. Lexmark Int'l., Inc.*, 137 S.Ct. 1523, 1532-33 (2017), which held that the sale of a product extinguishes *all* patent rights associated with that product, and a product manufacturer loses all the rights of ownership, including the ability to restrict the use or repair of that product. *Impression Prods.*, 137 S. Ct. at 1532-34. As the Court stated:

> "[T]he exhaustion doctrine is not a presumption about the authority that comes along with a sale; it is instead a limit on 'the scope of the *patentee's rights.*' The right to use, sell, or import an item exists independently of the Patent Act. What a patent adds – and grants exclusively to the patentee – is a limited right to prevent others from engaging in those practices. Exhaustion extinguishes that exclusionary power. As a result, the sale transfers the right to use, sell, or import because those are the rights that come along with ownership, and the buyer is free and clear of an infringement lawsuit because there is no exclusionary right left to enforce.

Id. at 1534 (emphasis in original) (citations omitted). The Court also helpfully explained how its ruling was necessary to preserve the sanctity of the repair doctrine:

> Congress enacted and has repeatedly revised the Patent Act against the backdrop of the hostility toward restraints on alienation. That enmity is reflected in the exhaustion doctrine. The patent laws do not include the right to "restrain[ ] . . . further alienation" after an initial sale; such conditions have been "hateful to the law from Lord Coke's day to ours" and are "obnoxious to the public interest." "The inconvenience and annoyance to the public that an opposite conclusion would occasion are too obvious to require illustration."

Id. at 1532. Perhaps anticipating a litigant like Karl Storz, the Court continued:

> But an illustration never hurts. Take a shop that restores and sells used cars. The business works because the shop can rest assured that, so long as those bringing in the cars own them, the shop is free to repair and resell those vehicles.

Id. (internal cites omitted). Consequently, "patent 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." *Id*. at 1535. For purposes of the repair doctrine, the endoscope repair market is no different than the exemplary car repair market discussed in *Impression Prods.*, and Karl Storz retains no patent rights in its products after their sale, rendering its reliance on an "implied license" irrelevant.

B. There is No "Readily Replaceable" Requirement for Permissible Repair

Karl Storz's first ground for appeal is that (i) permissible repair is limited to "readily replaceable" parts, (ii) if the parts are not "readily replaceable" then the

repair is, by definition, impermissible reconstruction. *See* Opening Br. at 4, 7-8 (Issue No. 1), 30-39. As support for its "readily replaceable test," introduced for the first time on appeal, Opening Br. at 4, Karl Storz relies on a single decision of this Court, *Husky Injection Molding v. R&D Tool & Eng'g Co.*, 291 F.3d 780 (Fed. Cir. 2002). Describing that case, Karl Storz states:

> 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.

Opening Br. at 32. Of course, this Court said no such thing regarding "non-readily replaceable" parts in *Husky*. Instead, the Court simply noted that the parts at issue in that case *were* readily replaceable, and thus by definition such activities were permissible repair. *Husky Injection Molding*, 291 F.3d at 787 ("At a minimum, repair exists if the part being repaired is a readily replaceable part."). But Karl Storz does not simply make the logical fallacy of assuming that "non-readily replaceable" parts would lead to the opposite conclusion. Instead, it conspicuously ignores the reality that *Husky* expressly declined to address the issue. *Id*. ("Difficult questions may exist as to the line between *Sandvik Aktiebolag* and *Wilbur-Ellis* where readily replaceable parts are not involved. We need not resolve those questions here.") (emphasis added).

Another fundamental flaw in Karl Storz's argument is that it assumes that the scope of the repair doctrine depends on the nature of the part being replaced or the

complexity or difficulty of the repair process. To the contrary, as this Court has held, 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. *Surfco*, 264 F.3d at 1066; *Jazz Photo Corp. v. ITC*, 264 F.3d 1094, 1105 (Fed. Cir. 2001) ("Underlying the repair/reconstruction dichotomy is the principle of exhaustion of the patent right."). "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.'" *Surfco*, 264 F.3d at 1066 (quoting *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 346 (1961)). Thus, whether the replaced part is "readily replaceable" or whether the repair process is complex, requires complete disassembly of the product or requires breaking parts of the product to accomplish the repair is beside the point. Once sold, the patentee's rights in a product are entirely extinguished, and the product owner may replace any part of the product, as long as the owner does not create a whole new article. *Impression Prods.*, 137 S.Ct. at 1536.

As in *Husky*, this case does not involve a difficult question on the margins. That IMS has performed the repair at issue more than IMS repair sales times and often repairs the same Karl Storz endoscope multiple times over the life of the endoscope, demonstrates that rod lenses and shrink-wrap are "replaceable." Appx3295, Appx3362, Appx2475, ¶ 10. What is more, while not pertinent to this analysis, IMS presented evidence from the manager of its repair operations that the rod lenses use

in the optical relay of a rigid endoscope are "readily" replaceable parts. Appx2473-2474, ¶¶ 1, 4. Repair of the optical relay does not require complete disassembly of the endoscope or require repair or replacement of the inner tubular shaft which houses the optical relay. Appx2474, ¶ 7. IMS replaces IMS repair sales of rod lenses a year in rigid endoscopes, indicating that the parts are regularly and readily replaced. Appx2474, ¶ 4. Further the low cost of rod lenses and spacers in comparison to other components and that repair of the optical relay typically occurs far more frequently than most other types of repairs, Appx2474, ¶¶ 5-6, is further support for the conclusion that the optical relay is a readily replaceable part. Once again however, whatever "readily" replaceable means in the context of Karl Storz's non-existent test, the facts regarding the IMS repair process are not in dispute, that the rod lenses and shrink wrap are "replaceable" is not in dispute, and there is no "readily" replaceable standard under any existing precedent.

C. Permissible Repair Goes Well Beyond the Replacement of "Readily Replaceable" Parts

Not only is the foundation of Karl Storz's argument based on an inaccurate reading of *Husky*, it avoids the great weight of authority from this Court and the Supreme Court which have found permissible repair no matter how "readily replaceable" a part is. More than sixty years ago, the Supreme Court held that the "'[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.'" *Jazz Photo*, 264 F.3d at 1107 (quoting *Aro*, 365 U.S. at 346). Further, "the size or relative importance of the replacement part to the patented combination is not relevant when determining whether conduct constitutes repair or replacement." *Sage Prods.*, 45 F.3d at 1578 (citing *Aro*). Thus, the distinction between "reconstruction" and "repair" is not affected by whether the replaced element is "essential" or a "distinguishing" part of the invention. *Id*. (citing *Aro* and *Dawson Chem. Co. v. Rohm & Haas*, 448 U.S. 176, 217 (1980)). Rather, the right to repair "encompasses any repair that is necessary for the 'maintenance of the use of the whole' of the patented combination through replacement of a spent, unpatented element.'" *Id*. (quoting *Aro*, 365 U.S. at 346).

This Court has likewise applied the repair doctrine broadly to include the complete disassembly of patented articles accompanied by replacement of unpatented parts in order to preserve the utility for which the article was originally intended. *Jazz Photo*, 264 F.3d at 1103-04; *see also Sage Prods.*, 45 F.3d at 1578 ("This court has consistently applied this broad interpretation of the doctrine." (citing cases)). For example, in *General Electric Co.*, the Navy disassembled patented gun mounts from Navy ships into their smallest separable parts. *General Electric Co. v. United States*, 572 F.2d 745, 781 (Ct. Cl. 1978). The parts were then reassembled using new parts or parts salvaged from other gun mounts with no attempt to return reused parts to the gun mounts from which they were taken, nor

were the reassembled mounts necessarily sent to their original ships. *Id*. Despite the complete disassembly, mixing-and-matching of parts, and replacement of any number of parts, the Court nonetheless found the Navy's conduct to be permissible repair, without regard to whether the parts replaced were "readily replaceable." *Id*. at 786.

Similarly, in *Dana Corp.*, the alleged infringer acquired worn truck clutches and disassembled them into individual parts which were cleaned and sorted into bins. Rebuilt clutches were then reassembled from these used parts, or from new parts, in an assembly-line process. *Dana Corp.*, 827 F.2d at 759. This Court rejected the argument that the worn clutches were "spent" or that the rebuilding of the clutches constituted a "second creation" of the patented entity and held that the defendant was engaged in nothing more than permissible repair. *Id*. at 760; *see also Wilbur-Ellis v. Kuther*, 377 U.S. 422, 423 (1964) (patented fish canning machines were not spent even though they were "corroded, rusted, and inoperative"); *see also Bottom Line Mgmt.*, 228 F.3d at 1356 ("The term 'spent' as the Supreme Court and [the Federal Circuit] have used it, is but a shorthand way of stating that the patented article had so deteriorated that *it could not be repaired* and could be resurrected only by reconstruction, *i.e.*, by making a new article.") (emphasis added).

Jazz Photo illustrates that even invasive and destructive repairs comprising multiple steps do not constitute "reconstruction." *Jazz Photo* involved fourteen

patents relating to what the OEM had designed to be "single-use" cameras, but which the accused infringer reloaded and repurposed for further use. The accused infringer performed the steps of (1) removing the cardboard cover, (2) cutting open the plastic casing (usually by cutting at least one weld), (3) replacing the winding wheel or modifying the film cartridge to be inserted, (4) resetting the film counter; (5) replacing the battery in flash cameras, (6) winding new film out of a canister onto a spool or into a roll, (7) resealing the body using tape or glue, and (8) applying a new cardboard cover." *Id.* at 1101.[2] Despite these significant and destructive steps in the repair process going well beyond "readily replaceable" parts, as well as the complete replacement of key components (including the film itself, the *sine qua non* of a camera), the Court held that the original sale of the camera exhausted the seller's patent rights, and the complete refurbishment of the cameras was nothing more than permissible repair. *Id*. at 1107.

This Court has also repeatedly held that permissible repair includes "replacement of a part that must be broken or removed to repair the device," which is the antithesis of replacement of a "readily replaceable" part. *See Fuji Photo Film*, 474 F.3d at 1296 (citing cases); *see also Jazz Photo*, 264 Fed.3d at 1101 (permissible repair includes cutting at least one weld to open camera); *Bottom Line Mgmt.*, 228

[2] In a related case, *Fuji Photo Film*, 474 F.3d at 1296, this Court held that these steps, plus the additional step of breaking the back of the camera to remove the film and adding a new back cover, still fell within the scope of permissible repair.

F.3d at 1355 (breaking studs that held spent part in place and replacing with new studs constitutes permissible repair). Likewise, it is well recognized that permissible repair goes beyond replacement of "readily replaceable" parts to include modifying a product for another use, as in *Jazz Photo*. *See also Wilbur-Ellis*, 377 U.S. at 423 (changing the size of cans in fish canning machine not reconstruction); *Kendall Co.*, 85 F. 3d at 1573, 1575; *Surfco*, 85 F.3d at 1057, 1066.

Thus, the scope of permissible repair is not limited to "readily replaceable" parts, and the Court should reject Karl Storz's attempt to impose a non-existent "readily replaceable" test on a product owner's right to repair.

III. *QUANTA COMPUTER* DID NOT CURTAIL THE SCOPE OF RIGHTFUL REPAIR

Countless decisions of this Court and district courts have recognized that replacement of any portion of a patented product is permissible repair, regardless of how essential the feature is to the patented invention or whether the feature was the "heart of the invention." *See e.g., Aktiebolag*, 121 F.3d at 672-73 ("The [Supreme] Court [in *Aro*] … rejected the 'heart of the invention test.'"); *Husky Injection Molding*, 291 F.3d at 787 (same); *Sage Prods.*, 45 F.3d at 1578 (citing *Aro*). Not a single court applying the repair doctrine since *Aro* has held that the importance or novelty of the repaired feature is relevant to the repair doctrine, regardless of whether the patent at issue is a "combination patent" or the replaced part is the "novel and distinguishing" part of the invention. The district court correctly relied on this

authority in concluding that the purported "essential" nature of the optical relay "does not affect the repair versus reconstruction analysis." Appx24.

Nonetheless, Karl Storz's second ground for appeal, also raised for the first time on appeal, is that *Quanta Computer Inc. v. LG Elecs, Inc.*, 553 U.S. 617 (2008), completely upended repair doctrine jurisprudence, resurrecting the "heart of the invention" test rejected by *Aro* and its progeny (including post-*Quanta* progeny), where one or more of the elements of a patent claim are allegedly inventive. *See* Opening Br. at 8 (Issue No. 2), 39-43. Specifically, Karl Storz argues for the first time on appeal that *Quanta* requires courts to now assess on an element-by-element basis whether certain claim limitations are themselves "novel and distinguishing" before considering applicability of the repair doctrine. *Id*. at 42-43. Not surprisingly, despite *Quanta* being decided 15 years ago, no court has interpreted *Quanta* in this fashion, nor applied the standards Karl Storz espouses. Simply put, the Supreme Court in *Quanta* did not limit *Aro* and the scope of the repair doctrine to so-called "combination patents," and the convoluted argument Karl Storz uses to reach that conclusion does not withstand scrutiny.

At the outset, *Quanta* did not involve repair of a patented product, and so the repair doctrine was not at issue. Rather, in *Quanta*, LGE alleged that the combination of licensed microprocessors and chipsets sold by Intel (the Intel Products) with non-Intel memory and buses constituted infringement of its patents. *Quanta*, 553.U.S. at

623-24. LGE argued that the authorized sale of the Intel Products did not exhaust its patent rights because the Intel Products did not fully practice the patents. One argument LGE made was to apply reverse logic from the *Aro* repair doctrine standard in an attempt to avoid patent exhaustion. LGE argued that since *Aro* held that replacement of less than the totality of claimed elements was permissible repair, the sale of a product which practiced less than the totality of the claimed elements could not constitute exhaustion. *Id*. at 632.

The Supreme Court rejected LGE's reverse logic, holding that exhaustion applied because the Intel Products "substantially embodied the patents." *Id*. at 638. As to LGE's reliance on *Aro*, the Court in *Quanta* first noted that the repair doctrine was irrelevant. *Id*. at 635 ("First, the replacement question is not at issue here."). Thus, the Court rejected any equivalence between exhaustion, *i.e*. whether a product "sufficiently embodies" a patent, and permissible repair under *Aro*, *i.e.,* whether a repair creates a whole new article. Importantly, *Quanta* did not address the repair doctrine at all, and so did not hold that the replacement of parts which were themselves inventive fell outside of the scope of permissible repair under *Aro*.

Moreover, although completely unnecessary to the finding of permissible repair, the patents in suit here, unlike those in *Quanta*, claim a combination of existing, known elements. *See Quanta*, 553 U.S. at 635 (the LGE patents "do not

disclose a new combination of existing parts").[3] The claimed tubular shaft, transparent shrink wrap and optical components are all separately unpatented and known in the prior art. Even the combination of shrink wrap around optical components was admittedly known in the prior art. Appx37 ('945 patent) at 1:23-39 (use of opaque shrink wrap around optical components disclosed in prior art); Appx45 ('044 patent) at 1:39-55 (same). It is only the combination of these known elements that the patents claim is inventive. In fact, Karl Storz argues that it is the combination of some of these elements (the transparent shrink wrap and optical components that make up the optical relay) is the "novel and distinguishing part of the invention." *See e.g.*, Opening Br. at 43. Thus, even accepting Karl Storz's flawed interpretation of *Quanta*, the '945 and'044 patents would be so-called "combination patents" to which *Aro*'s holding would still apply.

In addition, Karl Storz's new exception to the repair doctrine for "non-combination" patents would quickly swallow *Aro*'s holding that the essential nature of a replaced part is irrelevant to application of the repair doctrine. According to Karl Storz, if one or more elements of a patent claim are "themselves inventive," then the

[3] One commentator relied on by Karl Storz has criticized the inartful language used in this portion of *Quanta*, noting that "[a]ll inventions are combinations and all patent claims are to combinations in the sense that they require the presence of all the claim elements as claimed. The Court's suggestion [in *Quanta*] that a patented invention's treatment for exhaustion purposes might vary depending on whether it meets a definition of 'combination' is most unfortunate." Donald S. Chisum, 5 Chisum on Patents § 16.03[2][a][i][E][8][c] (2022).

patent is not a combination patent, and the "heart of the invention" test, expressly rejected in *Aro*, is suddenly reborn. *See e.g.,* Opening Br. at 41. But the essence of every "heart of the invention" argument is that the repaired portion of the patented product is itself inventive. For example, in *Aro* itself, the patentee argued that the particular shape of the fabric which was replaced "was the advance in the art … which brought the combination up to the inventive level." *Aro*, 365 U.S. at 344. Similarly, in *Fuji Photo Film*, this Court reversed the ITC's holding that replacement of a component integral to a specific patent claim constitutes reconstruction based on *Aro*. *Fuji Photo Film*, 474 F.3d at 1297. Under Karl Storz's theory, the holding of both of those cases would be reversed. Worse still, Karl Storz's theory would require a court to evaluate novelty on an element-by-element basis before entertaining a repair doctrine defense. There is simply no basis in law for such a requirement, and Karl Storz cites none.

Karl Storz's argument is simply a roundabout attempt to impose post-sale restrictions on the rights of ownership such as those the Supreme Court rejected in *Impression Products*. Karl Storz's sale of a patented endoscope transfers to its customer all of the rights that come along with ownership, and Karl Storz has no exclusionary patent right remaining. *Impression Prods.*, 137 S.Ct. at 1534. The product sale exhausts Karl Storz's patent rights, regardless of whether the '945 and '044 patents are "combination" patents or whether the customer repairs the "novel

and inventive" aspect of the product. *Id*. at 1535. The only restriction on the customer is that it cannot create a new article, *Aro*, 365 U.S. at 346, which IMS's repair of the Karl Storz endoscopes does not do, as a matter of fact and law.

For these reasons, the Court should affirm the district court's conclusion that the essential nature of the optical relay is not relevant to the repair doctrine analysis.

IV. THE TRIAL COURT CORRECTLY CONCLUDED THAT IMS'S REPAIRS DO NOT CREATE A NEW ARTICLE

For decades, IMS has repaired the optical relays of its customers damaged Karl Storz rigid endoscopes, replacing broken rod lenses in order to restore the endoscope to working order. The tubular shaft surrounding the optical relay, as well as the remaining components, are reused. As the district court found, the end result is the endoscope as originally sold, except for a different adhesive seal, a different shrink wrap and different rod lenses and spacers, some of which have been harvested from other Karl Storz endoscopes. Appx21. By repairing the optical relay, IMS thus preserves the useful life of the undamaged components, as well as of the endoscope as a whole. Despite these undisputed facts, as its third ground for appeal, Karl Storz argues that there is a dispute of fact whether IMS's repairs of its endoscopes created an "essentially new article" and so is impermissible reconstruction. *See* Opening Br. at 8 (Issue No. 3), 43-48. Once again however, the *facts* regarding what occurs during the repair process are not in dispute, only the legal conclusion regarding

whether those repairs are so extensive that IMS is manufacturing new endoscopes rather than fixing them.

A. The Right to Repair is Incredibly Broad

Once sold, patented articles become the private property of the purchasers and are no longer protected by the patent laws. *Impression Prods.*, 137 S.Ct. at 1531-32; *Jazz Photo*, 264 F.3d at 1102. The purchaser of a patented article has the rights of any owner of personal property, including the right to repair it, modify it, discard it or resell it. *Jazz Photo*, 264 F.3d at 1102. Those rights include the right to repair the original article to preserve its useful life. *Id*. Impermissible "reconstruction," as distinguished from permissible "repair," is "'limited to such a true reconstruction of the [patented] entity as to "*in fact make a new article*," … after the [patented] entity, *viewed as a whole*, has become spent.'" *Id*. (quoting *Aro*, 365 U.S. at 346) (emphasis added). Further, "[t]he term 'spent' as the Supreme Court and [the Federal Circuit] have used it, is but a shorthand way of stating that the patented article had so deteriorated that *it could not be repaired* and could be resurrected only by reconstruction, *i.e.*, by making a new article." *Bottom Line Mgmt.*, 228 F.3d at 1356 (emphasis added).

"The Supreme Court has taken an expansive view of conduct that constitutes permissible repair of a patented combination of unpatented elements." *Sage Prods.*,

45 F.3d at 1578. The parameters of this expansive doctrine include at least the following:

(i) the right of repair applies no matter how large, distinguishing, or essential the repaired portion of the device may be. *See Porter v. Farmers Supply Serv. Inc.*, 790 F.2d 882, 885 (Fed. Cir. 1986); *Aktiebolag*, 121 F.3d at 672-73 *Sage Prods.*, 45 F.3d at 1578;

(ii) the right of repair applies regardless of whether an OEM *wants* its products repaired, designs its products to be repaired, or takes steps to make repair more difficult. *See Jazz Photo*, 264 F.3d at 1106; *Fuji Photo Film* at 1296; *Hewlett-Packard Co. v. Repeat-O-Type Stencil Mfg. Corp.*, 123 F.3d 1445, 1453 (Fed. Cir. 1997);

(iii) the right of repair applies regardless of whether part of the device must be broken or removed to make the repair. *See Fuji Photo Film*, 474 F.3d at 1296 (citing cases); *Jazz Photo*, 264 Fed.3d at 1101; *Bottom Line Mgmt.*, 228 F.3d at 1355;

(iv) the right of repair includes the right to completely disassemble and reassemble a patented product with new or reused parts. *See General Electric*, 572 F.2d at 784; *Dana Corp.*, 827 F.2d at 759;

(v) the right of repair includes the right to assemble a finished device using parts from multiple used devices. *See General Electric*, 572 F.2d at 784; *Dana Corp.*, 827 F.2d at 759;

(vi) the right of repair includes the right to modify a patented product by using replacement components with a different design. *See Kendall Co.*, 85 F. 3d at 1573, 1575; *Surfco*, 85 F.3d at 1057, 1066;

(vii) the right of repair includes the right to replace components even if they are not worn or spent. *See Surfco*, 85 F.3d at 1057, 1066;

(viii) the right of repair includes the right to use replacement parts made by others. *See Kendall Co.*, 85 F. 3d at 1573, 1575; *Sage Prods.*, 45 F.3d at 1578-79; *Porter*, 790 F.2d at 885-86;

(ix) the right of repair includes the sequential replacement of parts in successive repairs, *even if that culminates in an entirely new device*, so long as no single instance of repair constitutes the full reconstruction. *See FMC Corp. v. Up-Right Inc.*, 21 F.3d 1073, 1077 (Fed. Cir. 1994).

(x) the right of repair is not limited to the original purchaser but applies to all downstream owners and repairers. *See Bottom Line Mgmt.*, 228 F.3d at 1354-55;

(xi) the right of repair applies regardless of whether the patent covering a device includes apparatus or method claims. *See Jazz Photo*, 264 F.3d at 1108;

As the district court correctly concluded, the accused repair activities at issue here fit easily within the boundaries of permissible repair,[4] and this Court should affirm the ruling of summary judgment in IMS's favor.

B. The Material Facts Regarding the Karl Storz Endoscopes and the IMS Repair Process Are Not Disputed

The parties have stipulated to the material facts regarding the endoscopes at issue and the repairs conducted by IMS. Where, as here, no material facts are in dispute, the Court must decide as a matter of law whether the repair in question is truly a repair, or if in fact the putative repair involves the creation of a new article. Nevertheless, in an attempt to reverse the district court decision, Karl Storz re-labels this legal analysis as a subsequent "fact" question – even after the actual facts regarding the product and the repair are established. Opening Br. at 43-48.

Beyond its erroneous factual/legal distinction, Karl Storz's chief argument is that endoscopes repaired by IMS are "quite different" from the original Karl Storz endoscope. This point, however, is not material to application of the repair doctrine, even if true. First, it is undisputed that only the components of the optical relay of the endoscope are replaced, with both new and reused components – the rest of the endoscope is reused. Appx2235, ¶ 23; Appx2473, ¶ 7. Second, numerous cases have

[4] As the district court noted, both *Jazz Photo* and *General Electric* involved repairs far more extensive than the ones at issue here but were nonetheless deemed permissible repair. Appx22.

held that the owner of a product has the absolute right to repair, even if the result of the repair is a product with different capabilities, functionality, components or performance. *See Wilbur-Ellis*, 377 U.S. at 423; *Kendall Co.*, 85 F. 3d at 1573, 1575; *Surfco*, 85 F.3d at 1057, 1066; *Sage Prods.*, 45 F.3d at 1578-79; *Porter*, 790 F.2d at 885-86. As Karl Storz's own newly introduced *Husky Injection Molding* case observes, the question of what constitutes "reconstruction of the entire device" outside the scope of permissible repair is primarily one of magnitude, not performance or the essential nature of the repaired components:

> [I]f 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.
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> * * *
>
> [T]he Supreme Court explicitly rejected a "heart of the invention" standard, noting that no matter how essential an element of the combination is to the patent, "no element, separately viewed, is within the [patent] grant."

Husky Injection Molding, 291 F.3d at 786-787. Because the right of repair expressly includes repairs that change the form and function of a patented device, all of Karl Storz's arguments in this regard are thus irrelevant and must fail.

Karl Storz also argues that there is a genuine dispute of fact as to whether IMS created a new article because IMS purportedly replaces every claimed element except the "tubular shaft." Opening Br. at 44-45. Again, because the repair process and the parts that are replaced are not in dispute, Appx2234-2236, ¶¶ 15-33, the

argument is a legal one regarding applicability of the repair doctrine, not a factual one regarding the nature of repair which could prevent summary judgment. For one, Karl Storz concedes that the preambles of all the claims are limiting, so every claim requires "an endoscope," not just a select list of internal components. Appx4701. It is undisputed that IMS does not replace any part of the endoscope other than the adhesive, the shrink wrap, and any damaged lenses or spacers in the optical relay as part of this repair. Even without the preamble, it is undisputed that IMS does not replace the claimed "tubular shaft," thus further demonstrating permissible repair. Indeed, even if the patents had just claimed the optical relay, it is undisputed that IMS scavenges and reuses lenses and other relay components for use in its repairs, which also fits comfortably within the scope of permissible repair based on existing precedent. *See e.g.*, *General Electric*, 572 F.2d at 784 (disassembly of gun mounts into parts and reassembly with new and salvaged parts is permissible repair); *Dana Corp.*, 827 F.2d at 759 (holding that complete disassembly and reassembly of a patented product with new or reused parts constitutes permissible repair, even if the reused parts came from multiple used devices).

C. The Trial Court Correctly Concluded that IMS's Repairs Fit Comfortably Within the Right to Repair

IMS's repair of broken components within the optical relay of Karl Storz's endoscopes easily fall within the scope of permissible repair. In short, IMS does not create a new endoscope but rather replaces only unpatented rod lenses, spacers and

shrink wrap, while reusing any such components which are undamaged. IMS does not replace any of the other components of the endoscope when repairing the optical relay – the original eyepiece, light post, block, ocular assembly, objective assembly, illumination fibers, distal lens, inner and outer tubular shafts are all preserved. Appx2232-2236, ¶¶ 1, 4-6, 10, 30. Thus, IMS' repair process is not so extensive as to constitute a "second creation" of the patented endoscope, as would be required for impermissible reconstruction. *Jazz Photo*, 264 F.3d at 1103 (quoting *Aro*, 365 U.S. at 346).

The parties have stipulated the IMS repair process for the optical relay, and that process is straightforward and easy to understand: IMS opens the endoscope, removes and disassembles the optical relay and replaces the optical relay with one made of new and/or reused parts. Appx2234-2236, ¶¶ 15-33. Broken components are discarded, and undamaged components are recycled. Appx2235, ¶¶ 20-22. Repair of the optical relay does not require the technician to disassemble other parts of the endoscope or to repair or replace the inner tubular shaft which houses the optical relay. Appx2473, ¶ 7, Appx2235, ¶ 23.

As the district court correctly concluded, "[t]he end result [of the IMS repair] 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." Appx21. Such activity is far less complicated and extensive than the repair of the single-use cameras in *Jazz Photo* and *Fuji Photo Film*, the rebuilding of gun mounts from parts in *General Electric,* the creation of truck clutches from pieces of worn clutches in *Dana Corp* or the repair of corroded and rusted canning machines in *Wilbur-Ellis*, all of which were held to be permissible repair. *See also* Appx22 ("IMS's activities are even less akin to reconstruction than those in *Jazz Photo*" because IMS does not repurpose the device or change its functionality). As this Court noted in *Jazz Photo*, "'what harm is done to the patentee in the use of his right of invention, when the repair and replacement of a partial injury are confined to the machine which the purchaser has bought?'" *Jazz Photo*, 264 F.3d at 1103 (quoting *Wilson v. Simpson*, 50 U.S. (9 How.) 109, 123 (1850)).

Moreover, that IMS technicians use a torch to remove the adhesive that seals the endoscope, Appx2235, ¶¶ 16-17, and cut the shrink wrap to remove it, Appx2235, ¶ 18, is of no moment. The "replacement of a part that must be broken or removed to repair the device does not convert permissible repair into impermissible reconstruction." *Fuji Photo Film*, 474 F.3d at 1296 (citing cases); *see also Jazz Photo*, 264 F.3d at 1101 (permissible repair includes cutting at least one weld to open camera); *Bottom Line Mgmt.*, 228 F.3d at 1355 (breaking studs that held spent part in place and replacing with new studs constitutes permissible repair).

Again, Karl Storz's customers have all property rights associated with the endoscopes they purchase, including the right to repair or modify them to preserve their useful life. *Impression Prods.*, 137 S.Ct. at 1531-32; *Jazz Photo*, 264 F.3d at 1102. Those rights include using a torch to disassemble the endoscope. As the district court found, "tearing apart a device does not equal reconstruction unless it is followed by the creation of 'a new article,'" Appx26, which does not occur here.

Karl Storz cites only one case that found an alleged infringer's activity constituted impermissible reconstruction, *Aktiebolag v. E.J. Co.*, 121 F.3d 669 (Fed. Cir. 1997). *See* Opening Br. at 33-34. IMS' repair process, however, differs significantly from the activity in *Aktiebolag*. *Aktiebolag* involved a drill that had a bit with a unique carbide tip geometry. *Id*. at 670. Over time, the drill tip required resharpening, which even the patentee did not contend was impermissible reconstruction. *Id*. at 671. However, when the tip had completely worn away so that it could no longer be resharpened, the defendant then "re-tipped" its customers' drills. Re-tipping involved removing the worn tip with a torch, brazing a rectangular piece of new carbide onto the drill shank and recreating the patented geometry of the cutting edges of the drill tip by extensively grinding the carbide. *Id*. at 671-72.

Aktiebolag differs from this case in several respects. First, the defendant in *Aktiebolag* admitted that the entire drill was spent when the drill bit could no longer be resharpened. *Id*. at 673. As the district court here noted, the patented drill in

Aktiebolag "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." Appx22. Such is not the case here, as the rest of an endoscope can and does last much longer than the rod lenses in the optical relay. Second, in *Aktiebolag*, there was no evidence of a market for drill retipping, which the court held was a factor showing that there is a reasonable expectation that a part of a patented combination requires frequent replacement. *Id*. at 674. In stark contrast, here a robust endoscope repair industry exists, and even Karl Storz acknowledges that it competes with ISOs, like IMS, which repair its products, Appx2233, ¶ 7, and IMS regularly receives Karl Storz endoscopes for repair that have been previously repaired by others. Appx2475, ¶ 10. Third, unlike the drill tip in *Aktiebolag*, which could be resharpened multiple times, rod lenses are fragile and it is common for them to break, Appx2234, ¶ 12, Appx2474, ¶ 3, while the lifespan of the endoscope is as long as 20-25 years. Appx2233, ¶ 8, Appx2474, ¶ 3. It cannot be seriously contended that an endoscope, which can last decades, is completely "spent" when a single rod lens is cracked or broken. Fourth, *Aktiebolag* involved the creation of a new drill tip from a blank piece of carbide, unlike the IMS' repair process, which does not involve creating new parts but instead involves only the reuse or replacement of individual unpatented parts.

IMS' activities thus preserve the useful life of the undamaged components of the endoscope, as well as the endoscope as a whole and so constitute permissible

repair. *See e.g.*, *Fuji Photo Film*, 474 F.3d at 1296 ("[I]n view of the continued utility of the … other significant parts in the original camera, replacing the film is a permissible repair."); *see also Aro*, 365 U.S. at 346 (reconstruction limited to such a true reconstruction as to make a new article after the patented entity, viewed as a whole, has become spent). In short, the IMS repair process does not create a "new endoscope," it merely restores a broken endoscope to working order.

D. Karl Storz's Remaining Arguments are Irrelevant to Application of the Repair Doctrine

1. Karl Storz's "Brand" on the Repaired Endoscopes Is Irrelevant to Proper Application of the Repair Doctrine

Karl Storz grouses that "IMS advertises its endoscopes as 'Certified Pre-Owned' Karl Storz endoscopes, with only Karl Storz branding – but no IMS branding…". Opening Br. at 3. The repair doctrine, however, does not require a repair shop to emblazon its name on a repaired product (imagine cars driving down the street with "Repaired by Al's Auto" painted on the doors). Likewise, that IMS operates a certified pre-owned program (certified by IMS, not Karl Storz) also has no bearing on this lawsuit for patent infringement or proper application of the repair doctrine.

2. FDA Standards Are Irrelevant to Proper Application of the Repair Doctrine

Yet another irrelevant argument Karl Storz makes is its claim that IMS's endoscopes are not "FDA cleared," Opening Br. at 46, but whether that is true or not

is immaterial to the issue of permissible repair. Not a single decision of this Court or any district court has cited FDA requirements or the relative quality of a repair as a relevant factor in distinguishing permissible repair from impermissible reconstruction. As the district court concluded, purported disputes about FDA compliance or the quality of IMS's repairs is immaterial to the issue of permissible repair. Appx26, n. 5, Appx27.[5] Karl Storz also alleges that breaking the seal on a Karl Storz endoscope poses a health risk to the public, Opening Br. at 36, but none of the evidence cited for that claim mentions any health risk to the public. *Id*. At another point, Karl Storz claims that endoscopes repaired by IMS "can lead to compromised and customer feedback/experiences." Opening Br. at 23, but none of the cited portions of the record says a single thing about an IMS repair leading to compromised or customer feedback/experiences *See id*. (citing Appx522, ¶ 80, Appx658-659, ¶ 343). Karl Storz also claims through unsubstantiated testimony that an endoscope used in a surgical procedure began to customer feedback/ experiences but it is unknown what

[5] Contrary to Karl Storz's claims, Opening Br. at 23, the district court did not state that IMS's seals are not validated by the FDA. The record contains no evidence of FDA regulations relating to sealing endoscopes, and the testimony Karl Storz cites does not even address IMS's sealing process or whether that process violates any FDA regulation. *Id*. at 36-37 (citing Appx3854 and Appx4303); *see also* Appx3856 at 67:24-68:1 ("I do not know the epoxy that's used by an independent service organization or third party either."). Karl Storz's witness was "not sure" whether the FDA requires testing of the sealing epoxy, and he did not know whether a different epoxy complied with FDA requirements. Appx3856 at 68:20-69:3.

caused the reported problem or which ISO repaired the device.[6] *See id*. at 24 (citing Appx4011 at 93:1-8 ("… that would represent an example of materials used by somebody other than Karl Storz …")). The bottom line, though, is that whether repaired endoscopes are inferior in any way is absolutely immaterial to whether those repairs constitute the creation of a new article, as discussed below.

3. IMS Performs High Quality Repairs, but Repair Quality Is Irrelevant to Proper Application of the Repair Doctrine

Karl Storz claims that IMS's repair process produces an inferior endoscope, Opening Br. at 3, 17, but it distorts the facts. Contrary to Karl Storz's claims, the district court did not find that IMS-repaired endoscopes are inferior. *See e.g.*, Opening Br. at 3, 17. Rather, citing the opinion of Karl Storz's expert, the Court stated only that there was "[e]vidence in the summary judgment record" which could support an inference that IMS endoscopes are inferior to and different from Karl Storz's originally manufactured endoscopes.[7] Appx26. IMS contested this evidence,

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[6] Such baseless allegations are nothing new. In the district court, Karl Storz asserted that endoscopes repaired by IMS posed a danger to the public based on claims in a product liability lawsuit against Karl Storz. Appx4581-4582 (citing Appx661-662, ¶ 348). Karl Storz's allegation was false. In truth, the lawsuit alleged that the endoscope at issue *was defective as designed by Karl Storz*, and the only claim against IMS was an unrelated claim for negligent supervision and training involving cleaning and sterilization. Appx4629 (citing Appx4605-4615, ¶¶ 24-26, 41-45).

[7] The district court presumably made this statement to show that IMS was entitled to judgment as a matter of law, *even viewing facts in the light most favorable to Karl Storz*, as required for summary judgment. *See* Appx4 ("All reasonable doubts about the facts have been resolved in favor of the nonmoving party."). While it is

and the district court did not rule one way or the other on that issue. Rather, the district court correctly held that even assuming that were true, whether endoscopes repaired by IMS were somehow "inferior" was not material because IMS had the right to modify the endoscopes. Appx27.

Because the issue is legally irrelevant, IMS would normally give it short shrift, but given the importance IMS places on quality and safety, as well as Karl Storz's penchant for distorting the facts, IMS feels compelled to set the record straight. Karl Storz cites to a handful of anecdotal hearsay reports of endoscope failures of undetermined cause, out of more than IMS repair sales repairs by IMS of more than IMS repair sales Karl Storz rigid endoscopes with shrink wrap over a twelve-year period. Appx3295, Appx3362, Appx2475, ¶ 10. Karl Storz transparently attempts to imply that these few complaints are representative of all endoscopes repaired by IMS. *See* Opening Br. at 46 ("IMS's endoscopes have a smaller field of view"), 47 ("IMS's endoscopes are eight centimeters longer than Karl Storz endoscopes"). In truth, the record shows only a *single report* of a repaired endoscope that allegedly had a limited field of view, Appx659, ¶ 344, and a *single report* of a repaired endoscope with a shaft that was 8 centimeters longer, and in neither case did Karl Storz establish that the repair at issue was performed by IMS, as opposed to another ISO. Appx660, ¶ 346.

not surprising Karl Storz would trumpet the quote, that it would truncate the quote and falsely suggest a finding by the District Court in that regard is troubling.

Similarly, Karl Storz's evidence of poorer image quality in IMS-repaired endoscopes is based on a single, unsubstantiated statement from one of its own witnesses, who is admittedly not an optical engineer. *See* Opening Br. at 22 (citing Appx3849 at 39:4-40:11, Appx3851 at 49:2-6); Appx3849 at 38:25.[8]

Karl Storz also points to an onsite field evaluation at customer feedback/ experiences [redacted] which included eleven IMS-repaired endoscopes, *see* Opening Br. at 23-24 (citing Appx658-659, ¶ 343), but it omits that this evaluation encompassed the hospital's entire inventory of 108 Karl Storz endoscopes, Appx3870 at 122:6-17, Appx3872 at 133:8-11, Appx3874 at 140:1-4. The other 97 endoscopes were either OEM endoscopes, Appx3870 at 125:9-18, or endoscopes presumably repaired by a third-party other than IMS. Karl Storz's witness discussed several of the endoscopes in that evaluation, but he addressed only one of the endoscopes identified as being repaired by IMS (*see* Appx659, ¶ 343), and the problem with that endoscope was unrelated to the optical relay. Appx3876 at 147:24-148:2 (referencing exposed light fibers in endoscope with Serial No. 1426713).

What is more, there is no evidence that the *cause* of the issues Karl Storz references can be attributed to an IMS repair or to replacement of the optical relay. For example, one complaint related to an endoscope that showed "peppering,"

[8] Karl Storz's expert likewise relies on this witness' testimony for his claims of poor image quality. Appx659-660, ¶ 345 (citing Appx3849 at 39:1-9).

Apppx3879 at 158:7-159:25, but Karl Storz's witness testified that peppering is caused by expansion and contraction of the endoscope during normal sterilization, not by repair of the optical relay. Appx3879 at 161:2-12, Appx3880 at 165:3-8. Further, as Karl Storz has stipulated, the typical reason that rod lenses in an optical relay break is torquing during surgical procedures *or some other misuse by the operator of the endoscope*, Appx2234, ¶ 13, and so it is more likely that any failure of the optical relay is due to misuse, not an improper repair.[9]

IV. EVEN IF THEY HAD MERIT, WHICH THEY DO NOT, KARL STORZ IS FORECLOSED FROM RAISING ARGUMENTS ON APPEAL THAT WERE NOT PRESENTED TO THE DISTRICT COURT

Perhaps because the "readily replaceable" test does not exist, and the through-the-looking-glass argument that *Quanta* secretly upended the holding *Aro* is likewise baseless, Karl Storz did not raise these arguments to the district court, providing an independent basis upon which this Court can reject Karl Storz's appeal.

A. A Party Cannot Raise Arguments on Appeal that Were Not Presented to the District Court

This Court has "regularly stated and applied the important principle that a position not presented in the tribunal under review will not be considered on appeal

[9] The parties also stipulated that there are numerous common problems associated with damaged rigid endoscopes – many of which, such as dented or bent shafts or damage to other ocular components of the endoscope, have nothing to do with the optical relay. Appx2234, ¶ 12.

in the absence of exceptional circumstances." *In re Google Tech. Holdings LLC*, 980 F.3d 858, 863 (Fed. Cir. 2020) (citations omitted). As the Court has stated:

> By and large, it is our place to review judicial decisions -- including claim interpretations and grants of summary judgment -- reached by trial courts. No matter how independent an appellate court's review of an issue may be, it is still no more than that -- a review. With a few notable exceptions, such as some jurisdictional matters, appellate courts do not consider a party's new theories, lodged first on appeal. If a litigant seeks to show error in a trial court's overlooking an argument, it must first present that argument to the trial court. In short, this court does not "review" that which was not presented to the district court.

Sage Prods. v. Devon Indus., Inc., 126 F.3d 1420, 1426 (Fed. Cir. 1997).[10] This rule applies in the specific circumstances of a patent holder raising new arguments on appeal after a district court has awarded summary judgment to an alleged infringer. *Golden Bridge Tech., Inc. v. Nokia, Inc.*, 527 F.3d 1318, 1322-23 (Fed. Cir. 2008). A party "cannot simply choose to make its arguments in iterative fashion, raising a new one on appeal after losing on its other at the district court." *Id*. at 1323; *see also Fresenius USA, Inc. v. Baxter Int'l., Inc.*, 582 F.3d 1288, 1295 (Fed. Cir. 2009) ("By failing to properly raise that argument before the district court, Baxter has waived it, and we decline to consider it.").

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[10] Waiver is governed by local circuit law, and under Eleventh Circuit law, "the doctrine of waiver prohibits parties from raising new argument on appeal that were not raised at the district court." *Sweepstakes Patent Co., LLC v. Burns*, 610 Fed. Appx. 1006, 1008, 2015 U.S. App. LEXIS 6429 at *3-*4 (Fed. Cir. April 20, 2015) (citing *Mesa Air Grp. v. Delta Air Lines, Inc.*, 573 F.3d 1124, 1128-29 (11th Cir. 2009)); *see also Bryant v. Jones*, 575 F.3d 1281, 1296 (11th Cir. 2009)(citing cases).

This case presents no exceptional circumstances that would allow Karl Storz to raise a new argument on appeal. In *Forshey v. Principi*, 284 F.3d 1335, 1355-57 (Fed. Cir. 2002), the Court set out an exemplary set of limited circumstances in which it would deviate from the general rule foreclosing new arguments on appeal. Those circumstances include the passage of new legislation, a change in the jurisprudence of the reviewing court or the Supreme Court, applying the correct law even if the parties did not argue it below (but only if an issue is properly before the court) and where a party appeared *pro se* before the lower court. *Id*.; *see also Golden Bridge*, 527 F.3d at 1323. Other grounds, including the hiring of new counsel on appeal, have been specifically rejected. *Golden Bridge*, 527 F.3d at 1323 ("Substitution of new appellate counsel is not one of, or even in proportion to, the limited circumstances outlined in *Forshey*."). Likewise, the Court has routinely refused to consider new claim construction arguments (*In re Google Tech. Holdings*, 980 F.3d at 863), new infringement arguments (*Sage*, 126 F.3d at 1426) and new invalidity arguments (*Golden Bridge*, 527 F.3d at 1052-53) raised for the first time on appeal.

B. Karl Storz Did Not Argue in the District Court that the Repair Doctrine is Limited to "Readily Replaceable" Parts

Karl Storz faults IMS and the district court for not addressing whether the optical relay of its endoscopes were "readily replaceable" parts. Opening Br. at 34-35. This claim is wrong, as IMS submitted evidence that rod lenses are readily

replaceable parts, Appx2474, ¶ 4, and, more importantly, the repair doctrine is not limited to readily replaceable parts but rather extends to complex repairs that include complete disassembly of a device or require breaking or removing parts in order to perform a repair.

What is more, Karl Storz never argued to the district court the repair doctrine applied only to "readily replaceable" parts. Instead, in opposition to IMS's summary judgment motion, Karl Storz argued that the repair doctrine applied only to "consumable" parts that are meant to be maintained and replaced. *See* Appx4559 ("precedent limits 'repair' under the doctrine to the replacement of unpatented, consumable parts that are meant to be maintained and replaced."); Appx4568 ("The Supreme Court has established the repair doctrine as a narrow defense for the replacement of consumable parts that are meant to be maintained and replaced."); *see also* Appx4568-4571; Appx4577-4579.

In the district court, Karl Storz never raised the issue of whether the optical relay of its endoscopes is "readily replaceable." In fact, it did not cite, much less discuss, *Husky Injection Molding*, which is the sole case relied upon for its argument that the repair doctrine does not apply to parts that are not "readily replaceable." Opening Br. 4, 31, 32, 33. In a thoughtful and well supported opinion, the district court addressed and rejected each of the arguments Karl Storz actually did raise regarding application of the repair doctrine, such as its "consumable" test. Appx23-

28. The district court did not address whether the optical relay was "readily replaceable" because Karl Storz never claimed that issue was relevant to application of the repair doctrine. Having failed to raise that argument in the district court, Karl Storz is foreclosed from raising it on appeal to this Court.

C. Karl Storz Did Not Argue in the District Court that *Quanta Computer* Limited the Scope of *Aro Manufacturing*

Karl Storz argues that the Supreme Court held in *Quanta* that *Aro* does not apply because the patents in suit are not so-called "combination" patents. *See* Opening Br. at 41. As discussed above, this argument misses the mark because *Quanta* does not address the repair doctrine or limit *Aro*, and, in any event, the inventive aspect of the patents at issue is merely a combination of a known tubular shaft, known transparent shrink wrap and known optical components to purportedly improve the assembly of an endoscope. Thus, even accepting Karl Storz's interpretation of *Quanta*, the patents in suit are combination patents, and so *Aro*'s rejection of a "heart of the invention' test applies.

As importantly, Karl Storz never argued in the district court that under *Quanta*, *Aro*'s rejection of the "heart of the invention" test did not apply. In the district court, IMS argued that under *Aro* and the numerous decisions by this Court applying *Aro*, the distinction between "reconstruction" and "repair" is not affected by whether the replaced element is "essential" or a "distinguishing" part of the invention. Appx3641, Appx3643 (Opening Br.); Appx4624-4627 (Reply Br.). Karl

Storz disputed that the right of repair does not depend on how essential the replaced component is to the patented device, Appx4588, but it did not cite *Quanta* at all or argue that under *Quanta*, IMS must show that Karl Storz's claims are inventive only because they are "a new combination of existing parts." Opening Br. at 42. Having failed to make this argument in the district court, Karl Storz is foreclosed from asserting it on appeal.

CONCLUSION

For the foregoing reasons, the Court should affirm the district court's decision granting summary judgment to IMS and entering final judgment in favor of IMS.

Dated: January 23, 2023

Respectfully Submitted,

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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

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