

2022-1978

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**United States Court of Appeals  
for the Federal Circuit**

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KARL STORZ ENDOSCOPY-AMERICA, INC.,

*Plaintiff-Appellant*

– v. –

STERIS INSTRUMENT MANAGEMENT SERVICES, INC.,

*Defendant-Appellee*

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*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*

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**REPLY BRIEF FOR PLAINTIFF-APPELLANT**

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MARCH 15, 2023

## 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

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## SUMMARY OF ARGUMENT

Appellee IMS takes a consistent approach throughout its Response Brief (“Opp.”). First, for each reversible error identified by Appellant Karl Storz, IMS ignores (and asks this Court to ignore) the controlling precedent, including the *Husky* decision concerning “readily replaceable” and the Supreme Court’s *Quanta* decision limiting the applicability of *Aro* to combination patents. Next, IMS ignores that its repair defense was decided on summary judgment, irrelevantly arguing the strength of its own “evidence” while evading the real issue, that Karl Storz (the non-moving party) identified more than enough evidence to create numerous genuine disputes precluding summary judgment of repair.

## ARGUMENT

### **I. The District Court Committed Reversible Legal Error By Ignoring Evidence Showing That the Karl Storz Optical Relays Are Not “Readily Replaceable” Parts**

As established in Karl Storz’s opening brief, this Court holds that while replacement of “readily replaceable” parts may be permissible repair, replacing parts that are not “readily replaceable” is impermissible reconstruction. *See, e.g., Husky Injection Molding Sys. v. R&D Tool & Eng’g Co.*, 291 F.3d 780, 787 (Fed. Cir. 2002); *Aktiebolag v. E.J. Co.*, 121 F.3d 669, 674 (Fed. Cir. 1997).

Accordingly, the district court committed reversible legal error by ignoring the summary judgment evidence showing that the Karl Storz optical assembly was



not “readily replaceable.” Such facts (which on summary judgment must be viewed in the light most favorable to the non-movant, Karl Storz) should have precluded a finding of summary judgment that IMS’s accused infringing activities were permissible repair.

Indeed, the district court did not even address or determine whether there was a genuine issue of fact concerning this material question of whether the Karl Storz optical assembly was “readily replaceable.” Moreover, despite moving for summary judgment on the defense of repair, IMS did not even assert that the Karl Storz optical assembly was readily replaceable, much less establish that there was no genuine dispute concerning this material fact. For these reasons alone, IMS did not meet its burden and the summary judgment ruling should be reversed.

In the face of this material “readily replaceable” dispute, IMS takes two “head-in-the-sand” approaches. First, IMS simply ignores the law on this issue, disregarding and misstating this Court’s *Husky* holding and analysis to wrongly contend that whether the Karl Storz optical relay was readily replaceable is irrelevant. *E.g.*, Opp. at 13-14. Second, IMS argues that it presented evidence that the Karl Storz optical relays are in fact “readily replaceable.” But IMS ignores that it moved for summary judgment of repair and its (unmet) burden was to show that there was no material dispute on this material fact, not just to now belatedly allege some evidence on the issue.

Neither of these approaches should be sufficient to avoid reversal here.

**A. The District Court Committed Reversible Error By Not Requiring IMS to Meet Its Burden of Establishing That the Karl Storz Optical Assemblies Are “Readily Replaceable”**

IMS moved for summary judgment on its defense of repair and thus bore the burden of establishing that there was no genuine dispute that Karl Storz’s optical assemblies are “readily replaceable.” It did not even assert this material fact, much less meet its burden. In light of this fatal failure of proof, IMS now ignores this Court’s precedent and simply argues that whether parts are readily replaceable is irrelevant to the issue of repair. IMS is wrong.

To support its position, IMS now accuses Karl Storz of mischaracterizing this Court’s *Husky* decision. Opp. at 14. The opposite is true.

As Karl Storz accurately established, in *Husky*, this Court explains that 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.” *Husky*, 291 F.3d at 787.

*Husky* identifies the “readily replaceable” end of the spectrum as illustrated by prior decisions such as *Wilbur-Ellis* and *Aro*. *Id.* at 291 F.3d at 786-87 (citing *Wilbur-Ellis Co. v. Kuther*, 377 U.S. 422 (1964) and *Aro Mfg. Co. v. Convertible*

*Top Replacement Co.*, 365 U.S. 336 (1961)). *Husky* explains that in light of cases such as these, a “safe harbor exists . . . **if the particular part is readily** ‘replaceable.’” *Id.* at 787.

And (again, as Karl Storz accurately explained), *Husky* identifies the *Aktiebolag* decision as illustrative of the other end of the spectrum, where the replaced parts (drill tips) were not “readily replaceable” and, therefore, their replacement was infringing reconstruction, not permissible repair. *Id.* at 787 (citing *Aktiebolag*, 121 F.3d at 674). In describing the *Aktiebolag* replaced drill tip, the Federal Circuit could have been describing the Karl Storz optical assemblies: the accused infringing retipping “did not involve ‘just attaching a new part for a worn part,’ but instead required ‘several steps to replace, configure and integrate the tip onto the shank;’” “‘the drill tip was not manufactured to be a replaceable part;’” and “‘the tip was not attached to the shank in a manner to be easily detachable.’” *Id.* at 787 (quoting *Aktiebolag*, 121 F.3d at 673-74).

The *Husky* Court then explains that deciding where to draw the line between the *Wilbur-Ellis* of the spectrum and the *Aktiebolag* end of the spectrum, the line that separates a part that is readily replaceable part from one that is not, could pose difficult questions: “Difficult questions may exist as to the line between [] *Aktiebolag* and *Wilbur-Ellis* where readily replaceable parts are not involved.” *Husky*, 291 F.3d at 787. But the *Husky* Court concluded it did not need to address

where to draw that line because “here there is no question that the particular parts were readily ‘replaceable’ parts.”<sup>1</sup> *Id.* at 788.

IMS ignores all of the foregoing to argue that it is free to replace any part, whether readily replaceable or not. This directly contradicts *Aktiebolag* and *Husky*’s analysis and holding thereon. In *Aktiebolag*, the part in question (a drill tip) was both replaceable and in fact replaced. But such replacement constituted infringing reconstruction, not permissible repair, because, in the words of *Husky*, “**readily replaceable parts [were] not involved.**” *Husky*, 291 F.3d at 787 (emphases added). For example, although the tip was in fact replaced, it was not readily replaceable because the accused infringing retipping “did not include ‘just attaching a new part for a worn part,’ but instead required ‘several steps to replace, configure and integrate the tip onto the shank;” “the drill tip was not manufactured to be a replaceable part;” and “the tip was not attached to the shank in a manner to be easily detachable.” *Id.* at 787 (quoting *Aktiebolag*, 121 F.3d at 673-74).

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<sup>1</sup> IMS misreads *Husky* to argue that the *Husky* Court declined to address the question of whether replacing parts that were not readily replaceable was permissible repair. *Opp.* at 14. It did not, as *Husky*’s entire explanation of *Aktiebolag* was to confirm that replacing non-readily replaceable parts (such as the replaced drill tip of *Aktiebolag*) was refurbishment, not repair. *Husky Injection Molding Sys. v. R&D Tool & Eng’g Co.*, 291 F.3d 780, 787 (Fed. Cir. 2002). The question *Husky* declined to address was where to draw the line between a part that was readily replaceable and one that was not. It did not need to address that issue because “here there is no question that the particular parts were ‘readily replaceable’ parts.” *Id.* at 788.

Contrary to IMS’s attempt to rewrite or ignore the law, *Husky* leaves no doubt on this issue, specifically defining the repair safe harbor in terms of whether a part is **readily** replaceable:

- “We conclude that the same safe harbor exists where activity ‘akin to repair’ is involved as when repair is involved. In both cases, there is no infringement **if the particular part is readily ‘replaceable.’**”
- “A purchaser is within its rights to modify a machine **by substituting a readily replaceable part** whether the replacement serves some public policy purpose.”

*Id.* at 787, 788 (emphases added).

After laying out the proper methodology (which IMS now ignores), the *Husky* Court then asked and answered the material question that the district court and IMS’s summary judgment motion failed to address: is the part being replaced readily replaceable? The *Husky* Court concluded that the repair defense applied to the replacement of carrier plates in an injection molding system because “here there is no question that the particular parts were readily ‘replaceable’ parts.” *Id.* at 788. For example, because “Husky sold substitute molds and carrier plates, and provided separate quotations for the injection molding system and the mold/carrier plate assembly [,] [w]e conclude that the carrier plates were readily replaceable.”

*Id.* at 788-89.

In contrast, IMS did not even assert that the Karl Storz optical assembly was readily replaceable, much less meet its burden of establishing that there was no genuine dispute concerning this material fact. Nor did the district court address this question, much less determine that there was no genuine issue of fact. For either of these reasons alone, the summary judgment of “repair” should be reversed.

**B. Under *Aktiebolag* and *Husky*, Reversal Is Required Because There Is a Genuine Dispute Concerning Whether the Karl Storz Optical Assembly Is “Readily Replaceable”**

**1. *Karl Storz Identified Evidence Sufficient to Show That Its Optical Assembly Is Not “Readily Replaceable”***

Even aside from IMS’s complete failure to meet its burden, summary judgment of repair should be reversed because Karl Storz identified evidence showing that its optical assembly is in fact **not** readily replaceable. *See, e.g.*, Opening Br. at 35-39. This evidence was and is sufficient to raise a genuine dispute concerning this material fact and defeat summary judgment.

For example, as with the drill tip of *Aktiebolag* (but unlike the clearly readily replaceable carrier plate of *Husky*), Karl Storz does not sell its optical assemblies as replacement parts. *Compare* Appx8 (SJ Order); Appx525, ¶ 85; Appx2406 at 134:13-14, *with* *Aktiebolag*, 121 F.3d at 673-74, *and* *Husky*, 291 F.3d at 788-89. And just like the drill tip in *Aktiebolag*, the Karl Storz optical assembly is not easily detachable. *Compare* Appx1666 at 68:5-69:20, *and* Appx2234-2236, ¶¶ 16,

with *Aktiebolag*, 121 F.3d at 674. And as the accused process of replacing the tip in *Aktiebolag* “did not involve ‘just attaching a new part for a worn part,’ but instead required ‘several steps to replace, configure and integrate the tip onto the shank,” *e.g.*, *Aktiebolag*, 121 F.3d at 673, IMS’s process of replacing the Karl Storz optical assembly requires multiple, extensive, and invasive steps. *Compare* Opening Br. at 18-21, and Appx2234-2236, ¶¶ 15-33, with *Husky*, 291 F.3d at 787 (quoting *Aktiebolag*, 121 F.3d at 673-74).

Applying *Aktiebolag* and *Husky*, any and all of this evidence should have been sufficient to defeat summary judgment here. But there is more. For example, other evidence that the Karl Storz optical assembly is not readily replaceable includes the fact that IMS cannot replace the optical assembly without first breaking an FDA-validated permanent seal. Appx510-511, ¶¶ 57-58; Appx3854 at 60:3-12; *see also* Appx1666-1667 at 68:5-70:19; Appx2235, ¶ 16. 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; Appx9 (SJ Order); Appx1283 at 44:21-45:8. 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. Once IMS breaks the seal, the 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 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; Appx2235, ¶ 16; Appx3854 at 60:3-61:4; Appx4303 at 183:8-12. 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.

**2. *IMS Ignores Karl Storz's Evidence and IMS's Burden On Summary Judgment***

Despite all of the foregoing evidence to the contrary, IMS argues that this case is like *Husky* and does not “involve [a] difficult question[.]” concerning whether the Karl Storz optical assembly is “readily replaceable. Opp. at 15. But IMS makes this argument only by completely ignoring and failing to address or acknowledge **any and all** of the foregoing evidence showing that the Karl Storz optical assembly, like the *Aktiebolag* drill tip, is **not** readily replaceable.

Rather than acknowledging the summary judgment posture of this appeal and IMS's resulting burden to show no genuine dispute of fact, IMS simply pretends Karl Storz's extensive evidence does not exist. Instead, IMS focuses solely on its own alleged evidence to argue that there is evidence supporting a finding that the optical assembly is readily replaceable. *Id.* at 15-16.



**First**, this is not the issue. Karl Storz is not appealing a jury verdict, and the issue therefore is not whether there was substantial evidence supporting some non-existent jury finding on the readily replaceable question. Rather, Karl Storz is appealing a grant of **summary judgment**, and the issue is whether IMS met its burden of proving there was no genuine dispute concerning whether the optical assembly was readily replaceable. In light of the evidence identified by Karl Storz, such a genuine dispute exists regardless of any evidence that IMS now argues on appeal (after ignoring its burden below) because “[a]ll doubt respecting the presence or absence of material factual issues must be resolved in the favor of the party opposing summary judgment.” *Dana Corp. v. Am. Precision Co.*, 827 F.2d 755, 758 (Fed. Cir. 1987).

Put another way, summary judgment is appropriate only where no “reasonable jury could return a verdict for the nonmoving party.” *Hewlett-Packard Co. v. Repeat-O-Type Stencil Mfg. Corp.*, 123 F.3d 1445, 1450 (Fed. Cir. 1997). Given that all justifiable factual inferences must be drawn in favor of the party opposing summary judgment, it is undisputed that a jury could reasonably conclude that the Karl Storz optical assembly is not readily replaceable based on the wealth of the supporting evidence identified by Karl Storz. *See, e.g., Meyer Intellectual Props. Ltd. v. Bodum, Inc.*, 690 F.3d 1354, 1366 (Fed. Cir. 2012). Indeed, in *Aktiebolag*, the Federal Circuit reversed summary judgment of repair

based on similar (and less) evidence presented here. 121 F.3d at 674. And IMS does not even argue that the evidence identified by Karl Storz is insufficient to create a genuine issue on the readily replaceable question of fact. IMS could not because it does not even address Karl Storz's evidence. Opp. at 15-16.

**Second**, most of IMS's supposed counter-evidence is not only irrelevant on summary judgment, it also is irrelevant to the "readily replaceable" question altogether. Most of IMS's evidence and arguments focus on the wrong question, *i.e.*, whether the optical assembly was simply "replaceable" rather than whether it was "readily replaceable." *Id.* Just like the drill tip in *Aktiebolag*, there is no dispute here that IMS replaced the Karl Storz optical assembly; the question is whether it was **readily** replaceable.<sup>2</sup>

And IMS's evidence concerning the actual question at hand is the self-serving testimony given by an IMS employee "that the rod lenses use [sic] in the [Karl Storz] optical relay of a rigid endoscope are 'readily' replaceable parts." *Id.*

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<sup>2</sup> IMS relies heavily on the fact that it has set up an elaborate and wide-ranging operation that allows it to infringe on a large scale as somehow excusing its infringing conduct as repair. Opp. at 15-16. It identifies no law to support the notion that infringing conduct should be considered repair if that infringement conduct is repeated many, many times. Moreover, IMS's argument that this extensive operation shows that the optical assembly was replaceable is not the question. The question is whether the optical assembly is **readily** replaceable, and the extensive and invasive operations and steps that IMS must perform to replace the optical assembly help prove that it is **not** readily replaceable.

Putting aside the self-serving nature of this party testimony, it does not even concern the optical relay assembly itself, it concerns the rod lenses. Moreover, this testimony is contradicted by the undisputed facts, which established that 60-100% of the replacement lenses are IMS cylindrical lenses, not the original Karl Storz dog-bone lenses (which are not sold as replacement parts). *Compare* Appx1655 at 22:17-24, *with* Appx8 (SJ Order); Appx2236, ¶ 31. The unique design of Karl Storz optical relays necessitates dog-bone shaped lenses to allow the endoscope to flex. Appx520-522, ¶¶ 77-79. The replacement 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. Far from being readily replaceable, IMS replaces the Karl Storz lenses with an inferior lens that results in an inferior product.

In any event, on summary judgment, IMS’s newly asserted “evidence” does not and cannot defeat Karl Storz’s extensive evidence on which a reasonable jury could determine that the Karl Storz optical assembly is not readily replaceable. *See, e.g., Aktiebolag*, 121 F.3d at 674. Accordingly, there is at least a genuine

issue of fact concerning whether the optical assembly is readily replaceable and summary judgment was inappropriate.

### **C. IMS Relies on Inapplicable Case Law**

IMS cites to a series of Federal Circuit decisions and argues that they establish a bright line rule that the replacement of any parts is allowable “repair,” regardless of whether or not they are readily replaceable (and regardless of any other circumstances). *E.g.*, *Opp.* at 16-20. IMS’s argument is wrong for at least three reasons.

**First**, as established in Karl Storz’s opening brief (but steadfastly ignored by IMS’s brief and arguments), this Court has repeatedly stated 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 . . . **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.** . . . 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).

**Second**, IMS’s argument that the replacement of any part or parts is always allowable repair directly contradicts Federal Circuit precedent, including the *Aktiebolag* and *Husky* decisions for the reasons discussed above.

**Third**, for the reasons discussed below, the decisions forwarded by IMS are materially different and distinguishable from this case. IMS’s attempts to avoid the import of *Aktiebolag* and *Husky* ignores these distinctions and this Court’s warning that “[e]ach 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.” *Id.*

**1. General Electric**

The *General Electric* decision on which IMS relies does not somehow negate or overturn *Husky* and the *Husky* Court’s summary and analysis of repair/reconstruction law: *General Electric* was decided twenty-four years prior to *Husky*, is consistent with the *Husky* analysis, and is distinguishable from the current case. *General Electric Co. v. United States*, 572 F.2d 745 (Ct. Cl. 1978).

As an initial matter, the posture of the cases are different, as *General Electric* was not decided on summary judgment but after a trial and “voluminous” findings of fact. *See id.* 572 F.2d at 748.

In addition, the facts are materially different. In *General Electric*, the issue was whether, during the Vietnam War, the U.S. Navy’s “maintenance” of gun mounts using parts sold and provided by patent owner GE infringed GE’s patents or was permissible repair. *Id.* at 779, 781-82, 783-84. The *General Electric* Court found that because the replacement parts were purchased or acquired from *General Electric* itself, the *General Electric* “case is very close to *Wilbur-Ellis*,” which *Husky* identified as representative of the “readily replaceable” end of the spectrum. *Id.* 572 F.2d at 784-85; *Husky*, 291 F.3d at 787.

Indeed, what IMS fails to address or acknowledge is that these facts—that plaintiff GE had a business of selling replacement parts for the gun mounts, that GE in fact sold these replacement parts to the U.S. Navy, and that the parts the Navy used to maintain and reassemble the gun mounts came from GE—were the primary reason that the Court found repair. *General Electric*, 572 F.2d at 781-82, 783-84. Thus, *General Electric* is akin to the *Husky* case, where the patent owner itself sold replacement parts, establishing that the parts in question were “readily replaceable.” In contrast, in *Aktiebolag* and the instant case, the patent owner did not make or sell replacement parts—IMS replaced all or nearly all the parts with non-Karl Storz parts. Appx21 (SJ Order); Appx1685 at 143:17-144:9, Appx1695-1696 at 185:18-186:2; Appx2235-2236, ¶¶ 18-21, 30-33.

Moreover, there was no allegation or evidence in *General Electric* that the replacement of these GE parts with parts sold by GE “did not involve ‘just attaching a new part for a worn part,’” as is the case in *Aktiebolag* **and** here. *Husky*, 291 F.3d at 787 (quoting *Aktiebolag*, 121 F.3d at 673-74).

## 2. *Dana*

The *Dana* decision is similar to *General Electric* and does not support IMS’s arguments. Opp. at 18. *Dana* issued fifteen years prior to *Husky* and, like *General Electric* and *Husky*, concerned a situation where the patentee clearly intended that the parts in question be readily replaceable because the patentee sold replacement parts and published a repair manual. *Dana*, 827 F.2d at 759. There likewise was no evidence that replacing the clutch parts in question was anything other than attaching a new part for an old part. Thus, *Dana* was on the *Husky*, *General Electric*, and *Wilbur-Ellis* readily replaceable end of the spectrum, not the opposite end of the spectrum where *Aktiebolag* (**and Karl Storz/IMS**) reside. *See id.* at 759-60.

Indeed, IMS not only ignores these critical distinctions, it conspicuously omits that in *Dana*, it was “undisputed that Dana intends that its clutches be repairable” and “Dana does not contend that replacement of the [parts] constitutes a reconstruction [rather than a repair].” *Id.* at 759; Opp. at 18.

### 3. *Jazz Photo* and *Fuji Photo*

IMS also relies on the related *Jazz Photo* and *Fuji Photo* decisions as supporting its argument that, despite the explicit teaching of *Husky*, whether replaced parts are “readily replaceable” is irrelevant to the repair defense. Opp. at 18-20 (citing *Jazz Photo Corp. v. Int’l Trade Comm’n*, 264 F.3d 1094 (Fed. Cir. 2001) and *Fuji Photo Film Co. v. ITC*, 474 F.3d 1281 (Fed. Cir. 2007)). Neither concerns a summary judgement decision; instead, each concerns the results of a full ITC hearing and subsequent Commission review. *Jazz Photo*, 264 F.3d at 1098; *Fuji Photo*, 474 F.3d at 1286-87.

The *Jazz Photo* decision issued before *Husky*, while *Fuji Photo* issued after *Husky* and cites it with approval. See *Fuji Photo*, 474 F.3d at 1296. Neither, however, addresses the “readily replaceable” issue because it was not raised—presumably because each concerned the ultimate readily replaceable claim element, a roll of film in a camera. *Jazz Photo*, 264 F.3d at 1101; *Fuji Photo*, 474 F.3d at 1296-97. As the defendant in *Jazz Photo* described, they were “not building new [cameras] but simply replacing the film in used cameras.” *Jazz Photo*, 264 F.3d at 1101.

Moreover, these decision involved the relatively simple operation of opening and resealing a camera to replace the used film container therein. Neither *Jazz Photo* nor *Fuji Photo* (or any of the other decision relied on by IMS) involve the



breaking of an FDA-validated seal that resulted in a permanently different and compromised medical device. In contrast to these cameras, the seal at issue here is a seal with multiple welds that must withstand repeated exposure to water vapor, at a high temperature and high pressure. Appx9 (SJ Order); Appx1283, 44:21-45:8; Appx3854 at 60:7-61:4. In fact, before any OEM endoscope can enter the marketplace, the FDA must confirm that the seal can withstand repeated exposure to these extreme conditions. Appx3854 at 59:24-61:4. Given these robustness requirements, IMS cannot simply cut a weld to open a seal. Rather, IMS must use a HydroFlux welder to compromise the bonds prior to even attempting to break the seal. Appx1666 at 68:5-11; *see also* Appx2235, ¶ 16. After using the welder, IMS places the endoscope in a jig to hold it firm while a technician uses a specialized tool to break open the seal. Appx1666 at 68:12-15; *see also* Appx2235, ¶ 16. Next, IMS heats the glue over the screws, removes the glue, and then removes screws holding the ocular base in place. Appx1666 at 68:16-69:20; *see also* Appx2235, ¶ 16. If IMS still cannot open the seal after performing these steps, IMS will “machine” the eyepiece off. Appx1671 at 86:2-4; *see also* Appx510, ¶ 57. After all this, IMS is never able to fix or recreate a sealed optical assembly with the same safety and performance specifications. Appx9-10 (SJ Order); Appx26-27 (SJ Order); *see also* Appx660-661, ¶ 346.

IMS's extensive process does not establish an indisputably readily replaceable optical assembly, and the district court never found otherwise.

## **II. 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”**

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. 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* to conclude that the novelty of the optic assembly “does not affect the repair versus reconstruction analysis.” Appx24.

But as established in Karl Storz's opening brief, under the Supreme Court's decision in *Quanta*, *Aro* does not apply here because *Aro* 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) (citing *Aro*, 365 U.S. 336). The Supreme Court explained that *Aro* 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. *Quanta*, 553 U.S. at 635.

Thus, the district court's reliance on *Aro* was incorrect because the district court found that some of the elements in Karl Storz's 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.

In response, IMS takes a now familiar tack: first, IMS ignores the limitations on *Aro* as set forth by the Supreme Court in *Quanta*; second, IMS ignores that the district court has already found—and the undisputed evidence shows—that IMS replaces the entire claimed novel optic relay assembly. *E.g.*, Opp. at 20-25.

**A. *Quanta* Confirms the Limited Scope of *Aro* and that *Aro* is Inapplicable to Karl Storz’s Claims**

*Aro* held that there is “no legally recognizable or protected ‘essential’ element, ‘gist,’ or ‘heart’ of the invention in a **combination patent.**” *Aro*, 365 U.S. at 346. IMS’s argument that there “is simply no basis in law” for limiting *Aro* to combination patents ignores the Supreme Court’s holding to the contrary. Opp. at 24. In *Quanta*, the Supreme Court expressly reminded lower courts this holding in *Aro* is limited to combination patents, stating:

*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.** 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.

*Quanta*, 553 U.S. at 635 (2008) (emphases added). The Supreme Court explained that *Aro* 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.* And contrary to IMS’s argument that this Court should simply ignore the Supreme Court on this issue because *Quanta* somehow does not apply to patent exhaustion, the Supreme Court made clear that “importantly, **Aro** is not squarely applicable to **the exhaustion of patents** like the LGE Patents **that do not disclose a new combination** of existing parts.” *Id.*

In addition to arguing this Court should similarly ignore the Supreme Court, IMS also argues that *Quanta* should not be followed because no other court has done so. *Opp.* at 21. What IMS fails to disclose is that the Federal Circuit has not yet had the opportunity to address this *Quanta* holding. IMS omits the fact that **only one** Federal Circuit decision has addressed the question of repair since *Quanta: Auto. Body Parts Ass'n v. Ford Global Techs., LLC*, 930 F.3d 1314 (Fed. Cir. 2019). But this *Auto. Body Parts* case involved design patents, making both *Quanta*’s and *Aro*’s discussion regarding combination patents irrelevant—because *Auto Body Parts* involved design patent claims, the “heart of invention” holding in *Aro* was not at issue and was not addressed. Nonetheless, *Auto Body Parts* did favorably cite and rely upon other holdings in *Quanta*.

This is the first opportunity the Federal Circuit has had to follow and rely upon *Quanta*’s directive to limit the application of *Aro*. Despite IMS’s urging, the

Court should follow the Supreme Court’s precedent (and the express language of *Aro* itself) and limit *Aro* to combination patents.

**B. IMS Replaces the Entire Inventive Optical Assembly**

IMS’s argument that *Quanta*’s limitation on *Aro* is irrelevant ignores that (1) the district court found that a specific element of the claims—the optical assembly—was itself novel and patentable; and (2) that the summary judgment evidence showed and the district court found that IMS replaced this entire inventive optical assembly.

The Supreme Court’s *Quanta* decision compels a finding that *Aro* 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 inventive: “without question, the way the optical relay is assembled is the novel and distinguishing part of the invention.” Appx23-24.

IMS’s argument that limiting *Aro* as *Quanta* requires would not affect the outcome of its summary judgment motion ignores all of the foregoing, including the district court’s finding that specific elements—the optical assembly—are novel and patentable apart from their combination with any other elements.

IMS's argument also simply ignores that the district court's finding that the summary judgment evidence showed that IMS rebuilds and replaces the entire inventive aspect of the Asserted Patents: the optical relay. Appx4627 ("it is immaterial that IMS replaces the entire optical relay"). While IMS lists multiple parts it does not replace, these parts are **not** the inventive optical assembly; indeed, other than the tubular shaft in which the optical assembly, **the parts that IMS touts it does not replace are not even claimed in the asserted claims.** Compare Opp. at 32, with Appx39 (Claim 1), and Appx47 (Claim 1).

For these reasons, 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.

### **III. Reversal Is Required Because There Is at Least a Material Dispute of Fact Concerning 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 Mgmt. v. Pan Man, Inc.*, 228 F.3d 1352, 1355 (Fed. Cir. 2000). 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.

**A. The Magnitude of Replaced Parts Shows That IMS Makes an Essentially New Article**

According to IMS, “the question of what constitutes ‘reconstruction of the entire device’ outside the scope of permissible repair is primarily one of magnitude.” Opp. at 30. Under IMS’s own test (based on the *Husky* decision), Karl Storz has demonstrated that IMS’s action are reconstruction, and not repair.

As discussed above, not only does IMS replace the entire inventive aspect of the asserted claims (the optical assembly), but the district court found that the summary judgment evidence established that IMS replaces every claimed element but for one, the tubular shaft. Appx21; Opening Br. at 43-45.

This case is thus akin to the example provided in *Husky*, where all claimed elements of an automobile are replaced except for the sparkplugs:

Despite the number of cases concerning repair and reconstruction, difficult questions remain. . . . Some few situations suggest an obvious answer. For example, 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.

*Husky*, 291 F.3d at 786.

At the very least, IMS's evidence and the district court's conclusion that IMS replaces the entire inventive aspect and all claim elements but for one creates a genuine dispute as to whether IMS created an "essentially new article."

**B. The Material Differences Between IMS's and Karl Storz's Products Shows That IMS Makes an Essentially New Article**

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. Karl Storz's opening brief lists the litany of material differences, Opening Br. at 45-48, and the district court itself summarized some of those differences as follows:

**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 (emphasis added).

IMS argues that none of these differences matter, extracting a litany of bright-line rules from various cases that, if adopted and applied as IMS proposes, would mean that nothing is ever reconstruction, that every recreation or



modification of a patented article is permissible repair. Once again, this simply is not the law:

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.*, 21 F.3d at 1078 (emphases added).

In light of the “facts and circumstances presented” in **this** case, “the exercise of sound common sense and an intelligent judgment” means that the vast differences between the original Karl Storz article and IMS’s at the very least creates a genuine dispute as to whether IMS created an “essentially new article.”

#### **IV. Karl Storz Did Not Waive Its Appeal Arguments Below**

IMS’s argument that Karl Storz waived its appeal arguments is baseless. IMS misstates and misapplies the law on this issue and, in any event, Karl Storz preserved each of these issues below.

## A. The “Waiver” Standard

“Waiver<sup>3</sup> is governed by local circuit law” and this case originated from the Eleventh Circuit.<sup>4</sup> *Sweepstakes Patent Co., LLC v. Burns*, 610 F. App’x 1006, 1008 (Fed. Cir. 2015).

In the Eleventh Circuit, “[p]arties can most assuredly waive or forfeit positions and issues on appeal, but not individual arguments.” *Bourtzakis v. United States AG*, 940 F.3d 616, 620-21 (11th Cir. 2019) (finding that appellee could raise any argument in support of his position that his prior conviction was not an aggravated felony). “Offering a new argument or case citation in support of a position advanced in the district court is permissible—and often advisable.” *Sec’y, United States DOL v. Preston*, 873 F.3d 877, 883 n.5 (11th Cir. 2017). Parties are even allowed to raise “new argument(s) . . . based on a different line of precedents, [that are] inconsistent with the old argument.” *Northeastern Eng’rs Fed. Credit Union v. Home Depot, Inc.*, 931 F.3d 1065, 1086 (11th Cir. 2019).

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<sup>3</sup> Appellant understands that the issue raised by appellee was “forfeiture” and not “waiver.” See *In re Google Tech. Holdings LLC*, 980 F.3d 858, 862-63 (Fed. Cir. 2020). However, as noted in *In re Google Tech.*, courts, more often than not, use the term “waiver” when discussing forfeiture.

<sup>4</sup> The Federal Circuit applies similar doctrine of waiver rules (i.e., doctrine of forfeiture). See *O2 Micro Int’l Ltd. v. Beyond Innovation Tech. Co., Ltd.*, 521 F.3d 1351, 1359-60 (Fed. Cir. 2008).

**B. Karl Storz Did Not “Waive” Its Readily Replaceable Argument**

IMS’s argument that Karl Storz somehow waived its argument IMS is not replacing a “readily replaceable part” is incorrect. First, there is no dispute that Karl Storz raised the issue below that IMS’s accused activities are not repair as IMS alleges, but infringing reconstruction. Having raised this issue, Karl Storz is free to advance any argument in support of that preserved issue.

Moreover, Karl Storz raised the “readily replaceable” argument at the district court. For example, Karl Storz argued that in contrast to past cases finding repair (Appx4585-4592), IMS’s actions constituted reconstruction because (i) extensive steps were needed to remove the optical assembly, and build and integrate a new optical assembly into the endoscope (Appx4574-4576), (ii) the replacement of the optical assembly required the breaking a FDA-validated permanent seal (Appx4559, Appx4578), (iii) Karl Storz does not sell replacement optical assemblies (Appx4577), and (iv) the optical assembly is not a consumable part (Appx4576-4577). Both IMS and the district court wrongly ignored or flat-out rejected these arguments. *See e.g.*, Appx26, Appx28; Appx4624-4629.

**C. Karl Storz Did Not Waive Its Argument That IMS Replaces the Entire Inventive Aspect**

Again, the issue here is whether IMS’s actions are permissible repair or infringing reconstruction. Having preserved that issue below, Karl Storz may

present any argument to support its position that IMS's actions are infringing reconstruction.

But also again, Karl Storz in fact presented its argument that IMS is replacing the entire inventive aspect of the claims and *Aro* did not apply because the Asserted Patents were not combination patents:

Instead, STERIS-IMS replaces the *entire optical relay* with *all* the optical components irrespective of whether they are broken.

Still further, the Asserted Patents are not combination patents. *Aro Mfg.*, 365 U.S. at 337. Although directed to endoscopes and methods of assembling endoscopes, the claim limitations are for the optical relay.

[] This is not the mere combination of known elements in an endoscope.

Appx4583 (citation omitted). While the district court conceded that IMS replaces the entire inventive aspect of the claims, it nonetheless continued to reject (wrongly) Karl Storz's argument based on *Aro*:

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).

Appx23-24.

**CONCLUSION**

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

Dated: March 15, 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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