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Before the United States Copyright Office and Library of Congress
In the Matter of Exemptions to Permit Circumvention of Access Controls on Copyrighted Works
Docket No. 2026-4 | Tenth Triennial Section 1201 Rulemaking (2027 Cycle)

Comments of the Advanced Medical Technology Association (AdvaMed) in Opposition to Petitions to Renew the Medical Device Repair Exemption

Interested Party:

Advanced Medical Technology Association (AdvaMed), the Medtech Association, appreciates the opportunity to provide comments and evidence in opposition to petitions to renew the exemption at 37 C.F.R. § 201.40(b)(17). AdvaMed is the leading trade association of the medical technology industry, representing more than 650 companies that develop, manufacture, and distribute medical devices, diagnostic tests, digital health technologies, and medical imaging products. AdvaMed's membership spans the entire medical technology sector, including small, entrepreneurial innovators, mid-sized companies, and global industry leaders, giving the Association a uniquely comprehensive perspective on the opportunities and challenges facing medtech companies of all sizes.

AdvaMed is uniquely positioned to provide a comprehensive industry perspective on issues affecting the development, regulation, and availability of medical technologies. AdvaMed advocates for innovative technologies that save and improve lives, enable earlier diagnosis and treatment, enhance quality of life, and help create a more efficient and sustainable health care system.

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Exemption Addressed in This Submission

This comment addresses a single current exemption, codified at 37 C.F.R. § 201.40(b)(17) ("Exemption"), which defines the class of copyrighted works as:

> "Computer programs that are contained in and control the functioning of a lawfully acquired medical device or system, and related data files, when circumvention is a necessary step to allow the diagnosis, maintenance, or repair of such a device or system."

On the Office's renewal petition form, this exemption appears as "Computer programs that control medical devices or systems, and related data files, for diagnosis, maintenance, or repair of the device or system."

Renewal Petitions Addressed

The Office's notice of inquiry provides that where "a single exemption receives multiple renewal petitions, commenters may respond to all of them in a single submission." AdvaMed responds in this submission to each of the following.

Petitioner	Docket ID	Declarant
Brown's Medical Imaging	COLC-2026-0100-0029	Scott Ohle (Aug. 21, 2026)
Caylor Equipment Services LLC	COLC-2026-0100-0005	Unsigned as posted (Aug. 14, 2026)
Crothall Facilities Management, Inc. / Intelas	COLC-2026-0100-0010	Geoffrey Hunt (Aug. 19, 2026)
East Coast Medical Systems, Inc. (ECMS)	COLC-2026-0100-0043	Jimmy Kallam (Aug. 24, 2026)
iFixit	COLC-2026-0100-0037	Kyle Wiens (Aug. 24, 2026)
ImageOne Medical Group, LLC	COLC-2026-0100-0009	Jeremy Hesser (Aug. 19, 2026)
Marshall R. Shannon	COLC-2026-0100-0006	Marshall R. Shannon (July 2026)
TriMedx Holdings, LLC	COLC-2026-0100-0044	Laura Sahm (Aug. 24, 2026)

I. INTRODUCTION AND SUMMARY OF OPPOSITION

The Advanced Medical Technology Association ("AdvaMed") submits these comments in opposition to the eight petitions identified above, each of which asks the Office to readopt the medical device repair exemption at 37 C.F.R. § 201.40(b)(17) through the streamlined renewal procedure. AdvaMed asks the Office to find that the record assembled in the eighth and ninth triennial proceedings is no

longer a reliable basis for readopting this exemption as currently written, and to carry the question forward into the public comment phase where a record can be built.

Legal and factual developments since the ninth proceeding compel that conclusion. Each falls squarely within the categories the Office has identified as constituting meaningful opposition.

A. New legal development: the D.C. Circuit's Opinion of September 1, 2026

On September 1, 2026, the United States Court of Appeals for the District of Columbia Circuit decided *Medical Imaging & Technology Alliance and Advanced Medical Technology Association v. Library of Congress, et al*, No. 25-5328, slip op. (D.C. Cir. Sept. 1, 2026) ("*MITA IV*")[1] and identified the protected work before the agency as clinical operation software — the software that runs the device in patient care. It described AdvaMed's contrary position and rejected it for want of proof, not for want of merit: AdvaMed's "argument turns centrally on the proposition that there is a distinct body of repair software independent from the clinical-operation software and that it occupies its own standalone market," and "Appellants, however, made no such record in the rulemaking process or before the district court." The court was equally direct about why the Librarian never reached the question: "the Librarian did not address the proposed distinction between operating works and repair works. But that is because Appellants did not demonstrate before the agency the existence of this distinction that it now presses. At most, comments before the agency discuss the possible distinction only in vague terms and provide no supporting evidence."

That holding is not an endorsement of the exemption's application to servicing and diagnostic works. It is a ruling about an insufficient record.

B. New factual development: first-hand evidence from manufacturers

AdvaMed has gathered first-hand evidence from medical device manufacturers and submits it with these comments (See Exhibits). This evidence establishes three facts the prior record does not contain—

1. **System Servicing/Diagnostic Software and Maintenance-Related Documentation, which we refer to collectively as "Servicing Works", are works distinct from the Clinical Operation Software that clinicians use to care for patients.**
2. **Servicing Works are protected by technological measures separate from, differently purposed than, and administered by a different party than the technological measures that protect Clinical Operation Software.**
3. **Servicing Works are licensed or used by OEMs in commercial services in their own commercial markets, distinct from the sale or lease of the medical device**

[1] *MITA IV* available at https://media.cadc.uscourts.gov/opinions/docs/2026/09/25-5328-2190869.pdf

they relate to, on their own terms— including both to and, at other times, in competition with independent service organizations.

Clinical Operation Software is the software that healthcare providers use to operate a medical device to perform patient care activities.

System Servicing/Diagnostic Software includes software applications, diagnostic tools, calibration programs, configuration utilities, service interfaces, and related digital resources used to install, inspect, calibrate, test, maintain, diagnose the system, troubleshoot, update, or repair a medical device to its intended performance and safety specifications. For example, System Servicing/Diagnostic Software can be used to:

- Check for system errors or malfunctions;
- Access system diagnostic information and service logs;
- Calibrate the device after a repair;
- Troubleshoot errors;
- Install software updates or patches; and/or
- Verify that the device is functioning properly before it returns to clinical operation use for patients.

Maintenance-Related Documentation is non-software, digital work used for servicing, such as digital service manuals or repair procedure documentation.

C. Relief requested

AdvaMed asks the Office to find meaningful opposition and decline to recommend renewal of § 201.40(b)(17) under the streamlined procedure; in the alternative, to exercise the authority it has reserved to find that opposition evidence casts doubt on renewal of part of an exemption and to decline streamlined renewal as to separately controlled and separately licensed Servicing Works; to consider Mr. Shannon's submission solely as a renewal petition and give no effect to the expansion he requests within it; and to frame the resulting issues for comment in the notice of proposed rulemaking. Part X sets out this request in full, and the Appendix offers illustrative regulatory language should the Office prefer to narrow rather than defer.

II. THE STANDARD GOVERNING THIS PHASE

A. Streamlined renewal depends on the continuing reliability of the prior record

The streamlined procedure exists to readopt exemptions that draw no meaningful opposition. A renewal petition, the Office explains, "requests the readoption of a current exemption based on an attestation that the prior rulemaking record remains a reliable basis." Each petitioner accordingly

affirms "that, to the best of the petitioner's knowledge, there has not been any material change in the facts, law, or other circumstances in the rulemaking record that resulted in the exemption being issued initially." The purpose of comments at this stage is correspondingly narrow: "to identify whether the prior rulemaking record remains a reliable basis for renewal." It does not.

B. Meaningful opposition is shown by new legal or factual developments

The Office "will not recommend renewal of a current exemption under the streamlined procedure if it receives comments showing 'meaningful opposition,'" which "may be satisfied with 'evidence that the prior rulemaking record is no longer a valid basis to support recommending renewal of an exemption.'" The notice of inquiry identifies three illustrative categories of qualifying evidence: "a change in case law affecting whether a particular use is noninfringing, new technological developments affecting the availability for use of copyrighted works, or new business models affecting the market for or value of copyrighted works."

AdvaMed presents evidence in all three categories. Part III addresses the change in case law. Part IV addresses the technological development—the migration of Servicing Works off the device and onto manufacturer-controlled remote infrastructure—and the business-model development—the tiered, credentialed, fee-bearing licensing of access to those works. None of this is conclusory opinion or speculation, which the Office has rightly said is insufficient. It is documentary and testimonial evidence from the manufacturers whose works and access controls are at issue, corroborated by the petitioners' own descriptions of what they need and why.

C. The Office may decline renewal as to part of an exemption

The notice of inquiry provides that "[t]he Office may also consider whether opposition evidence casts doubt only as to renewal of part of a current exemption." That authority is directly applicable here.

AdvaMed's evidence addresses a definable subset of the works the exemption arguably covers—separately controlled, separately licensed Servicing Works. Even if the Office concludes that the prior record remains reliable as to clinical operation software, it should still find that record unreliable as to a subset of Servicing Works and decline streamlined renewal accordingly.

III. THE FIRST NEW DEVELOPMENT: THE D.C. CIRCUIT'S SEPTEMBER 1, 2026 DECISION

A. What the court decided, and on what premises

MITA IV reviewed the Librarian's adoption of the exemption in the eighth rulemaking and her renewal of it in the ninth, under the arbitrary-and-capricious standard of the Administrative Procedure Act. The court affirmed. In doing so, it made the premises of the Librarian's reasoning explicit, factor by factor.

On the first factor, the court upheld the transformativeness finding on the ground that independent service organizations "put clinical operation software to a new use when it is used as a tool for

repairing medical devices, transforming the machines from nonfunctional to functional devices — a use that is markedly different from the original, manufacturer-intended purpose." The record, the court said, "amply supported the Librarian's finding in the Ninth Rulemaking that 'the original purpose of the software is to operate a device that functions as designed' — not to repair devices."

On the second factor, the court accepted that the works are functional rather than expressive, "used … for their functional and informational aspects that enable users to control and understand the operation of the equipment." On the third, it observed that the Register and Librarian gave the factor "little weight" and that AdvaMed had "offered no argument or analysis of the third factor in the context of clinical operation software."

On the fourth factor, the court upheld the finding that the exemption was "unlikely to harm the market for the embedded software" because "medical device and system software and data files are sold with the equipment and have no independent value separate from the devices." It added that while the exemption "enables competition in the maintenance and repair services market, that does not itself demonstrate an adverse effect on the market for the original device or its clinical operation software, which is the protected work."

B. Each premise is true of Clinical Operation Software and false of Servicing Works

Read together, those passages describe a coherent analysis of Clinical Operation Software only. Clinical Operation Software is authored to run a device in patient care and is licensed with the equipment when sold rather than licensed separately.

But every premise fails when the work is a Servicing Work. The original and only purpose of a diagnostic utility, a calibration program, or a service manual is to diagnose, calibrate, and service the device. A servicer who uses System Servicing/Diagnostic Software to diagnose, calibrate, and service the device is not putting it to a new use; the servicer is putting it to its sole intended use, in direct commercial competition with its author. And those works are not "sold with the equipment." In fact, they are licensed separately, at separate prices, on separate terms, to buyers who include the petitioners themselves. Part V documents both points.

C. The decision turned on the absence of a record, which this proceeding can supply

MITA IV rested its holding on what the administrative record did and did not contain. On the first factor: AdvaMed "did not demonstrate before the agency the existence of this distinction that it now presses." On the fourth: "Appellants did not introduce evidence into the administrative record to prove their claims." On the third: AdvaMed's argument "presume[d] that the exemption references a distinct and independent body of purely repair software" that had never been established. And on the classification question generally: "Nor have they shown that the Librarian's classification of the relevant software exemption was unreasoned or unsupported by the administrative record."

A decision that an agency acted reasonably on the record before it in a prior rulemaking is not a determination that the same conclusion would follow on a different and more robust record in the

present rulemaking. The court took care to say so, resting its holding on the record's contents rather than on any judgment about the underlying facts. The tenth triennial proceeding is the forum in which the record can be corrected, and this phase is where the Office decides whether it should be.

D. The decision is itself a change in case law affecting whether the use is noninfringing

MITA IV is the first appellate decision to analyze this exemption under the four statutory fair-use factors. It supplies the controlling framework for that analysis in the jurisdiction whose law governs the Librarian's rulemaking, and it makes the classification of the copyrighted work the hinge of the inquiry: whether the secondary use is transformative and whether it harms a cognizable market both turn on what the work is and what it was authored to do. Because the prior rulemaking record contains no answer to that question, the decision that makes the question dispositive is a legal development that goes directly to the reliability of that record.

IV. THE SECOND NEW DEVELOPMENT: FIRST-HAND EVIDENCE FROM MEDICAL DEVICE MANUFACTURERS

The sworn declarations submitted with these comments are by executives of medical device manufacturers. Each declarant speaks from expert knowledge and operational responsibility for the servicing of their company's medical devices.

A. Three categories of works, not one

The evidence distinguishes three things that the current exemption treats as a single undifferentiated class. The first category is authored to operate the machines in the care, diagnosis, monitoring, or treatment of patients. The second and third are authored to diagnose, service, calibrate, and maintain the machines. That difference is essential to the fair-use question, and the prior rulemaking record does not address it.

Clinical Operation Software is the software health care professionals use to operate a medical device in the performance of patient care activities — e.g., to turn on and operate the device to acquire an image, to deliver a therapy, or to monitor a patient.

System Servicing/Diagnostic Software comprises the applications, diagnostic tools, calibration programs, configuration utilities, and service interfaces used to install, inspect, calibrate, test, maintain, diagnose, troubleshoot, update, or repair a device to its intended performance and safety specifications.

Examples of System Servicing/Diagnostic Software that are separate from Clinical Operation software are described in Exhibits A – E.

- **Exhibit A** [Carestream] describes System Servicing/Diagnostic Software such as detector and generator configuration and diagnostic applications, some of which are standalone applications (not integrated with Clinical Operation Software).
- **Exhibit B** [GE Healthcare] describes the Common Service Desktop application, which is separate System Servicing/Diagnostic Software used to view logs, test, calibrate, configure, troubleshoot, update, or verify performance of their devices. The Common Service Desktop includes various classes of software. Class A2 and A3 service software is licensed on request. Class C contains productivity and efficiency software and is only made available via sale and license to entitled customers and channel partners under contract with GE HealthCare. Class M software (externally referred to as GE HealthCare Highly Confidential) is for GE HealthCare internal use only or has been identified as a GE HealthCare trade secret. Class M software may be made available to channel partners under a channel partner agreement with GE HealthCare in some regions outside the U.S.
- **Exhibit C** [Hologic] describes company-designed calibration and service applications that are separate from Clinical Operation Software.
- **Exhibit D** [Philips] describes proprietary software utilized "to perform various service tasks on the devices, including but not limited to system diagnostics, system installation, and system configuration."
- **Exhibit E** [Siemens Healthineers] describes software that "provide[s] information, data, and tools that pertain to the performance of the device itself," that "can provide an individual with access to certain diagnostic tests that can be performed on the system," that "can monitor hardware and component status," that "can output error codes/logs," and that "can also support assembly, installation, adjustment, and calibration, in addition to testing and diagnosing a system for maintenance and repair . . . For some imaging devices, most of the System Servicing/Diagnostic Software is hosted on the cloud, physically separated from the imaging device and from the Clinical Operation Software that resides on it."

Maintenance-Related Documentation comprises service manuals, repair and installation procedures, service bulletins, diagnostic guides, parts lists, acceptance and compliance test procedures, and similar materials.

- **Exhibit A** [Carestream] describes the "Carestream Service Portal," which provides access to maintenance documentation, service bulletins, software and firmware update information, modification and installation instructions, process checklists, manuals, diagnostic guides, parts lists, best practices information, and acceptance and compliance test procedures.

- **Exhibit B** [GE Healthcare] describes different classes of Maintenance-Related Documentation. Class A1 documentation is public, similar to Clinical Operation documentation. Access to Class A2, A3, C1, C2, or C3 documentation is conditioned on having either an active licensing or service agreement.
- **Exhibit C** [Hologic] describes Service Manuals, User Manuals, and Quality Control Manuals.
- **Exhibit D** [Philips] describes Maintenance-Related Documentation organized by Level, where "[b]asic maintenance manuals are available at Level 0 on request" and "[m]ore advanced documentation is available at Level 1 under license, subject to training and confidentiality requirements. Level 2 documentation poses additional safety, cybersecurity, or remanufacturing risks and is limited to Philips only . . . This documentation is nearly exclusively stored on a cloud server and is not stored on the medical device. It is therefore maintained separately from both the Clinical Operation Software and the System Servicing/Diagnostic Software that reside on the device, and it is accessed through a Philips-hosted cloud server (InCenter) rather than through the device's clinical interface."
- **Exhibit E** [Siemens Healthineers] describes service manuals and other technical documentation used to service a system, which are usually stored in an electronic library on a website, with certain access controls for non-public information. On some older imaging systems, this documentation may be stored directly on the system.

B. The Servicing Works sit behind their own Technological Protection Measures

The access controls for Servicing Works differ from those for Clinical Operation Software. They use different mechanisms, serve different purposes, and are held by different parties. The following table summarizes the declarants' accounts.

Exhibit	Control on Servicing Works	Control on Clinical Operation Software
Exhibit A Carestream	"SecureLink" — a USB multifactor-authentication device containing an encrypted file identifying the individual service engineer, used together with a password unique to that engineer. The Service Portal holding maintenance documentation is separately password-protected.	Windows authentication with optional proximity-badge multifactor authentication, administered by the healthcare facility customer.

Exhibit	Control on Servicing Works	Control on Clinical Operation Software
Exhibit B GE Healthcare	Access to Class C and Class M System Servicing/Diagnostic Software is controlled by the type of physical SSA USB key or digital license key installed in the system.	Controlled by user credentials which are administered by the customer.
Exhibit C Hologic	Access to the System Servicing/Diagnostic Software is controlled by passwords, license keys, license controls, and USB security devices.	Access to the Clinical Operation Software is controlled by passwords and license controls administered by the clinical users.
Exhibit D Philips	Access to the System Servicing/Diagnostic Software is controlled by the IST smartcard, the encrypted user-specific certificate, the matching account password, and the user's IST entitlements, each of which is issued and administered by Philips. IST is Philips' proprietary Integrated Security Tool ("IST"), which controls both authentication and entitlement. Through IST, Philips applies encrypted certificates together with multifactor authentication to the device. The user must present a physical smartcard, which uses a proprietary program, in order to present the medical device with an encrypted, time-limited, user-specific certificate, and the user must enter the matching password for that specific user account. Upon successful login, the system presents only the service software tools that the user is entitled to use, based on the user's IST entitlements. Service documentation requiring licensed access is encrypted and cannot be downloaded, saved, or printed.	The Clinical Operation Software is managed separately. Its logins are username and password based, more like a Windows-type login, and they do not involve the IST smartcard, the encrypted user-specific certificate, or the entitlement system that determines which service software tools a user may access. Access to the Clinical Operation Software is controlled by the technologist and information technology or hospital administration accounts . . . , which are administered by the health care facility that owns or leases the device and its information technology personnel. Those logins are not in place to protect copyrighted material; they are in place to allow device owners to ensure that only hospital-authorized clinical staff or other individuals can access a system's medical features and/or patient data.

Exhibit	Control on Servicing Works	Control on Clinical Operation Software
	Tools and documents are tiered across Levels 0 through 3.	
Exhibit E Siemens Healthineers	Access to Siemens Healthineers' System Servicing/Diagnostic Software generally requires a Service Key — a character string, generally 256 characters, entered at the servicing software interface. Keys are time-limited, tiered as basic, advanced, or proprietary, and generated from information specific to the device or supplied by a USB dongle, which is a physical device often connected over USB. Service Keys are distributed and approved by Siemens Healthineers. The distribution and availability of service keys for a system depends on the category of the service key and, for advanced service keys, on eligibility criteria such as training and contract terms. Access to non-public Maintenance-Related Documentation stored on an electronic library website is controlled by a login and password, which are provided upon permission from Siemens Healthineers. For non-public Maintenance-Related Documentation stored on older imaging systems, a service key provides access. This is separate and apart from the controls for Clinical Operation Software.	An operator login account and password, with accounts created on the device for each user. The login is initially provided by Siemens Healthineers and is thereafter controlled by the customer operating the system for patient use.

Three features of that evidence deserve emphasis.

The measures are held by different parties and serve different ends. Technological access to Clinical Operation Software is handed to the *device owner*, who administers it to keep unauthorized people

away from patient data and clinical functions. As Ms. Dickson (Philips) puts it, those logins exist "to allow device owners to ensure that only hospital-authorized clinical staff or other individuals can access a system's medical features and/or patient data."[2] The control on servicing software is retained and administered by the *manufacturer*, and it exists to control access to the manufacturer's copyrighted Servicing Works. Two measures, two purposes, two custodians. Section 1201(a)(1)(C) directs the Librarian to grant exemptions by reference to a "class of copyrighted works." Works separated by their authorship purpose, their access architecture, and their distribution terms are not one class.

The measures operate in series, not in the alternative. Goncalo Arnaut (Siemens Healthineers) describes the sequence precisely: users log in to the system through the clinical operation software, navigate to a service menu item, and then, once selected, "access to the System Servicing/Diagnostic Software itself requires a service key distributed and approved by Siemens Healthineers at the level corresponding to the information or tools sought. For advanced service keys, the person or organization must also satisfy eligibility criteria such as training and contract terms."[3] Clearing the first gate does not clear the second. A servicer who has lawful access to Clinical Operation Software still confronts a separate technological measure guarding a separate body of works, the Servicing Works — which is the definition of a distinct access control on a distinct class.

The second measure may be calibrated to the sensitivity of the work behind it.

- "Philips provides Level 0 access to ISOs, hospital biomeds, and others on request. Philips licenses Level 1 access to hospital biomeds under certain cooperative service agreements, subject to requirements for system-specific service training and non-disclosure agreements. Level 2 and Level 3 access is not available for license and is retained for Philips."[4] Philips reserves Levels 2 and 3 for its own trained engineers and specialists because those tiers "contain tools that are highly proprietary, pose a greater risk to patient or servicer safety, or that can alter or impact the performance or cybersecurity of the device."[5]
- Siemens Healthineers tiers its service keys as basic, advanced, and proprietary, and conditions advanced keys on eligibility criteria such as training and contract terms.[6]
- GE Healthcare also tiers access to System Servicing/Diagnostic Software, segmenting service software into classes—

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[2] Exhibit D, Declaration of Jacqueline Dickson ¶ 9 (Sept. 28, 2026).

[3] Exhibit E, Declaration of Goncalo Arnaut ¶ 10 (Sept. 25, 2026).

[4] Exhibit D, Dickson Decl. ¶ 12.

[5] *Id.* ¶ 11.

[6] Exhibit E, Arnaut Decl. ¶¶ 7, 9.

> Class A2 and A3 service software is licensed on request with some regions charging a reasonable fee and others, like the U.S., providing the license at no additional charge). Class C (externally referred to as Technical Service) contains productivity and efficiency software and is only made available via sale and license to entitled customers and channel partners under contract with GE HealthCare . . . Class M software (externally referred to as GE HealthCare Highly Confidential) . . . is for GE HealthCare internal use only or has been identified as a GE HealthCare trade secret. Class M may be made available to channel partners under a channel partner agreement with GE HealthCare in some regions outside the U.S.[7]

This is not an undifferentiated wall around a device. It is a graduated licensing structure over a catalog of works.

C. Access to the Servicing Works is licensed and sold in a market of its own

The premise of the Register's prior resolution of the fourth fair use factor— that these works "are sold with the equipment and have no independent value separate from the devices" — is the premise the new evidence most directly contradicts.

Each declarant describes a functioning commercial market for access to the Servicing Works, with prices, terms, counterparties, and competitors.

- Carestream service and diagnostic applications reside on the device, but licenses access to the System Servicing/Diagnostic Software separately from the sale or lease of the device either through OEM service agreements or separate licensing.[8] Entities without a Carestream service agreement "may send individual field engineers to Carestream OEM service training and pay a yearly subscription on a per-person, per-unit basis to obtain these credentials."[9] Carestream described the market for these Servicing Works as including "biomedical engineers, channel partners, and ISO [independent service organization] and MVS [multi-vendor service] field engineers", including from "MVS organizations operating within competing equipment OEMs such as GE, Philips, and Siemens (Block)."[10]
- GE HealthCare licenses access to its System Servicing/Diagnostic Software separately from the sale or lease of the device.[11] Access to Class A2/A3 is made available to any customer or ISO through licensing. Access to Class C1/C2/C3 is made available to any customer through a service agreement or licensing. The consideration charged for such access depends on the

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[7] Exhibit B, Declaration of Jerome Duhamel ¶ 7 (Sept. 28, 2026).

[8] Exhibit A, Declaration of Garrett Huntley ¶ 12 (Sept. 25, 2026).

[9] *Id.* ¶ 13.

[10] Exhibit A, Huntley Decl. ¶ 14.

[11] Exhibit B, Duhamel Decl. ¶ 11.

commercial policy of the country. The access provided may include licenses to Common Service Desktop restricted tools, training, and/or support. As "[c]sutomers may obtain maintenance or repair services through GE HealthCare, independent service organizations, [hospital] in-house service departments, and sometimes other manufacturers", when "software access . . . is required beyond the access already provided in Class A1, those parties can contact GE HealthCare to determine what licensing options are available."[12]

- Hologic also licenses its System Servicing/Diagnostic Software separately from the sale or lease of the device, which is offered to factory-trained and authorized service personnel through service program offerings which provide credentialing.[13] "The consideration charged for such access is determinable across type of customer, access needed, and other economic factors of install base support scale."[14] The market for these Servicing Works includes hospital service personnel (BMETs) or third-party authorized service providers, including other OEMs and ISOs, such as "GE HealthCare, Siemens [Healthineers], Trimedix, Crothall, 626 Holdings, Cassling, Aramark, and Frontier."[15] Additionally, "[i]f additional authorized software access or expertise is required, customers may request a limited use license via one-time charge or provide credentialing that entitles access via factory-provided technical instruction."[16]
- Philips divides its service software into Levels that designate who may obtain a given tool and on what conditions. Level 0 tools are available to any person, including independent service organizations and hospital biomedical engineers, on request.[17] Level 1 tools are licensed to hospital biomedical engineers "under certain cooperative service agreements that include license fees, under specific terms and conditions including completion of Philips service training for that product, and execution of a non-disclosure agreement."[18] Levels 2 and 3 are not available for licensing. Philips's maintenance documentation is tiered on the same scheme: basic manuals at Level 0 on request, more advanced documentation at Level 1 under license subject to training requirements, and Level 2 documentation retained by Philips.[19]
- "Siemens Healthineers licenses usage of its System Servicing/Diagnostic Software at certain levels separately from the sale of the device. Access can be made available to the device owner upon system purchase or at a later time and can also be licensed at certain levels to

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[12] Exhibit B, Duhamel Decl. ¶ 13.

[13] Exhibit C, Declaration of Pierre Malboeuf ¶ 11 (Sept. 24, 2026).

[14] *Id.* ¶ 12.

[15] *Id.* ¶ 13.

[16] *Id.* ¶ 14.

[17] Exhibit D, Dickson Decl. ¶ 12.

[18] *Id.* ¶ 15.

[19] *Id.* ¶ 16.

other servicing organizations."[20] The term of a license "can be short, for example a few days, or long term, as for example annually."[21] Arnaut described the participants in the market for Siemens Healthineers's System Servicing/Diagnostic Software as including "customers that purchased an imaging system . . . as well as independent service organizations and [other] manufacturer service technicians that seek to acquire or obtain such access."[22]

A per-person, per-unit, per-year subscription is a price. A cooperative service agreement carrying license fees, training requirements, and a non-disclosure agreement is a set of terms. A service key issued for days or for a year under a license agreement is a term of years. And each declarant identifies the participants in the market for Servicing Works that includes competitors in the market for servicing: independent service organizations, in-house biomedical engineering departments, and other manufacturers. The Servicing Works at issue therefore do have independent value apart from the devices themselves. That value is captured through licensing—precisely the transaction that many service organizations contend the Exemption lets them avoid.

This is not wholly new to the Office. In the eighth rulemaking, the Register acknowledged that "the record suggests that some system features on certain devices may be separately licensed through a subscription service," but concluded nonetheless that the works had no independent value. The evidence now before the Office converts that passing acknowledgment into a documented, priced, and competitively contested market. A premise that was assumed on a thin record can no longer be assumed.

D. Servicing Works increasingly are not contained in the medical device at all

The Exemption by its terms reaches "[c]omputer programs that are contained in and control the functioning of a lawfully acquired medical device or system, and related data files." The evidence shows that some of the works the petitioners actually seek are not physically housed in the acquired medical device or system.

- Carestream's Maintenance-Related Documentation is stored on a web-based portal called the "Service Portal," along with a thumb drive option.[23]
- Philips stores Maintenance-Related Documentation nearly exclusively on a cloud server and not on the medical device and gates it through IST multifactor authentication against a cloud server, with an encrypted certificate valid only on the user's registered computer.[24]

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[20] Exhibit E, Arnaut Decl. ¶ 12.

[21] *Id.* ¶ 13.

[22] *Id.* ¶ 14.

[23] Exhibit A, Huntley Decl. ¶ 16.

[24] Exhibit E, Arnaut Decl. ¶¶ 17, 19.

- "For some Siemens Healthineers imaging devices, most of the System Servicing/Diagnostic Software is hosted on the cloud, separated physically from the imaging device and from the imaging device and from the Clinical Operational Software on the imaging device."[25] Maintenance-Related Documentation "usually stored in an electronic library on a website with certain access controls for non-public information."[26]

Works hosted on a manufacturer's remote infrastructure, reached through credentialed authentication, are not contained in a lawfully acquired device and do not control its functioning. To whatever extent the exemption is being read to authorize circumventing those remote systems, it is being read past its text. This new technological development warrants examining the renewal of the exemption on a developed record rather than readoption by attestation.

E. Lawful routes to these works exist and are in use

The petitions are framed on the premise that owners and independent servicers have no lawful path to the materials they need. The evidence does not bear that out.

- Carestream gives ISOs access to the System Servicing/Diagnostic Software and Maintenance-Related Documentation through a defined route — OEM service training plus a per-person, per-unit annual subscription — for servicers who hold no Carestream service agreement.[27]
- Philips furnishes Level 0 tools and basic maintenance manuals to any person, including independent service organizations, on request.[28] "The System Servicing/Diagnostic Software and Maintenance-Related Documentation are monetized through the license fees charged for Level 1 access as part of certain cooperative service agreements with hospital biomedical engineering departments, subject to service training and non-disclosure requirements, and they participate in a market that includes ISOs, other OEMs, and in-house biomeds — a market in which the FDA estimated in 2018 that over 16,000 firms perform medical device service in the United States."[29]
- Siemens Healthineers licenses its System Servicing/Diagnostic Software to other servicing organizations including customers that purchased the device, independent service

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[25] Exhibit E, Arnaut Decl. ¶ 6.

[26] *Id.* ¶ 17.

[27] Exhibit A, Huntley Decl. ¶¶ 12-14.

[28] Exhibit D, Dickson Decl. ¶ 12.

[29] *Id.* ¶ 25.

organizations, and other manufacturers' service technicians.[30] Maintenance-Related Documentation is also licensed to servicing organizations.[31]

TriMedx's own petition describes that route working. The single incident it recounts ended with access granted: "[o]nly after extended negotiations between Trimedx and the OEM was a resolution reached and necessary access to provide the required regulatory compliance services by Trimedx was obtained." TriMedx's objection is to the cost and difficulty of the negotiation, not to the absence of a lawful channel. That is a commercial grievance about the terms of a license, which is a different matter from being adversely affected in the ability to make a noninfringing use. Trimedx's own evidence therefore shows the market for the service works, the non-transformative use of the service works by the servicers, and the harm to the market for manufacturer's copyrighted service works if the Exemption were renewed without revising its overbroad scope.

V. THE PETITIONS CONFIRM THAT THE WORKS IN DEMAND ARE SERVICING WORKS

The petitions for renewal—like the original petitions in the eighth rulemaking and the renewal petitions in the ninth rulemaking—are expressly predicated on the distinction between Clinical Operation Software and Servicing Works. In the two initial rulemakings, the petitioners sought the exemption to permit the copying, not of operating software, but of "medical equipment servicing materials," including "diagnostic software and data files" and electronically stored service manuals and similar documentation. They do so here and now, as well.

TriMedx states that to provide service, it "must be able to access and utilize both the medical devices themselves and any related service materials, including software and computer programs, service manuals, diagnostic software, patches, and service keys," and that the restrictions it objects to "take many forms, including denial of access to service manuals, diagnostic and calibration software, proprietary software keys and licensing, restrictions on parts availability, specialized tools, and training." The incident it recounts concerned what it contends to be "necessary software keys required to perform assembly, installation, adjustment, and testing."

iFixit identifies the obstacles as "[s]ervice credentials, restricted diagnostic software, firmware authentication, component pairing, and manufacturer-controlled authorization," and its illustration is that after replacing a component "an owner or servicing technician may need restricted service software to run required tests, calibrate the replacement component, restore configuration data, or clear an error."

ImageOne points to "[p]assword-protected diagnostic software and restricted access to error logs and service data files." ECMS seeks "[a]ccess to software functions, diagnostic information, system

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[30] Exhibit E, Arnaut Decl. ¶ 14.

[31] *Id.* ¶ 20.

logs, error logs, and other related data files." Brown's Medical Imaging and Caylor Equipment Services each seek access to "software-generated error logs and diagnostic data." Crothall and its Intelas division state that "[a]ccess to software error logs is a critical function."

Mr. Shannon's submission recounts that Philips required an IST dongle to reach on-device software tools, and that a user needed "a Philips IST smartcard, a valid IST account, and the appropriate system entitlements"; that customer biomedical engineers received "only a restricted set of service documentation and software tools"; that certain tasks were placed at Level 2 for Philips field service engineers *and authorized trade partners*; and that service manuals were reclassified between CSIP levels. He describes "a mapping among CSIP level, IST entitlement, and the service level recognized by the software." Whatever one makes of his objection to that architecture, his account is direct evidence that the Servicing Works are gated separately from the clinical operation software and distributed under entitlement-based licenses.

Not one petitioner asks to circumvent the TPMs protecting software that a technologist uses to acquire an image, a clinician uses to deliver a diagnosis or therapy, or that is necessary to operate a system generally. Every petitioner asks to reach the manufacturer's diagnostic tools, calibration utilities, service keys, service credentials, and service documentation.

Thus, to fully respond to the petitions and the objections to the petitions, the Office must take as given that 37 C.F.R. § 201.40(b)(17) authorizes circumvention for purposes of accessing Service Works, which is what the petitioners and proponents all along have asked for, but which the D.C. Circuit found uncertain. On that assumption, the Office will have to undertake a new and separate fair-use analysis taking into account that the copyists are reproducing the Service Works to put them to the exact use for which they were created, in direct economic competition with the works' authors, in the exact market in which the authors themselves license and use the works. And to undertake this new analysis (which it has not previously undertaken), the Office must have a complete record.

Or if the Office disagrees with the premise that 37 C.F.R. § 201.40(b)(17) authorizes the circumvention that its proponents all along have requested, it must say so expressly, so the more limited scope of its fair-use analysis can be properly evaluated by the commenting public. More simply put, the Office must state clearly what it believes it is authorizing by renewing 37 C.F.R. § 201.40(b)(17), so the commenting public can properly evaluate the adequacy of the Office's fair-use analysis.

VI. WHY THE NEW EVIDENCE IS MATERIAL RATHER THAN CUMULATIVE

Although AdvaMed does not ask the Office to conduct the fair-use analysis in this phase, it sets out the following to show why the new evidence bears on the reliability of the prior record rather than merely restating arguments the Office has already weighed. For the same purpose—to demonstrate how and why the new evidence requires a full evaluation of the petitions—AdvaMed attaches its opening merits brief to the D.C. Circuit and incorporates fully the fair use arguments from that brief.

See **Exhibit F**, at 17, 27-55. As to each fair-use factor, the Librarian's prior analysis and findings rested on a factual premise that the new evidence contradicts as to Servicing Works.

A. First factor: for Servicing Works, the original purpose and the secondary use are identical

The Supreme Court held in *Andy Warhol Foundation for the Visual Arts v. Goldsmith* that "[i]f an original work and a secondary use share the same or highly similar purposes, and the secondary use is of a commercial nature, the first factor is likely to weigh against fair use, absent some other justification for copying." 598 U.S. 508, 532–33 (2023). The D.C. Circuit's contrary result *MITA IV* turned on the finding that servicers "put clinical operation software to a new use"[32] when they use it as a repair tool.

A diagnostic utility has no other use. Philips's service software exists "to perform various service tasks on the devices";[33] Siemens Healthineers's exists to run diagnostic tests, monitor component status, output error codes, and "support assembly, installation, adjustment, and calibration, in addition to testing and diagnosing a system for maintenance and repair."[34] Carestream's System Servicing/Diagnostic Software (e.g., detector and generator configuration and diagnostic applications) are used to check for system errors or malfunctions, access system diagnostic information and service logs, calibrate the device after a repair, troubleshoot errors, install software updates or patches, and verify that the device is functioning properly before it is returned to clinical use."[35] A servicer who uses those works to diagnose and repair a system is not adding a further purpose or a different character. The servicer is doing the one thing the work was authored to do, for a fee, in competition with the author. The Ninth Circuit reached exactly that conclusion on materially similar facts in *Triad Systems Corp. v. Southeastern Express Co.*, 64 F.3d 1330, 1337 (9th Cir. 1995), where the copyright owner "invented, developed, and marketed its software to enable its customers and its own technicians to service Triad computers," and the independent servicer was "getting a free ride when it use[d] that software to perform precisely the same service."

B. Fourth factor: there is a market, and the overbroad exemption operates directly on it

The Librarian's fourth-factor analysis depended on the absence of a market for the protected works, and thus the absence of a market harm. The evidence in Part V establishes the market for Service Works: license fees under cooperative service agreements, service keys issued for terms of days or a year under license agreements and service contracts, and annual per-person, per-unit subscriptions for service credentials and documentation. The purchasers in that market include the petitioners and

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[32] Med. Imaging & Tech. All. v. Libr. of Cong., No. 25-5328, slip op. at 15 (D.C. Cir. Sept. 1, 2026) ("*MITA IV*") https://media.cadc.uscourts.gov/opinions/docs/2026/09/25-5328-2190869.pdf.

[33] Exhibit D, Dickson Decl. ¶ 6.

[34] Exhibit E, Arnaut Decl. ¶ 6.

[35] Exhibit A, Huntley Decl. ¶ 6.

their peers, who use the Works to compete with the Works' authors in the machine servicing market. Circumvention substitutes for the license directly, and a use that "supplants any part of the normal market for a copyrighted work would ordinarily be considered an infringement." *Harper & Row, Publishers, Inc. v. Nation Enterprises*, 471 U.S. 539, 566–68 (1985) (quoting S. Rep. No. 94-473, p. 65 (1975)).

The D.C. Circuit's answer — that competition in the repair services market "does not itself demonstrate an adverse effect on the market for the original device or its clinical operation software, *which is the protected work*"[36] — is correct with respect to circumvention to copy Clinical Operation Software, but it is inapplicable to a Service Work that is sold or licensed in the separate servicing market. Where the protected work is a service tool, harm to the market for service tools is not a collateral effect in a downstream market. It is the harm the fourth factor asks about.

C. Second and third factors: no compelling justification has been offered, because none was requested

Where the first and fourth factors weigh against fair use, only "a particularly compelling justification" under the second and third factors can sustain the use. Warhol, 598 U.S. at 547. The Librarian gave the third factor "little weight," and the D.C. Circuit observed that no party had developed it in the relevant frame. No justification has been offered for copying Servicing Works in their entirety, because no one has yet been asked for one. That is a gap in the record, not a finding in the exemption's favor.

D. Section 117(c) marks the line Congress drew

Congress legislated on machine maintenance and repair and drew the line narrowly. Section 117(c) permits a copy made "solely by virtue of the activation of a machine," used "in no other manner" and "destroyed immediately after the maintenance or repair is completed." Service software tools are not copied by activating a machine, and service manuals are not computer programs at all. The fact that Congress addressed this subject and confined its exception to incidental activation copies is a reason for caution before a regulatory exemption is readopted, without a record, in a form that reaches well past software necessary to activate the machine.

VII. THE PETITIONS DO NOT SATISFY THE SHOWING THE STREAMLINED PROCEDURE REQUIRES

The showing required of a renewal petitioner is deliberately minimal, and AdvaMed does not suggest otherwise. But minimal is not nothing. The petitioner must supply a brief explanation of the continuing need for the exemption, resting on personal knowledge and experience relevant to the

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[36] *MITA IV*, slip op. at 15.

exemption it has selected, and must attest that nothing material has changed since the record that produced the exemption. Several of these petitions fall short of even that threshold, independent of the evidence set out above.

A. Summary of the deficiencies

Petitioner	What the petition actually describes	Principal deficiency
TriMedx Holdings	Denial of access to service manuals, diagnostic and calibration software, proprietary software keys and licensing; one incident within the past year, resolved by negotiation	Pleads an access and competition grievance rather than an adverse effect on noninfringing use; seeks renewal for "regulatory compliance," a purpose the codified exemption does not contain
Brown's Medical Imaging	Access restrictions that "can interfere" with service; error logs and diagnostic data	Conditional and general; identifies no technological measure actually circumvented and no instance of adverse effect
Crothall / Intelas	Ability to service "can be impacted by software access"; error logs are "a critical function"	Three operative sentences, entirely speculative
Caylor Equipment Services	Access restrictions affecting installed software, diagnostic information, and related data files	As posted, the declaration block shows a date but no legible name or signature
ImageOne Medical Group	Servicing Siemens PET/CT, CT, and MRI systems; password-protected diagnostic software and restricted error logs	Selects the consumer device repair exemption while describing medical imaging systems and requesting renewal of the medical device exemption
iFixit	Service credentials, restricted diagnostic software, firmware authentication, component pairing; hypothetical patient monitor and infusion pump examples	Rests on "repair advocacy and consultation" rather than personal knowledge and experience of medical device servicing
East Coast Medical Systems	Access to software functions, diagnostic information, system logs and error logs; servicers "may be unable" to complete repairs	Conditional throughout; no described instance of circumvention or adverse effect

Petitioner	What the petition actually describes	Principal deficiency
Marshall R. Shannon	Philips CSIP Level 0–2 architecture, IST smartcards, accounts, certificates and entitlements; commingled service environments; private litigation	Combines a renewal request with a substantial expansion request on the renewal form; see Part VIII

B. ImageOne selected a different exemption than the one it describes

The Office's renewal form directs petitioners to "[c]heck the appropriate box below that corresponds with the current temporary exemption … the petitioners seek to renew," and to "check only one box." ImageOne's petition selects the exemption for "Computer programs that control devices designed primarily for use by consumers for diagnosis, maintenance, or repair of the device," and it is posted on the Office's petition page under the device repair class. Its narrative, however, states that ImageOne "services and repairs Siemens PET/CT, CT, and MRI systems for imaging centers, hospitals, and cancer treatment facilities throughout Florida," and it closes by requesting "renewal of the current exemption for computer programs that control medical devices or systems, and related data files."

PET/CT, CT, and MRI systems are not devices designed primarily for use by consumers. The declarant's personal knowledge and experience therefore are not relevant to the exemption the petition selects, which is the specific compliance failure the Office has invited opponents to identify. AdvaMed takes no position in this submission on the consumer device repair exemption and addresses ImageOne here solely because its explanation of need and its closing request are directed at § 201.40(b)(17). To the extent the Office treats the ImageOne petition as directed at a different exemption, AdvaMed reserves its position and notes that the Office's instruction that "[e]ach submission must address only a single exemption" precludes AdvaMed from responding to that different class here.

C. iFixit's declaration does not rest on personal knowledge of medical device servicing

The Office requires that a renewal declaration "be based on the petitioner's personal knowledge and experience relevant to the exemption sought to be renewed." iFixit neither owns, operates, nor services medical devices. Its explanation of need is expressly founded on something else: "[b]ased on its repair advocacy and consultation with health equipment owners and repair professionals, iFixit believes that the need for the current exemption continues to exist." Its illustrations are framed conditionally and generically — what a technician "may need" after replacing "a failed battery, sensor, or control board in a patient monitor," or to "diagnose a fault or verify a repair in an infusion pump or medical-imaging system." No device, no facility, and no incident is identified.

AdvaMed does not question iFixit's good faith or the sincerity of its advocacy. The point is evidentiary. A belief formed from advocacy and from consultations with unnamed third parties is not the first-hand account the declaration form calls for, and it carries correspondingly little weight against the sworn, first-hand manufacturer testimony submitted with these comments. The Office noted in the ninth cycle that where petitioners file highly similar renewal petitions across proceedings, they should supply contemporary evidence of ongoing need and reliance. iFixit supplies none.

D. Caylor's declaration appears unsigned as posted

The Office requires that "[o]ne named petitioner must sign a declaration attesting to the continued need for the exemption and the truth of the supporting explanation." On the Caylor Equipment Services petition as posted, the declaration block carries a date of August 14, 2026, but the fields provided for the declarant's name, organization, and signature appear blank. AdvaMed raises this for the Office's verification rather than asserting it as established fact; the omission may be an artifact of the posted copy. If it reflects the filing itself, the petition does not satisfy the Office's declaration requirement.

E. TriMedx states a competition grievance, not an adverse effect on noninfringing use

TriMedx's petition is the most substantial of the eight, and it is candid about what it is asking for. Manufacturer service restrictions, it says, "are anti-competitive and designed to protect manufacturers' revenue, not to advance patient safety or public interest," and the exemption should be retained because it "protects competitive markets, ensures hospitals have genuine choice in service providers, enables regulatory compliance, and keeps medical devices in service."

Those are serious policy concerns, and they belong to agencies and to Congress. They are not the question 17 U.S.C. § 1201(a)(1)(C) puts to the Librarian, which is whether users of a copyrighted work are or are likely to be adversely affected in their ability to make noninfringing uses of a particular class of copyrighted works. A grievance about the price and terms on which a licensor sells is not a showing that the licensee cannot make a noninfringing use. To the contrary, it is a showing that a market exists but that the petitioner would prefer different terms in it.

Two further features of the TriMedx petition bear on this phase. First, it asks the Office to renew an exemption "for the purpose of diagnosis, maintenance, repair, and regulatory compliance of such devices." The codified exemption contains no regulatory compliance purpose, and § 201.40(b)(17)(i)–(ii) confine maintenance and repair to servicing or restoring a device so that it works in accordance with its original specifications. A petition that describes a broader activity than the exemption authorizes is, under the Office's own rule, to be considered solely as a renewal petition for the exemption as written. Second, the one concrete incident TriMedx recounts arose "[w]ithin the past year" and ended in access being granted after negotiation. That account demonstrates the existence of a functioning licensing market rather than the absence of one.

F. The remaining petitions are conditional and general

Brown's Medical Imaging, Caylor Equipment Services, Crothall and its Intelas division, and East Coast Medical Systems each submit short, generally phrased explanations in the conditional. Access restrictions "can interfere with timely and effective service"; the ability to service "can be impacted by software access"; servicers "may be unable to fully diagnose equipment problems." Brown's and Caylor share several operative sentences nearly verbatim. Crothall's explanation runs to three operative sentences and asks for "an extension" of the exemption rather than its readoption as codified. None identifies a technological measure actually encountered, an instance in which service could not be completed, or any reliance on the exemption during the current triennial period. The Office has said that "[c]onclusory opinions and speculation are insufficient" to defeat renewal; the same quality of showing cannot be sufficient to secure it, particularly against the evidentiary record submitted here.

VIII. OPPOSITION TO THE EXPANSION SOUGHT IN THE SHANNON PETITION

Mr. Shannon's submission is captioned "Petition to Renew and Supporting Statement and Petition for a New or Modified Exemption for Medical-Device Diagnosis, Installation, Maintenance, Repair, Calibration, and Return to Service." It combines a request to renew § 201.40(b)(17) with a request for a materially broader exemption. AdvaMed opposes the renewal request for the reasons given in Parts IV through VII. It opposes the expansion separately and for additional reasons.

A. The expansion is not properly before the Office in this phase

The notice of inquiry is unambiguous: "Only petitions requesting renewal of current exemptions as currently written in the Code of Federal Regulations, without modification, may be considered under the streamlined renewal procedure. Accordingly, a petitioner may not use a renewal petition to request new language or exempted activities for a current exemption. To the extent a renewal petition includes such requests, it shall be considered solely as a renewal petition." A petitioner seeking expansion "may submit both a petition to renew the existing exemption and a separate petition for a new exemption that focuses on facts relevant to the proposed expansion." The renewal form itself repeats the instruction: "[y]ou must also submit the new exemption petition form to petition to expand or modify a current exemption."

Mr. Shannon acknowledges the rule. His submission states that he "understands that the Copyright Office requires separate forms for (1) renewal of an existing exemption as currently written and (2) any proposed new or modified exemption," and that "the fuller legal and evidentiary record for a proposed new or expanded exemption is developed during the later public-comment phase." No corresponding petition for a new exemption covering this subject matter appears among the new-exemption petitions the Office has posted, and the Office has indicated that it will consider his submission "as a renewal petition." The expansion request should accordingly be given no effect in this phase. AdvaMed addresses its substance below solely to preserve its objection.

B. The proposed class includes multiple classes of works with distinct markets, TPMs, and Public Policy Implications

The petition proposes the following class: "Computer programs that operate, control, diagnose, monitor, configure, calibrate, install, service, maintain, test, or restore medical devices or systems, including related service interfaces, logs, configuration data, certificates, credentials, utilities, and technical materials, when circumvention is performed by the owner or an authorized service provider solely for lawful diagnosis, installation, maintenance, repair, calibration, cybersecurity, or return to service."

The proposal begins with programs that "operate" and "control" medical devices and ends with "technical materials" generally. It thus merges into one class the two categories of work this comment asks the Office to keep apart, and it does so at the moment the D.C. Circuit in *MITA IV* has made the distinction dispositive. It also abandons the textual limits of the current exemption, which reaches only programs "contained in and control[ling] the functioning of" the device and the data files related to them. Nothing in the prior rulemaking record supports any of this, which is why it would require a new petition and a new record.

C. The proposal reaches activities the current exemption's definitions exclude

Section 201.40(b)(17) defines its own scope. "Maintenance" is "the servicing of the device or system in order to make it work in accordance with its original specifications and any changes to those specifications authorized for that device or system," and "repair" is "the restoring of the device or system to the state of working in accordance with" those same specifications. The petition asks the Office to cover "owner-authorized installation, reinstallation, software setup, operating-system and application restoration, relocation, commissioning, calibration, performance verification, service-data access, cybersecurity-related reconfiguration, and return to service for new, used, and resold medical devices," and states that the exemption "should not be limited to replacing a failed component."

Installing and commissioning a resold system that was never working to a specification in the petitioner's hands is not restoring it to its original specification. Reconfiguring a device's security posture is not servicing it to its original specification either. These are new activities, not clarifications of old ones, and the petition itself concedes as much by describing them as a "clarification or modified exemption." The Office's rule assigns such requests to the new-petition track precisely so that a record can be made about their effects.

D. The proposal exceeds the Librarian's authority

The triennial rulemaking, as the notice of inquiry states, "addresses only the prohibition on circumvention of access controls; the statute does not grant authority to adopt exemptions to the anti-trafficking provisions of sections 1201(a)(2) or 1201(b)." The proposed class expressly includes "certificates, credentials," and the petition asks that covered circumvention encompass the

"creation, modification, replacement, renaming, movement, reset, restoration, or deletion of files, registry entries, certificates, credentials, settings, scheduled tasks, or network destinations."

An exemption framed around creating and substituting credentials and certificates — the very artifacts that constitute the access control — is not within an authority under § 1201(a)(1). The manufacturer evidence in Part IV is directly relevant:

- **Exhibit A** [Carestream] - the SecureLink credential is the technological measure;
- **Exhibit B** [GE HealthCare] – the technological measures include Secure Service Access (SSA) Keys which can be physically distributed in the form of a USB key with a Digi code (SS hard keys) or remotely installed (SSA license key);
- **Exhibit C** [Hologic] – the technological measures include license keys and license controls/management;
- **Exhibit D** [Philips] - an encrypted, time-limited, user-specific certificate and smartcard are among the technological measures; and
- **Exhibit E** [Siemens Healthineers] – Technological measures include a service key, which is typically generated using information pertaining to the device or based on information provided via a dongle.

A rule permitting these to be created, replaced, or reset at will would not be an exemption from the prohibition on circumventing an access control. It would be authorization to manufacture the key.

E. The remote-monitoring request raises questions this proceeding cannot answer

The petition asks that an owner or servicer "be permitted to disable, block, reconfigure, or remove remote monitoring, automatic uploads, SMTP destinations, credentials, certificates, scheduled tasks, and related pathways." Those pathways carry device status notifications, error logs, utilization information, and service events. Whether they may be disabled, and by whom, implicates device performance monitoring, cybersecurity, and the manufacturer's own obligations with respect to the devices it has placed into service (e.g., FDA post-market surveillance). It is not a question about access to a copyrighted work, and no record in this proceeding addresses it. The Office should decline to reach it.

F. The "commingling" theory asks for a rule of decision, not an exemption

A substantial portion of the petition asks the Office to adopt principles governing liability rather than to define a class of works. It asks the Office to "separate access from use"; to hold that "[e]ntering a combined service environment should not create an irrebuttable presumption that the servicer opened, copied, or used every protected work available within that environment"; to direct that a software reload "should not, by itself, support an inference of evidence destruction"; to convene "a formal stakeholder meeting, technical conference, roundtable, evidentiary hearing, or other

proceeding"; and to preserve a record for congressional review of whether "additional statutory protections, fee-shifting, a safe harbor, an enforcement mechanism, or formal coordination are needed."

Section 1201(a)(1)(C) directs a prospective, class-based determination about the succeeding three-year period. It does not authorize the Librarian to allocate burdens of proof, to create presumptions about what a litigant accessed, to establish safe harbors, or to shift fees. The Office has said plainly that the streamlined proceeding "is not a forum to litigate other concerns," and that opposition comments should not address "whether any user's activities may or may not be consistent with the exemption" as codified. That constraint binds proponents as much as opponents. AdvaMed accordingly does not respond to the characterizations of particular disputes in the petition, and asks the Office not to rest any determination on them.

The petition is also closely bound up with its author's own litigation. It describes Philips North America LLC v. Image Technology Consulting, LLC, No. 3:22-cv-00147 (N.D. Tex.), in which Mr. Shannon is a named defendant and in which he states that a "prior judgment and injunction" has been entered; correspondence from opposing counsel; a separate action against a different servicer; and a declaratory judgment action he filed on April 21, 2026, docketed as No. 3:26-cv-01276 (N.D. Tex.). A triennial exemption is not a vehicle for revisiting an adjudicated dispute, and in any event an exemption to § 1201(a)(1) would not answer the contract, trade secret, and computer-access claims his materials describe.

G. The petition's own evidence supports AdvaMed's position on the dispositive fact

One part of the petition deserves the Office's particular attention, because it is the most detailed account in this docket of how the works at issue are actually controlled — and it comes from a petitioner. Mr. Shannon contends that a Philips service pack "would thereafter be required to access on device software tools," that users "would need a Philips IST smartcard, a valid IST account, and the appropriate system entitlements," that "customer biomedical engineers would receive only a restricted set of service documentation and software tools," that certain tasks were "placed at Level 2 for Philips field service engineers *and authorized trade partners*," and that service manuals were reclassified from one CSIP level to another. He describes "a mapping among CSIP level, IST entitlement, and the service level recognized by the software," and objects that "a user may therefore confront one technological gate controlling multiple layers of service functionality."

His objection is to the architecture. But his description of it is evidence, and it corroborates the manufacturer declarations on every material point: the servicing tools and service documentation sit behind a manufacturer-administered technological measure distinct from the clinical login; access is granted by entitlement level; and the levels are tied to training, authorization, and contractual status. That is a separately controlled, separately licensed body of works. It is the proposition the D.C. Circuit held had never been established in *MITA IV*, offered here by a proponent of the exemption.

H. Disposition requested

The Office should consider the Shannon submission solely as a petition to renew § 201.40(b)(17) as currently written, give no effect to the expansion requested within it, and decline to renew on the grounds set out in Parts IV through VIII.

IX. RELIEF REQUESTED

For the reasons set out above, AdvaMed respectfully requests that the Office take the following actions.

First, find that these comments and exhibits constitute meaningful opposition and decline to recommend renewal of 37 C.F.R. § 201.40(b)(17) under the streamlined procedure. The comments present evidence in each of the three categories the notice of inquiry identifies: a change in case law affecting whether the use is noninfringing, a technological development affecting the availability for use of the works, and new business models affecting the market for and value of those works.

Second, and in the alternative, exercise the authority the Office has reserved to consider "whether opposition evidence casts doubt only as to renewal of part of a current exemption," and decline streamlined renewal as to System Servicing / Diagnostic Software, service keys and service credentials, and Maintenance-Related Documentation that are protected by technological measures separate from those controlling the clinical operation software and that are licensed or sold separately from the device. The Appendix offers illustrative regulatory language for that purpose.

Third, treat the petitions for System Servicing / Diagnostic Software, service keys and service credentials, and Maintenance-Related Documentation as petitions for a new exemption in the public comment phase, as section III of the notice of inquiry contemplates, so that a substantive record can be developed on the questions the prior record does not answer.

Fourth, consider the submission of Marshall R. Shannon solely as a renewal petition and give no effect to the expansion requested within it.

Fifth, identify in the notice of proposed rulemaking, for comment during the public comment phase, the legal and factual issues framed here:

- how system Servicing Works (Servicing / Diagnostic Software and Maintenance-Related Documentation) should be classified relative to Clinical Operation Software;
- whether the technological measures protecting Servicing Works are separate from the technological measures protecting Clinical Operation Software, a separate class of works;
- the existence, structure, and economics of the market in which access to Servicing Works is licensed or otherwise monetized, including who are the participants within the market;

- the significance of hosting Servicing Works off of the lawfully acquired medical device or system on manufacturer-controlled infrastructure; and
- the fair-use consequences of the answer to each of the foregoing issues under *Andy Warhol Foundation for the Visual Arts v. Goldsmith*.

X. EVIDENCE SUBMITTED WITH THESE COMMENTS

AdvaMed submits the declarations in Exhibits A-E, each made on the declarant's personal knowledge by an individual with operational responsibility for servicing the declarant company's medical devices.

Respectfully submitted,

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September 28, 2026

Appendix: Illustrative Narrowing Language

If the Office concludes that the prior record remains reliable as to clinical operation software but not as to the works described in Part V, it may address the difference by adding a third definitional paragraph to the exemption. AdvaMed offers the following as illustrative rather than final, and would welcome the opportunity to refine it on a developed record.

> *(iii) This paragraph (b)(17) does not apply to computer programs, applications, diagnostic or calibration utilities, service interfaces, or data files, or to maintenance-related documentation, that are both (A) protected by a technological measure separate from the technological measure that controls access to the computer programs used by health care personnel to operate the device or system for patient care, and (B) made available by the manufacturer under a license, lease, subscription, service key, or service agreement separate from the sale or lease of the device or system.*

Language of this kind would preserve the exemption in the form the D.C. Circuit evaluated — as applied to the Clinical Operation Software embedded in a device the user lawfully acquired — while leaving the separately controlled and separately licensed Servicing Works to be addressed on a record built for that purpose.

EXHIBITS

Exhibit	Description	Subject
Exhibit A	Declaration of Garrett Huntley, Senior Director of Federal and Service Solutions, **Carestream Health, Inc.**	Service and diagnostic applications; SecureLink multifactor service credentials; Service Portal documentation; per-person, per-unit annual subscriptions for third-party service personnel who successfully complete OEM training.
Exhibit B	Declaration of Jerome Duhamel, Global Service Operations GM of GE Medical Systems SCS (an affiliate of "**GE HealthCare**")	Service and diagnostic applications; Secure Service Access keys (SSA keys): USB key with a Digi code (SSA hard keys) & remotely installed (SSA license keys); Tiered licensing of service software and documentation.
Exhibit C	Declaration of Pierre Malboeuf, Vice President, Service Delivery, **Hologic Inc.**	System Servicing/Diagnostic Software licensed to third-party servicing personnel who undergo factory training
Exhibit D	Declaration of Jacqueline Dickson, CSIP Services Operations Director, **Philips**	Tiered service software and documentation; Integrated Security Tool certificates, smartcards, and entitlements; licensing of Level 1 access under cooperative service agreements; cloud storage of service documentation
Exhibit E	Declaration of Goncalo Arnaut, Head of Customer Services for North America, **Siemens Healthineers**	System servicing and diagnostic software; service keys and dongles; separate clinical operator logins; leasing and licensing of service access to owners and servicing organizations; cloud hosting
Exhibit F	Appellants' Opening Brief, *Advanced Med. Tech. Ass'n v. Libr. of Cong.*, No. 25-5328 (D.C. Cir. filed Nov. 7, 2025).	To demonstrate how and why the new evidence requires a full evaluation of the petitions, AdvaMed attaches its opening merits brief to the D.C. Circuit and incorporates the fair use arguments from that brief fully into these comments. See pp. 17, 27-55.

EXHIBIT A

Declaration submitted in support of Comments from:

Advanced Medical Technology Association (AdvaMed)
1301 Pennsylvania Ave NW, Ste 400
Washington, DC 20004

DECLARATION OF GARRETT HUNTLEY

I, Garrett Huntley, declare as follows based on my personal knowledge:

I. DECLARANT AND COMPANY BACKGROUND

1. I am the Senior Director of Federal and Service Solutions for Carestream Health, Inc. ("Carestream"). I have held this position since 2024. My responsibilities include sale and revenue generation for Carestream's break/fix service business, biomedical and clinical applications training offerings .

2. I have 10 years of experience in contract management, medical imaging equipment sales, and medical imaging equipment service and support. In my role, I am familiar with Carestream's medical devices, clinical operation software, system servicing and diagnostic software, Maintenance-Related Documentation, access controls, licensing practices, and service offerings described below.

3. Carestream develops, manufactures, sells, and/or leases Digital radiography equipment and systems, and associated detectors and generators, along with other medical imaging equipment, used for general clinical purposes, including diagnostic imaging in patient care.

II. RELEVANT SOFTWARE AND MATERIALS

4. As used in this declaration:

(a) "Clinical Operation Software" means software that health care professionals use to operate a medical device to perform patient care activities;

(b) "System Servicing/Diagnostic Software" includes software applications, diagnostic tools, calibration programs, configuration utilities, service interfaces, and related digital resources used to install, inspect, calibrate, test, maintain, diagnose, troubleshoot, update, or repair a medical device to its intended performance and safety specifications; and

(c) Maintenance-Related Documentation is non-software, digital work used for servicing, such as digital service manuals or repair procedure documentation.

5. Carestream uses Clinical Operation Software on its DRX line of X-ray imaging solutions to enable clinicians to acquire, review, and manage diagnostic images and operate the imaging system for patient care. That software includes the Carestream Main Application.

6. Carestream uses System Servicing/Diagnostic Software for those devices. Some of that service and diagnostic software is integrated with the Carestream Main Application, and other service and diagnostic software is managed as standalone applications, such as detector and generator configuration and diagnostic applications. This software is used to check for system errors or malfunctions, access system diagnostic information and service logs, calibrate the device after a repair, troubleshoot errors, install software updates or patches, and verify that the device is functioning properly before it is returned to clinical use.

III. TECHNOLOGICAL PROTECTION MEASURES (TPMs) & DIFFERENTIAL ACCESS

7. Access to Carestream's System Servicing/Diagnostic Software is controlled by a technological protection measure that Carestream refers to as "SecureLink." Access to the service and diagnostic applications requires both a service multi-factor authentication (MFA) device and a password that are unique to each individual service engineer. The USB MFA device contains an encrypted file identifying the service engineer.

8. These TPMs are separate and apart from the protections or controls governing access to the Clinical Operation Software. Carestream service access is unique to Carestream-issued service credentials and the SecureLink MFA device, while clinical users access the Clinical Operation Software using Windows authentication, with optional proximity badge multi-factor authentication.

9. Access to the Clinical Operation Software is controlled by Windows authentication and optional proximity badge MFA, which is administered by the healthcare facility that owns or leases the device and its information technology personnel. By contrast, access to the System Servicing/Diagnostic Software is controlled by the SecureLink service key and the unique service engineer password associated with it, which are issued and administered by Carestream.

10. A person who has authorized access to the Clinical Operation Software does not thereby receive authorized access to the System Servicing/Diagnostic Software. To obtain such access, the person or organization must complete Carestream OEM service training and obtain SecureLink credentials from Carestream, either under an OEM service agreement with Carestream or, in the case of service providers that do not hold a Carestream service agreement, by sending individual field engineers to Carestream OEM service training and paying an annual subscription assessed on a per-person, per-unit basis.

11. These access controls serve to maintain patient safety, cybersecurity control, device integrity, and protect proprietary materials.

IV. LICENSING, SERVICE OFFERINGS, AND DISTINCT MARKET

12. The System Servicing/Diagnostic Software resides on the medical device and is not sold as a standalone product. Carestream provides *access* to this software separately from the sale or lease of the device, through the SecureLink service key and through Carestream's Service Portal. Service Portal and SecureLink access is provided to OEM-trained device owners, channel partners, independent service organizations (ISOs) and multi-vendor service (MVS) personnel contracted to service Carestream equipment.

13. This access to the software is offered both through OEM service agreements and through licensing. Customers who purchase OEM service agreements and who are OEM-trained on the equipment have access via Carestream's SecureLink service key. Other service providers that do not have service agreements with Carestream but service or maintain Carestream equipment, including ISOs and MVS organizations, may send individual field engineers to Carestream OEM service training and pay a yearly subscription on a per-person, per-unit basis to obtain these credentials. The access provided includes the SecureLink service key and credentials, and access to the Service Portal and its Maintenance-Related Documentation described below.

14. The market for these products and services includes biomedical engineers, channel partners, and ISO and MVS field engineers. Carestream competes in servicing and repairing medical devices, including its own, primarily with the third-party service providers, in the form of ISOs and MVS organizations, including MVS organizations operating within competing equipment OEMs such as GE, Philips, and Siemens (Block).

15. Customers can only be assured they are receiving quality maintenance and repair services on their System Servicing/Diagnostic Software if their service personnel have completed Carestream OEM service training and acquired SecureLink credentials and Service Portal access.

V. MAINTENANCE-RELATED DOCUMENTATION

16. Carestream provides extensive Maintenance-Related Documentation to OEM-trained field service engineers. It includes maintenance documentation; service bulletins; software and firmware update information; modification and installation instructions; service documentation, in the form of process checklists, manuals, diagnostic guides, and parts lists; user guides, best practices information, new version release notes; and acceptance and compliance test procedures.

17. This documentation is provided through a web-based portal called the "Service Portal", along with a thumb drive option. It is therefore maintained separately from the Clinical Operation Software and the System Servicing/Diagnostic Software that resides on the device and is accessed through a Carestream-hosted portal rather than through the device's clinical interface.

18. The documentation in the Service Portal is used by OEM-trained field service professionals who maintain SecureLink credentials. They may access the portal at any time, and the portal can

be used to download information or for real time assistance during service, installation, or preventive maintenance activities. The Service Portal provides the same level of detail to outside OEM-trained field service engineers as is supplied to Carestream OEM field engineers.

19. Access to this documentation is controlled by TPMs: the Carestream Service Portal is password protected, and the SecureLink service key requires password authentication. These measures are separate and apart from the protections governing the Clinical Operation Software because Service Portal and SecureLink credentials are issued and controlled by Carestream and are conditioned on completion of Carestream OEM service training. Access to the Clinical Operation Software is controlled by Windows authentication and optional proximity badge MFA administered by the healthcare facility.

VI. UNAUTHORIZED ACCESS [AND PRACTICAL EFFECTS]

20. Carestream developed SecureLink in-house to protect against unauthorized use of, or infringement relating to, its equipment and service resources. Enforcement is contractual, based on agreements with customers and trained service providers who receive the SecureLink passwords after completion of Carestream certified training.

21. Unauthorized circumvention of the TPMs described above would permit persons who have not completed the proper Carestream OEM service training, and who are not subject to the contractual terms under which SecureLink credentials and Service Portal access are granted, to access the System Servicing/Diagnostic Software and Maintenance-Related Documentation, putting patient safety at risk.

VII. CONCLUSION

23. The Clinical Operation Software, System Servicing/Diagnostic Software, and Maintenance-Related Documentation described above are distinct in function and subject to distinct access controls: the Clinical Operation Software is protected by Windows authentication and optional proximity badge MFA administered by the healthcare facility, while the System Servicing/Diagnostic Software and Maintenance-Related Documentation are protected by the SecureLink MFA device, unique service engineer passwords, and by password-protected Service Portal credentials, issued and administered by Carestream.

24. The System Servicing/Diagnostic Software and Maintenance-Related Documentation are monetized through OEM service agreements and through annual per-person, per-unit subscriptions paid by service providers that complete Carestream OEM service training.

25. Allowing improperly trained service personnel to service and repair sophisticated diagnostic equipment is a patient safety risk.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed on September 25, 2026, in Rochester, New York.

Garrett Huntley Digitally signed by Garrett Huntley
Date: 2026.09.25 15:29:38 -04'00'

Garrett Huntley
Senior Director of Federal and Service Solutions
Carestream Health, Inc.

EXHIBIT B

Declaration submitted in support of Comments from:
Advanced Medical Technology Association (AdvaMed)
1301 Pennsylvania Ave NW, Ste 400
Washington, DC 20004

DECLARATION OF JEROME DUHAMEL

I, Jerome Duhamel, declares as follows based on my personal knowledge:

I. DECLARANT AND COMPANY BACKGROUND

1. I am the Global Service Operations GM of GE Medical Systems SCS (an affiliate of "GE HealthCare"). I lead our global service operations Center of Excellence across service delivery, commercial enablement, digital platforms, business operations, business intelligence and service productivity.

2. I have 20 years of experience in GE HealthCare product service. In my role, I am familiar with the company's medical devices, Clinical Operation Software, System Servicing/Diagnostic Software, Maintenance-Related Documentation, access controls, licensing practices, and service offerings described below.

3. GE HealthCare develops, manufactures, sells, and/or leases imaging devices in MR, PET, CT, MI, Xray, and Ultrasound used for diagnostic and interventional procedures.

II. RELEVANT SOFTWARE AND MATERIALS

As used in this declaration:

(a) "Clinical Operation Software" means software that health care professionals use to operate a medical device to perform patient care activities;

(b) "System Servicing/Diagnostic Software" includes software applications, diagnostic tools, calibration programs, configuration utilities, service interfaces, and related digital resources used to install, inspect, calibrate, test, maintain, diagnose, troubleshoot, update, or repair a medical device to its intended performance and safety specifications; and

(c) "Maintenance-Related Documentation" is documentation used for servicing, such as service manuals or repair procedures.

4. GE HealthCare uses Clinical Operation Software on all products to enable clinicians to operate the device.

5. GE HealthCare uses System Servicing/Diagnostic Software for above mentioned devices, including Common Service Desktop. This software is used to view logs, test, calibrate, configure, troubleshoot, update or verify performance of the device.

III. TECHNOLOGICAL PROTECTION MEASURES (TPMs) AND DIFFERENTIAL ACCESS

6. Access to the System Servicing/Diagnostic Software is available on the device with no access restriction for all logged users for Class A1 tools (referred to externally as General Service) and controlled by Secure Service Access keys (SSA keys) which can be physically distributed in the form of a USB key with a Digi code (SSA hard keys) or remotely installed (SSA license key).

7. These TPMs are separate and apart from the protections or controls governing access to the Clinical Operation Software because they govern access levels to the Common Service Desktop only. Clinical Operations Software is accessible to any user once logged in. Common Service Desktop has a range of tools: Class A (referred to externally as General Service) for general service required by regional laws and regulations (e.g., AIAT regulations in the U.S. and regional laws) required to return the equipment to an operational state in accordance with GE HealthCare specifications (e.g., basic startup/installation instructions and AIAT guidelines or equivalent). Class A is available publicly, including to independent service organizations (Class A1 service software is accessible on the device without needing any additional keys or licenses; Class A2 and A3 service software is licensed on request with some regions charging a reasonable fee and others, like the U.S., providing the license at no additional charge). Class C (externally referred to as Technical Service) contains productivity and efficiency software and is only made available via sale and license to entitled customers and channel partners under contract with GE HealthCare. Finally, Common Service Desktop contains Class M software (externally referred to as GE HealthCare Highly Confidential) that is for GE HealthCare internal use only or has been identified as a GE HealthCare trade secret. Class M may be made available to channel partners under a channel partner agreement with GE HealthCare in some regions outside the U.S.

8. Access to the Clinical Operation Software is controlled by user credentials which are administered by the customer. By contrast, access to the System Servicing/Diagnostic Software Class C and M are controlled by the type of physical SSA USB key or digital license key installed in the system; by default, all Class A1 software will be accessible and other levels of software will be enabled based on installed key access level.

9. A person who has authorized access to the Clinical Operation Software does receive access to Class A1 System Servicing/Diagnostic Software by default; those tools are used for daily calibration activities such as tube calibration or warm up. For elevated access, the person or organization must license the key from GE HealthCare as described in Section 7 above.

10. These access controls serve purposes including, for example, safety of operation, system integrity, subscription-based offering, and protection of proprietary material.

IV. LICENSING, SERVICE OFFERINGS

11. GE HealthCare licenses access to its System Servicing/Diagnostic Software separately from the sale or lease of the device. Access to Class A2/A3 is made available to any customer or independent service organization through licensing. Access to Class C1/C2/C3 is made available to any customer through a service agreement or licensing.

12. The consideration charged for such access depends on the commercial policy of the country. The access provided may include licenses to Common Service Desktop restricted tools, training and/or support.

13. Customers may obtain maintenance or repair services through GE HealthCare, independent service organizations, their in-house service departments, and sometimes other manufacturers. If additional software access or expertise is required beyond the access already provided in Class A1, those parties can contact GE HealthCare to determine what licensing options are available.

V. MAINTENANCE-RELATED DOCUMENTATION

14. GE HealthCare publicly provides Maintenance-Related Documentation that includes detailed Class A1 service manuals containing step by step procedures, schematics and pictures on its online manual & documents website: https://www.gehealthcare.com/en-us/support/manuals

15. Clinical Operation Software and System Servicing/Diagnostic Software are documented in the product User/Operator manual and Service Manual, both available on the above website.

16. Maintenance-Related Documentation is used by operators, independent service organizations, GE HealthCare's channel partners and GE HealthCare when operating, installing or servicing the equipment.

17. Access to Class A1 documentation is public just like Clinical Operation documentation (also called operator manual).

18. GE HealthCare licenses access to Class A2/A3/C1/C2/C3 documentation, which GE HealthCare makes available and conditioned to an active licensing or service agreement.

VI. UNAUTHORIZED ACCESS AND PRACTICAL EFFECTS

19. GE HealthCare has encountered unauthorized access, distribution and use involving System Servicing/Diagnostic Software or Maintenance-Related Documentation. GE HealthCare

enforces against unauthorized use of its System Servicing/Diagnostic Software, SSA keys and Maintenance-Related Documentation through means such as cease-and-desist letters.

20. Unauthorized circumvention of the TPMs described above could grant unauthorized access to systems and compromise system integrity which could in turn compromise operator and patient safety and lead to wrong diagnosis.

VII. CONCLUSION

21. The Clinical Operation Software, System Servicing/Diagnostic Software, and Maintenance-Related Documentation described above are distinct in function and are subject to distinct access controls. Clinical Operation Software and Class A1 System Servicing/Diagnostic Software is controlled through user login. Access to Class A2/A3/C1/C2/C3 is dependent on the license key installed in the system. Access to Class M is limited to GE Healthcare internal as it is deemed highly confidential. As noted above, in some regions outside the U.S., Class M may be made available to channel partners under an agreement with GE HealthCare.

22. Class A2/A3/C1/C2/C3 System Servicing/Diagnostic Software and/or Maintenance-Related Documentation is made available through licenses or service agreements, and servicing of medical devices is performed by GE HealthCare, its channel partners, independent service organizations, in-house service departments of end-users, and other manufacturers.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed on September 28th, 2026, in Buc, France

Signature: _____

Print Name: Jerome Duhamel

Title: Global Service Operations GM

Company Name: GE Medical Systems SCS

EXHIBIT C

Declaration submitted in support of Comments from:

Advanced Medical Technology Association (AdvaMed)
1301 Pennsylvania Ave NW, Ste 400
Washington, DC 20004

DECLARATION OF PIERRE MALBOEUF

I, Pierre Malboeuf declare as follows based on my personal knowledge:

I. DECLARANT AND COMPANY BACKGROUND

1. I am the Vice President, Service Delivery of Hologic Inc. ("Hologic"). I have held this position since 2023. My responsibilities include service delivery of Hologic Technical and Field Service support to both customers and Hologic personnel. Product and software design are inherent to the products Hologic manufactures, distributes, and services.

2. I have 29 years of experience in Service Operations and Field Services. In my role, I am familiar with the company's medical devices, clinical operation software, system servicing and diagnostic software, Maintenance-Related Documentation, access controls, licensing practices, and service offerings described below.

3. Hologic develops, manufactures, sells, and/or leases innovative medical technologies that effectively detect, diagnose and treat health conditions used for disease detection in breast health, gynecological health, sexual health, body composition, and skeletal health.

II. RELEVANT SOFTWARE AND MATERIALS

As used in this declaration:

(a) "Clinical Operation Software" means software that health care professionals use to operate a medical device to perform patient care activities;

(b) "System Servicing/Diagnostic Software" includes software applications, diagnostic tools, calibration programs, configuration utilities, service interfaces, and related digital resources used to install, inspect, calibrate, test, maintain, diagnose, troubleshoot, update, or repair a medical device to its intended performance and safety specifications; and

(c) "Maintenance-Related Documentation" is non-software, digital work used for servicing, such as digital service manuals or repair procedure documentation.

4. Hologic uses Clinical Operation Software on Breast Health platforms to enable clinicians to diagnose and treat breast cancer.

5. Hologic uses System Servicing/Diagnostic Software for those devices, including company-designed calibration and software service tools. This software is used to assist the service

technician in problem diagnosis, calibration assistance, and allows for the calibration of the mechanical and imaging sections of the product.

III. TECHNOLOGICAL PROTECTION MEASURES (TPMs) AND DIFFERENTIAL ACCESS

6. Access to the System Servicing/Diagnostic Software is controlled by passwords, license keys, license controls.

7. These TPMs are separate and apart from the protections or controls governing access to the Clinical Operation Software because they are separate software applications and have different access controls.

8. Access to the Clinical Operation Software is controlled by passwords and license controls controlled by clinical users. By contrast, access to the System Servicing/Diagnostic Software is controlled by passwords, license keys, license controls, and USB security devices.

9. A person who has authorized access to the Clinical Operation Software does not thereby receive authorized access to the System Servicing/Diagnostic Software. To obtain such access, the person or organization must contact Hologic Technical Support, where credentialing is verified for proper access allowance and safety control.

10. These access controls serve purposes including safety, system integrity, cybersecurity, protection of proprietary materials, and license management.

IV. LICENSING, SERVICE OFFERINGS, AND DISTINCT MARKET

11. Hologic can sell or provide access to its System Servicing/Diagnostic Software separately from the sale or lease of the device. Access is offered to factory-trained and authorized service personnel through service program offerings which provide credentialing.

12. The consideration charged for such access is determinable across type of customer, access needed, and other economic factors of install base support scale. The access provided may include calibration guided assistance as well as access to troubleshooting reference materials.

13. The market for these works and services includes hospital service personnel (BMETs) or third-party authorized service providers. Hologic competes in servicing and repairing these devices with other OEMs and ISOs, including GE Healthcare, Siemens Healthcare, Trimedix, Crothall, 626 Holdings, Cassling, Aramark, and Frontier.

14. Customers may obtain maintenance or repair services through OEM service or ISO service. If additional authorized software access or expertise is required, customers may request a limited use license via one-time charge or provide credentialing that entitles access via factory-provided technical instruction.

V. MAINTENANCE-RELATED DOCUMENTATION

15. Hologic provides Maintenance-Related Documentation that includes Service Manuals, User Manuals, Quality Control Manuals and required safety updates.

16. This documentation is stored in hard copy format with every shipped product. Relative to the Clinical Operation Software and System Servicing/Diagnostic Software, it is separated at the product level.

17. The documentation is used by authorized service providers when performing service and calibration requirements and for the purpose of restoring or maintaining the product to the manufacturer's specifications.

18. Access to this documentation is controlled by passwords and license controls. These measures are separate and apart from protections governing Clinical Operation Software because they are separate from the clinical software and are distinct from both clinical and service operations.

19. Hologic offers factory authorized training and credentialing access to this documentation through various entitlements based on customer need, demand, and partnership in post-warranty agreements.

VI. UNAUTHORIZED ACCESS AND PRACTICAL EFFECTS

20. Unauthorized circumvention of the TPMs described above could jeopardize system integrity, calibration of radiation releasing components, and provide for unsafe patient conditions.

21. Authorized access to System Servicing/Diagnostic Software and Maintenance-Related Documentation is available through factory-provided service manuals, and via factory-authorized training and license access subject to conditions of Hologic Learning and Development.

VII. CONCLUSION

24. The Clinical Operation Software, System Servicing/Diagnostic Software, and Maintenance-Related Documentation described above are distinct in function and are subject to different and distinct access controls.

25. System Servicing/Diagnostic Software and/or Maintenance-Related Documentation is monetized through Hologic Surecare Agreements and participants in this market that include direct customers, third-party service providers, and OEMs.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed on 9.24.26 in Pittsburgh, PA

/s/ *Pierre Malboeuf*

Pierre Malboeuf
Vice President, Service Delivery
Hologic, Inc.

EXHIBIT D

Declaration submitted in support of Comments from:

Advanced Medical Technology Association (AdvaMed)
1301 Pennsylvania Ave NW, Ste 400
Washington, DC 20004

DECLARATION OF JACQUELINE DICKSON

I, Jacqueline Dickson, declare as follows based on my personal knowledge:

I. DECLARANT AND COMPANY BACKGROUND

1. I am the CSIP Services Operations Director of Philips North America LLC ("Philips"). I have held this position since 2024. My responsibilities include oversight and support relating to service governance, access management, investigations, compliance activities, and cross-functional escalation management. These responsibilities require regular interaction with personnel from service, cybersecurity, privacy, legal, regulatory, and business organizations, and provide me with direct knowledge of the policies, procedures, and operational controls relevant to the matters discussed in this declaration.

2. I have 22 years of experience in service operations related to medical devices, with a focus on governance and administration of service documentation and service applications. In my role, I am familiar with Philips' medical devices, clinical operation software, system servicing and diagnostic software, Maintenance-Related Documentation, access controls, licensing practices, and service offerings described below.

3. Philips develops, manufactures, sells, and/or leases a comprehensive portfolio of medical systems including medical imaging systems (e.g., magnetic resonance imaging (MRI), computed tomography (CT), ultrasound systems, diagnostic x-ray (radiography and fluoroscopy), and image-guided therapy systems for angiography).

II. RELEVANT SOFTWARE AND MATERIALS

4. As used in this declaration:

(a) "Clinical Operation Software" means software that health care professionals use to operate a medical device and to perform patient care activities;

(b) "System Servicing/Diagnostic Software" includes software applications, diagnostic tools, calibration programs, configuration utilities, service interfaces, and related digital resources used to install, inspect, calibrate, test, maintain, diagnose, troubleshoot, update, or repair a medical device to its intended performance and safety specifications; and

(c) "Maintenance-Related Documentation" is non-software, digital work used for servicing, such as digital service manuals or repair procedure documentation.

5. Philips uses Clinical Operation Software on its medical imaging systems to enable clinicians to operate the device's medical features and to access patient information in the course of patient care. Devices typically have two or more types of accounts for the Clinical Operation Software, including a login for technologists to access the clinical interface and patient information, and an information technology or hospital administration account used to configure clinical user accounts.

6. Philips uses System Servicing/Diagnostic Software for those devices. That software is proprietary to Philips and is used to perform various service tasks on the devices, including but not limited to system diagnostics, system installation, and system configuration. Some of that software may be used to check systems for errors, access system diagnostic information and service logs, perform system calibration or troubleshooting, verify device operation, modify device configurations (e.g., radiation dose), and customize devices. These service software tools are divided into categories that Philips calls "Levels." Access to the tools in each Level is protected by TPMs and is governed by different terms and conditions, as described below.

III. TECHNOLOGICAL PROTECTION MEASURES (TPMs) & DIFFERENTIAL ACCESS

7. Philips uses several TPMs to control access to its System Servicing/Diagnostic Software. The principal measure is Philips' proprietary Integrated Security Tool ("IST"), which controls both authentication and entitlement. Through IST, Philips applies encrypted certificates together with multifactor authentication to the device. The user must present a physical smartcard, which uses a proprietary program, in order to present the medical device with an encrypted, time-limited, user-specific certificate, and the user must enter the matching password for that specific user account. Upon successful login, the system presents only the service software tools that the user is entitled to use, based on the user's IST entitlements.

8. These TPMs are separate and apart from the protections or controls governing access to the Clinical Operation Software. The Clinical Operation Software is managed separately. Its logins are username and password based, more like a Windows-type login, and they do not involve the IST smartcard, the encrypted user-specific certificate, or the entitlement system that determines which service software tools a user may access.

9. Access to the Clinical Operation Software is controlled by the technologist and information technology or hospital administration accounts described above, which are administered by the health care facility that owns or leases the device and its information technology personnel. Those logins are not in place to protect copyrighted material; they

are in place to allow device owners to ensure that only hospital-authorized clinical staff or other individuals can access a system's medical features and/or patient data. By contrast, access to the System Servicing/Diagnostic Software is controlled by the IST smartcard, the encrypted user-specific certificate, the matching account password, and the user's IST entitlements, each of which is issued and administered by Philips.

10. A person who has authorized access to the Clinical Operation Software does not thereby receive authorized access to the System Servicing/Diagnostic Software. A system owner is not authorized to access the protected System Servicing/Diagnostic Software, so it has no authority to authorize others to access or use such proprietary Philips software. To obtain such access, the person or organization must satisfy the conditions that apply to the Level of the tool sought. Level 0 tools are available to any person, including independent service organizations ("ISOs") or hospital biomeds, on request. Level 1 tools are available to hospital biomeds under a license granted as part of certain cooperative service agreements that include license fees, and subject to specific terms and conditions, including completion of Philips service training for that product and execution of a non-disclosure agreement. Level 2 tools are not available for licensing and are reserved for trained Philips engineers. Level 3 tools present an even greater risk if used with insufficient training and are likewise not available for licensing and are restricted to a small number of more highly trained and experienced service specialists.

11. These access controls serve purposes including protecting proprietary Philips software, patient and servicer safety, the performance and cybersecurity of the device, and license management. All Levels contain proprietary software developed by Philips and should only be used by sufficiently trained individuals given the safety-critical nature of medical device servicing. Level 2 and Level 3 in particular contain tools that are highly proprietary, pose a greater risk to patient or servicer safety, or that can alter or impact the performance or cybersecurity of the device. The strict restrictions Philips places on these tools are in line with FDA guidelines for remanufacturing and cybersecurity for medical devices.

IV. LICENSING, SERVICE OFFERINGS, AND DISTINCT MARKET

12. Philips licenses access to its System Servicing/Diagnostic Software separately from the sale or lease of the device, on terms that correspond to the Level of the tool. Philips provides Level 0 access to ISOs, hospital biomeds, and others on request. Philips licenses Level 1 access to hospital biomeds under certain cooperative service agreements, subject to requirements for system-specific service training and non-disclosure agreements. Level 2 and Level 3 access is not available for license and is retained for Philips.

13. Access is offered both through separate service agreements and through licensing. The consideration charged for Level 1 access takes the form of license fees included in

certain cooperative service agreements. The access provided includes the licensed service software tools themselves, the IST credentials and encrypted certificate required to authenticate to them, the IST entitlements that determine which tools the licensee may use, and access to the Maintenance-Related Documentation described below at the corresponding Level.

14. The market for these works and services includes hospital biomedical engineering departments that license the Level 1 works as part of certain cooperative service agreements, and Philips' own engineers and service specialists, for whom the Level 2 and Level 3 works are reserved and whose tools support Philips' own service activities. Philips competes in servicing and repairing these devices with ISOs, other OEMs, and in-house biomeds. In the FDA's 2018 report, "FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices," the FDA estimated that over 16,000 firms perform medical device service in the United States.

15. Customers may obtain maintenance or repair services from whomever they chose, including Philips, their own in-house biomedical engineering personnel, ISOs, or other OEMs. If additional authorized System Servicing/Diagnostic Software access or expertise would assist with a service, the customer or servicer may request Level 0 tools, or, in the case of hospital biomeds, may obtain a license to Level 1 tools as part of a cooperative service agreement upon completion of Philips service training for that product and execution of a non-disclosure agreement. Use of Level 2 or Level 3 tools is for servicing is reserved for Philips.

V. MAINTENANCE-RELATED DOCUMENTATION

16. Philips provides Maintenance-Related Documentation, which is likewise organized by Level. Basic maintenance manuals are available at Level 0 on request. More advanced documentation is available at Level 1 under license, subject to training and confidentiality requirements. Level 2 documentation poses additional safety, cybersecurity, or remanufacturing risks and is limited to Philips only.

17. This documentation is nearly exclusively stored on a cloud server and is not stored on the medical device. It is therefore maintained separately from both the Clinical Operation Software and the System Servicing/Diagnostic Software that reside on the device, and it is accessed through a Philips-hosted cloud server (InCenter) rather than through the device's clinical interface.

18. The documentation may be used by those performing service, including ISOs, hospital biomeds, and Philips personnel, with access on demand, based on a user's entitlements, at the time of need.

19. Access to this documentation is controlled by TPMs. Philips uses the proprietary IST to protect the login for service documentation, and multifactor authentication is required: the user must log in to the IST application on their computer to activate the encrypted certificate, and must use the IST account to log in to the cloud server (InCenter). The certificate is valid only on that user's computer; a user cannot log in from a different computer without re-registering with IST. Once logged in, the server presents only the materials that match the user's entitlements. To open protected Level 1 or higher materials, which are encrypted, the IST application must be active and logged in on the computer, and the tool then decrypts the documentation for viewing. These protection measures prevent the protected documents from being downloaded, saved, or printed. Level 0 documentation requires a login using IST credentials but is not encrypted, and select documents, such as Instructions for Use for the medical devices, are available with a "guest" login and are not subject to these additional protections. These measures are wholly separate and apart from the logins used for the Clinical Operation Software, because IST credentials, certificates, and entitlements are issued and controlled by Philips, whereas the Clinical Operation Software logins are username and password accounts administered by the health care facility and its information technology personnel.

20. Philips offers access to this documentation separately from the sale or lease of the device, on terms that correspond to the Level of the material: Level 0 maintenance manuals are available to any person, including ISOs and hospital biomeds, on request; more advanced Level 1 documentation is available under license, subject to completion of Philips service training for the product and execution of a non-disclosure agreement; and Level 2 documentation is not offered for license and is limited to Philips.

VI. UNAUTHORIZED ACCESS AND PRACTICAL EFFECTS

21. Philips enforces against unauthorized use of, and infringement relating to, its System Servicing/Diagnostic Software, service keys, and Maintenance-Related Documentation. Philips enforces both through more informal means, such as cease-and-desist letters, and through more formal means, up to and including litigation. Philips has obtained judgments in multiple litigations, including against Transtate/Avante, KPI Ultrasound, and Image Technology.

22. Unauthorized circumvention of the TPMs described above would permit persons who have not completed Philips service training for the product, and who are not subject to the license terms and non-disclosure agreements under which Philips grants access, to obtain access to the System Servicing/Diagnostic Software and the Maintenance-Related Documentation. That includes the Level 2 and Level 3 tools and the Level 2 documentation that Philips does not license to anyone, which are highly proprietary, pose

a greater risk to patient or servicer safety, or can alter or impact the performance or cybersecurity of the device.

23. Based on my responsibilities and experience, authorized access to Philips' service software and Maintenance-Related Documentation is available through IST and, in the case of documentation, through the InCenter cloud server, subject to the conditions that apply to each Level: Level 0 tools and documentation are provided on request, and Level 1 tools and documentation are licensed to hospital biomeds as part of certain cooperative service agreements that include license fees, completion of Philips service training for that product, and execution of a non-disclosure agreement.

VII. CONCLUSION

24. The Clinical Operation Software, System Servicing/Diagnostic Software, and Maintenance-Related Documentation described above are distinct in function and are subject to distinct access controls. The Clinical Operation Software is protected by username and password accounts administered by the health care facility and its information technology personnel, and those accounts exist to control who may access the device's medical features and patient data. The System Servicing/Diagnostic Software and Maintenance-Related Documentation are protected by Philips' proprietary Integrated Security Tool, which requires a physical smartcard, an encrypted user-specific certificate, and the matching account password, and which presents only those tools and materials that match the user's Philips-issued entitlements.

25. The System Servicing/Diagnostic Software and Maintenance-Related Documentation are monetized through the license fees charged for Level 1 access as part of certain cooperative service agreements with hospital biomedical engineering departments, subject to service training and non-disclosure requirements, and they participate in a market that includes ISOs, other OEMs, and in-house biomeds — a market in which the FDA estimated in 2018 that over 16,000 firms perform medical device service in the United States.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed on September 28, 2026 in Highland Heights, Ohio.

/s/ Jacqueline M. Dickson

Jacqueline Dickson
CSIP Services Operations Director
Philips North America LLC

EXHIBIT E

Declaration submitted in support of Comments from:

Advanced Medical Technology Association (AdvaMed)
1301 Pennsylvania Ave NW, Ste 400
Washington, DC 20004

DECLARATION OF GONCALO ARNAUT

I, Goncalo Arnaut, declare as follows based on my personal knowledge:

I. DECLARANT AND COMPANY BACKGROUND

1. I am the Head of Customer Services for North America at Siemens Medical Solutions USA, Inc. ("Siemens Healthineers"). I have held this position since 2024. My responsibilities include oversight of customer service operations for Siemens Healthineers medical imaging systems in North America, including service delivery, maintenance and repair support, service-related software access, service key administration, technical training and credentialing requirements, cybersecurity considerations related to service activities, and the protection and appropriate use of proprietary service materials.

2. I have been with Siemens Healthineers for 22 years, having worked in the field of customer services for medical imaging equipment since 2013. In my role, I am familiar with Siemens Healthineers' medical devices, Clinical Operation Software, System Servicing/ Diagnostic Software, Maintenance-Related Documentation, access controls, licensing practices, and service offerings as described below.

3. Siemens Healthineers develops, manufactures, sells, and/or leases medical imaging devices and systems, including for x-ray imaging, molecular imaging, computed tomography (CT) imaging, magnetic resonance (MR) imaging, and angiography imaging used for diagnosis in clinical applications including for detection of abnormalities, to track disease, and/or visualize the anatomy of the patient in clinical fields including oncology, cardiology, neurology, and women's health.

II. RELEVANT SOFTWARE AND MATERIALS

4. As used in this declaration:

(a) "Clinical Operation Software" means software that health care professionals use to operate a medical device to perform patient care activities;

(b) "System Servicing/Diagnostic Software" includes software applications, diagnostic tools, calibration programs, configuration utilities, service interfaces, and related digital resources used to install, inspect, calibrate, test, maintain,

diagnose, troubleshoot, update, or repair a medical device to its intended performance and safety specifications; and

(c) Maintenance-Related Documentation is non-software, digital work used for servicing, such as digital service manuals or repair procedure documentation.

5. Siemens Healthineers uses Clinical Operation Software on its imaging devices to enable clinicians to operate the device for patient use. Access to the Clinical Operation Software is typically through an operator login account followed by a password, and accounts can be created on the device for each user.

6. Siemens Healthineers uses System Servicing/Diagnostic Software on its imaging devices. This software provides information, data, and tools that pertain to the performance of the device itself. It can provide an individual with access to certain diagnostic tests that can be performed on the system, it can monitor hardware and component status, and it can output error codes and logs. It can also support assembly, installation, adjustment, and calibration, in addition to testing and diagnosing a system for maintenance and repair. For some Siemens Healthineers imaging devices, most of the System Servicing/Diagnostic Software is hosted on the cloud, separated physically from the imaging device and from the Clinical Operation Software on the imaging device.

III. TECHNOLOGICAL PROTECTION MEASURES (TPMs) & DIFFERENTIAL ACCESS

7. Access to Siemens Healthineers' System Servicing/Diagnostic Software generally requires a service key. The key is a character string, generally 256 characters, that is entered at the user interface of the System Servicing/Diagnostic Software. The character string for the key may be updated and is checked for approval for usage on the System Servicing/Diagnostic Software, and a key may be approved for access for a set period, such as days or weeks. Service keys are provided at various levels to access certain information or tools within the System Servicing/Diagnostic Software, and generally can be categorized at basic, advanced, and proprietary levels. A service key is typically generated using information pertaining to the imaging device, as for example from the imaging device workstation, and can also be generated based on information provided via a dongle, which is a physical device often connected over USB.

8. These TPMs are separate and apart from the protections or controls governing access to the Clinical Operation Software. The TPM for the Clinical Operation Software, which is used to operate the device for patient use, is typically an operator login account followed by a password, and accounts can be created on the device for each user. The service key is a distinct measure: following login to the device through the Clinical Operation Software, the user must navigate to a service menu item and then access to the System Servicing/Diagnostic Software at its own user interface requires input of the

service key. For some imaging devices, most of the System Servicing/Diagnostic Software is also hosted on the cloud, physically separated from the imaging device and from the Clinical Operation Software that resides on it.

9. Access to the Clinical Operation Software is controlled by the operator login account and password. That login and password are initially provided to the customer by Siemens Healthineers, and the customer operating the system for patient use then controls login and password access. By contrast, service keys are distributed and approved by Siemens Healthineers. The distribution and availability of service keys for a system depends on the category of the service key and, for advanced service keys, on eligibility criteria such as training and contract terms.

10. Access to the Clinical Operation Software does not thereby provide for automatic access to the System Servicing/Diagnostic Software. An operator login permits a user to reach the service menu item, but access to the System Servicing/Diagnostic Software itself requires a service key distributed and approved by Siemens Healthineers at the level corresponding to the information or tools sought. For advanced service keys, the person or organization must also satisfy eligibility criteria such as training and contract terms.

11. These access controls serve several important purposes. They support patient safety and device integrity by helping ensure that the Clinical Operation Software is accessible only to customer-designated users and that certain service functions are performed by appropriately trained and qualified personnel. They also reduce cybersecurity risks associated with unauthorized access to the Clinical Operation Software and the System Servicing/Diagnostic Software. In addition, the controls protect proprietary service information and tools, support the administration of software licenses and contractual access rights, and reduce the risk that unauthorized or inappropriate service activities of which could affect the safe and proper clinical operation of the imaging system.

IV. LICENSING, SERVICE OFFERINGS, AND DISTINCT MARKET

12. Siemens Healthineers licenses usage of its System Servicing/Diagnostic Software at certain levels separately from the sale of the device. Access can be made available to the device owner upon system purchase or at a later time and can also be licensed at certain levels to other servicing organizations. Service keys to access the System Servicing/Diagnostic Software are provided depending on the level required and the license contract.

13. Access is offered both through separate service agreements and through licensing wherein then the service keys can be made available. The term of a license for service key use can be short, for example a few days, or long term, as for example annually. Service keys can be provided at no charge for certain levels, depending on the tasks required.

14. The market for these works and services is a post-sale market that arises after the sale of the imaging system itself and is intended to keep the equipment maintained and working. Participants in that market include customers that purchased an imaging system and that may also obtain or purchase service keys for access to service the system, as well as independent service organizations and manufacturer service technicians that seek to acquire or obtain such access. Siemens Healthineers competes in servicing and repairing these devices with independent service organizations, self-service parties such as hospital in-house service departments, and other manufacturers that also provide service.

15. Customers may obtain maintenance or repair services from Siemens Healthineers, from their own in-house service personnel, from independent service organizations, or from other manufacturers that provide service. If additional authorized System Servicing/Diagnostic Software access or expertise is required, the customer or servicer may obtain a service key at the applicable level through a license agreement or service contract with Siemens Healthineers, subject, for advanced service keys, to meeting eligibility criteria such as training and contract terms.

V. MAINTENANCE-RELATED DOCUMENTATION

16. Siemens Healthineers provides Maintenance-Related Documentation, which includes service manuals and other technical documentation used to service a system.

17. This documentation is typically separate from the Clinical Operation Software and the System Servicing/Diagnostic Software. It is usually stored in an electronic library on a website, with certain access controls for non-public information. Some older imaging systems store Maintenance-Related Documentation directly on the system.

18. The documentation is used to repair Siemens Healthineers imaging systems. Access to the Maintenance-Related Documentation for service and repair is granted by Siemens Healthineers and allows an account to be created on the website. Access may be provided to customers, to service organizations, or to Siemens Healthineers technicians. Some Maintenance-Related Documentation is provided publicly from the website without access controls.

19. Access to the non-public Maintenance-Related Documentation on the website is controlled by login and password, which are provided by permission from Siemens Healthineers. For non-public Maintenance-Related Documentation stored on older imaging systems, a service key provides access. These measures are separate and apart from the protections governing the Clinical Operation Software: the website login and password are different from the Clinical Operation Software login and password on the imaging device itself, and website access is granted by Siemens Healthineers, whereas the Clinical Operation Software login and password are controlled by the customer after Siemens Healthineers initially provides them.

20. Siemens Healthineers provides access to this documentation separately from the sale of the device, by granting an account on the website to customers, service organizations, and Siemens Healthineers technicians.

VI. UNAUTHORIZED ACCESS [AND PRACTICAL EFFECTS]

21. Unauthorized circumvention of the TPMs described above would permit persons who have not obtained a service key distributed and approved by Siemens Healthineers, and who have not satisfied the eligibility criteria such as training and contract terms that apply to advanced service keys, to access the System Servicing/Diagnostic Software and the non-public Maintenance-Related Documentation.

VII. CONCLUSION

22. The Clinical Operation Software, System Servicing/Diagnostic Software, and Maintenance-Related Documentation described above are distinct in function and are subject to distinct access controls. The Clinical Operation Software is protected by an operator login account and password that Siemens Healthineers initially provides to the customer and that the customer thereafter controls. The System Servicing/Diagnostic Software is protected by a service key — a character string, generally of 256 characters, generated from information pertaining to the imaging device or provided via a dongle, approved for a defined period, and issued at basic, advanced, or proprietary levels — which Siemens Healthineers distributes and approves. The non-public Maintenance-Related Documentation is protected at a website through login and password which is granted by Siemens Healthineers and, on older imaging systems, by a service key.

23. Usage of the System Servicing/Diagnostic Software is monetized through licenses providing service key access at certain levels, made available through license and service contracts with terms ranging from a few days to a year, and it participates in a post-sale market for keeping imaging equipment maintained and working — a market that includes device owners, independent service organizations, hospital in-house self-service parties, other manufacturers that provide service, and Siemens Healthineers' own service technicians.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed on September 25, 2026, in Cary, North Carolina.

Electronically signed by: GONCALO Arnaut
Reason: I am the author of this document
Date: Sep 25, 2026 13:16:55 EDT

Goncalo Arnaut
Head of Customer Services for North America - Siemens Healthineers

EXHIBIT F

No. 25-5328

In the

United States Court of Appeals

for the

District of Columbia Circuit

ADVANCED MEDICAL TECHNOLOGY ASSOCIATION, *et al.*,

Plaintiffs-Appellants,

– v. –

LIBRARY OF CONGRESS, *et al.*,

Defendants-Appellees.

On appeal from a final judgment of the
United States District Court for the District of Columbia
Case No. 1:22-cv-499 (U.S. District Beryl Howell)

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Parties and amici. Plaintiffs-appellants are the Advanced Medical Technology Association and Medical Imaging & Technology Alliance. Defendants-appellees are the Library of Congress and either Todd Blanche or Robert Newlen in his official capacity as Acting Librarian of Congress.

Rulings under review. The ruling under review is the district court's July 21, 2025, order in No. 1:22-cv-499 at Dkt. 48, as well as the memorandum opinion at Dkt. 49 and final judgment at Dkt. 50.

Related cases. This case was previously before this Court, which reversed the district court's earlier dismissal. *See Medical Imaging & Technology Alliance, et al. v. Library of Congress*, 103 F.4th 830, 840 n.4 (D.C. Cir. 2024). There are no related cases pending in this Court or any other court.

/s/ *Michael B. Kimberly*

CORPORATE DISCLOSURE STATEMENT

AdvaMed is a non-profit, membership-based trade association. It has no parent corporation and does not issue stock. MITA also is a non-profit, membership-based trade association. It is a division of the National Electrical Manufacturers Association. MITA does not issue stock.

/s/ *Michael B. Kimberly*

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GLOSSARY

APA:	Administrative Procedure Act
DMCA:	Digital Millennium Copyright Act
FDA:	Food and Drug Administration
ISO:	independent service operator
MITA:	Medical Imaging & Technology Alliance
NPRM:	notice of proposed rulemaking
OEM:	original equipment manufacturer
R&D:	research and development
TPM:	technological protective measure

INTRODUCTION

Advanced medical devices play an essential and life-saving role in today's technology-driven healthcare system. Sophisticated and complex machines like computerized tomography scanners, ultrasound systems, and magnetic resonance imaging machines allow for highly accurate imaging of internal organs and biological systems, facilitating early diagnoses of serious diseases. And advanced care technologies like respiratory ventilation systems and surgery-assisting robots allow for care with fewer complications, shorter hospital stays, and better outcomes.

Plaintiffs here are the Advanced Medical Technology Association (AdvaMed) and the Medical Imaging & Technology Alliance (MITA). Their mutual members invest billions of dollars every year designing, building, and servicing the life-sustaining medical devices on which the American healthcare system has come to depend.

At the same time that these companies are manufacturers of physical machines, they also are authors of the complex software programs, tools, files, and documentation needed to maintain and repair the machines. Coupling this software with the machines, manufacturers recoup their huge R&D investments in two ways: first through sales or leases of the machines themselves, and second through maintenance and servicing and licensing agreements for the software and documents necessary for the same.

These two complementary revenue streams are well understood by the healthcare providers who acquire and use AdvaMed's and MITA's members' advanced devices. Indeed, healthcare providers almost always must agree to the express terms of the software and documentation licenses when they acquire advanced medical devices like those at issue.

Nonetheless, a market has developed for unlicensed maintenance, diagnosis, and repair services for advanced medical devices. To provide such services, third-party servicers circumvent the encryption protecting licensed field-service software programs and other materials. Once an unauthorized third-party servicer has gained access to a manufacturer's software-based maintenance tools, documents, and files, it puts them to their precise intended use: facilitating the maintenance, diagnosis, and repair of the machine. And in doing so, it substitutes for manufacturers' services.

A critical point warrants emphasis at the start: Third-party servicers do absolutely nothing "new" with the works that they appropriate to provide maintenance-and-repair services. They do not put them to some further, transformative *use*, nor do they do imbue the works with some new or different *character*. On the contrary, third-party servicers expressly disclaim that they transform or alter the software itself—because doing so would subject them to regulation by the FDA as remanufacturers. Instead (and to reiterate), all they do is put the service software tools and services-related documents and

files to their original purpose of facilitating the maintenance, diagnosis, and repair of the machines. And they do so *for a profit*, in direct competition with the authors of the works.

This kind of copy-to-compete reproduction is the very definition of infringing use. "The Copyright Act encourages creativity by granting to the author of an original work 'a bundle of exclusive rights,'" including the rights "to reproduce the copyrighted work" and "prepare derivative works." *Andy Warhol Foundation for the Visual Arts v. Goldsmith*, 598 U.S. 508, 526 (2023) (quoting *Harper & Row, Publishers v. Nation Enterprises*, 471 U.S. 539, 546 (1985)). As the Supreme Court recently explained, "copyright's bête noire" is "the problem of substitution," meaning "[t]he use of an original work to achieve a purpose that is the same as, or highly similar to, that of the original work," so that the copy stands as a "substitute" for the original and "shrink[s] the protected market opportunities of the copyrighted work." *Id.* at 528, 531 (cleaned up). That is exactly what unauthorized third-party servicing companies do when they break into advanced medical devices and copy protected works to perform maintenance, diagnosis, and repair services.

To be sure, copyright is not absolute, and Congress has provided expressly that "the fair use of a copyrighted work, . . . for purposes such as criticism, comment, news reporting, teaching . . . , scholarship, or research, is not an infringement of copyright." 17 U.S.C. § 107. But a fair use is a *transformative*

one—one that "has a purpose or character different from the original," so that it "does not supersede the objects of, or supplant, the work" in the market in which the work is sold. *Warhol*, 598 U.S. at 528-29. Plainly enough, making unauthorized copies of service software tools, operating manuals, and other protected works to perform unlicensed maintenance-and-repair services for a profit is not a transformative use. Rather, it is predatory appropriation designed to supplant the author's works with the copier's.

The Digital Millenium Copyright Act (DMCA) was enacted to prevent just this kind of digital piracy. The Act thus expressly prohibits users from circumventing any "technological measure that effectively controls access to a work." 17 U.S.C. § 1201(a)(1)(A). Under this anticircumvention rule, decrypting a copyrighted work without authorization is punishable with civil and, in some cases, criminal penalties.

At the same time that Congress made it unlawful to circumvent a copyright holder's encryption tools, it recognized that the DMCA's anticircumvention rule might be used to prevent otherwise lawful access to works and information. It thus directed the Library of Congress to grant exemptions to the anticircumvention rule through recurring, triennial rulemakings, to users who are likely to be "adversely affected by the [anticircumvention rule] in their ability to make *noninfringing uses*" of the work over the ensuing three years. 17 U.S.C. § 1201(a)(1)(C) (emphasis added).

This case concerns an exemption to the anticircumvention rule adopted in the Eight Triennial Rulemaking in 2021 and renewed in the Ninth Rulemaking in 2024: the Medical Devices Exemption. It is codified at 37 C.F.R. § 201.40(b)(17), and it grants a waiver from liability for circumvention of encryption protecting copyrighted software and other digital works used for servicing advanced medical devices.

The Exemption was granted at the request, and solely for the commercial benefit, of third-party servicers that provide unauthorized maintenance-and-repair services. Now in light of the Exemption, these (and all other) third-party servicers consider themselves free to copy diagnostic modules and service software, operating manuals and machine specifications, data reports and error logs, and other copyright-protected tools necessary to sell maintenance-and-repair services for a profit—the same services that manufacturers themselves use the software to sell and thus recoup the costs of developing their innovations.

The problem with the Exemption speaks for itself: Section 1201(a)(1) authorizes the Librarian of Congress to issue exemptions to the DMCA's anticircumvention rule for "noninfringing uses" only. But to make unauthorized reproductions of copyrighted works and to use them for the same purpose as the originals, solely to compete with the authors of the originals in the market that monetizes the works, is *not* a "noninfringing" fair use.

Case law offers no support for the Librarian's or district court's contrary conclusion. Quite the opposite. For example, in *Triad Systems v. Southeastern Express*, 64 F.3d 1330 (9th Cir. 1995), the Ninth Circuit concluded that analytically identical conduct was "neither creative nor transformative," "entirely commercial in nature," and therefore infringing. *Id.* at 1336-37. There, "Triad invented, developed, and marketed its software to enable its customers and its own technicians to service Triad computers." *Id.* at 1337. The Ninth Circuit rejected the third-party servicer's fair-use defense, explaining that it "ha[d] invented nothing of its own," but instead was "getting a free ride when it use[d] that software to perform precisely the same service," in competition with Triad, without paying for a license. *Id.* at 1336.

Yet here, in granting and renewing the Exemption, the Librarian concluded that third-party servicers use the copied works in new and "transformative" ways. That is unequivocally wrong. To conclude otherwise is to ignore the facts as well as the law. The district court, for its part, agreed with the Librarian as far as she went—and also offered additional rationales not furnished by the Librarian, which is not permissible.

At the end, both the Librarian and the district court laid bare their true reasoning: They believe that manufactures charge "exorbitant" licensing fees (5-JA-1693) for access to works related to maintenance and repair, and as a consequence "providers must spend more to service their equipment than if"

manufacturers did not enjoy copyright protection (2-JA-647). That is a stunning argument for a copyright regulator to make. To declare that an unauthorized copying of computer code is a "fair use" *because* it allows a competitor to take business from the author at lower prices is to flip copyright law on its head. Reversal is manifestly warranted.

JURISDICTION

The district court had jurisdiction under 28 U.S.C. § 1331. It entered a final judgment on July 21, 2025, and appellants filed an appeal on September 12, 2025. 1-JA-8. This Court's jurisdiction rests on 28 U.S.C. § 1291.

PERTINENT STATUTES AND REGULATIONS

The pertinent statutes are set out in an attached addendum.

ISSUE PRESENTED FOR REVIEW

Whether the Library's adoption and renewal of a DMCA exemption permitting the circumvention of technological protective measures for copyrighted software used for servicing and repairing medical devices (37 C.F.R. § 201.40(b)(17)) violated the APA because it was arbitrary and capricious, not in accordance with law, or in excess of statutory authority or limitation.

STATEMENT OF FACTS

A. Legal background

1. The fair use doctrine. The Copyright Act of 1976 prohibits unauthorized reproduction of "original works of authorship fixed in any tangible

medium of expression." 17 U.S.C. § 102(a). Among the works covered by the Act are "computer program[s]." *Id.* §§ 101, 109(b)(1)(A).

Copyright serves practical objectives, foremost "to encourage the production of works" that, without copyright protection, could be "reproduce[d] more cheaply" by freeriders in the marketplace. *Google LLC v. Oracle America, Inc.*, 593 U.S. 1, 16 (2021). It thus "grant[s] to the author of an original work 'a bundle of exclusive rights,'" including the right to forbid unauthorized reproduction of the work. *Warhol*, 598 U.S. at 526 (quoting *Harper & Row*, 471 U.S. at 546).

The rights granted by the Act are not absolute. They are tempered to account for the "competing claims upon the public interest" by authors (on the one hand) and users (on the other). *Warhol*, 598 U.S. at 526. The Act balances the incentive to innovate against the need for "broad public availability" of creative works in several ways. *Id.* For example, it "limits the duration of copyright" and "makes facts and ideas uncopyrightable." *Id.* And pertinent here, it "limits the scope of copyright" through the common-law "fair use" doctrine *Id.* at 526-27.

The fair-use doctrine is codified at 17 U.S.C. § 107, which specifies that "the fair use of a copyrighted work, . . . for purposes such as criticism, comment, news reporting, teaching . . . , scholarship, or research, is not an infringement of copyright." To determine whether a use is "fair" and thus

noninfringing, the statute sets out four factors for consideration:

1. the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes;

2. the nature of the copyrighted work;

3. the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and

4. the effect of the use upon the potential market for or value of the copyrighted work.

17 U.S.C. § 107(1)–(4). These four fair-use factors "are all weighed in the 'equitable rule of reason' balance." *Sony Corp. of America v. Universal City Studios, Inc.*, 464 U.S. 417, 454 (1984). Yet the fourth factor is "undoubtedly the single most important element of fair use." *Harper & Row*, 471 U.S. at 566; *see also Stewart v. Abend*, 495 U.S. 207, 238 (1990) (referring to the fourth factor as the "most important, and indeed, central" of the § 107 factors); 4 Nimmer on Copyright § 13F.03 (2022) (similar).

The fourth factor is first among equals because of its direct link with copyright's animating principles. The fair-use doctrine tolerates appropriation only when the copy does not substitute the original in the market in which the author herself commercializes the work. As the Supreme Court has put it, "[f]air use, when properly applied, is limited to copying by others which does not materially impair the marketability of the work which is copied." *Harper & Row*, 471 U.S. at 566-67. Because some duplication is *non*-competitive,

non-substitutive, and necessary for further creativity, the fair-use doctrine acknowledges that a "rigid application of the copyright statute" may in some circumstances "stifle the very creativity which that law is designed to foster." *Warhol*, 598 U.S. at 527 (quoting *Stewart*, 495 U.S. at 236).

2. Transformative use. In conjunction with the fair-use factors, the Supreme Court has instructed courts to determine whether a secondary use of a copyrighted work is *transformative* of the original. The Supreme Court first introduced the concept of "transformative" use in *Campbell v. Acuff-Rose Music*, 510 U.S. 569 (1994), as a consideration under the first factor. Since then, lower courts have expanded the reach of the inquiry to "engulf all of fair use." Jane Ginsburg, *Fair Use Factor Four Revisited: Valuing The Value of the Copyrighted Work*, 67 J. Copyright Society U.S.A. 19, 19-20 (2020). The question of transformative use cuts across the four factors for the same two reasons that the fourth factor predominates over the others:

First, "[t]he more the appropriator is using the copied material for new, transformative purposes, . . . the less likely it is that the appropriation will serve as a substitute for the original or its plausible derivatives, shrinking the protected market opportunities of the copyrighted work." *Warhol*, 598 U.S. at 531 (quoting *Authors Guild v. Google, Inc.*, 804 F.3d 202, 214 (2d Cir. 2015) (Leval, J.)). For example, because reproduction for parody or criticism "uses the work to serve a distinct end," it "ordinarily does not supersede the objects

of, or supplant, the work" in its own commercial market. *Id.* at 528. Transformative uses thus avoid "the problem of substitution—copyright's bête noire." *Id.* No one would say that *The Hunger Pains* by the Harvard Lampoon competes as a substitute for *The Hunger Games* by Suzanne Collins in the market for pleasure reading.

Second, "[t]he more the appropriator is using the copied material for new, transformative purposes, the more it serves copyright's goal of enriching public knowledge." *Warhol*, 598 U.S. at 531 (quoting *Authors Guild*, 804 F.3d at 214). Turning to parody again, it "has an obvious claim to transformative value" because "it can provide social benefit, by shedding light on an earlier work, and, in the process, *creating a new one*." *Id.* at 530 (emphasis added) (quoting *Campbell*, 510 U.S. at 579). But, of course, parody "needs to mimic an original to make its point." *Id.* (quoting *Campbell*, 510 U.S. at 580-81). Thus, focusing on transformative use helps to isolate those cases in which permitting unauthorized copying fosters further creations.

For these reasons, "the sorts of copying that courts and Congress most commonly have found to be fair uses" are those listed in the statute itself: criticism, comment, news reporting, teaching, scholarship, and research. *Warhol*, 598 U.S. at 528 (citing *Campbell*, 510 U.S. at 577-78). These "easily understood" examples entail the use of a copy that will "serve a manifestly

different purpose from the [original] work itself" and are thus inherently transformative. *Id.*

3. The DMCA. The proliferation in the 1990s of digital copyrighted works, and the ease with which they could be copied electronically, introduced new challenges for copyright owners. Many creators began using various kinds of encryption to control access to their works and thwart copying. To support those efforts, "Congress enacted the DMCA in 1998 'to strengthen copyright protection in the digital age.'" *Egilman v. Keller & Heckman, LLP*, 401 F. Supp. 2d 105, 112 (D.D.C. 2005).

The DMCA protects copyright by prohibiting users of a copyrighted work from "circumvent[ing] a technological measure that effectively controls access to [the] work" (17 U.S.C. § 1201(a)(1)(A))—a prohibition that we refer to as the anticircumvention rule. To circumvent protective tools is to de-scramble or decrypt by bypassing, removing, or deactivating a technological protective measure "without the authority of the copyright owner." *Id.* § 1201(a)(3). Violations of the DMCA's anticircumvention rule are punishable with private civil remedies, and in the case of a willful violation "for purposes of commercial advantage," criminal penalties. *Id.* § 1204(a).

Congress recognized, however, that unchecked use of encryption might obstruct noninfringing access to works and information. Because it did not intend for the DMCA to inhibit noninfringing uses, the DMCA instructs the

Register of Copyrights and Librarian of Congress to undertake triennial rule-makings to consider petitions for three-year "exemptions" from the DMCA's prohibitions for limited purposes. 17 U.S.C. § 1201(a)(1)(C). Such exemptions are authorized only if users are likely to be "adversely affected by" the anti-circumvention rule exclusively "in their ability to make *noninfringing* uses." *Id.* (emphasis added). A DMCA exemption thus requires the Librarian to find that the proposed uses of the class of copyrightable works at issue are noninfringing, typically implicating the fair-use doctrine.

4. Section 117(c). Shortly before Congress began debating the DMCA, the Ninth Circuit issued its decision in *MAI Systems Corp. v. Peak Computer, Inc.*, 991 F.2d 511 (9th Cir. 1993). There, the court held that "a 'copying' for purposes of copyright law occurs when a computer program is transferred from a permanent storage device [*i.e.*, hard drive] to a computer's RAM." *Id.* at 518. On that reasoning, the mere act of turning a computer on is an act of infringement. *Id.* at 518-519.

Congress narrowly abrogated that holding with the DMCA, enacting a limited but categorical copyright exception for copying operating software as necessary to activate machines for maintenance and repair. Section 117(c) of the Copyright Act, as amended by the DMCA, thus expressly allows owners and lessees of software-operated machines "to make or authorize the making of a copy of a computer program" in limited circumstances, when:

(1) the "copy is made solely by virtue of the activation of a machine" and "for purposes only of maintenance or repair of that machine,"

(2) the copy "is used in no other manner" than activation for maintenance and repair, and

(3) the copy "is destroyed immediately after the maintenance or repair is completed."

17 U.S.C. § 117(c). As scholars have noted, "Section 117(c) reversed *MAI*'s application of the RAM Copy Doctrine" in the limited context of activating computers for maintenance and repair. Melissa A. Bogden, *Fixing Fixation: The RAM Copy Doctrine*, 43 Ariz. St. L.J. 181, 197 (2011).

B. Factual background

1. Today, advances in medical technology are driven by software every bit as much as hardware engineering and design. This software includes not only an advanced medical machine's operating system—typically Windows or Linux (3-JA-1034; 5-JA-1483)—but also "field service software and information" (5-JA-1427, 1649), including proprietary "diagnostic tools" (5-JA-1381, 1422) and other "specialized service tools" (5-JA-1409) stored on the machine and used to identify and resolve malfunctions, report equipment usage, and identify replacement needs. *See* 5-JA-1425, 1429, 1483, 1631.

Device manufacturers make enormous investments of time and money to develop and bring medical devices and their software to market. 4-JA-1377-78; 5-JA-1599-1600. They rely on copyright protections—including the anti-

circumvention rule—to recoup their investments, facilitate further innovations, and protect the integrity of their software. 4-JA-1371; 5-JA-1593.

2. Manufacturers use a variety of technological measures like digital certificates and encryption keys to guard against unauthorized copying of the software and other protected materials stored on the machines. These access controls limit aspects of their software that may be viewed, used, copied, and modified. 5-JA-1429, 1511. They not only safeguard manufacturers' intellectual property, but also protect the integrity of the device and the privacy of patient data while ensuring that only appropriate users operate medical device software. 5-JA-1511.

Improper use of manufacturer's proprietary software for servicing medical devices creates substantial risks to users, patients, and providers. 4-JA-1372-73; 5-JA-1594-95. Failure to repair devices properly also can cause delays and misdiagnoses. *Id.* Given these risks, the FDA strictly regulates medical device manufacturers, requiring them to obtain approvals before commercially distributing devices (21 C.F.R. Parts 801, 814) and to report serious malfunction incidents (21 C.F.R. Part 803). *See* 4-JA-1373-75; 5-JA-1595-97. FDA also has recognized the importance of allowing manufacturers to train and equip their "own service personnel with additional documentation or enhanced software programs, with privileged access codes" to provide particularly complex services and repairs. 5-JA-1408 n.2.

3. Third-party servicing companies—sometimes referred to as independent service operators, or ISOs—provide unregulated third-party maintenance-and-repair services for medical devices. They are not subject to the FDA regulations that apply to original equipment manufacturers (referred to as OEMs). Nor are they subject to the same training and quality control measures. Many manufacturers nevertheless provide support to third-party servicers to enable them to perform basic maintenance-and-repair services, including limited licensing of copyrighted documentation and software. *See, e.g.*, 4-JA-1061; 5-JA-1429, 1583.

Some third-party servicers gain access to and reproduce copyrighted software without obtaining a license. 5-JA-1410, 1587-89. They then use the copies to provide the same maintenance-and-repair services that manufacturers do, putting the software and other works to the same use, in direct competition with the manufacturers' service programs. *See, e.g.*, 5-JA-1429.

C. Procedural background

1. The Eighth Triennial Rulemaking. Third-party servicers Summit Imaging and Transtate Equipment Company petitioned in the Eighth Triennial Rulemaking for access to "[e]lectronic servicing materials in the form of computer programs and data files that control functions of or store data relating to the functioning of lawfully acquired medical systems and devices." 3-JA-1020; *see generally* 3-JA-1016-1034; 4-JA-1035-1353.

In seeking the exemption, the proponents explained that their need was not to copy the machines' operating system software, which typically is Linux or Windows (and is already permitted by § 117(c)). *See* 3-JA-1023-24. Rather, their need is to copy "diagnostic software and data files" (3-JA-1024) and "medical equipment servicing materials in the form of computer programs" and "databases and manuals" that "are necessary for servicing (diagnosis, repair, and maintenance) of the medical devices and systems" (3-JA-1031-32). Transtate explained further that, "[w]hen performing the servicing activities, the diagnostic and testing modules are used to diagnose the operating conditions and to determine if the system or device is performing according to specifications." 4-JA-1050. And the proponents were clear why they believe third-party services are important: Without them, owners "cannot take advantage of the lower prices offered by . . . ISOs." 4-JA-1057.

Plaintiffs and one of their mutual members submitted comments opposing the proposed exemption. *See* 4-JA-1354-1380; 5-JA-1381-1430.

The Register—the official who makes exemption recommendations to the Librarian—proposed granting the exemption to allow the copying of "[c]omputer programs that are contained in and control the functioning of a lawfully acquired medical device or system, and related data files, when circumvention is a necessary step to allow the diagnosis, maintenance, or repair of such a device or system." 3-JA-766.

The Register concluded that use of copyrighted software for maintenance and repair of advanced medical devices is a noninfringing "fair use." 2-JA-627-631. Concerning the first factor, she concluded "that proponents' proposed use is likely transformative and so the first factor favors fair use." 2-JA-628. The Register further opined that medical-device system software is entitled to diminished copyright protection because it is "not used for [its] expressive qualities, but rather for [its] functional and informational aspects that enable users to control and understand the operation of the equipment." 2-JA-629. She concluded, in addition, that servicers' copying of the entirety of manufacturers' works "should be given little weight here because the use is necessary to accomplish the transformative purposes of diagnosis, maintenance, and repair." 2-JA-630. And concerning harm to the market for the copyrighted software, the Register concluded that "there is no indication that the software serves any function, or has any value, except for use with the medical device or system for which it was designed." 2-JA-631.

With respect to her discretion to consider other factors under the Section 1201(a)(1)(C) framework, the Register observed that "OEMs charge higher prices" than third-party services for maintenance and repair and therefore "medical service providers must spend more to service their equipment" if they use manufacturers' services "than if they were able to engage in self-repair or have an ISO perform repairs on their behalf." 2-JA-647.

The Register thus recommended granting the Exemption. 2-JA-650-51. The Librarian adopted the Exemption according to the Register's recommendation, the content of which we thus attribute to the Librarian. It is codified at 37 C.F.R. § 201.40(b)(15) and went into immediate effect.

2. The lawsuit and Ninth Triennial Rulemaking. Plaintiffs brought this suit challenging the Medical Devices Exemption as unlawful under the APA, or in the alternative, as an *ultra vires* action by the Librarian. The district court dismissed the complaint, holding that the claims were "barred by sovereign immunity because the Librarian's decisions are not subject to APA review." Dist. Ct. Dkt. 27, at 17.

This Court reversed. *See Medical Imaging & Technology Alliance v. Library of Congress*, 103 F.4th 830 (D.C. Cir. 2024). It held that "DMCA rules are subject to the APA just like other copyright rules," and it remanded for this Court "to assess the APA claims in the first instance." *Id.* at 833.

In the meantime, the Library commenced and concluded the Ninth Triennial Rulemaking. Transtate and Summit petitioned for renewal of the Medical Devices Exemption. 5-JA-1481-1509. Plaintiffs and others submitted comments opposing renewal. 5-JA-1510-1656. Apart from repeating their prior arguments, opponents argued that the fair-use determination undergirding the Exemption conflicts with the Supreme Court's intervening de-

cision in *Warhol*, which reiterated that commercial use of a copyrighted work for the same purpose as the original work is not fair use.

The Register recommended that the Librarian renew the Exemption. 3-JA-809-812. She determined that the "analysis from the 2021 cycle remains sound" notwithstanding *Warhol*. 3-JA-811-12. The Librarian agreed, and the Exemption is now codified at 37 C.F.R. § 201.40(b)(17).

Plaintiffs thereafter amended the complaint in this case to challenge both the adoption of the Medical Devices Exemption in the Eighth Triennial Rulemaking and its renewal in the Ninth. The parties then exchanged cross-motions for summary judgment.

3. The district court's decision. In an opinion accusing plaintiffs of "overreact[ing]" like "Chicken Little" (5-JA-1693 n.9) and aiming only to protect "an ability to charge exorbitant prices" (5-JA-1693), the district court granted summary judgment to the Library. *See* 5-JA-1657-1716.

The district court's analysis focused on the first fair use factor, and in particular whether the third-party servicers' use was transformative. It maintained that the Librarian had found that the operating software and related data files for medical devices were *not* originally invented and developed for the "primary purpose" of servicing the devices. 5-JA-1709. It thus held that third-party servicers make transformative use of the works because "repair and maintenance" has a "different character" and "employ[s] the code in a

different manner" from how the software is "originally used by the machine to operate the device." 5-JA-1679 (cleaned up and citations omitted).

Even if that were wrong, the court continued, "ISOs' use of [service] materials still may be considered transformative" because use of software tools, data, and files "requires input of [the user's] knowledge, creative and analytical thinking, and mechanical skills." 5-JA-1686. In the district court's view, this was a "secondary function" that "transform[ed] the basic knowledge conveyed in the copyrighted materials into a distinct and meaningful output, which is considered transformative." *Id.*

The district court opined that the copying at issue is transformative for the additional reason that "diagnosis, maintenance, and repair has a concrete 'transformative' effect on the *device* by changing some aspect of how it works." 5-JA-1686. The court agreed with plaintiffs that "the first fair use factor [asks] whether the use transforms the copyrighted material itself" and not a "separate related object." *Id.* And it acknowledged that "technically the hardware and software may be distinct." 5-JA-1687. But it held that "the software has no use or value apart from the device," and because maintenance of the device "facilitate[s] use of the software," servicers' use of the copied software has a "transformative effect on the *use* of the software." *Id.*

The district court rejected plaintiffs' position that it was arbitrary for the Librarian to analogize to her 2015 rulemaking, where she granted a similar

exemption for maintenance and repair of motor vehicles, despite that the exemption there expressly envisioned transformative alterations. *See* 5-JA-1687-89. And the district court finally rejected the argument that the Librarian had not taken adequate account of *Warhol*. *See* 5-JA-1689-1690.

"In sum," the district court concluded, "the Librarian's conclusion that all of the uses contemplated by the Exemption are transformative—and that the transformative quality was more significant than the commercial, for-profit nature of most diagnosis, maintenance, and repair services—was consistent with fair use law, including precedent such as *Warhol*, and supported by well-reasoned analysis." 5-JA-1692.

Having held that the Librarian's fair-use analysis was reasonable, the district court turned to a recitation of why it believed the Exemption is consistent with copyright policy. 5-JA-1704-1710. On that front, the court noted that, with § 117(c), Congress expressed an "intent to ensure that maintenance and repairs were not monopolized by copyright owners of computer programs." 5-JA-1706. And with the Exemption, the Librarian has now "go[ne] beyond the statutory provision" to provide protections that Congress did not provide itself in § 117(c). 5-JA-1707. This, the district court reasoned, means that the Exemption is consistent with congressional intent.

Finally, the district court held that the Librarian adequately addressed all the comments submitted to it. 5-JA-1710-15. Having done so, it held that the Exemption is lawful and should be upheld. 5-JA-1715-16.

SUMMARY OF ARGUMENT

Under any reasonable application of the fair-use factors, the Medical Devices Exemption permits infringing uses and is unlawful.

Start with the first factor, "the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes." 17 U.S.C. § 107. Where, as here, "an original work and a secondary use share the same or highly similar purposes, *and* the secondary use is of a commercial nature," the first factor almost always will weigh against fair use. *Warhol*, 598 US at 532-33 (emphasis added).

Here, the Exemption has authorized copying of field-service software tools, manuals, and other files that were created for the purpose of facilitating maintenance-and-repair services. It does so to permit third parties to use them *for exactly the same commercial purpose*. There is no dispute that third-party servicers copy these protected works in order to put them to their original, intended uses of facilitating maintenance-and-repair services in a competitive commercial market, substituting their own services for the services of the works' authors. This is the textbook definition of substitutive, commercial use—not transformative use.

The Librarian's contrary finding turned on a misimpression that the works being copied are merely operating software. The district court agreed. Both were wrong. To be crystal clear: This case is *not* about operating software, which is covered separately by 17 U.S.C. § 117. There is no support for a contrary conclusion in the administrative record.

The district court offered other rationales for upholding a finding of transformative use. But none was adopted by the Librarian, and each offends basic principles of copyright law. None is a ground for affirming.

Take next the fourth factor, which is closely related to the first factor. It asks whether the copier's use of the protected work will cause market harm to the author. Generally speaking, when the copy is commercially substitutive, the answer is perforce *yes*. That is the case here. Indeed, the record shows that market harm was the *point* of the Exemption: Proponents sought the Exemption, and the Librarian granted it, to ensure that third-party servicers would be able to offer substitutive maintenance-and-repair services at lower cost, taking market share from higher-cost manufacturers and destroying the licensing market for the protected software.

The Librarian (and district court) denied that there is a separate market for the works at issue, but the evidence—including evidence introduced by the proponents themselves—confirms that there *is* a separate market for software licenses. And the harm inflicted on that market is undeniable. The district

court assumed as much and offered another rationale not adopted by the Librarian. That post hoc explanation is both wrong and procedurally unavailable.

When the first and fourth factors weigh against fair use (as they do here), only an especially "compelling justification" under the second and third factors can save a copier's appropriation. Here there is no justification, much less a compelling one, under the second and third factors.

Finally, the Exemption impermissibly amends § 117(c), which codifies a narrow exemption for copying a limited range of digital works for machine maintenance and repair. The Court thus should remand with instructions to vacate the Exemption.

STANDING

AdvaMed and MITA are trade associations. 4-JA-1354, 1369. Their mutual members include Philips North America, which commented on the Exemption (5-JA-1405-1430, 1510-1548), as well as almost all other major manufacturers of advanced medical devices. AdvaMed's and MITA's members—and their devices and software—are the objects regulated by the Medical Devices Exemption. By the Exemption's operation, AdvaMed's and MITA's members are denied a right under the DMCA to challenge circumvention of the technological protective measures they use to guard against unauthorized copying of software and data stored on their devices. That injury is redressable by an order setting aside the Exemption.

STANDARD OF REVIEW & BURDEN OF PROOF

This Court "review[s] the district court's grant of summary judgment de novo" and the Librarian's decision "under the standard of the Administrative Procedure Act." *Grossmont Hospital v. Burwell*, 797 F.3d 1079, 1082 (D.C. Cir. 2015). Under the APA, review of an "agency's interpretation of its governing statute" calls for "independent judgment" without deference. *Environmental Defense Fund v. EPA*, 124 F.4th 1, 11 (D.C. Cir. 2024).

A court's review for arbitrariness calls for a determination whether "the agency has . . . entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be . . . the product of agency expertise." *Solondz v. FAA*, 141 F.4th 268, 276 (D.C. Cir. 2025).

A court may not "substitute" its own reasoning for the agency's and "may only uphold a rule 'on the basis articulated by the agency' in the rule making record." *Genuine Parts v. EPA*, 890 F.3d 304, 314 (D.C. Cir. 2018).

Plaintiffs bear the burden of showing that the Exemption violates the APA. But "those who seek an exemption" under 17 U.S.C. § 1201(a)(1) "bear the burden of establishing that the requirements for granting an exemption have been satisfied" in the underlying rulemaking. 2-JA-426. Plaintiffs thus meet their burden under the APA by showing that the proponents failed to meet *their* burden under § 1201(a)(1).

ARGUMENT

The Exemption authorizes infringing uses of copyrighted works and is unlawful. The Librarian erred in holding that copying "diagnostic software and data files" (3-JA-1024) for their intended purposes of maintenance and repair is "transformative." The Librarian's contrary conclusion is not only legally wrong, but it is based on illogical factual assumptions unsupported by evidence and irrelevant policy considerations that have no place in the fair use analysis. It cannot stand.

I. THE MEDICAL DEVICES EXEMPTION UNLAWFULLY PERMITS INFRINGING USES

A. First factor: The uses permitted by the Exemption are substitutive rather than transformative

The Librarian erred in her fair-use analysis, which turned principally on the question whether third-party servicers make transformative use of the "diagnostic software and data files" (3-JA-1024 (Summit petition)) and other "medical equipment servicing materials" that "are necessary for servicing . . . medical devices and systems" (3-JA-1031-32 (Transtate petition)) by putting them to work for maintenance and repair.

The Librarian concluded that they *do* make transformative use of those protected works, and the district court agreed. In fact, the Librarian approved (and the district court upheld) an exemption for *substitutive* uses, allowing third-party servicers to compete directly with manufacturers without paying

for licenses, thus substantially undermining the market for manufacturers' own services and licenses.

1. The permitted uses are not transformative, but rather commercially substitutive

a. The uses permitted by the Exemption are not transformative. A secondary use of a copyrighted work is transformative when it puts the work to "a further purpose" or imbues it with a "different character." *Warhol*, 598 U.S. at 532. But not just "any further purpose, or any different character" will do—to make a "transformative use of an original," a user "must go beyond that required to qualify as a derivative" use. *Id.* at 529. For example, an "adaptation of a book into a movie" is a "substantial" transformation, but it serves the same basic purpose (conveying a story for entertainment value) and is thus only derivative. *Id.*

Putting a work to a "transformative" use within the meaning of the fair-use doctrine requires putting the work to a new and unintended use, akin to those "listed in the preamble paragraph of § 107: criticism, comment, news reporting, teaching scholarship, or research." *Id.* at 528 (cleaned up). A parody, for example "has an obvious claim to transformative value" because it puts reproduced original material to "a distinct purpose of commenting on the original or criticizing it." *Id.* at 530 (discussing *Campbell*, 510 U.S at 579-583). By definition, the author of the original could not have criticism of her

own work as an original purpose of her creation.

b. The uses permitted by the Exemption are not transformative. It permits circumvention to copy "software, data files, and electronic service materials necessary for performing . . . servicing activities." 4-JA-1036. *Accord* 4-JA-1047-48 ("servicing computer programs and data files" and "electronic manuals"); 5-JA-1444 ("documentation and software to support planned maintenance activities and to execute common corrective maintenance activities"). Third-party servicers put those works to their exact intended uses—the same ones to which the works' authors put them.

There is nothing even remotely transformative about this. To begin with, third-party servicing companies do not imbue the works with a "new expression, meaning, or message." *Warhol*, 598 U.S. at 541. In fact, the Exemption's proponents expressly affirmed that they did not seek "an exemption to modify medical devices or systems, or their software" to avoid FDA regulation. 2-JA-627. The Librarian therefore did "not consider whether modification" of either the machines or their software "is not infringing." *Id.* She instead noted that "'modification' is not part of the proposed exemption for medical devices," and the "exemption requires the device to be restored to normal functionality and no changes be made to the firmware." 2-JA-648. Third-party servicers do not substantively modify anything.

Nor do third-party services put manufacturers' original creations to a "transformative" new *use* or *purpose*. With due respect to the Libarian and the district court, this point is not debatable. The Exemption's proponents were clear that they sought an exemption for "diagnostic software and data files" stored on, or embedded in, medical devices. 3-JA-1024. That is, they sought permission to copy "medical equipment servicing materials in the form of computer programs and data files," including manuals, "which are necessary for servicing (diagnosis, repair, and maintenance) of the medical devices and systems." 3-JA-1031-32. No petitioner sought an exemption to copy general operating software, which is typically Windows or Linux. Indeed, no such exemption would have been necessary in light of 17 U.S.C. § 117(c).

The works at issue here are only software service tools and maintenance-related documentation and files. These works, by definition, were created for the sole purpose of facilitating machine maintenance, diagnosis, and repair of the machines. As Philips explained in its 2024 comment letter, third-party servicers thus "seek to use copyrighted service software authored by [manufacturers] for the exact same purpose as it was created," which is "to service medical imaging systems." 5-JA-1510.

Confronting a similar circumstance shortly before enactment of the DMCA, the Ninth Circuit explained in *Triad Systems* that a third-party servicer in a case like this "invent[s] nothing of its own," and "its use of [the

manufacturer's] software is . . . neither creative nor transformative and does not provide the marketplace with new creative works." 64 F.3d at 1336. Or, to put it in *Warhol*'s words, third-party servicers' use of manufacturers' works "share[s] substantially the same purpose" as the original intended use, thus "supplanting the original" in the marketplace for maintenance-and-repair services without adding a "further purpose or different character" of any kind. 598 U.S. at 526, 528 (citing *Campbell*, 510 U.S. at 579).

c. There can be no doubt that the uses to which the works are being put are purely commercial: Third-party servicers use the copied materials to provide maintenance-and-repair services, which they sell for a fee. They accordingly "stand[] to profit from exploitation of the copyrighted material without paying the customary price" (a licensing fee), which is prototypical commercial use. *Harper & Row*, 471 U.S. at 562.

When third-party servicers put the works at issue here to their original and intended use without adding any new expression or applying any creative energies to them, the commerciality of the use assumes added weight. To be sure, "the fact that a use is commercial as opposed to nonprofit . . . is not [singularly] dispositive" of the first fair-used factor. *Warhol*, 598 U.S. at 531 (quoting *Google*, 593 U.S. at 32). It is, instead, "to be weighed against the degree to which the use has a further purpose or different character." *Id.* That makes sense: The less transformative a secondary use is, the more likely it is

to "serve as a substitute for the original or its plausible derivatives, shrinking the protected market opportunities of the copyrighted work"—and thus the more problematic it is that the secondary use is intended to make the user a profit at the author's expense. *Id.*

The only two courts to consider copyright infringement in this context are in accord: When a third-party servicer copies digital works and uses them to provide the very same maintenance-and-repair services that they were created to facilitate, the "use of [the] software [is] entirely commercial in nature." *Triad Systems*, 64 F.3d at 1337. *Accord Advanced Computer Services v. MAI Systems Corp.*, 845 F. Supp. 356, 365 (E.D. Va. 1994) (holding in a similar case that "the sole purpose of [the] use of [the] copyrighted software is in connection with the provision of computer maintenance services," which "is a commercial use").

It bears repeating here that third-party servicers earn their profit by taking business *from* the works' authors. Machine manufacturers "compete with ISOs for the post warranty servicing [contracts]" through which the works are monetized, but "ISOs often charge much less." 4-JA-1055. Of course, the reason that third-party servicers (ISOs) offer less expensive maintenance-and-repair services is because they are free-riding on the investments made by manufacturers. ISOs do not have to recoup the enormous R&D investments that manufacturers make to engineer their sophisticated medical

devices and author the software tools and other works necessary to keep them running. Their substitutive, commercial use of copyrighted materials is "presumptively an unfair exploitation of the monopoly privilege that belongs to the owner of the copyright." *Sony*, 464 U.S. at 451.

2. The Librarian's and district court's contrary conclusions are manifestly wrong

The Librarian disagreed on these points, concluding that third-party servicers *do* make a "transformative" use of field service software and maintenance-related documentation—by simply using those works for maintenance-and-repair services. Just to state that conclusion is to refute it.

In the Eighth Rulemaking, the Register's recommendation devoted a mere three sentences to the question of transformativeness:

> Here, the proposed activities are intended to restore a medical device or system's functionality, not to commercialize the embedded copyrighted software and other servicing materials. The Register has previously concluded that diagnosis and repair are likely to be transformative uses. The Register accordingly concludes that proponents' proposed use is likely transformative and so the first factor favors fair use.

2-JA-628. That is an illogical *ipse dixit*. It makes no sense to say that the only purpose of the copiers' use is to provide a service (restoring the machine's functionality), and not to make money in the competitive, commercial market for the service. When software is copied to provide maintenance-and-repair services to end-users in a commercial market for a fee, it is an obviously

commercial use. In fact, the use is not only commercial, but also a direct market substitution for manufacturers' services—the precise opposite of transformative use. *Warhol*, 598 U.S. at 528. To take the Librarian's logic to its natural conclusion would mean that when someone illegally copies a motion picture and sells tickets to watch the copy in his basement, he is putting the copy to the supposedly transformative use of "entertaining his customers," and the fact that he is making money in direct competition with movie theaters by doing so is irrelevant. That is not defensible.

Nor was it sufficient for the Librarian to analogize to the 2015 rule-making, in which she "previously concluded that diagnosis and repair are likely to be transformative uses." As commenters explained, the exemption at issue in 2015 authorized uses that included "copying the work to create new applications" and "extend[ed] to modification" of the works at issue. 1-JA-247. Here, no such transformative modifications are taking place. Again, the Librarian recognized this expressly, noting that "'modification' is not part of the proposed exemption for medical devices," which requires users to provide services with "no changes . . . made" to the works at issue. 2-JA-648.

Opponents of the Exemption highlighted this distinction in the Eighth Rulemaking (*e.g.*, 4-JA-1377), but the Librarian declined to address it (*see* 2-JA-627-631). They did so again in the Ninth Rulemaking (*e.g.*, 5-JA-1533), and the Librarian again declined to address it (*see* 3-JA-809-812).

That alone is a basis for vacating the Librarian's decisions as arbitrary and capricious. It is fundamental that "an agency must respond to comments 'that can be thought to challenge a fundamental premise' underlying the proposed agency decision." *Bloomberg L.P. v. SEC*, 45 F.4th 462, 476 (D.C. Cir. 2022). And "the failure to respond to significant comments . . . violates a substantive guarantee of the APA." *Western Coal Traffic League v. STB*, 998 F.3d 945, 954 (D.C. Cir. 2021).

We made this precise argument to the district court, but it waived it away, holding that "categorical" fair-use analysis required by the DMCA "requires some degree of generalization," and "[a]nalogizing . . . to another context involving . . . diagnosis, maintenance, and repair was therefore not only acceptable but showed exemplary thoroughness." 5-JA-1688. That answer likewise ignores the difference, which is that the 2015 exemption for automobile maintenance and repair expressly *included* transformative modifications, whereas the Exemption here expressly *disclaimed* them. Generalization is one thing, but ignoring a clear distinction is something else.

From there, the district court gave another response that the Librarian omitted, reasoning that the Librarian's analysis in the 2015 rulemaking didn't depend on modification. 5-JA-1689. There is no basis for that conclusion. The Library emphasized modification in the 2015 rulemaking (1-JA-247), and it did not suggest that it was irrelevant to transformativeness. Moreover,

modification was central to the transformative-use arguments presented by proponents to the Librarian in 2015. The Electronic Frontier Foundation, for instance, asserted that the 2015 record was "replete with transformative uses of vehicle software," including "modifying software to alter its functionality." EFF Reply Comments 5-6, https://perma.cc/P63H-J26Y. *Accord* SEMA Reply Comments 8, https://perma.cc/G2YU-YJYU.

Regardless, the district court's *sua sponte* reasoning was not adopted by the Librarian (or even pressed by his litigation counsel), so this is no basis for affirming. "[J]udicial review of agency action is limited to the grounds that the agency invoked when it took action." *DHS v. Regents of the University of California*, 591 U.S. 1, 20 (2020). The Court "cannot affirm based on a post hoc litigation rationalization" that differs from the reasons given by the agency itself. *Gulf Restoration Network v. Haaland*, 47 F.4th 795, 804 (D.C. Cir. 2022). That is so regardless of whether the post hoc reasoning is supplied by counsel for the agency or *sua sponte* by the district court.

b. In the Ninth Rulemaking, the Librarian concluded that the permitted uses are transformative because "the purpose of the use of software in repair is to render a non-functional device functional again, while the original purpose of the software is to operate a device that functions as designed." 3-JA-812. There are two ways to interpret this reasoning, both reflecting error.

***First*,** the Librarian can be understood to say that the original purpose of

the works at issue is *not* the facilitation of maintenance-and-repair services and instead only "to operate a device that functions as designed." From that angle, the Librarian seems to have concluded that the works at issue are the machines' operating software, and not field-service software tools or maintenance-related documentation.

That was the district court's belief, as well. It characterized the Exemption as allowing copying of "operating system software," which has as an "original use" the operation of a functioning machine. 5-JA-1683-84. That stands in contrast, according to the district court, with the "secondary use by ISOs to repair the device." 5-JA-1684. *Accord id.* n.5 (drawing "a distinction between the original purpose of getting the device to operate . . . and the secondary one of fixing the device to improve or maintain its operation"). Indeed, the district court went so far as to attribute to the Librarian a "factual finding" that "the operating software and related data files for medical devices were *not* originally invented and developed for the primary purpose of having OEMs service those devices." 5-JA-1709.

If that is what the Librarian meant, her decision was unequivocally wrong and ran "counter to the evidence before the agency." *Motor Vehicle Manufacturers Association v. State Farm Mutual Auto Insurance*, 463 U.S. 29, 43 (1983). As we have now repeatedly shown, the Exemption was only about software tools, manuals, documentation, and similar files used in mainten-

ance and repair.

That is what makes so puzzling the district court's assertion that "substantial evidence" supports "the Librarian's factual finding" that the works at issue were not created to facilitate maintenance and repair. 5-JA-1709. Having declared as much, the district court did not then recite the supposed evidence supporting the finding, or even where the finding was made. Instead, the district court cited to the entire fair-use section of its own opinion, running from 5-JA-1675 to 5-JA-1703. But that part of the opinion also does not cite evidence to support such a finding. The closest is footnote 5 on page 5-JA-1684, which simply recites the Librarian's factual *assumptions* (points that she "noted" and "recogniz[ed]"), again without citation to evidence.

The Librarian's and district court's evident belief that the Exemption concerns "operating system software" (5-JA-1683), which is created "to operate a device that functions as designed" (3-JA-812) and not to maintain or repair it, is just wrong. There is no evidence to support it—*none, nowhere*.

At the risk of excessive repetition: An exemption for copying operating software would not be necessary in light of § 117(c). The petitioners thus were explicit that they sought the Exemption for "medical equipment servicing materials" (3-JA-1031), including "diagnostic software and data files" (3-JA-1024) and electronically stored service manuals and similar documentation. (*e.g.*, 3-JA-1031-32; 4-JA-1078-79; 5-JA-1432, n.3). Those works very

plainly *are* "originally invented and developed for the primary purpose of having OEMs service those devices." 5-JA-1709.

Of course, even if this case were about general operating software, the uses at issue would be derivative at most and thus still protected. The language of the Exemption itself makes this clear—it allows the copying of computer programs and other protected works only if their reproduction is "a *necessary* step to allow the diagnosis, maintenance, or repair" of a medical device. 37 C.F.R. § 201.40(b)(17) (emphasis added). To characterize such copying as transformative depends on the implausible notion that, although (1) complex medical devices require diagnosis, maintenance, and repair during their lifetimes, (2) manufacturers know that such services will be required because they provide them, and (3) copying the machine's operating software is *necessary* to perform such tasks, manufacturers nevertheless did not design or intend their operating software to be used for that end. That rationale finds no support in the administrative record. And either way, such a use would be at most a derivative "adapt[ation]" of the original software and files. 17 U.S.C. § 101 (defining derivative use).

Second, the Librarian may alternatively be understood to say that third-party servicers' use is transformative of the *machine* (i.e., it "render[s] a non-functional device functional again") rather than of the works being copied. The district court echoed that reasoning, too, explaining that "diagnosis,

maintenance, and repair has a concrete 'transformative' effect *on the device* by changing some aspect of how it works." 5-JA-1686 (emphasis added). But that also is no answer, because the first fair-use factor is concerned with whether the *copied works* are transformed by the *copier*. It is not whether their use accomplishes the transformation of some distinct physical object like a machine, allowing some "end-user's utilization of the product," which is "largely irrelevant" to the fair-use inquiry. *Zomba Enterprises v. Panorama Records*, 491 F.3d 574, 582 (6th Cir. 2007).

We made this point in proceedings below. In response, the district court seemed to agree that transformation of the machine is insufficient. 5-JA-1687. But, the court concluded, "[a]lthough technically the hardware and software may be distinct, the device is simply a vessel for, or a reader of, the copyrighted material," and "[n]either is operational or commercially valuable without the other." 5-JA-1687. The court thus held that "maintenance and repairs to device components . . . has a transformative effect on the *use* of the software" by fixing the machine and ensuring it remains "commercially valuable." *Id.*

That again is not a reason the Librarian gave, and it is candidly hard to understand. Service software tools and maintenance manuals may lack utility without the devices to which they apply, but that is true of many copyrighted works. A computer programmer who creates a new software repair tool for Android smartphones has written something innovative and useful. To be

sure, the software requires a smartphone running Android to do its work, and it would not be "commercially valuable" without smartphones to run on. But that hardly means that a competitor's appropriation of the tool for its own use to provide competing maintenance-and-repair services for smartphones is "transformative," simply because the purpose is to make a smartphone functional and thus capable of running the software. That rationale is wholly out of place in a case about copyright.

c. Beyond these points, the district court added substantial new lines of reasoning not introduced by the Librarian in the rulemaking. We do not dwell on the district court's *sua sponte* analyses, because, again, the Court "may only uphold a rule 'on the basis articulated by the agency' in the rule making record." *Genuine Parts*, 890 F.3d at 314.

Yet one rejoinder warrants emphasis for clarity's sake. The district court reasoned that even if manufacturers "created [the works at issue] for use in performing their own repairs" (as unquestionably they did), and assuming further that third-party servicers use the works for the precise same purpose (as unquestionably they do), the use "still may be considered transformative." 5-JA-1685-86. That is because "use of those materials by ISOs or owners to achieve a secondary purpose to carry out repairs on specific, individual machines requires input of their own knowledge, creative and analytical thinking, and mechanical skills," which "transforms the basic knowledge conveyed

in the copyrighted materials." 5-JA-1686.

Put mildly, that is legally wrong and factually unsupported. Legally, it's like saying that a singer who offers a commercial performance of the copyrighted song makes a "fair use" of the work if her rendition requires her to "input" her training and creativity into the rendition. No. When an artist sings a song in a commercial performance, she must obtain a license from the author. That is so regardless of whether her performance is a precisely duplication of the original or instead offers some "important new expression." *Warhol*, 598 U.S. at 541. Creative interpretation of a preexisting work makes the performance derivative, if even that—it does not mean the result is a noninfringing fair use. *Id.*

But in this context, the proponents could not get even that far, because there is no evidence whatsoever to suggest that machine technicians do anything creative at all. Again, they expressly disclaimed transformation or alteration to avoid FDA regulation.

Of course, even if it were otherwise, what goes for the song would go for the repairs: Mixing software tools designed for maintenance and repair with the "knowledge, creative and analytical thinking, and mechanical skills" of a service technician (5-JA-1686) is *at most* akin to a derivative performance of an original work, as to which a license still must be obtained. To make a "transformative use of an original," a user "must go beyond that required to

qualify as a derivative" use, putting the work to use in an unintended market in which the author does not participate. *Warhol*, 598 U.S. at 529. That does not describe this case.

B. Fourth factor: Unauthorized copying directly undercuts the market in which manufacturers license the works at issue

1. The purpose of the Exemption is to inflict substantial harm on the marketability of the original works

a. Under the fourth fair-use factor, the Court must consider "whether the use in question substitutes for either a purchase or license that would typically be offered by the copyright owner and falls within the exclusive rights granted" by the Copyright Act. 4 Patry on Copyright § 10:150.10 (2025 update). This consideration—long recognized as "the single most important element of fair use" (*Harper & Row*, 471 U.S. at 566)—is closely related to the first factor. *Warhol*, 598 U.S. at 536 n.12. "While the first factor considers whether and to what extent an original work and secondary use have substitutable purposes, the fourth factor focuses on actual or potential market substitution." *Id.*

Under this factor, the Court must consider "not only the extent of market harm caused by the particular actions of the alleged infringer, but also whether unrestricted and widespread conduct of the sort engaged in . . . would result in a substantially adverse impact on the potential market for the original." *Campbell*, 510 U.S. at 590 (cleaned up).

Sensibly, an "inference of market harm" arises in cases "involving . . . mere duplication for commercial purposes." *Campbell*, 510 U.S. at 591 (citing *Sony*, 464 U.S. at 451); *see also, e.g.*, *Philpot v. Independent Journal Review*, 92 F.4th 252, 261 (4th Cir. 2024) (courts must "presume a cognizable market harm exists when a commercial use is not transformative but instead 'amounts to mere duplication of the entirety of an original'") (quoting *Campbell*, 510 U.S. at 591). Such a presumption is "common sense," because "when a commercial use amounts to mere duplication of the entirety of an original, it clearly supersedes the objects of the original and serves as a market replacement for it." *Campbell*, 510 U.S. at 591. "If it were possible to reproduce [an author's] unaltered work, as a whole, without compensation," it "would surely have a 'substantially adverse impact' on [the author's] ability to license [the work]." *Murphy v. Millennium Radio Group LLC*, 650 F.3d 295, 308 (3d Cir. 2011) (quoting *Campbell*, 510 U.S. at 590).

b. That is the case here. To start, there is plainly a market for the works at issue. Manufacturers sell licenses and subscriptions to use their maintenance-and-repair software, files, and documents. 4-JA-1067-68; 4-JA-1079; 4-JA-1361; 5-JA-1580. If third-party servicers wish to use manufacturers' software and documents to provide maintenance-and-repair services in competition with manufacturers, their technicians must therefore obtain the necessary training and pay a licensing fee. *E.g.*, 4-JA-1079-1080.

Beyond that, we have just shown that the copying of manufacturers' maintenance-related software and documents is commercially substitutive. "This is not a case where the copyist's work fills a market that the copyright owner will likely avoid, as is true for 'a lethal parody' or 'a scathing theater review.'" *Dr. Seuss Enterprises, L.P. v. ComicMix LLC*, 983 F.3d at 443, 460 (9th Cir. 2020) (quoting *Campbell*, 510 U.S. at 591-92). Rather, third-party servicers aim to take a greater share of the market for maintenance-and-repair services *from* manufacturers. *E.g.*, 5-JA-1439 (the point of the Exemption is to allow machine owners "to get faster and more affordable services from ISOs" rather than from manufacturers); 5-JA-1707 (district court noting that the exemption codified at § 117(c) "depriv[es] OEMs of licensing fees they would otherwise receive from repair services").

Allowing third-party servicers to copy manufacturers' service-related software tools and other digital materials without paying for them, so they may use them in their for-profit maintenance-and-repair businesses, therefore will, as a matter of "common sense" (*Campbell*, 510 U.S. at 591), have an adverse effect on the market for the software. Apart from depriving manufacturers of licensing revenue from the copiers themselves, many healthcare providers will stop paying for licenses and software subscriptions if they can obtain access to the protected works from lower-cost third-party servicers instead. Likewise, many will switch away from higher-cost OEM-affiliated

technicians, who must recoup the cost of training and licensing, electing instead to use third-party technicians who freeride on OEM innovations.

These market harms were not only acknowledged, but embraced, by the Librarian and petitioners throughout both rulemakings. The petitioners complained that manufacturers' training requirements, software licenses, and service contracts are "unnecessarily expensive" (4-JA-1044) and come at "undue expense" (4-JA-1042; 5-JA-1437). The Librarian was told repeatedly that "ISOs often charge much less than OEMs." 4-JA-1055; *accord* 3-JA-1022; 4-JA-1039; 4-JA-1057; 4-JA-1079. She also was told the reason why: Manufacturers require licensing fees for the "medical equipment software required for servicing of the medical equipment." 4-JA-1062; *accord* 3-JA-1024; 4-JA-1079; 5-JA-1434.

The higher prices resulting from licensing fees was thus presented as the very reason for the Exemption. But, again, that turns copyright law upside down. Manufacturers charge more because they, unlike third-party servicers, *actually innovate*. And they are granted a statutory monopoly for just that reason, so that they can recoup their enormous R&D investments and *continue* to innovate. *See Google*, 593 U.S. at 16-17.

Anyway, the point is simply that, in the Librarian's view, higher prices from a manufacturers' statutory copyright monopoly was a problem to over-

come—meaning, in effect, that substitutive market harm is the Exemption's *raison d'être*. Thus, the fourth factor weighs decisively against fair use.

2. The Librarian and district court erred in holding that there is no market to harm

a. The Librarian disagreed. She concluded that "most medical device and system software and data files generally have no independent value separate from being used with the equipment." 2-JA-631. Thus, although she acknowledged that "the record suggests that some system features on certain devices may be separately licensed through a subscription service," the Librarian determined that the copying at issue "is unlikely to harm the market for the embedded software" because "there is no indication that the software serves any function, or has any value, except for use with the medical device or system for which it was designed." *Id.*

That is a *non sequitur*. The question under the fourth factor is not whether the copyrighted material has a use, or can be sold in a market, *other than* its intended use or intended market. It is irrelevant that the materials are useful only in connection "with the medical device or system for which it was designed." The only questions under the fourth factor are (1) whether there is a market for buying or licensing the protected works, and (2) whether the author's position in that market is harmed by the copying. *Harper & Row*, 471 U.S. at 566; 4 Nimmer on Copyright § 13.05.

The evidence before the Librarian showed unequivocally that the answer to both questions here is *yes*. Transtate itself submitted a market analysis detailing the "dynamics" of the "medical equipment maintenance market." 4-JA-1132. In this market, manufacturers have a "large share" because of their "wide geographic presence and strong technical expertise." 4-JA-1133. But there has been an "emergence of ISOs dedicated to solely providing maintenance services" because they charge less. 4-JA-1135.

The evidence established further that, in the medical equipment maintenance market, manufacturers use encryption to "limit access to software and data files necessary to service [medical] equipment." 4-JA-1119. They sell "licenses to use the software," which also may be accessed by "an OEM technician" in lieu of an ISO. 4-JA-1079; *see also* 5-JA-1580 (manufacturers sell and lease certain software "functionalities" individually). As AdvaMed explained in both rulemakings, "there is a market for some medical device software modules as standalone works," which are "activated and maintained through a subscription model." 4-JA-1361; 5-JA-1580.

We made these points to the district court. But it concluded, like the Library, that "the software cannot be used without the equipment, and the equipment cannot be used without the software, so the market for the equipment and the software is one in the same." 5-JA-1697. But as we have shown, there *is* a market for the software separate from the equipment—as the Librar-

ian admitted but ignored. 2-JA-631 ("the record suggests that some system features on certain devices may be separately licensed through a subscription service"). The Library's ultimate conclusion to the contrary once again is "counter to the evidence before the agency." *State Farm*, 463 U.S. at 43.

b. Perhaps appreciating the insufficiency of the Librarian's answer on this point, the district court went on to assume our "premises as true," meaning that the works at issue are licensed and sold in the "separate market for diagnosis, maintenance, and repairs." 5-JA-1698. From there, it offered yet another explanation not furnished by the Librarian (and thus off the table). It reasoned that "the commercial value of the copyrighted materials in the latter market comes not from the copyrighted materials alone but rather relies on the application of labor, creative analytics and expertise." *Id.* On this ground, the district court made the stunning assertion that third-party servicers "arguably are creating a market by adding their own skill and expertise to provide a service using copyrighted materials." 5-JA-1699.

That reasoning once more turns copyright principles upside down. Consider again the singer/performance analogy. It may be true that the "commercial value" of a song "comes not from the copyrighted materials alone but rather relies on the" singer's interpretation and creativity to produce a sound. Sheet music has no value without a performance of its contents. But that observation has no relevance to the fourth fair-use factor, and it nowise

indicates that the author of the song is disentitled to copyright protection against exploitative performances.

In the context of the analogy, the fourth factor asks simply: (1) Is there a market for performances of the song? And (2) would allowing singers to copy the song's lyrics and tune, in unlicensed performances, have a "substantially adverse impact on the potential market for the original?" *Campbell*, 510 U.S. at 590. The answer to both questions is (as before) an obvious *yes*. And no one seriously could contend that the singer is not exploiting the market for the original and instead "creating a market" of her own. Quite the opposite: One would say that she is freeriding on the market that the *author* has created, by performing the song for commercial entertainment, without paying for a license. That's Copyright 101.

All of that holds true here. Again, the Librarian acknowledged this. She was clear that the purpose of the Exemption was to *overcome* manufacturers' copyright protection so that third-party servicers can put the works at issue to their intended uses, in competition with manufacturers, at lower prices. 2-JA-647. Depriving manufacturers of licensing revenue in the market for maintenance and repair (and thus "help[ing] to address the broader competitive concerns" in that market (*id.*)) is the *point* of the Exemption. *Cf.* 5-JA-1707 (district court noting that the exemption codified at § 117(c) "depriv[es]

OEMs of licensing fees they would otherwise receive from repair services"). There is thus no logical ground for denying market harm.

c. *Triad Systems* is once again instructive. There, "Triad invented, developed, and marketed its software to enable its customers and its own technicians to service Triad computers." 64 F.3d at 1337. The Ninth Circuit recognized that the third-party servicer in that case was "getting a free ride when it use[d] that software to perform precisely the same service" in competition with Triad, but without paying a licensing fee. *Id.* The court thus had no trouble concluding that "a finding of fair use is unwarranted" given the substitutive effect. *Id.* Because the defendant's "use of Triad's software [was] entirely commercial in nature" and substituted for Triad's own services, it was an infringing use, not a fair use—period. *Id.* at 1337.

That is this case exactly. For its part, the district court dismissed the Ninth Circuit's reasoning in *Triad Systems* as "sparse and thus hardly instructive," noting that it "predate[s] not only the DMCA's § 117(c) but also several key fair use decisions from the Supreme Court." 5-JA-1708-1709. But the district court did not point to any substantive inconsistencies between the Ninth Circuit's reasoning in *Triad Systems* and the Supreme Court's subsequent decisions. And none are apparent. Indeed, the Ninth Circuit addressed all the relevant considerations under contemporary doctrine: transformativeness, substitution, commerciality, market harm, and so on. As for the length

of the Ninth Circuit's decision, its fair-use analysis spans five paragraphs and is, on its own terms, complete and sound.

C. Second and third factors: There is no other "compelling justification" for finding the permitted uses noninfringing

Because the Exemption authorizes third-party servicers to put manufacturers' copyrighted works to commercial, non-transformative uses to compete at an unfair advantage, only "a particularly compelling justification" under the second and third fair-use factors could save the Exemption from invalidation. *Warhol*, 598 U.S. at 547. But the Librarian offered no justification, let alone a compelling one, for copying the works at issue—other than lowering prices for device maintenance and repair, which is no justification at all under settled copyright law.

a. Under the second factor, the Court must evaluate "the nature of the copyrighted work" (17 U.S.C. § 107(2)), including whether "it serves an artistic rather than a utilitarian function." *Google*, 593 U.S. at 20. No doubt, "computer programs differ from books, films, and many other 'literary works' in that such programs almost always serve functional purposes" rather than artistic, expressive ones. *Id.* at 21. Yet "[b]y defining computer programs in § 101, Congress chose to place this subject matter within the copyright regime." *Id.* at 23. And "unless a persuasive fair use justification is involved, authors of factual works, like authors of fiction, should be entitled to copy-

right protection of their protected expression." *Authors Guild*, 804 F.3d at 220. Put simply, "[t]he mere fact that the original is a factual work [does] not imply that others may freely copy it." *Id.*

Courts have recognized that a justification may exist where copying facilitates "a service important to the public." *Romanova v. Amilus Inc*, 138 F.4th 104, 116-17 (2d Cir. 2025) (Leval, J.) (collecting cases). But in each of those cases, the service was not substitutive or exploitative—it was instead transformative. *Id.* For example, in *Authors Guild v. HathiTrust*, 755 F.3d 87 (2d Cir. 2014), the service was conversion of copyrighted works into formats readable by the blind; and in *A.V. ex rel. Vanderhye v. iParadigms, LLC*, 562 F.3d 630 (4th Cir. 2009), the service was copying of student theses into a database to help universities detect plagiarism.

The same is true of the case on which the district court relied (5JA1682-84), *American Society for Testing & Materials v. Public.Resource.Org, Inc.*, which produced two opinions at 82 F.4th 1262 (D.C. Cir. 2023) and 896 F.3d 437 (D.C. Cir. 2018). The Court there concluded that the copiers' purpose (reporting legal standards to the public at large) was non-commercial and resembled "the purposes listed in the preamble paragraph of § 107," including "news reporting, teaching," and "research." *Warhol*, 598 U.S. at 529. As construed by the Court, those purposes were wholly different from (and not

substitutions for) the purposes of the original author, which was the creation of state-of-the-art industry standards.

These cases demonstrate that the second factor "favors fair use" only when, *because* the works are factual, "the secondary use transformatively provides valuable [new] information about the original, rather than replicating protected expression" and "substitute[ing] for the original." 4 Patry on Copyright § 10:138 (quoting *Authors Guild*, 804 F.3d at 220).

Not so here. There already is an established market for medical machine maintenance-and-repair services, independent of unauthorized copying. Copying merely permits ISOs to compete substitutively, at a lower price. In the copyright context, that is the *opposite* of justification. As the Supreme Court explained in *Google*, the purpose of copyright is "to encourage the production of works that others might reproduce more cheaply" by granting the author the right to exclude third parties from engaging in such reproduction, even though doing so generally will "raise prices." 593 U.S. at 16-17. But a manufacturer's "higher service rates cannot be said to violate the public interest" under copyright principles because a manufacturer "should be entitled to rely on [higher] service fees to recoup its investment costs in developing the software" and the machines that depend on it. *Advanced Computer Services*, 845 F. Supp. at 365.

b. Finally, the third factor directs courts to examine "the amount and substantiality of the portion used in relation to the copyrighted work as a whole." 17 U.S.C. § 107(3). This is not a justificative consideration, but rather a hurdle to overcome. When a copier takes all or a substantial portion of the original, fair use is less likely because substantial copying "is evidence of the qualitative value of the copied material, both to the originator and to the plagiarist who seeks to profit from marketing someone else's copyrighted expression." *Harper & Row*, 471 U.S. at 565. Here, the entire works are copied and used for commercial gain. There is thus no way in which the third factor could help to justify fair use in this case.

D. The Exemption purports to amend, and therefore is in conflict with, the plain language of 17 U.S.C. § 117(c)

The district court concluded its fair-use analysis with its own views on the purpose of 17 U.S.C. § 117(c)—views that, because they were not offered by the Librarian, were improper for the court to consider at all, much less base its decision on. *See* 5-JA-1704-10.

Section 117(c)'s text is explicit and narrow: It permits copying only of "a computer program," and then only when the copy "is made solely by virtue of the activation of a machine" and is "destroyed immediately after the maintenance or repair is completed." As both the Librarian and the district court acknowledged, that is "a narrower range of activities than those" covered by

the Exemption. JA1707. Service software tools are not copied by virtue of machine activation, and manuals and other written works needed for maintenance and repair are not computer programs at all. *See* JA1356.

Yet the district court, drawing on snippets of legislative history, took the position that § 117(c) reflects a broader "intent" to "ensure that maintenance and repairs [are] not monopolized by copyright owners of computer programs" and that "owners and lessees can maintain and repair their devices without being beholden to OEMs." JA1706-1707. Although the district court acknowledged that the "Exemption goes beyond" the statute by authorizing copying that § 117(c) does not, it concluded that the Exemption is "consistent with" the provision's broader "intent." JA1707.

That reasoning is misguided. "[A] broadly stated legislative purpose cannot trump more narrowly worded statutory text." *United States v. Hillie*, 39 F.4th 674, 688 (D.C. Cir. 2022). "[W]hatever degree of confidence about congressional purpose one derives from the legislative history, that purpose must find expression 'within the permissible limits of the language' before it can be given effect" by a court. *U.S. ex rel. Totten v. Bombardier Corp.*, 380 F.3d 488, 495 (D.C. Cir. 2004).

If § 117(c) is relevant here at all, it is only to show that Congress understood that copying to provide substitutive third-party maintenance-and-repair services is *not* fair use. Thus, when it made the policy decision to exempt copy-

ing for maintenance and repair that occurs as a consequence of activating a machine, it did so not by amending the fair use doctrine, but by adopting a simple, standalone carveout from the Act.

The district court's theory that Congress simply lacked the foresight to draft a "broader statutory exemption" because it "did not anticipate the need" for one in 1998 (5-JA-1707) is both irrelevant and wrong. Irrelevant, because it is not the district court's place to substitute its judgment for Congress's. Wrong, because use of licensed software in connection with maintenance and repairs was well known in 1998, as *Triad* demonstrates.

If Congress had wanted to draft a broader exception, it could have done so—but it did not. And even if there were ground to conclude today that § 117(c)'s scope is unduly narrow, it would be for Congress, not the Librarian or district court, to enlarge it.

II. THE COURT SHOULD VACATE THE EXEMPTION

When an APA plaintiff succeeds in showing that an agency has undertaken a final action that is inconsistent with law, arbitrary and capricious, or unsupported by evidence, "[t]he ordinary practice is to vacate unlawful agency action." *United Steel v. Mine Safety & Health Administration*, 925 F.3d 1279, 1287 (D.C. Cir. 2019) (citing 5 U.S.C. § 706). That ordinary practice is warranted here.

In proceedings below, the Library proposed that the district court instead issue a declaration that the Exemption is unlawful and otherwise enjoin the Library from implementing it. That would not suffice. The injuries arising from the Exemption are worked not just by the Librarian, but also by the private third parties violating plaintiffs' members' rights under the Exemption's authorization. As long as the Exemption stands, third-party servicers may utilize it as a rationale for infringing manufacturers' copyrights. Only the relief required expressly by 5 U.S.C. § 706(2)—an order setting the Exemption aside—will accord plaintiffs the full relief to which they are entitled.

CONCLUSION

The Court should reverse the decision below and remand with instructions to set aside the Medical Devices Exemption, 37 C.F.R. § 201.40(b)(17).

Respectfully submitted,

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Dated: November 7, 2025

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g)(1), undersigned counsel for appellant certifies that this brief:

(i) complies with the type-volume limitation of Circuit Rule 32 because it contains 12,994 words, including footnotes and excluding the parts of the brief exempted by Rule 32(f); and

(ii) complies with the typeface and type style requirements of Rule 32(a) because it is typeset in Century Supra font in 14 points.

Dated: November 7, 2025 /s/ *Michael B. Kimberly*

CERTIFICATE OF SERVICE

Undersigned counsel for appellant certifies that on this date, the foregoing document was served electronically via the Court's CM/ECF system upon all counsel of record.

Dated: November 7, 2025 /s/ *Michael B. Kimberly*

ADDENDUM
OF STATUTES AND REGULATIONS

17 U.S.C. § 1201(a) ..... Add. 1

17 U.S.C. § 117(c) ..... Add. 3

37 C.F.R. § 201.40(b)(17) ..... Add. 3

Section 1201(a) of Title 17 of the U.S. code specifies:

(a) Violations Regarding Circumvention of Technological Measures.

(1) (A) No person shall circumvent a technological measure that effectively controls access to a work protected under this title. The prohibition contained in the preceding sentence shall take effect at the end of the 2-year period beginning on the date of the enactment of this chapter.

(B) The prohibition contained in subparagraph (A) shall not apply to persons who are users of a copyrighted work which is in a particular class of works, if such persons are, or are likely to be in the succeeding 3-year period, adversely affected by virtue of such prohibition in their ability to make noninfringing uses of that particular class of works under this title, as determined under subparagraph (C).

(C) During the 2-year period described in subparagraph (A), and during each succeeding 3-year period, the Librarian of Congress, upon the recommendation of the Register of Copyrights, who shall consult with the Assistant Secretary for Communications and Information of the Department of Commerce and report and comment on his or her views in making such recommendation, shall make the determination in a rulemaking proceeding for purposes of subparagraph (B) of whether persons who are users of a copyrighted work are, or are likely to be in the succeeding 3-year period, adversely affected by the prohibition under subparagraph (A) in their ability to make noninfringing uses under this title of a particular class of copyrighted works. In conducting such rulemaking, the Librarian shall examine—

(i) the availability for use of copyrighted works;

(ii) the availability for use of works for nonprofit archival, preservation, and educational purposes;

(iii) the impact that the prohibition on the circumvention of technological measures applied to copyrighted works has on criticism, comment, news reporting, teaching, scholarship, or research;

(iv) the effect of circumvention of technological measures on the market for or value of copyrighted works; and

(v) such other factors as the Librarian considers appropriate.

(D) The Librarian shall publish any class of copyrighted works for which the Librarian has determined, pursuant to the rulemaking conducted under subparagraph (C), that noninfringing uses by persons who are users of a copyrighted work are, or are likely to be, adversely affected, and the prohibition contained in subparagraph (A) shall not apply to such users with respect to such class of works for the ensuing 3-year period.

(E) Neither the exception under subparagraph (B) from the applicability of the prohibition contained in subparagraph (A), nor any determination made in a rulemaking conducted under subparagraph (C), may be used as a defense in any action to enforce any provision of this title other than this paragraph.

(2) No person shall manufacture, import, offer to the public, provide, or otherwise traffic in any technology, product, service, device, component, or part thereof, that—

(A) is primarily designed or produced for the purpose of circumventing a technological measure that effectively controls access to a work protected under this title;

(B) has only limited commercially significant purpose or use other than to circumvent a technological measure that effectively controls access to a work protected under this title; or

(C) is marketed by that person or another acting in concert with that person with that person's knowledge for use in circumventing a technological measure that effectively controls access to a work protected under this title.

(3) As used in this subsection—

(A) to "circumvent a technological measure" means to descramble a scrambled work, to decrypt an encrypted work, or otherwise to avoid, bypass, remove, deactivate, or impair a technological measure, without the authority of the copyright owner; and

(B) a technological measure "effectively controls access to a work" if the measure, in the ordinary course of its operation, requires the application of information, or a process or a treatment, with the authority of the copyright owner, to gain access to the work.

Section 117(c) of Title 17 of the U.S. Code specifies:

(c) Machine Maintenance or Repair.—Notwithstanding the provisions of section 106, it is not an infringement for the owner or lessee of a machine to make or authorize the making of a copy of a computer program if such copy is made solely by virtue of the activation of a machine that lawfully contains an authorized copy of the computer program, for purposes only of maintenance or repair of that machine, if—

(1) such new copy is used in no other manner and is destroyed immediately after the maintenance or repair is completed; and

(2) with respect to any computer program or part thereof that is not necessary for that machine to be activated, such program or part thereof is not accessed or used other than to make such new copy by virtue of the activation of the machine.

Section 201.40(b)(17) of Title 37 of the Code of Federal Regulations specifies:

Exemptions to prohibition against circumvention.

(17) Computer programs that are contained in and control the functioning of a lawfully acquired medical device or system, and related data files, when circumvention is a necessary step to allow the diagnosis, maintenance, or repair of such a device or system. For purposes of this paragraph (b)(17):

(i) The "maintenance" of a device or system is the servicing of the device or system in order to make it work in accordance with its original specifications and any changes to those specifications authorized for that device or system; and

(ii) The "repair" of a device or system is the restoring of the device or system to the state of working in accordance with its original specifications and any changes to those specifications authorized for that device or system.

Declaration submitted in support of Comments from:

Advanced Medical Technology Association (AdvaMed)
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DECLARATION OF GARRETT HUNTLEY

I, Garrett Huntley, declare as follows based on my personal knowledge:

I. DECLARANT AND COMPANY BACKGROUND

1. I am the Senior Director of Federal and Service Solutions for Carestream Health, Inc. ("Carestream"). I have held this position since 2024. My responsibilities include sale and revenue generation for Carestream's break/fix service business, biomedical and clinical applications training offerings .

2. I have 10 years of experience in contract management, medical imaging equipment sales, and medical imaging equipment service and support. In my role, I am familiar with Carestream's medical devices, clinical operation software, system servicing and diagnostic software, Maintenance-Related Documentation, access controls, licensing practices, and service offerings described below.

3. Carestream develops, manufactures, sells, and/or leases Digital radiography equipment and systems, and associated detectors and generators, along with other medical imaging equipment, used for general clinical purposes, including diagnostic imaging in patient care.

II. RELEVANT SOFTWARE AND MATERIALS

4. As used in this declaration:

(a) "Clinical Operation Software" means software that health care professionals use to operate a medical device to perform patient care activities;

(b) "System Servicing/Diagnostic Software" includes software applications, diagnostic tools, calibration programs, configuration utilities, service interfaces, and related digital resources used to install, inspect, calibrate, test, maintain, diagnose, troubleshoot, update, or repair a medical device to its intended performance and safety specifications; and

(c) Maintenance-Related Documentation is non-software, digital work used for servicing, such as digital service manuals or repair procedure documentation.

5. Carestream uses Clinical Operation Software on its DRX line of X-ray imaging solutions to enable clinicians to acquire, review, and manage diagnostic images and operate the imaging system for patient care. That software includes the Carestream Main Application.

6. Carestream uses System Servicing/Diagnostic Software for those devices. Some of that service and diagnostic software is integrated with the Carestream Main Application, and other service and diagnostic software is managed as standalone applications, such as detector and generator configuration and diagnostic applications. This software is used to check for system errors or malfunctions, access system diagnostic information and service logs, calibrate the device after a repair, troubleshoot errors, install software updates or patches, and verify that the device is functioning properly before it is returned to clinical use.

III. TECHNOLOGICAL PROTECTION MEASURES (TPMs) & DIFFERENTIAL ACCESS

7. Access to Carestream's System Servicing/Diagnostic Software is controlled by a technological protection measure that Carestream refers to as "SecureLink." Access to the service and diagnostic applications requires both a service multi-factor authentication (MFA) device and a password that are unique to each individual service engineer. The USB MFA device contains an encrypted file identifying the service engineer.

8. These TPMs are separate and apart from the protections or controls governing access to the Clinical Operation Software. Carestream service access is unique to Carestream-issued service credentials and the SecureLink MFA device, while clinical users access the Clinical Operation Software using Windows authentication, with optional proximity badge multi-factor authentication.

9. Access to the Clinical Operation Software is controlled by Windows authentication and optional proximity badge MFA, which is administered by the healthcare facility that owns or leases the device and its information technology personnel. By contrast, access to the System Servicing/Diagnostic Software is controlled by the SecureLink service key and the unique service engineer password associated with it, which are issued and administered by Carestream.

10. A person who has authorized access to the Clinical Operation Software does not thereby receive authorized access to the System Servicing/Diagnostic Software. To obtain such access, the person or organization must complete Carestream OEM service training and obtain SecureLink credentials from Carestream, either under an OEM service agreement with Carestream or, in the case of service providers that do not hold a Carestream service agreement, by sending individual field engineers to Carestream OEM service training and paying an annual subscription assessed on a per-person, per-unit basis.

11. These access controls serve to maintain patient safety, cybersecurity control, device integrity, and protect proprietary materials.

IV. LICENSING, SERVICE OFFERINGS, AND DISTINCT MARKET

12. The System Servicing/Diagnostic Software resides on the medical device and is not sold as a standalone product. Carestream provides *access* to this software separately from the sale or lease of the device, through the SecureLink service key and through Carestream's Service Portal. Service Portal and SecureLink access is provided to OEM-trained device owners, channel partners, independent service organizations (ISOs) and multi-vendor service (MVS) personnel contracted to service Carestream equipment.

13. This access to the software is offered both through OEM service agreements and through licensing. Customers who purchase OEM service agreements and who are OEM-trained on the equipment have access via Carestream's SecureLink service key. Other service providers that do not have service agreements with Carestream but service or maintain Carestream equipment, including ISOs and MVS organizations, may send individual field engineers to Carestream OEM service training and pay a yearly subscription on a per-person, per-unit basis to obtain these credentials. The access provided includes the SecureLink service key and credentials, and access to the Service Portal and its Maintenance-Related Documentation described below.

14. The market for these products and services includes biomedical engineers, channel partners, and ISO and MVS field engineers. Carestream competes in servicing and repairing medical devices, including its own, primarily with the third-party service providers, in the form of ISOs and MVS organizations, including MVS organizations operating within competing equipment OEMs such as GE, Philips, and Siemens (Block).

15. Customers can only be assured they are receiving quality maintenance and repair services on their System Servicing/Diagnostic Software if their service personnel have completed Carestream OEM service training and acquired SecureLink credentials and Service Portal access.

V. MAINTENANCE-RELATED DOCUMENTATION

16. Carestream provides extensive Maintenance-Related Documentation to OEM-trained field service engineers. It includes maintenance documentation; service bulletins; software and firmware update information; modification and installation instructions; service documentation, in the form of process checklists, manuals, diagnostic guides, and parts lists; user guides, best practices information, new version release notes; and acceptance and compliance test procedures.

17. This documentation is provided through a web-based portal called the "Service Portal", along with a thumb drive option. It is therefore maintained separately from the Clinical Operation Software and the System Servicing/Diagnostic Software that resides on the device and is accessed through a Carestream-hosted portal rather than through the device's clinical interface.

18. The documentation in the Service Portal is used by OEM-trained field service professionals who maintain SecureLink credentials. They may access the portal at any time, and the portal can

be used to download information or for real time assistance during service, installation, or preventive maintenance activities. The Service Portal provides the same level of detail to outside OEM-trained field service engineers as is supplied to Carestream OEM field engineers.

19. Access to this documentation is controlled by TPMs: the Carestream Service Portal is password protected, and the SecureLink service key requires password authentication. These measures are separate and apart from the protections governing the Clinical Operation Software because Service Portal and SecureLink credentials are issued and controlled by Carestream and are conditioned on completion of Carestream OEM service training. Access to the Clinical Operation Software is controlled by Windows authentication and optional proximity badge MFA administered by the healthcare facility.

VI. UNAUTHORIZED ACCESS [AND PRACTICAL EFFECTS]

20. Carestream developed SecureLink in-house to protect against unauthorized use of, or infringement relating to, its equipment and service resources. Enforcement is contractual, based on agreements with customers and trained service providers who receive the SecureLink passwords after completion of Carestream certified training.

21. Unauthorized circumvention of the TPMs described above would permit persons who have not completed the proper Carestream OEM service training, and who are not subject to the contractual terms under which SecureLink credentials and Service Portal access are granted, to access the System Servicing/Diagnostic Software and Maintenance-Related Documentation, putting patient safety at risk.

VII. CONCLUSION

23. The Clinical Operation Software, System Servicing/Diagnostic Software, and Maintenance-Related Documentation described above are distinct in function and subject to distinct access controls: the Clinical Operation Software is protected by Windows authentication and optional proximity badge MFA administered by the healthcare facility, while the System Servicing/Diagnostic Software and Maintenance-Related Documentation are protected by the SecureLink MFA device, unique service engineer passwords, and by password-protected Service Portal credentials, issued and administered by Carestream.

24. The System Servicing/Diagnostic Software and Maintenance-Related Documentation are monetized through OEM service agreements and through annual per-person, per-unit subscriptions paid by service providers that complete Carestream OEM service training.

25. Allowing improperly trained service personnel to service and repair sophisticated diagnostic equipment is a patient safety risk.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed on September 25, 2026, in Rochester, New York.

Garrett Huntley Digitally signed by Garrett Huntley
Date: 2026.09.25 15:29:38 -04'00'

Garrett Huntley
Senior Director of Federal and Service Solutions
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Declaration submitted in support of Comments from:
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DECLARATION OF JEROME DUHAMEL

I, Jerome Duhamel, declares as follows based on my personal knowledge:

I. DECLARANT AND COMPANY BACKGROUND

1. I am the Global Service Operations GM of GE Medical Systems SCS (an affiliate of "GE HealthCare"). I lead our global service operations Center of Excellence across service delivery, commercial enablement, digital platforms, business operations, business intelligence and service productivity.

2. I have 20 years of experience in GE HealthCare product service. In my role, I am familiar with the company's medical devices, Clinical Operation Software, System Servicing/Diagnostic Software, Maintenance-Related Documentation, access controls, licensing practices, and service offerings described below.

3. GE HealthCare develops, manufactures, sells, and/or leases imaging devices in MR, PET, CT, MI, Xray, and Ultrasound used for diagnostic and interventional procedures.

II. RELEVANT SOFTWARE AND MATERIALS

As used in this declaration:

(a) "Clinical Operation Software" means software that health care professionals use to operate a medical device to perform patient care activities;

(b) "System Servicing/Diagnostic Software" includes software applications, diagnostic tools, calibration programs, configuration utilities, service interfaces, and related digital resources used to install, inspect, calibrate, test, maintain, diagnose, troubleshoot, update, or repair a medical device to its intended performance and safety specifications; and

(c) "Maintenance-Related Documentation" is documentation used for servicing, such as service manuals or repair procedures.

4. GE HealthCare uses Clinical Operation Software on all products to enable clinicians to operate the device.

5. GE HealthCare uses System Servicing/Diagnostic Software for above mentioned devices, including Common Service Desktop. This software is used to view logs, test, calibrate, configure, troubleshoot, update or verify performance of the device.

III. TECHNOLOGICAL PROTECTION MEASURES (TPMs) AND DIFFERENTIAL ACCESS

6. Access to the System Servicing/Diagnostic Software is available on the device with no access restriction for all logged users for Class A1 tools (referred to externally as General Service) and controlled by Secure Service Access keys (SSA keys) which can be physically distributed in the form of a USB key with a Digi code (SSA hard keys) or remotely installed (SSA license key).

7. These TPMs are separate and apart from the protections or controls governing access to the Clinical Operation Software because they govern access levels to the Common Service Desktop only. Clinical Operations Software is accessible to any user once logged in. Common Service Desktop has a range of tools: Class A (referred to externally as General Service) for general service required by regional laws and regulations (e.g., AIAT regulations in the U.S. and regional laws) required to return the equipment to an operational state in accordance with GE HealthCare specifications (e.g., basic startup/installation instructions and AIAT guidelines or equivalent). Class A is available publicly, including to independent service organizations (Class A1 service software is accessible on the device without needing any additional keys or licenses; Class A2 and A3 service software is licensed on request with some regions charging a reasonable fee and others, like the U.S., providing the license at no additional charge). Class C (externally referred to as Technical Service) contains productivity and efficiency software and is only made available via sale and license to entitled customers and channel partners under contract with GE HealthCare. Finally, Common Service Desktop contains Class M software (externally referred to as GE HealthCare Highly Confidential) that is for GE HealthCare internal use only or has been identified as a GE HealthCare trade secret. Class M may be made available to channel partners under a channel partner agreement with GE HealthCare in some regions outside the U.S.

8. Access to the Clinical Operation Software is controlled by user credentials which are administered by the customer. By contrast, access to the System Servicing/Diagnostic Software Class C and M are controlled by the type of physical SSA USB key or digital license key installed in the system; by default, all Class A1 software will be accessible and other levels of software will be enabled based on installed key access level.

9. A person who has authorized access to the Clinical Operation Software does receive access to Class A1 System Servicing/Diagnostic Software by default; those tools are used for daily calibration activities such as tube calibration or warm up. For elevated access, the person or organization must license the key from GE HealthCare as described in Section 7 above.

10. These access controls serve purposes including, for example, safety of operation, system integrity, subscription-based offering, and protection of proprietary material.

IV. LICENSING, SERVICE OFFERINGS

11. GE HealthCare licenses access to its System Servicing/Diagnostic Software separately from the sale or lease of the device. Access to Class A2/A3 is made available to any customer or independent service organization through licensing. Access to Class C1/C2/C3 is made available to any customer through a service agreement or licensing.

12. The consideration charged for such access depends on the commercial policy of the country. The access provided may include licenses to Common Service Desktop restricted tools, training and/or support.

13. Customers may obtain maintenance or repair services through GE HealthCare, independent service organizations, their in-house service departments, and sometimes other manufacturers. If additional software access or expertise is required beyond the access already provided in Class A1, those parties can contact GE HealthCare to determine what licensing options are available.

V. MAINTENANCE-RELATED DOCUMENTATION

14. GE HealthCare publicly provides Maintenance-Related Documentation that includes detailed Class A1 service manuals containing step by step procedures, schematics and pictures on its online manual & documents website: https://www.gehealthcare.com/en-us/support/manuals

15. Clinical Operation Software and System Servicing/Diagnostic Software are documented in the product User/Operator manual and Service Manual, both available on the above website.

16. Maintenance-Related Documentation is used by operators, independent service organizations, GE HealthCare's channel partners and GE HealthCare when operating, installing or servicing the equipment.

17. Access to Class A1 documentation is public just like Clinical Operation documentation (also called operator manual).

18. GE HealthCare licenses access to Class A2/A3/C1/C2/C3 documentation, which GE HealthCare makes available and conditioned to an active licensing or service agreement.

VI. UNAUTHORIZED ACCESS AND PRACTICAL EFFECTS

19. GE HealthCare has encountered unauthorized access, distribution and use involving System Servicing/Diagnostic Software or Maintenance-Related Documentation. GE HealthCare

enforces against unauthorized use of its System Servicing/Diagnostic Software, SSA keys and Maintenance-Related Documentation through means such as cease-and-desist letters.

20. Unauthorized circumvention of the TPMs described above could grant unauthorized access to systems and compromise system integrity which could in turn compromise operator and patient safety and lead to wrong diagnosis.

VII. CONCLUSION

21. The Clinical Operation Software, System Servicing/Diagnostic Software, and Maintenance-Related Documentation described above are distinct in function and are subject to distinct access controls. Clinical Operation Software and Class A1 System Servicing/Diagnostic Software is controlled through user login. Access to Class A2/A3/C1/C2/C3 is dependent on the license key installed in the system. Access to Class M is limited to GE Healthcare internal as it is deemed highly confidential. As noted above, in some regions outside the U.S., Class M may be made available to channel partners under an agreement with GE HealthCare.

22. Class A2/A3/C1/C2/C3 System Servicing/Diagnostic Software and/or Maintenance-Related Documentation is made available through licenses or service agreements, and servicing of medical devices is performed by GE HealthCare, its channel partners, independent service organizations, in-house service departments of end-users, and other manufacturers.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed on September 28th, 2026, in Buc, France

Signature: _____

Print Name: Jerome Duhamel

Title: Global Service Operations GM

Company Name: GE Medical Systems SCS

Declaration submitted in support of Comments from:

Advanced Medical Technology Association (AdvaMed)
1301 Pennsylvania Ave NW, Ste 400
Washington, DC 20004

DECLARATION OF PIERRE MALBOEUF

I, Pierre Malboeuf declare as follows based on my personal knowledge:

I. DECLARANT AND COMPANY BACKGROUND

1. I am the Vice President, Service Delivery of Hologic Inc. ("Hologic"). I have held this position since 2023. My responsibilities include service delivery of Hologic Technical and Field Service support to both customers and Hologic personnel. Product and software design are inherent to the products Hologic manufactures, distributes, and services.

2. I have 29 years of experience in Service Operations and Field Services. In my role, I am familiar with the company's medical devices, clinical operation software, system servicing and diagnostic software, Maintenance-Related Documentation, access controls, licensing practices, and service offerings described below.

3. Hologic develops, manufactures, sells, and/or leases innovative medical technologies that effectively detect, diagnose and treat health conditions used for disease detection in breast health, gynecological health, sexual health, body composition, and skeletal health.

II. RELEVANT SOFTWARE AND MATERIALS

As used in this declaration:

(a) "Clinical Operation Software" means software that health care professionals use to operate a medical device to perform patient care activities;

(b) "System Servicing/Diagnostic Software" includes software applications, diagnostic tools, calibration programs, configuration utilities, service interfaces, and related digital resources used to install, inspect, calibrate, test, maintain, diagnose, troubleshoot, update, or repair a medical device to its intended performance and safety specifications; and

(c) "Maintenance-Related Documentation" is non-software, digital work used for servicing, such as digital service manuals or repair procedure documentation.

4. Hologic uses Clinical Operation Software on Breast Health platforms to enable clinicians to diagnose and treat breast cancer.

5. Hologic uses System Servicing/Diagnostic Software for those devices, including company-designed calibration and software service tools. This software is used to assist the service

technician in problem diagnosis, calibration assistance, and allows for the calibration of the mechanical and imaging sections of the product.

III. TECHNOLOGICAL PROTECTION MEASURES (TPMs) AND DIFFERENTIAL ACCESS

6. Access to the System Servicing/Diagnostic Software is controlled by passwords, license keys, license controls.

7. These TPMs are separate and apart from the protections or controls governing access to the Clinical Operation Software because they are separate software applications and have different access controls.

8. Access to the Clinical Operation Software is controlled by passwords and license controls controlled by clinical users. By contrast, access to the System Servicing/Diagnostic Software is controlled by passwords, license keys, license controls, and USB security devices.

9. A person who has authorized access to the Clinical Operation Software does not thereby receive authorized access to the System Servicing/Diagnostic Software. To obtain such access, the person or organization must contact Hologic Technical Support, where credentialing is verified for proper access allowance and safety control.

10. These access controls serve purposes including safety, system integrity, cybersecurity, protection of proprietary materials, and license management.

IV. LICENSING, SERVICE OFFERINGS, AND DISTINCT MARKET

11. Hologic can sell or provide access to its System Servicing/Diagnostic Software separately from the sale or lease of the device. Access is offered to factory-trained and authorized service personnel through service program offerings which provide credentialing.

12. The consideration charged for such access is determinable across type of customer, access needed, and other economic factors of install base support scale. The access provided may include calibration guided assistance as well as access to troubleshooting reference materials.

13. The market for these works and services includes hospital service personnel (BMETs) or third-party authorized service providers. Hologic competes in servicing and repairing these devices with other OEMs and ISOs, including GE Healthcare, Siemens Healthcare, Trimedix, Crothall, 626 Holdings, Cassling, Aramark, and Frontier.

14. Customers may obtain maintenance or repair services through OEM service or ISO service. If additional authorized software access or expertise is required, customers may request a limited use license via one-time charge or provide credentialing that entitles access via factory-provided technical instruction.

V. MAINTENANCE-RELATED DOCUMENTATION

15. Hologic provides Maintenance-Related Documentation that includes Service Manuals, User Manuals, Quality Control Manuals and required safety updates.

16. This documentation is stored in hard copy format with every shipped product. Relative to the Clinical Operation Software and System Servicing/Diagnostic Software, it is separated at the product level.

17. The documentation is used by authorized service providers when performing service and calibration requirements and for the purpose of restoring or maintaining the product to the manufacturer's specifications.

18. Access to this documentation is controlled by passwords and license controls. These measures are separate and apart from protections governing Clinical Operation Software because they are separate from the clinical software and are distinct from both clinical and service operations.

19. Hologic offers factory authorized training and credentialing access to this documentation through various entitlements based on customer need, demand, and partnership in post-warranty agreements.

VI. UNAUTHORIZED ACCESS AND PRACTICAL EFFECTS

20. Unauthorized circumvention of the TPMs described above could jeopardize system integrity, calibration of radiation releasing components, and provide for unsafe patient conditions.

21. Authorized access to System Servicing/Diagnostic Software and Maintenance-Related Documentation is available through factory-provided service manuals, and via factory-authorized training and license access subject to conditions of Hologic Learning and Development.

VII. CONCLUSION

24. The Clinical Operation Software, System Servicing/Diagnostic Software, and Maintenance-Related Documentation described above are distinct in function and are subject to different and distinct access controls.

25. System Servicing/Diagnostic Software and/or Maintenance-Related Documentation is monetized through Hologic Surecare Agreements and participants in this market that include direct customers, third-party service providers, and OEMs.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed on 9.24.26 in Pittsburgh, PA

/s/ *Pierre Malboeuf*

Pierre Malboeuf
Vice President, Service Delivery
Hologic, Inc.

Declaration submitted in support of Comments from:

Advanced Medical Technology Association (AdvaMed)
1301 Pennsylvania Ave NW, Ste 400
Washington, DC 20004

DECLARATION OF JACQUELINE DICKSON

I, Jacqueline Dickson, declare as follows based on my personal knowledge:

I. DECLARANT AND COMPANY BACKGROUND

1. I am the CSIP Services Operations Director of Philips North America LLC ("Philips"). I have held this position since 2024. My responsibilities include oversight and support relating to service governance, access management, investigations, compliance activities, and cross-functional escalation management. These responsibilities require regular interaction with personnel from service, cybersecurity, privacy, legal, regulatory, and business organizations, and provide me with direct knowledge of the policies, procedures, and operational controls relevant to the matters discussed in this declaration.

2. I have 22 years of experience in service operations related to medical devices, with a focus on governance and administration of service documentation and service applications. In my role, I am familiar with Philips' medical devices, clinical operation software, system servicing and diagnostic software, Maintenance-Related Documentation, access controls, licensing practices, and service offerings described below.

3. Philips develops, manufactures, sells, and/or leases a comprehensive portfolio of medical systems including medical imaging systems (e.g., magnetic resonance imaging (MRI), computed tomography (CT), ultrasound systems, diagnostic x-ray (radiography and fluoroscopy), and image-guided therapy systems for angiography).

II. RELEVANT SOFTWARE AND MATERIALS

4. As used in this declaration:

(a) "Clinical Operation Software" means software that health care professionals use to operate a medical device and to perform patient care activities;

(b) "System Servicing/Diagnostic Software" includes software applications, diagnostic tools, calibration programs, configuration utilities, service interfaces, and related digital resources used to install, inspect, calibrate, test, maintain, diagnose, troubleshoot, update, or repair a medical device to its intended performance and safety specifications; and

(c) "Maintenance-Related Documentation" is non-software, digital work used for servicing, such as digital service manuals or repair procedure documentation.

5. Philips uses Clinical Operation Software on its medical imaging systems to enable clinicians to operate the device's medical features and to access patient information in the course of patient care. Devices typically have two or more types of accounts for the Clinical Operation Software, including a login for technologists to access the clinical interface and patient information, and an information technology or hospital administration account used to configure clinical user accounts.

6. Philips uses System Servicing/Diagnostic Software for those devices. That software is proprietary to Philips and is used to perform various service tasks on the devices, including but not limited to system diagnostics, system installation, and system configuration. Some of that software may be used to check systems for errors, access system diagnostic information and service logs, perform system calibration or troubleshooting, verify device operation, modify device configurations (e.g., radiation dose), and customize devices. These service software tools are divided into categories that Philips calls "Levels." Access to the tools in each Level is protected by TPMs and is governed by different terms and conditions, as described below.

III. TECHNOLOGICAL PROTECTION MEASURES (TPMs) & DIFFERENTIAL ACCESS

7. Philips uses several TPMs to control access to its System Servicing/Diagnostic Software. The principal measure is Philips' proprietary Integrated Security Tool ("IST"), which controls both authentication and entitlement. Through IST, Philips applies encrypted certificates together with multifactor authentication to the device. The user must present a physical smartcard, which uses a proprietary program, in order to present the medical device with an encrypted, time-limited, user-specific certificate, and the user must enter the matching password for that specific user account. Upon successful login, the system presents only the service software tools that the user is entitled to use, based on the user's IST entitlements.

8. These TPMs are separate and apart from the protections or controls governing access to the Clinical Operation Software. The Clinical Operation Software is managed separately. Its logins are username and password based, more like a Windows-type login, and they do not involve the IST smartcard, the encrypted user-specific certificate, or the entitlement system that determines which service software tools a user may access.

9. Access to the Clinical Operation Software is controlled by the technologist and information technology or hospital administration accounts described above, which are administered by the health care facility that owns or leases the device and its information technology personnel. Those logins are not in place to protect copyrighted material; they

are in place to allow device owners to ensure that only hospital-authorized clinical staff or other individuals can access a system's medical features and/or patient data. By contrast, access to the System Servicing/Diagnostic Software is controlled by the IST smartcard, the encrypted user-specific certificate, the matching account password, and the user's IST entitlements, each of which is issued and administered by Philips.

10. A person who has authorized access to the Clinical Operation Software does not thereby receive authorized access to the System Servicing/Diagnostic Software. A system owner is not authorized to access the protected System Servicing/Diagnostic Software, so it has no authority to authorize others to access or use such proprietary Philips software. To obtain such access, the person or organization must satisfy the conditions that apply to the Level of the tool sought. Level 0 tools are available to any person, including independent service organizations ("ISOs") or hospital biomeds, on request. Level 1 tools are available to hospital biomeds under a license granted as part of certain cooperative service agreements that include license fees, and subject to specific terms and conditions, including completion of Philips service training for that product and execution of a non-disclosure agreement. Level 2 tools are not available for licensing and are reserved for trained Philips engineers. Level 3 tools present an even greater risk if used with insufficient training and are likewise not available for licensing and are restricted to a small number of more highly trained and experienced service specialists.

11. These access controls serve purposes including protecting proprietary Philips software, patient and servicer safety, the performance and cybersecurity of the device, and license management. All Levels contain proprietary software developed by Philips and should only be used by sufficiently trained individuals given the safety-critical nature of medical device servicing. Level 2 and Level 3 in particular contain tools that are highly proprietary, pose a greater risk to patient or servicer safety, or that can alter or impact the performance or cybersecurity of the device. The strict restrictions Philips places on these tools are in line with FDA guidelines for remanufacturing and cybersecurity for medical devices.

IV. LICENSING, SERVICE OFFERINGS, AND DISTINCT MARKET

12. Philips licenses access to its System Servicing/Diagnostic Software separately from the sale or lease of the device, on terms that correspond to the Level of the tool. Philips provides Level 0 access to ISOs, hospital biomeds, and others on request. Philips licenses Level 1 access to hospital biomeds under certain cooperative service agreements, subject to requirements for system-specific service training and non-disclosure agreements. Level 2 and Level 3 access is not available for license and is retained for Philips.

13. Access is offered both through separate service agreements and through licensing. The consideration charged for Level 1 access takes the form of license fees included in

certain cooperative service agreements. The access provided includes the licensed service software tools themselves, the IST credentials and encrypted certificate required to authenticate to them, the IST entitlements that determine which tools the licensee may use, and access to the Maintenance-Related Documentation described below at the corresponding Level.

14. The market for these works and services includes hospital biomedical engineering departments that license the Level 1 works as part of certain cooperative service agreements, and Philips' own engineers and service specialists, for whom the Level 2 and Level 3 works are reserved and whose tools support Philips' own service activities. Philips competes in servicing and repairing these devices with ISOs, other OEMs, and in-house biomeds. In the FDA's 2018 report, "FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices," the FDA estimated that over 16,000 firms perform medical device service in the United States.

15. Customers may obtain maintenance or repair services from whomever they chose, including Philips, their own in-house biomedical engineering personnel, ISOs, or other OEMs. If additional authorized System Servicing/Diagnostic Software access or expertise would assist with a service, the customer or servicer may request Level 0 tools, or, in the case of hospital biomeds, may obtain a license to Level 1 tools as part of a cooperative service agreement upon completion of Philips service training for that product and execution of a non-disclosure agreement. Use of Level 2 or Level 3 tools is for servicing is reserved for Philips.

V. MAINTENANCE-RELATED DOCUMENTATION

16. Philips provides Maintenance-Related Documentation, which is likewise organized by Level. Basic maintenance manuals are available at Level 0 on request. More advanced documentation is available at Level 1 under license, subject to training and confidentiality requirements. Level 2 documentation poses additional safety, cybersecurity, or remanufacturing risks and is limited to Philips only.

17. This documentation is nearly exclusively stored on a cloud server and is not stored on the medical device. It is therefore maintained separately from both the Clinical Operation Software and the System Servicing/Diagnostic Software that reside on the device, and it is accessed through a Philips-hosted cloud server (InCenter) rather than through the device's clinical interface.

18. The documentation may be used by those performing service, including ISOs, hospital biomeds, and Philips personnel, with access on demand, based on a user's entitlements, at the time of need.

19. Access to this documentation is controlled by TPMs. Philips uses the proprietary IST to protect the login for service documentation, and multifactor authentication is required: the user must log in to the IST application on their computer to activate the encrypted certificate, and must use the IST account to log in to the cloud server (InCenter). The certificate is valid only on that user's computer; a user cannot log in from a different computer without re-registering with IST. Once logged in, the server presents only the materials that match the user's entitlements. To open protected Level 1 or higher materials, which are encrypted, the IST application must be active and logged in on the computer, and the tool then decrypts the documentation for viewing. These protection measures prevent the protected documents from being downloaded, saved, or printed. Level 0 documentation requires a login using IST credentials but is not encrypted, and select documents, such as Instructions for Use for the medical devices, are available with a "guest" login and are not subject to these additional protections. These measures are wholly separate and apart from the logins used for the Clinical Operation Software, because IST credentials, certificates, and entitlements are issued and controlled by Philips, whereas the Clinical Operation Software logins are username and password accounts administered by the health care facility and its information technology personnel.

20. Philips offers access to this documentation separately from the sale or lease of the device, on terms that correspond to the Level of the material: Level 0 maintenance manuals are available to any person, including ISOs and hospital biomeds, on request; more advanced Level 1 documentation is available under license, subject to completion of Philips service training for the product and execution of a non-disclosure agreement; and Level 2 documentation is not offered for license and is limited to Philips.

VI. UNAUTHORIZED ACCESS AND PRACTICAL EFFECTS

21. Philips enforces against unauthorized use of, and infringement relating to, its System Servicing/Diagnostic Software, service keys, and Maintenance-Related Documentation. Philips enforces both through more informal means, such as cease-and-desist letters, and through more formal means, up to and including litigation. Philips has obtained judgments in multiple litigations, including against Transtate/Avante, KPI Ultrasound, and Image Technology.

22. Unauthorized circumvention of the TPMs described above would permit persons who have not completed Philips service training for the product, and who are not subject to the license terms and non-disclosure agreements under which Philips grants access, to obtain access to the System Servicing/Diagnostic Software and the Maintenance-Related Documentation. That includes the Level 2 and Level 3 tools and the Level 2 documentation that Philips does not license to anyone, which are highly proprietary, pose

a greater risk to patient or servicer safety, or can alter or impact the performance or cybersecurity of the device.

23. Based on my responsibilities and experience, authorized access to Philips' service software and Maintenance-Related Documentation is available through IST and, in the case of documentation, through the InCenter cloud server, subject to the conditions that apply to each Level: Level 0 tools and documentation are provided on request, and Level 1 tools and documentation are licensed to hospital biomeds as part of certain cooperative service agreements that include license fees, completion of Philips service training for that product, and execution of a non-disclosure agreement.

VII. CONCLUSION

24. The Clinical Operation Software, System Servicing/Diagnostic Software, and Maintenance-Related Documentation described above are distinct in function and are subject to distinct access controls. The Clinical Operation Software is protected by username and password accounts administered by the health care facility and its information technology personnel, and those accounts exist to control who may access the device's medical features and patient data. The System Servicing/Diagnostic Software and Maintenance-Related Documentation are protected by Philips' proprietary Integrated Security Tool, which requires a physical smartcard, an encrypted user-specific certificate, and the matching account password, and which presents only those tools and materials that match the user's Philips-issued entitlements.

25. The System Servicing/Diagnostic Software and Maintenance-Related Documentation are monetized through the license fees charged for Level 1 access as part of certain cooperative service agreements with hospital biomedical engineering departments, subject to service training and non-disclosure requirements, and they participate in a market that includes ISOs, other OEMs, and in-house biomeds — a market in which the FDA estimated in 2018 that over 16,000 firms perform medical device service in the United States.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed on September 28, 2026 in Highland Heights, Ohio.

/s/ Jacqueline M. Dickson

Jacqueline Dickson
CSIP Services Operations Director
Philips North America LLC

Declaration submitted in support of Comments from:

Advanced Medical Technology Association (AdvaMed)
1301 Pennsylvania Ave NW, Ste 400
Washington, DC 20004

DECLARATION OF GONCALO ARNAUT

I, Goncalo Arnaut, declare as follows based on my personal knowledge:

I. DECLARANT AND COMPANY BACKGROUND

1. I am the Head of Customer Services for North America at Siemens Medical Solutions USA, Inc. ("Siemens Healthineers"). I have held this position since 2024. My responsibilities include oversight of customer service operations for Siemens Healthineers medical imaging systems in North America, including service delivery, maintenance and repair support, service-related software access, service key administration, technical training and credentialing requirements, cybersecurity considerations related to service activities, and the protection and appropriate use of proprietary service materials.

2. I have been with Siemens Healthineers for 22 years, having worked in the field of customer services for medical imaging equipment since 2013. In my role, I am familiar with Siemens Healthineers' medical devices, Clinical Operation Software, System Servicing/ Diagnostic Software, Maintenance-Related Documentation, access controls, licensing practices, and service offerings as described below.

3. Siemens Healthineers develops, manufactures, sells, and/or leases medical imaging devices and systems, including for x-ray imaging, molecular imaging, computed tomography (CT) imaging, magnetic resonance (MR) imaging, and angiography imaging used for diagnosis in clinical applications including for detection of abnormalities, to track disease, and/or visualize the anatomy of the patient in clinical fields including oncology, cardiology, neurology, and women's health.

II. RELEVANT SOFTWARE AND MATERIALS

4. As used in this declaration:

(a) "Clinical Operation Software" means software that health care professionals use to operate a medical device to perform patient care activities;

(b) "System Servicing/Diagnostic Software" includes software applications, diagnostic tools, calibration programs, configuration utilities, service interfaces, and related digital resources used to install, inspect, calibrate, test, maintain,

diagnose, troubleshoot, update, or repair a medical device to its intended performance and safety specifications; and

(c) Maintenance-Related Documentation is non-software, digital work used for servicing, such as digital service manuals or repair procedure documentation.

5. Siemens Healthineers uses Clinical Operation Software on its imaging devices to enable clinicians to operate the device for patient use. Access to the Clinical Operation Software is typically through an operator login account followed by a password, and accounts can be created on the device for each user.

6. Siemens Healthineers uses System Servicing/Diagnostic Software on its imaging devices. This software provides information, data, and tools that pertain to the performance of the device itself. It can provide an individual with access to certain diagnostic tests that can be performed on the system, it can monitor hardware and component status, and it can output error codes and logs. It can also support assembly, installation, adjustment, and calibration, in addition to testing and diagnosing a system for maintenance and repair. For some Siemens Healthineers imaging devices, most of the System Servicing/Diagnostic Software is hosted on the cloud, separated physically from the imaging device and from the Clinical Operation Software on the imaging device.

III. TECHNOLOGICAL PROTECTION MEASURES (TPMs) & DIFFERENTIAL ACCESS

7. Access to Siemens Healthineers' System Servicing/Diagnostic Software generally requires a service key. The key is a character string, generally 256 characters, that is entered at the user interface of the System Servicing/Diagnostic Software. The character string for the key may be updated and is checked for approval for usage on the System Servicing/Diagnostic Software, and a key may be approved for access for a set period, such as days or weeks. Service keys are provided at various levels to access certain information or tools within the System Servicing/Diagnostic Software, and generally can be categorized at basic, advanced, and proprietary levels. A service key is typically generated using information pertaining to the imaging device, as for example from the imaging device workstation, and can also be generated based on information provided via a dongle, which is a physical device often connected over USB.

8. These TPMs are separate and apart from the protections or controls governing access to the Clinical Operation Software. The TPM for the Clinical Operation Software, which is used to operate the device for patient use, is typically an operator login account followed by a password, and accounts can be created on the device for each user. The service key is a distinct measure: following login to the device through the Clinical Operation Software, the user must navigate to a service menu item and then access to the System Servicing/Diagnostic Software at its own user interface requires input of the

service key. For some imaging devices, most of the System Servicing/Diagnostic Software is also hosted on the cloud, physically separated from the imaging device and from the Clinical Operation Software that resides on it.

9. Access to the Clinical Operation Software is controlled by the operator login account and password. That login and password are initially provided to the customer by Siemens Healthineers, and the customer operating the system for patient use then controls login and password access. By contrast, service keys are distributed and approved by Siemens Healthineers. The distribution and availability of service keys for a system depends on the category of the service key and, for advanced service keys, on eligibility criteria such as training and contract terms.

10. Access to the Clinical Operation Software does not thereby provide for automatic access to the System Servicing/Diagnostic Software. An operator login permits a user to reach the service menu item, but access to the System Servicing/Diagnostic Software itself requires a service key distributed and approved by Siemens Healthineers at the level corresponding to the information or tools sought. For advanced service keys, the person or organization must also satisfy eligibility criteria such as training and contract terms.

11. These access controls serve several important purposes. They support patient safety and device integrity by helping ensure that the Clinical Operation Software is accessible only to customer-designated users and that certain service functions are performed by appropriately trained and qualified personnel. They also reduce cybersecurity risks associated with unauthorized access to the Clinical Operation Software and the System Servicing/Diagnostic Software. In addition, the controls protect proprietary service information and tools, support the administration of software licenses and contractual access rights, and reduce the risk that unauthorized or inappropriate service activities of which could affect the safe and proper clinical operation of the imaging system.

IV. LICENSING, SERVICE OFFERINGS, AND DISTINCT MARKET

12. Siemens Healthineers licenses usage of its System Servicing/Diagnostic Software at certain levels separately from the sale of the device. Access can be made available to the device owner upon system purchase or at a later time and can also be licensed at certain levels to other servicing organizations. Service keys to access the System Servicing/Diagnostic Software are provided depending on the level required and the license contract.

13. Access is offered both through separate service agreements and through licensing wherein then the service keys can be made available. The term of a license for service key use can be short, for example a few days, or long term, as for example annually. Service keys can be provided at no charge for certain levels, depending on the tasks required.

14. The market for these works and services is a post-sale market that arises after the sale of the imaging system itself and is intended to keep the equipment maintained and working. Participants in that market include customers that purchased an imaging system and that may also obtain or purchase service keys for access to service the system, as well as independent service organizations and manufacturer service technicians that seek to acquire or obtain such access. Siemens Healthineers competes in servicing and repairing these devices with independent service organizations, self-service parties such as hospital in-house service departments, and other manufacturers that also provide service.

15. Customers may obtain maintenance or repair services from Siemens Healthineers, from their own in-house service personnel, from independent service organizations, or from other manufacturers that provide service. If additional authorized System Servicing/Diagnostic Software access or expertise is required, the customer or servicer may obtain a service key at the applicable level through a license agreement or service contract with Siemens Healthineers, subject, for advanced service keys, to meeting eligibility criteria such as training and contract terms.

V. MAINTENANCE-RELATED DOCUMENTATION

16. Siemens Healthineers provides Maintenance-Related Documentation, which includes service manuals and other technical documentation used to service a system.

17. This documentation is typically separate from the Clinical Operation Software and the System Servicing/Diagnostic Software. It is usually stored in an electronic library on a website, with certain access controls for non-public information. Some older imaging systems store Maintenance-Related Documentation directly on the system.

18. The documentation is used to repair Siemens Healthineers imaging systems. Access to the Maintenance-Related Documentation for service and repair is granted by Siemens Healthineers and allows an account to be created on the website. Access may be provided to customers, to service organizations, or to Siemens Healthineers technicians. Some Maintenance-Related Documentation is provided publicly from the website without access controls.

19. Access to the non-public Maintenance-Related Documentation on the website is controlled by login and password, which are provided by permission from Siemens Healthineers. For non-public Maintenance-Related Documentation stored on older imaging systems, a service key provides access. These measures are separate and apart from the protections governing the Clinical Operation Software: the website login and password are different from the Clinical Operation Software login and password on the imaging device itself, and website access is granted by Siemens Healthineers, whereas the Clinical Operation Software login and password are controlled by the customer after Siemens Healthineers initially provides them.

20. Siemens Healthineers provides access to this documentation separately from the sale of the device, by granting an account on the website to customers, service organizations, and Siemens Healthineers technicians.

VI. UNAUTHORIZED ACCESS [AND PRACTICAL EFFECTS]

21. Unauthorized circumvention of the TPMs described above would permit persons who have not obtained a service key distributed and approved by Siemens Healthineers, and who have not satisfied the eligibility criteria such as training and contract terms that apply to advanced service keys, to access the System Servicing/Diagnostic Software and the non-public Maintenance-Related Documentation.

VII. CONCLUSION

22. The Clinical Operation Software, System Servicing/Diagnostic Software, and Maintenance-Related Documentation described above are distinct in function and are subject to distinct access controls. The Clinical Operation Software is protected by an operator login account and password that Siemens Healthineers initially provides to the customer and that the customer thereafter controls. The System Servicing/Diagnostic Software is protected by a service key — a character string, generally of 256 characters, generated from information pertaining to the imaging device or provided via a dongle, approved for a defined period, and issued at basic, advanced, or proprietary levels — which Siemens Healthineers distributes and approves. The non-public Maintenance-Related Documentation is protected at a website through login and password which is granted by Siemens Healthineers and, on older imaging systems, by a service key.

23. Usage of the System Servicing/Diagnostic Software is monetized through licenses providing service key access at certain levels, made available through license and service contracts with terms ranging from a few days to a year, and it participates in a post-sale market for keeping imaging equipment maintained and working — a market that includes device owners, independent service organizations, hospital in-house self-service parties, other manufacturers that provide service, and Siemens Healthineers' own service technicians.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed on September 25, 2026, in Cary, North Carolina.

Electronically signed by: GONCALO Arnaut
Reason: I am the author of this document
Date: Sep 25, 2026 13:16:55 EDT

Goncalo Arnaut
Head of Customer Services for North America - Siemens Healthineers

No. 25-5328

In the

United States Court of Appeals

for the

District of Columbia Circuit

ADVANCED MEDICAL TECHNOLOGY ASSOCIATION, *et al.*,

Plaintiffs-Appellants,

– v. –

LIBRARY OF CONGRESS, *et al.*,

Defendants-Appellees.

On appeal from a final judgment of the
United States District Court for the District of Columbia
Case No. 1:22-cv-499 (U.S. District Beryl Howell)

APPELLANTS' OPENING BRIEF

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Parties and amici. Plaintiffs-appellants are the Advanced Medical Technology Association and Medical Imaging & Technology Alliance. Defendants-appellees are the Library of Congress and either Todd Blanche or Robert Newlen in his official capacity as Acting Librarian of Congress.

Rulings under review. The ruling under review is the district court's July 21, 2025, order in No. 1:22-cv-499 at Dkt. 48, as well as the memorandum opinion at Dkt. 49 and final judgment at Dkt. 50.

Related cases. This case was previously before this Court, which reversed the district court's earlier dismissal. *See Medical Imaging & Technology Alliance, et al. v. Library of Congress*, 103 F.4th 830, 840 n.4 (D.C. Cir. 2024). There are no related cases pending in this Court or any other court.

/s/ *Michael B. Kimberly*

CORPORATE DISCLOSURE STATEMENT

AdvaMed is a non-profit, membership-based trade association. It has no parent corporation and does not issue stock. MITA also is a non-profit, membership-based trade association. It is a division of the National Electrical Manufacturers Association. MITA does not issue stock.

/s/ *Michael B. Kimberly*

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GLOSSARY

APA:	Administrative Procedure Act
DMCA:	Digital Millennium Copyright Act
FDA:	Food and Drug Administration
ISO:	independent service operator
MITA:	Medical Imaging & Technology Alliance
NPRM:	notice of proposed rulemaking
OEM:	original equipment manufacturer
R&D:	research and development
TPM:	technological protective measure

INTRODUCTION

Advanced medical devices play an essential and life-saving role in today's technology-driven healthcare system. Sophisticated and complex machines like computerized tomography scanners, ultrasound systems, and magnetic resonance imaging machines allow for highly accurate imaging of internal organs and biological systems, facilitating early diagnoses of serious diseases. And advanced care technologies like respiratory ventilation systems and surgery-assisting robots allow for care with fewer complications, shorter hospital stays, and better outcomes.

Plaintiffs here are the Advanced Medical Technology Association (AdvaMed) and the Medical Imaging & Technology Alliance (MITA). Their mutual members invest billions of dollars every year designing, building, and servicing the life-sustaining medical devices on which the American healthcare system has come to depend.

At the same time that these companies are manufacturers of physical machines, they also are authors of the complex software programs, tools, files, and documentation needed to maintain and repair the machines. Coupling this software with the machines, manufacturers recoup their huge R&D investments in two ways: first through sales or leases of the machines themselves, and second through maintenance and servicing and licensing agreements for the software and documents necessary for the same.

These two complementary revenue streams are well understood by the healthcare providers who acquire and use AdvaMed's and MITA's members' advanced devices. Indeed, healthcare providers almost always must agree to the express terms of the software and documentation licenses when they acquire advanced medical devices like those at issue.

Nonetheless, a market has developed for unlicensed maintenance, diagnosis, and repair services for advanced medical devices. To provide such services, third-party servicers circumvent the encryption protecting licensed field-service software programs and other materials. Once an unauthorized third-party servicer has gained access to a manufacturer's software-based maintenance tools, documents, and files, it puts them to their precise intended use: facilitating the maintenance, diagnosis, and repair of the machine. And in doing so, it substitutes for manufacturers' services.

A critical point warrants emphasis at the start: Third-party servicers do absolutely nothing "new" with the works that they appropriate to provide maintenance-and-repair services. They do not put them to some further, transformative *use*, nor do they do imbue the works with some new or different *character*. On the contrary, third-party servicers expressly disclaim that they transform or alter the software itself—because doing so would subject them to regulation by the FDA as remanufacturers. Instead (and to reiterate), all they do is put the service software tools and services-related documents and

files to their original purpose of facilitating the maintenance, diagnosis, and repair of the machines. And they do so *for a profit*, in direct competition with the authors of the works.

This kind of copy-to-compete reproduction is the very definition of infringing use. "The Copyright Act encourages creativity by granting to the author of an original work 'a bundle of exclusive rights,'" including the rights "to reproduce the copyrighted work" and "prepare derivative works." *Andy Warhol Foundation for the Visual Arts v. Goldsmith*, 598 U.S. 508, 526 (2023) (quoting *Harper & Row, Publishers v. Nation Enterprises*, 471 U.S. 539, 546 (1985)). As the Supreme Court recently explained, "copyright's bête noire" is "the problem of substitution," meaning "[t]he use of an original work to achieve a purpose that is the same as, or highly similar to, that of the original work," so that the copy stands as a "substitute" for the original and "shrink[s] the protected market opportunities of the copyrighted work." *Id.* at 528, 531 (cleaned up). That is exactly what unauthorized third-party servicing companies do when they break into advanced medical devices and copy protected works to perform maintenance, diagnosis, and repair services.

To be sure, copyright is not absolute, and Congress has provided expressly that "the fair use of a copyrighted work, . . . for purposes such as criticism, comment, news reporting, teaching . . . , scholarship, or research, is not an infringement of copyright." 17 U.S.C. § 107. But a fair use is a *transformative*

one—one that "has a purpose or character different from the original," so that it "does not supersede the objects of, or supplant, the work" in the market in which the work is sold. *Warhol*, 598 U.S. at 528-29. Plainly enough, making unauthorized copies of service software tools, operating manuals, and other protected works to perform unlicensed maintenance-and-repair services for a profit is not a transformative use. Rather, it is predatory appropriation designed to supplant the author's works with the copier's.

The Digital Millenium Copyright Act (DMCA) was enacted to prevent just this kind of digital piracy. The Act thus expressly prohibits users from circumventing any "technological measure that effectively controls access to a work." 17 U.S.C. § 1201(a)(1)(A). Under this anticircumvention rule, decrypting a copyrighted work without authorization is punishable with civil and, in some cases, criminal penalties.

At the same time that Congress made it unlawful to circumvent a copyright holder's encryption tools, it recognized that the DMCA's anticircumvention rule might be used to prevent otherwise lawful access to works and information. It thus directed the Library of Congress to grant exemptions to the anticircumvention rule through recurring, triennial rulemakings, to users who are likely to be "adversely affected by the [anticircumvention rule] in their ability to make *noninfringing uses*" of the work over the ensuing three years. 17 U.S.C. § 1201(a)(1)(C) (emphasis added).

This case concerns an exemption to the anticircumvention rule adopted in the Eight Triennial Rulemaking in 2021 and renewed in the Ninth Rulemaking in 2024: the Medical Devices Exemption. It is codified at 37 C.F.R. § 201.40(b)(17), and it grants a waiver from liability for circumvention of encryption protecting copyrighted software and other digital works used for servicing advanced medical devices.

The Exemption was granted at the request, and solely for the commercial benefit, of third-party servicers that provide unauthorized maintenance-and-repair services. Now in light of the Exemption, these (and all other) third-party servicers consider themselves free to copy diagnostic modules and service software, operating manuals and machine specifications, data reports and error logs, and other copyright-protected tools necessary to sell maintenance-and-repair services for a profit—the same services that manufacturers themselves use the software to sell and thus recoup the costs of developing their innovations.

The problem with the Exemption speaks for itself: Section 1201(a)(1) authorizes the Librarian of Congress to issue exemptions to the DMCA's anticircumvention rule for "noninfringing uses" only. But to make unauthorized reproductions of copyrighted works and to use them for the same purpose as the originals, solely to compete with the authors of the originals in the market that monetizes the works, is *not* a "noninfringing" fair use.

Case law offers no support for the Librarian's or district court's contrary conclusion. Quite the opposite. For example, in *Triad Systems v. Southeastern Express*, 64 F.3d 1330 (9th Cir. 1995), the Ninth Circuit concluded that analytically identical conduct was "neither creative nor transformative," "entirely commercial in nature," and therefore infringing. *Id.* at 1336-37. There, "Triad invented, developed, and marketed its software to enable its customers and its own technicians to service Triad computers." *Id.* at 1337. The Ninth Circuit rejected the third-party servicer's fair-use defense, explaining that it "ha[d] invented nothing of its own," but instead was "getting a free ride when it use[d] that software to perform precisely the same service," in competition with Triad, without paying for a license. *Id.* at 1336.

Yet here, in granting and renewing the Exemption, the Librarian concluded that third-party servicers use the copied works in new and "transformative" ways. That is unequivocally wrong. To conclude otherwise is to ignore the facts as well as the law. The district court, for its part, agreed with the Librarian as far as she went—and also offered additional rationales not furnished by the Librarian, which is not permissible.

At the end, both the Librarian and the district court laid bare their true reasoning: They believe that manufactures charge "exorbitant" licensing fees (5-JA-1693) for access to works related to maintenance and repair, and as a consequence "providers must spend more to service their equipment than if"

manufacturers did not enjoy copyright protection (2-JA-647). That is a stunning argument for a copyright regulator to make. To declare that an unauthorized copying of computer code is a "fair use" *because* it allows a competitor to take business from the author at lower prices is to flip copyright law on its head. Reversal is manifestly warranted.

JURISDICTION

The district court had jurisdiction under 28 U.S.C. § 1331. It entered a final judgment on July 21, 2025, and appellants filed an appeal on September 12, 2025. 1-JA-8. This Court's jurisdiction rests on 28 U.S.C. § 1291.

PERTINENT STATUTES AND REGULATIONS

The pertinent statutes are set out in an attached addendum.

ISSUE PRESENTED FOR REVIEW

Whether the Library's adoption and renewal of a DMCA exemption permitting the circumvention of technological protective measures for copyrighted software used for servicing and repairing medical devices (37 C.F.R. § 201.40(b)(17)) violated the APA because it was arbitrary and capricious, not in accordance with law, or in excess of statutory authority or limitation.

STATEMENT OF FACTS

A. Legal background

1. The fair use doctrine. The Copyright Act of 1976 prohibits unauthorized reproduction of "original works of authorship fixed in any tangible

medium of expression." 17 U.S.C. § 102(a). Among the works covered by the Act are "computer program[s]." *Id.* §§ 101, 109(b)(1)(A).

Copyright serves practical objectives, foremost "to encourage the production of works" that, without copyright protection, could be "reproduce[d] more cheaply" by freeriders in the marketplace. *Google LLC v. Oracle America, Inc.*, 593 U.S. 1, 16 (2021). It thus "grant[s] to the author of an original work 'a bundle of exclusive rights,'" including the right to forbid unauthorized reproduction of the work. *Warhol*, 598 U.S. at 526 (quoting *Harper & Row*, 471 U.S. at 546).

The rights granted by the Act are not absolute. They are tempered to account for the "competing claims upon the public interest" by authors (on the one hand) and users (on the other). *Warhol*, 598 U.S. at 526. The Act balances the incentive to innovate against the need for "broad public availability" of creative works in several ways. *Id.* For example, it "limits the duration of copyright" and "makes facts and ideas uncopyrightable." *Id.* And pertinent here, it "limits the scope of copyright" through the common-law "fair use" doctrine *Id.* at 526-27.

The fair-use doctrine is codified at 17 U.S.C. § 107, which specifies that "the fair use of a copyrighted work, . . . for purposes such as criticism, comment, news reporting, teaching . . . , scholarship, or research, is not an infringement of copyright." To determine whether a use is "fair" and thus

noninfringing, the statute sets out four factors for consideration:

1. the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes;

2. the nature of the copyrighted work;

3. the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and

4. the effect of the use upon the potential market for or value of the copyrighted work.

17 U.S.C. § 107(1)–(4). These four fair-use factors "are all weighed in the 'equitable rule of reason' balance." *Sony Corp. of America v. Universal City Studios, Inc.*, 464 U.S. 417, 454 (1984). Yet the fourth factor is "undoubtedly the single most important element of fair use." *Harper & Row*, 471 U.S. at 566; *see also Stewart v. Abend*, 495 U.S. 207, 238 (1990) (referring to the fourth factor as the "most important, and indeed, central" of the § 107 factors); 4 Nimmer on Copyright § 13F.03 (2022) (similar).

The fourth factor is first among equals because of its direct link with copyright's animating principles. The fair-use doctrine tolerates appropriation only when the copy does not substitute the original in the market in which the author herself commercializes the work. As the Supreme Court has put it, "[f]air use, when properly applied, is limited to copying by others which does not materially impair the marketability of the work which is copied." *Harper & Row*, 471 U.S. at 566-67. Because some duplication is *non*-competitive,

non-substitutive, and necessary for further creativity, the fair-use doctrine acknowledges that a "rigid application of the copyright statute" may in some circumstances "stifle the very creativity which that law is designed to foster." *Warhol*, 598 U.S. at 527 (quoting *Stewart*, 495 U.S. at 236).

2. Transformative use. In conjunction with the fair-use factors, the Supreme Court has instructed courts to determine whether a secondary use of a copyrighted work is *transformative* of the original. The Supreme Court first introduced the concept of "transformative" use in *Campbell v. Acuff-Rose Music*, 510 U.S. 569 (1994), as a consideration under the first factor. Since then, lower courts have expanded the reach of the inquiry to "engulf all of fair use." Jane Ginsburg, *Fair Use Factor Four Revisited: Valuing The Value of the Copyrighted Work*, 67 J. Copyright Society U.S.A. 19, 19-20 (2020). The question of transformative use cuts across the four factors for the same two reasons that the fourth factor predominates over the others:

First, "[t]he more the appropriator is using the copied material for new, transformative purposes, . . . the less likely it is that the appropriation will serve as a substitute for the original or its plausible derivatives, shrinking the protected market opportunities of the copyrighted work." *Warhol*, 598 U.S. at 531 (quoting *Authors Guild v. Google, Inc.*, 804 F.3d 202, 214 (2d Cir. 2015) (Leval, J.)). For example, because reproduction for parody or criticism "uses the work to serve a distinct end," it "ordinarily does not supersede the objects

of, or supplant, the work" in its own commercial market. *Id.* at 528. Transformative uses thus avoid "the problem of substitution—copyright's bête noire." *Id.* No one would say that *The Hunger Pains* by the Harvard Lampoon competes as a substitute for *The Hunger Games* by Suzanne Collins in the market for pleasure reading.

Second, "[t]he more the appropriator is using the copied material for new, transformative purposes, the more it serves copyright's goal of enriching public knowledge." *Warhol*, 598 U.S. at 531 (quoting *Authors Guild*, 804 F.3d at 214). Turning to parody again, it "has an obvious claim to transformative value" because "it can provide social benefit, by shedding light on an earlier work, and, in the process, *creating a new one*." *Id.* at 530 (emphasis added) (quoting *Campbell*, 510 U.S. at 579). But, of course, parody "needs to mimic an original to make its point." *Id.* (quoting *Campbell*, 510 U.S. at 580-81). Thus, focusing on transformative use helps to isolate those cases in which permitting unauthorized copying fosters further creations.

For these reasons, "the sorts of copying that courts and Congress most commonly have found to be fair uses" are those listed in the statute itself: criticism, comment, news reporting, teaching, scholarship, and research. *Warhol*, 598 U.S. at 528 (citing *Campbell*, 510 U.S. at 577-78). These "easily understood" examples entail the use of a copy that will "serve a manifestly

different purpose from the [original] work itself" and are thus inherently transformative. *Id.*

3. The DMCA. The proliferation in the 1990s of digital copyrighted works, and the ease with which they could be copied electronically, introduced new challenges for copyright owners. Many creators began using various kinds of encryption to control access to their works and thwart copying. To support those efforts, "Congress enacted the DMCA in 1998 'to strengthen copyright protection in the digital age.'" *Egilman v. Keller & Heckman, LLP*, 401 F. Supp. 2d 105, 112 (D.D.C. 2005).

The DMCA protects copyright by prohibiting users of a copyrighted work from "circumvent[ing] a technological measure that effectively controls access to [the] work" (17 U.S.C. § 1201(a)(1)(A))—a prohibition that we refer to as the anticircumvention rule. To circumvent protective tools is to de-scramble or decrypt by bypassing, removing, or deactivating a technological protective measure "without the authority of the copyright owner." *Id.* § 1201(a)(3). Violations of the DMCA's anticircumvention rule are punishable with private civil remedies, and in the case of a willful violation "for purposes of commercial advantage," criminal penalties. *Id.* § 1204(a).

Congress recognized, however, that unchecked use of encryption might obstruct noninfringing access to works and information. Because it did not intend for the DMCA to inhibit noninfringing uses, the DMCA instructs the

Register of Copyrights and Librarian of Congress to undertake triennial rule-makings to consider petitions for three-year "exemptions" from the DMCA's prohibitions for limited purposes. 17 U.S.C. § 1201(a)(1)(C). Such exemptions are authorized only if users are likely to be "adversely affected by" the anti-circumvention rule exclusively "in their ability to make *noninfringing* uses." *Id.* (emphasis added). A DMCA exemption thus requires the Librarian to find that the proposed uses of the class of copyrightable works at issue are noninfringing, typically implicating the fair-use doctrine.

4. Section 117(c). Shortly before Congress began debating the DMCA, the Ninth Circuit issued its decision in *MAI Systems Corp. v. Peak Computer, Inc.*, 991 F.2d 511 (9th Cir. 1993). There, the court held that "a 'copying' for purposes of copyright law occurs when a computer program is transferred from a permanent storage device [*i.e.*, hard drive] to a computer's RAM." *Id.* at 518. On that reasoning, the mere act of turning a computer on is an act of infringement. *Id.* at 518-519.

Congress narrowly abrogated that holding with the DMCA, enacting a limited but categorical copyright exception for copying operating software as necessary to activate machines for maintenance and repair. Section 117(c) of the Copyright Act, as amended by the DMCA, thus expressly allows owners and lessees of software-operated machines "to make or authorize the making of a copy of a computer program" in limited circumstances, when:

(1) the "copy is made solely by virtue of the activation of a machine" and "for purposes only of maintenance or repair of that machine,"

(2) the copy "is used in no other manner" than activation for maintenance and repair, and

(3) the copy "is destroyed immediately after the maintenance or repair is completed."

17 U.S.C. § 117(c). As scholars have noted, "Section 117(c) reversed *MAI*'s application of the RAM Copy Doctrine" in the limited context of activating computers for maintenance and repair. Melissa A. Bogden, *Fixing Fixation: The RAM Copy Doctrine*, 43 Ariz. St. L.J. 181, 197 (2011).

B. Factual background

1. Today, advances in medical technology are driven by software every bit as much as hardware engineering and design. This software includes not only an advanced medical machine's operating system—typically Windows or Linux (3-JA-1034; 5-JA-1483)—but also "field service software and information" (5-JA-1427, 1649), including proprietary "diagnostic tools" (5-JA-1381, 1422) and other "specialized service tools" (5-JA-1409) stored on the machine and used to identify and resolve malfunctions, report equipment usage, and identify replacement needs. *See* 5-JA-1425, 1429, 1483, 1631.

Device manufacturers make enormous investments of time and money to develop and bring medical devices and their software to market. 4-JA-1377-78; 5-JA-1599-1600. They rely on copyright protections—including the anti-

circumvention rule—to recoup their investments, facilitate further innovations, and protect the integrity of their software. 4-JA-1371; 5-JA-1593.

2. Manufacturers use a variety of technological measures like digital certificates and encryption keys to guard against unauthorized copying of the software and other protected materials stored on the machines. These access controls limit aspects of their software that may be viewed, used, copied, and modified. 5-JA-1429, 1511. They not only safeguard manufacturers' intellectual property, but also protect the integrity of the device and the privacy of patient data while ensuring that only appropriate users operate medical device software. 5-JA-1511.

Improper use of manufacturer's proprietary software for servicing medical devices creates substantial risks to users, patients, and providers. 4-JA-1372-73; 5-JA-1594-95. Failure to repair devices properly also can cause delays and misdiagnoses. *Id.* Given these risks, the FDA strictly regulates medical device manufacturers, requiring them to obtain approvals before commercially distributing devices (21 C.F.R. Parts 801, 814) and to report serious malfunction incidents (21 C.F.R. Part 803). *See* 4-JA-1373-75; 5-JA-1595-97. FDA also has recognized the importance of allowing manufacturers to train and equip their "own service personnel with additional documentation or enhanced software programs, with privileged access codes" to provide particularly complex services and repairs. 5-JA-1408 n.2.

3. Third-party servicing companies—sometimes referred to as independent service operators, or ISOs—provide unregulated third-party maintenance-and-repair services for medical devices. They are not subject to the FDA regulations that apply to original equipment manufacturers (referred to as OEMs). Nor are they subject to the same training and quality control measures. Many manufacturers nevertheless provide support to third-party servicers to enable them to perform basic maintenance-and-repair services, including limited licensing of copyrighted documentation and software. *See, e.g.*, 4-JA-1061; 5-JA-1429, 1583.

Some third-party servicers gain access to and reproduce copyrighted software without obtaining a license. 5-JA-1410, 1587-89. They then use the copies to provide the same maintenance-and-repair services that manufacturers do, putting the software and other works to the same use, in direct competition with the manufacturers' service programs. *See, e.g.*, 5-JA-1429.

C. Procedural background

1. The Eighth Triennial Rulemaking. Third-party servicers Summit Imaging and Transtate Equipment Company petitioned in the Eighth Triennial Rulemaking for access to "[e]lectronic servicing materials in the form of computer programs and data files that control functions of or store data relating to the functioning of lawfully acquired medical systems and devices." 3-JA-1020; *see generally* 3-JA-1016-1034; 4-JA-1035-1353.

In seeking the exemption, the proponents explained that their need was not to copy the machines' operating system software, which typically is Linux or Windows (and is already permitted by § 117(c)). *See* 3-JA-1023-24. Rather, their need is to copy "diagnostic software and data files" (3-JA-1024) and "medical equipment servicing materials in the form of computer programs" and "databases and manuals" that "are necessary for servicing (diagnosis, repair, and maintenance) of the medical devices and systems" (3-JA-1031-32). Transtate explained further that, "[w]hen performing the servicing activities, the diagnostic and testing modules are used to diagnose the operating conditions and to determine if the system or device is performing according to specifications." 4-JA-1050. And the proponents were clear why they believe third-party services are important: Without them, owners "cannot take advantage of the lower prices offered by . . . ISOs." 4-JA-1057.

Plaintiffs and one of their mutual members submitted comments opposing the proposed exemption. *See* 4-JA-1354-1380; 5-JA-1381-1430.

The Register—the official who makes exemption recommendations to the Librarian—proposed granting the exemption to allow the copying of "[c]omputer programs that are contained in and control the functioning of a lawfully acquired medical device or system, and related data files, when circumvention is a necessary step to allow the diagnosis, maintenance, or repair of such a device or system." 3-JA-766.

The Register concluded that use of copyrighted software for maintenance and repair of advanced medical devices is a noninfringing "fair use." 2-JA-627-631. Concerning the first factor, she concluded "that proponents' proposed use is likely transformative and so the first factor favors fair use." 2-JA-628. The Register further opined that medical-device system software is entitled to diminished copyright protection because it is "not used for [its] expressive qualities, but rather for [its] functional and informational aspects that enable users to control and understand the operation of the equipment." 2-JA-629. She concluded, in addition, that servicers' copying of the entirety of manufacturers' works "should be given little weight here because the use is necessary to accomplish the transformative purposes of diagnosis, maintenance, and repair." 2-JA-630. And concerning harm to the market for the copyrighted software, the Register concluded that "there is no indication that the software serves any function, or has any value, except for use with the medical device or system for which it was designed." 2-JA-631.

With respect to her discretion to consider other factors under the Section 1201(a)(1)(C) framework, the Register observed that "OEMs charge higher prices" than third-party services for maintenance and repair and therefore "medical service providers must spend more to service their equipment" if they use manufacturers' services "than if they were able to engage in self-repair or have an ISO perform repairs on their behalf." 2-JA-647.

The Register thus recommended granting the Exemption. 2-JA-650-51. The Librarian adopted the Exemption according to the Register's recommendation, the content of which we thus attribute to the Librarian. It is codified at 37 C.F.R. § 201.40(b)(15) and went into immediate effect.

2. The lawsuit and Ninth Triennial Rulemaking. Plaintiffs brought this suit challenging the Medical Devices Exemption as unlawful under the APA, or in the alternative, as an *ultra vires* action by the Librarian. The district court dismissed the complaint, holding that the claims were "barred by sovereign immunity because the Librarian's decisions are not subject to APA review." Dist. Ct. Dkt. 27, at 17.

This Court reversed. *See Medical Imaging & Technology Alliance v. Library of Congress*, 103 F.4th 830 (D.C. Cir. 2024). It held that "DMCA rules are subject to the APA just like other copyright rules," and it remanded for this Court "to assess the APA claims in the first instance." *Id.* at 833.

In the meantime, the Library commenced and concluded the Ninth Triennial Rulemaking. Transtate and Summit petitioned for renewal of the Medical Devices Exemption. 5-JA-1481-1509. Plaintiffs and others submitted comments opposing renewal. 5-JA-1510-1656. Apart from repeating their prior arguments, opponents argued that the fair-use determination undergirding the Exemption conflicts with the Supreme Court's intervening de-

cision in *Warhol*, which reiterated that commercial use of a copyrighted work for the same purpose as the original work is not fair use.

The Register recommended that the Librarian renew the Exemption. 3-JA-809-812. She determined that the "analysis from the 2021 cycle remains sound" notwithstanding *Warhol*. 3-JA-811-12. The Librarian agreed, and the Exemption is now codified at 37 C.F.R. § 201.40(b)(17).

Plaintiffs thereafter amended the complaint in this case to challenge both the adoption of the Medical Devices Exemption in the Eighth Triennial Rulemaking and its renewal in the Ninth. The parties then exchanged cross-motions for summary judgment.

3. The district court's decision. In an opinion accusing plaintiffs of "overreact[ing]" like "Chicken Little" (5-JA-1693 n.9) and aiming only to protect "an ability to charge exorbitant prices" (5-JA-1693), the district court granted summary judgment to the Library. *See* 5-JA-1657-1716.

The district court's analysis focused on the first fair use factor, and in particular whether the third-party servicers' use was transformative. It maintained that the Librarian had found that the operating software and related data files for medical devices were *not* originally invented and developed for the "primary purpose" of servicing the devices. 5-JA-1709. It thus held that third-party servicers make transformative use of the works because "repair and maintenance" has a "different character" and "employ[s] the code in a

different manner" from how the software is "originally used by the machine to operate the device." 5-JA-1679 (cleaned up and citations omitted).

Even if that were wrong, the court continued, "ISOs' use of [service] materials still may be considered transformative" because use of software tools, data, and files "requires input of [the user's] knowledge, creative and analytical thinking, and mechanical skills." 5-JA-1686. In the district court's view, this was a "secondary function" that "transform[ed] the basic knowledge conveyed in the copyrighted materials into a distinct and meaningful output, which is considered transformative." *Id.*

The district court opined that the copying at issue is transformative for the additional reason that "diagnosis, maintenance, and repair has a concrete 'transformative' effect on the *device* by changing some aspect of how it works." 5-JA-1686. The court agreed with plaintiffs that "the first fair use factor [asks] whether the use transforms the copyrighted material itself" and not a "separate related object." *Id.* And it acknowledged that "technically the hardware and software may be distinct." 5-JA-1687. But it held that "the software has no use or value apart from the device," and because maintenance of the device "facilitate[s] use of the software," servicers' use of the copied software has a "transformative effect on the *use* of the software." *Id.*

The district court rejected plaintiffs' position that it was arbitrary for the Librarian to analogize to her 2015 rulemaking, where she granted a similar

exemption for maintenance and repair of motor vehicles, despite that the exemption there expressly envisioned transformative alterations. *See* 5-JA-1687-89. And the district court finally rejected the argument that the Librarian had not taken adequate account of *Warhol*. *See* 5-JA-1689-1690.

"In sum," the district court concluded, "the Librarian's conclusion that all of the uses contemplated by the Exemption are transformative—and that the transformative quality was more significant than the commercial, for-profit nature of most diagnosis, maintenance, and repair services—was consistent with fair use law, including precedent such as *Warhol*, and supported by well-reasoned analysis." 5-JA-1692.

Having held that the Librarian's fair-use analysis was reasonable, the district court turned to a recitation of why it believed the Exemption is consistent with copyright policy. 5-JA-1704-1710. On that front, the court noted that, with § 117(c), Congress expressed an "intent to ensure that maintenance and repairs were not monopolized by copyright owners of computer programs." 5-JA-1706. And with the Exemption, the Librarian has now "go[ne] beyond the statutory provision" to provide protections that Congress did not provide itself in § 117(c). 5-JA-1707. This, the district court reasoned, means that the Exemption is consistent with congressional intent.

Finally, the district court held that the Librarian adequately addressed all the comments submitted to it. 5-JA-1710-15. Having done so, it held that the Exemption is lawful and should be upheld. 5-JA-1715-16.

SUMMARY OF ARGUMENT

Under any reasonable application of the fair-use factors, the Medical Devices Exemption permits infringing uses and is unlawful.

Start with the first factor, "the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes." 17 U.S.C. § 107. Where, as here, "an original work and a secondary use share the same or highly similar purposes, *and* the secondary use is of a commercial nature," the first factor almost always will weigh against fair use. *Warhol*, 598 US at 532-33 (emphasis added).

Here, the Exemption has authorized copying of field-service software tools, manuals, and other files that were created for the purpose of facilitating maintenance-and-repair services. It does so to permit third parties to use them *for exactly the same commercial purpose*. There is no dispute that third-party servicers copy these protected works in order to put them to their original, intended uses of facilitating maintenance-and-repair services in a competitive commercial market, substituting their own services for the services of the works' authors. This is the textbook definition of substitutive, commercial use—not transformative use.

The Librarian's contrary finding turned on a misimpression that the works being copied are merely operating software. The district court agreed. Both were wrong. To be crystal clear: This case is *not* about operating software, which is covered separately by 17 U.S.C. § 117. There is no support for a contrary conclusion in the administrative record.

The district court offered other rationales for upholding a finding of transformative use. But none was adopted by the Librarian, and each offends basic principles of copyright law. None is a ground for affirming.

Take next the fourth factor, which is closely related to the first factor. It asks whether the copier's use of the protected work will cause market harm to the author. Generally speaking, when the copy is commercially substitutive, the answer is perforce *yes*. That is the case here. Indeed, the record shows that market harm was the *point* of the Exemption: Proponents sought the Exemption, and the Librarian granted it, to ensure that third-party servicers would be able to offer substitutive maintenance-and-repair services at lower cost, taking market share from higher-cost manufacturers and destroying the licensing market for the protected software.

The Librarian (and district court) denied that there is a separate market for the works at issue, but the evidence—including evidence introduced by the proponents themselves—confirms that there *is* a separate market for software licenses. And the harm inflicted on that market is undeniable. The district

court assumed as much and offered another rationale not adopted by the Librarian. That post hoc explanation is both wrong and procedurally unavailable.

When the first and fourth factors weigh against fair use (as they do here), only an especially "compelling justification" under the second and third factors can save a copier's appropriation. Here there is no justification, much less a compelling one, under the second and third factors.

Finally, the Exemption impermissibly amends § 117(c), which codifies a narrow exemption for copying a limited range of digital works for machine maintenance and repair. The Court thus should remand with instructions to vacate the Exemption.

STANDING

AdvaMed and MITA are trade associations. 4-JA-1354, 1369. Their mutual members include Philips North America, which commented on the Exemption (5-JA-1405-1430, 1510-1548), as well as almost all other major manufacturers of advanced medical devices. AdvaMed's and MITA's members—and their devices and software—are the objects regulated by the Medical Devices Exemption. By the Exemption's operation, AdvaMed's and MITA's members are denied a right under the DMCA to challenge circumvention of the technological protective measures they use to guard against unauthorized copying of software and data stored on their devices. That injury is redressable by an order setting aside the Exemption.

STANDARD OF REVIEW & BURDEN OF PROOF

This Court "review[s] the district court's grant of summary judgment de novo" and the Librarian's decision "under the standard of the Administrative Procedure Act." *Grossmont Hospital v. Burwell*, 797 F.3d 1079, 1082 (D.C. Cir. 2015). Under the APA, review of an "agency's interpretation of its governing statute" calls for "independent judgment" without deference. *Environmental Defense Fund v. EPA*, 124 F.4th 1, 11 (D.C. Cir. 2024).

A court's review for arbitrariness calls for a determination whether "the agency has . . . entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be . . . the product of agency expertise." *Solondz v. FAA*, 141 F.4th 268, 276 (D.C. Cir. 2025).

A court may not "substitute" its own reasoning for the agency's and "may only uphold a rule 'on the basis articulated by the agency' in the rule making record." *Genuine Parts v. EPA*, 890 F.3d 304, 314 (D.C. Cir. 2018).

Plaintiffs bear the burden of showing that the Exemption violates the APA. But "those who seek an exemption" under 17 U.S.C. § 1201(a)(1) "bear the burden of establishing that the requirements for granting an exemption have been satisfied" in the underlying rulemaking. 2-JA-426. Plaintiffs thus meet their burden under the APA by showing that the proponents failed to meet *their* burden under § 1201(a)(1).

ARGUMENT

The Exemption authorizes infringing uses of copyrighted works and is unlawful. The Librarian erred in holding that copying "diagnostic software and data files" (3-JA-1024) for their intended purposes of maintenance and repair is "transformative." The Librarian's contrary conclusion is not only legally wrong, but it is based on illogical factual assumptions unsupported by evidence and irrelevant policy considerations that have no place in the fair use analysis. It cannot stand.

I. THE MEDICAL DEVICES EXEMPTION UNLAWFULLY PERMITS INFRINGING USES

A. First factor: The uses permitted by the Exemption are substitutive rather than transformative

The Librarian erred in her fair-use analysis, which turned principally on the question whether third-party servicers make transformative use of the "diagnostic software and data files" (3-JA-1024 (Summit petition)) and other "medical equipment servicing materials" that "are necessary for servicing . . . medical devices and systems" (3-JA-1031-32 (Transtate petition)) by putting them to work for maintenance and repair.

The Librarian concluded that they *do* make transformative use of those protected works, and the district court agreed. In fact, the Librarian approved (and the district court upheld) an exemption for *substitutive* uses, allowing third-party servicers to compete directly with manufacturers without paying

for licenses, thus substantially undermining the market for manufacturers' own services and licenses.

1. The permitted uses are not transformative, but rather commercially substitutive

a. The uses permitted by the Exemption are not transformative. A secondary use of a copyrighted work is transformative when it puts the work to "a further purpose" or imbues it with a "different character." *Warhol*, 598 U.S. at 532. But not just "any further purpose, or any different character" will do—to make a "transformative use of an original," a user "must go beyond that required to qualify as a derivative" use. *Id.* at 529. For example, an "adaptation of a book into a movie" is a "substantial" transformation, but it serves the same basic purpose (conveying a story for entertainment value) and is thus only derivative. *Id.*

Putting a work to a "transformative" use within the meaning of the fair-use doctrine requires putting the work to a new and unintended use, akin to those "listed in the preamble paragraph of § 107: criticism, comment, news reporting, teaching scholarship, or research." *Id.* at 528 (cleaned up). A parody, for example "has an obvious claim to transformative value" because it puts reproduced original material to "a distinct purpose of commenting on the original or criticizing it." *Id.* at 530 (discussing *Campbell*, 510 U.S at 579-583). By definition, the author of the original could not have criticism of her

own work as an original purpose of her creation.

b. The uses permitted by the Exemption are not transformative. It permits circumvention to copy "software, data files, and electronic service materials necessary for performing . . . servicing activities." 4-JA-1036. *Accord* 4-JA-1047-48 ("servicing computer programs and data files" and "electronic manuals"); 5-JA-1444 ("documentation and software to support planned maintenance activities and to execute common corrective maintenance activities"). Third-party servicers put those works to their exact intended uses—the same ones to which the works' authors put them.

There is nothing even remotely transformative about this. To begin with, third-party servicing companies do not imbue the works with a "new expression, meaning, or message." *Warhol*, 598 U.S. at 541. In fact, the Exemption's proponents expressly affirmed that they did not seek "an exemption to modify medical devices or systems, or their software" to avoid FDA regulation. 2-JA-627. The Librarian therefore did "not consider whether modification" of either the machines or their software "is not infringing." *Id.* She instead noted that "'modification' is not part of the proposed exemption for medical devices," and the "exemption requires the device to be restored to normal functionality and no changes be made to the firmware." 2-JA-648. Third-party servicers do not substantively modify anything.

Nor do third-party services put manufacturers' original creations to a "transformative" new *use* or *purpose*. With due respect to the Libarian and the district court, this point is not debatable. The Exemption's proponents were clear that they sought an exemption for "diagnostic software and data files" stored on, or embedded in, medical devices. 3-JA-1024. That is, they sought permission to copy "medical equipment servicing materials in the form of computer programs and data files," including manuals, "which are necessary for servicing (diagnosis, repair, and maintenance) of the medical devices and systems." 3-JA-1031-32. No petitioner sought an exemption to copy general operating software, which is typically Windows or Linux. Indeed, no such exemption would have been necessary in light of 17 U.S.C. § 117(c).

The works at issue here are only software service tools and maintenance-related documentation and files. These works, by definition, were created for the sole purpose of facilitating machine maintenance, diagnosis, and repair of the machines. As Philips explained in its 2024 comment letter, third-party servicers thus "seek to use copyrighted service software authored by [manufacturers] for the exact same purpose as it was created," which is "to service medical imaging systems." 5-JA-1510.

Confronting a similar circumstance shortly before enactment of the DMCA, the Ninth Circuit explained in *Triad Systems* that a third-party servicer in a case like this "invent[s] nothing of its own," and "its use of [the

manufacturer's] software is . . . neither creative nor transformative and does not provide the marketplace with new creative works." 64 F.3d at 1336. Or, to put it in *Warhol*'s words, third-party servicers' use of manufacturers' works "share[s] substantially the same purpose" as the original intended use, thus "supplanting the original" in the marketplace for maintenance-and-repair services without adding a "further purpose or different character" of any kind. 598 U.S. at 526, 528 (citing *Campbell*, 510 U.S. at 579).

c. There can be no doubt that the uses to which the works are being put are purely commercial: Third-party servicers use the copied materials to provide maintenance-and-repair services, which they sell for a fee. They accordingly "stand[] to profit from exploitation of the copyrighted material without paying the customary price" (a licensing fee), which is prototypical commercial use. *Harper & Row*, 471 U.S. at 562.

When third-party servicers put the works at issue here to their original and intended use without adding any new expression or applying any creative energies to them, the commerciality of the use assumes added weight. To be sure, "the fact that a use is commercial as opposed to nonprofit . . . is not [singularly] dispositive" of the first fair-used factor. *Warhol*, 598 U.S. at 531 (quoting *Google*, 593 U.S. at 32). It is, instead, "to be weighed against the degree to which the use has a further purpose or different character." *Id.* That makes sense: The less transformative a secondary use is, the more likely it is

to "serve as a substitute for the original or its plausible derivatives, shrinking the protected market opportunities of the copyrighted work"—and thus the more problematic it is that the secondary use is intended to make the user a profit at the author's expense. *Id.*

The only two courts to consider copyright infringement in this context are in accord: When a third-party servicer copies digital works and uses them to provide the very same maintenance-and-repair services that they were created to facilitate, the "use of [the] software [is] entirely commercial in nature." *Triad Systems*, 64 F.3d at 1337. *Accord Advanced Computer Services v. MAI Systems Corp.*, 845 F. Supp. 356, 365 (E.D. Va. 1994) (holding in a similar case that "the sole purpose of [the] use of [the] copyrighted software is in connection with the provision of computer maintenance services," which "is a commercial use").

It bears repeating here that third-party servicers earn their profit by taking business *from* the works' authors. Machine manufacturers "compete with ISOs for the post warranty servicing [contracts]" through which the works are monetized, but "ISOs often charge much less." 4-JA-1055. Of course, the reason that third-party servicers (ISOs) offer less expensive maintenance-and-repair services is because they are free-riding on the investments made by manufacturers. ISOs do not have to recoup the enormous R&D investments that manufacturers make to engineer their sophisticated medical

devices and author the software tools and other works necessary to keep them running. Their substitutive, commercial use of copyrighted materials is "presumptively an unfair exploitation of the monopoly privilege that belongs to the owner of the copyright." *Sony*, 464 U.S. at 451.

2. The Librarian's and district court's contrary conclusions are manifestly wrong

The Librarian disagreed on these points, concluding that third-party servicers *do* make a "transformative" use of field service software and maintenance-related documentation—by simply using those works for maintenance-and-repair services. Just to state that conclusion is to refute it.

In the Eighth Rulemaking, the Register's recommendation devoted a mere three sentences to the question of transformativeness:

> Here, the proposed activities are intended to restore a medical device or system's functionality, not to commercialize the embedded copyrighted software and other servicing materials. The Register has previously concluded that diagnosis and repair are likely to be transformative uses. The Register accordingly concludes that proponents' proposed use is likely transformative and so the first factor favors fair use.

2-JA-628. That is an illogical *ipse dixit*. It makes no sense to say that the only purpose of the copiers' use is to provide a service (restoring the machine's functionality), and not to make money in the competitive, commercial market for the service. When software is copied to provide maintenance-and-repair services to end-users in a commercial market for a fee, it is an obviously

commercial use. In fact, the use is not only commercial, but also a direct market substitution for manufacturers' services—the precise opposite of transformative use. *Warhol*, 598 U.S. at 528. To take the Librarian's logic to its natural conclusion would mean that when someone illegally copies a motion picture and sells tickets to watch the copy in his basement, he is putting the copy to the supposedly transformative use of "entertaining his customers," and the fact that he is making money in direct competition with movie theaters by doing so is irrelevant. That is not defensible.

Nor was it sufficient for the Librarian to analogize to the 2015 rule-making, in which she "previously concluded that diagnosis and repair are likely to be transformative uses." As commenters explained, the exemption at issue in 2015 authorized uses that included "copying the work to create new applications" and "extend[ed] to modification" of the works at issue. 1-JA-247. Here, no such transformative modifications are taking place. Again, the Librarian recognized this expressly, noting that "'modification' is not part of the proposed exemption for medical devices," which requires users to provide services with "no changes . . . made" to the works at issue. 2-JA-648.

Opponents of the Exemption highlighted this distinction in the Eighth Rulemaking (*e.g.*, 4-JA-1377), but the Librarian declined to address it (*see* 2-JA-627-631). They did so again in the Ninth Rulemaking (*e.g.*, 5-JA-1533), and the Librarian again declined to address it (*see* 3-JA-809-812).

That alone is a basis for vacating the Librarian's decisions as arbitrary and capricious. It is fundamental that "an agency must respond to comments 'that can be thought to challenge a fundamental premise' underlying the proposed agency decision." *Bloomberg L.P. v. SEC*, 45 F.4th 462, 476 (D.C. Cir. 2022). And "the failure to respond to significant comments . . . violates a substantive guarantee of the APA." *Western Coal Traffic League v. STB*, 998 F.3d 945, 954 (D.C. Cir. 2021).

We made this precise argument to the district court, but it waived it away, holding that "categorical" fair-use analysis required by the DMCA "requires some degree of generalization," and "[a]nalogizing . . . to another context involving . . . diagnosis, maintenance, and repair was therefore not only acceptable but showed exemplary thoroughness." 5-JA-1688. That answer likewise ignores the difference, which is that the 2015 exemption for automobile maintenance and repair expressly *included* transformative modifications, whereas the Exemption here expressly *disclaimed* them. Generalization is one thing, but ignoring a clear distinction is something else.

From there, the district court gave another response that the Librarian omitted, reasoning that the Librarian's analysis in the 2015 rulemaking didn't depend on modification. 5-JA-1689. There is no basis for that conclusion. The Library emphasized modification in the 2015 rulemaking (1-JA-247), and it did not suggest that it was irrelevant to transformativeness. Moreover,

modification was central to the transformative-use arguments presented by proponents to the Librarian in 2015. The Electronic Frontier Foundation, for instance, asserted that the 2015 record was "replete with transformative uses of vehicle software," including "modifying software to alter its functionality." EFF Reply Comments 5-6, https://perma.cc/P63H-J26Y. *Accord* SEMA Reply Comments 8, https://perma.cc/G2YU-YJYU.

Regardless, the district court's *sua sponte* reasoning was not adopted by the Librarian (or even pressed by his litigation counsel), so this is no basis for affirming. "[J]udicial review of agency action is limited to the grounds that the agency invoked when it took action." *DHS v. Regents of the University of California*, 591 U.S. 1, 20 (2020). The Court "cannot affirm based on a post hoc litigation rationalization" that differs from the reasons given by the agency itself. *Gulf Restoration Network v. Haaland*, 47 F.4th 795, 804 (D.C. Cir. 2022). That is so regardless of whether the post hoc reasoning is supplied by counsel for the agency or *sua sponte* by the district court.

b. In the Ninth Rulemaking, the Librarian concluded that the permitted uses are transformative because "the purpose of the use of software in repair is to render a non-functional device functional again, while the original purpose of the software is to operate a device that functions as designed." 3-JA-812. There are two ways to interpret this reasoning, both reflecting error.

***First*,** the Librarian can be understood to say that the original purpose of

the works at issue is *not* the facilitation of maintenance-and-repair services and instead only "to operate a device that functions as designed." From that angle, the Librarian seems to have concluded that the works at issue are the machines' operating software, and not field-service software tools or maintenance-related documentation.

That was the district court's belief, as well. It characterized the Exemption as allowing copying of "operating system software," which has as an "original use" the operation of a functioning machine. 5-JA-1683-84. That stands in contrast, according to the district court, with the "secondary use by ISOs to repair the device." 5-JA-1684. *Accord id.* n.5 (drawing "a distinction between the original purpose of getting the device to operate . . . and the secondary one of fixing the device to improve or maintain its operation"). Indeed, the district court went so far as to attribute to the Librarian a "factual finding" that "the operating software and related data files for medical devices were *not* originally invented and developed for the primary purpose of having OEMs service those devices." 5-JA-1709.

If that is what the Librarian meant, her decision was unequivocally wrong and ran "counter to the evidence before the agency." *Motor Vehicle Manufacturers Association v. State Farm Mutual Auto Insurance*, 463 U.S. 29, 43 (1983). As we have now repeatedly shown, the Exemption was only about software tools, manuals, documentation, and similar files used in mainten-

ance and repair.

That is what makes so puzzling the district court's assertion that "substantial evidence" supports "the Librarian's factual finding" that the works at issue were not created to facilitate maintenance and repair. 5-JA-1709. Having declared as much, the district court did not then recite the supposed evidence supporting the finding, or even where the finding was made. Instead, the district court cited to the entire fair-use section of its own opinion, running from 5-JA-1675 to 5-JA-1703. But that part of the opinion also does not cite evidence to support such a finding. The closest is footnote 5 on page 5-JA-1684, which simply recites the Librarian's factual *assumptions* (points that she "noted" and "recogniz[ed]"), again without citation to evidence.

The Librarian's and district court's evident belief that the Exemption concerns "operating system software" (5-JA-1683), which is created "to operate a device that functions as designed" (3-JA-812) and not to maintain or repair it, is just wrong. There is no evidence to support it—*none, nowhere*.

At the risk of excessive repetition: An exemption for copying operating software would not be necessary in light of § 117(c). The petitioners thus were explicit that they sought the Exemption for "medical equipment servicing materials" (3-JA-1031), including "diagnostic software and data files" (3-JA-1024) and electronically stored service manuals and similar documentation. (*e.g.*, 3-JA-1031-32; 4-JA-1078-79; 5-JA-1432, n.3). Those works very

plainly *are* "originally invented and developed for the primary purpose of having OEMs service those devices." 5-JA-1709.

Of course, even if this case were about general operating software, the uses at issue would be derivative at most and thus still protected. The language of the Exemption itself makes this clear—it allows the copying of computer programs and other protected works only if their reproduction is "a *necessary* step to allow the diagnosis, maintenance, or repair" of a medical device. 37 C.F.R. § 201.40(b)(17) (emphasis added). To characterize such copying as transformative depends on the implausible notion that, although (1) complex medical devices require diagnosis, maintenance, and repair during their lifetimes, (2) manufacturers know that such services will be required because they provide them, and (3) copying the machine's operating software is *necessary* to perform such tasks, manufacturers nevertheless did not design or intend their operating software to be used for that end. That rationale finds no support in the administrative record. And either way, such a use would be at most a derivative "adapt[ation]" of the original software and files. 17 U.S.C. § 101 (defining derivative use).

Second, the Librarian may alternatively be understood to say that third-party servicers' use is transformative of the *machine* (i.e., it "render[s] a non-functional device functional again") rather than of the works being copied. The district court echoed that reasoning, too, explaining that "diagnosis,

maintenance, and repair has a concrete 'transformative' effect *on the device* by changing some aspect of how it works." 5-JA-1686 (emphasis added). But that also is no answer, because the first fair-use factor is concerned with whether the *copied works* are transformed by the *copier*. It is not whether their use accomplishes the transformation of some distinct physical object like a machine, allowing some "end-user's utilization of the product," which is "largely irrelevant" to the fair-use inquiry. *Zomba Enterprises v. Panorama Records*, 491 F.3d 574, 582 (6th Cir. 2007).

We made this point in proceedings below. In response, the district court seemed to agree that transformation of the machine is insufficient. 5-JA-1687. But, the court concluded, "[a]lthough technically the hardware and software may be distinct, the device is simply a vessel for, or a reader of, the copyrighted material," and "[n]either is operational or commercially valuable without the other." 5-JA-1687. The court thus held that "maintenance and repairs to device components . . . has a transformative effect on the *use* of the software" by fixing the machine and ensuring it remains "commercially valuable." *Id.*

That again is not a reason the Librarian gave, and it is candidly hard to understand. Service software tools and maintenance manuals may lack utility without the devices to which they apply, but that is true of many copyrighted works. A computer programmer who creates a new software repair tool for Android smartphones has written something innovative and useful. To be

sure, the software requires a smartphone running Android to do its work, and it would not be "commercially valuable" without smartphones to run on. But that hardly means that a competitor's appropriation of the tool for its own use to provide competing maintenance-and-repair services for smartphones is "transformative," simply because the purpose is to make a smartphone functional and thus capable of running the software. That rationale is wholly out of place in a case about copyright.

c. Beyond these points, the district court added substantial new lines of reasoning not introduced by the Librarian in the rulemaking. We do not dwell on the district court's *sua sponte* analyses, because, again, the Court "may only uphold a rule 'on the basis articulated by the agency' in the rule making record." *Genuine Parts*, 890 F.3d at 314.

Yet one rejoinder warrants emphasis for clarity's sake. The district court reasoned that even if manufacturers "created [the works at issue] for use in performing their own repairs" (as unquestionably they did), and assuming further that third-party servicers use the works for the precise same purpose (as unquestionably they do), the use "still may be considered transformative." 5-JA-1685-86. That is because "use of those materials by ISOs or owners to achieve a secondary purpose to carry out repairs on specific, individual machines requires input of their own knowledge, creative and analytical thinking, and mechanical skills," which "transforms the basic knowledge conveyed

in the copyrighted materials." 5-JA-1686.

Put mildly, that is legally wrong and factually unsupported. Legally, it's like saying that a singer who offers a commercial performance of the copyrighted song makes a "fair use" of the work if her rendition requires her to "input" her training and creativity into the rendition. No. When an artist sings a song in a commercial performance, she must obtain a license from the author. That is so regardless of whether her performance is a precisely duplication of the original or instead offers some "important new expression." *Warhol*, 598 U.S. at 541. Creative interpretation of a preexisting work makes the performance derivative, if even that—it does not mean the result is a noninfringing fair use. *Id.*

But in this context, the proponents could not get even that far, because there is no evidence whatsoever to suggest that machine technicians do anything creative at all. Again, they expressly disclaimed transformation or alteration to avoid FDA regulation.

Of course, even if it were otherwise, what goes for the song would go for the repairs: Mixing software tools designed for maintenance and repair with the "knowledge, creative and analytical thinking, and mechanical skills" of a service technician (5-JA-1686) is *at most* akin to a derivative performance of an original work, as to which a license still must be obtained. To make a "transformative use of an original," a user "must go beyond that required to

qualify as a derivative" use, putting the work to use in an unintended market in which the author does not participate. *Warhol*, 598 U.S. at 529. That does not describe this case.

B. Fourth factor: Unauthorized copying directly undercuts the market in which manufacturers license the works at issue

1. The purpose of the Exemption is to inflict substantial harm on the marketability of the original works

a. Under the fourth fair-use factor, the Court must consider "whether the use in question substitutes for either a purchase or license that would typically be offered by the copyright owner and falls within the exclusive rights granted" by the Copyright Act. 4 Patry on Copyright § 10:150.10 (2025 update). This consideration—long recognized as "the single most important element of fair use" (*Harper & Row*, 471 U.S. at 566)—is closely related to the first factor. *Warhol*, 598 U.S. at 536 n.12. "While the first factor considers whether and to what extent an original work and secondary use have substitutable purposes, the fourth factor focuses on actual or potential market substitution." *Id.*

Under this factor, the Court must consider "not only the extent of market harm caused by the particular actions of the alleged infringer, but also whether unrestricted and widespread conduct of the sort engaged in . . . would result in a substantially adverse impact on the potential market for the original." *Campbell*, 510 U.S. at 590 (cleaned up).

Sensibly, an "inference of market harm" arises in cases "involving . . . mere duplication for commercial purposes." *Campbell*, 510 U.S. at 591 (citing *Sony*, 464 U.S. at 451); *see also, e.g.*, *Philpot v. Independent Journal Review*, 92 F.4th 252, 261 (4th Cir. 2024) (courts must "presume a cognizable market harm exists when a commercial use is not transformative but instead 'amounts to mere duplication of the entirety of an original'") (quoting *Campbell*, 510 U.S. at 591). Such a presumption is "common sense," because "when a commercial use amounts to mere duplication of the entirety of an original, it clearly supersedes the objects of the original and serves as a market replacement for it." *Campbell*, 510 U.S. at 591. "If it were possible to reproduce [an author's] unaltered work, as a whole, without compensation," it "would surely have a 'substantially adverse impact' on [the author's] ability to license [the work]." *Murphy v. Millennium Radio Group LLC*, 650 F.3d 295, 308 (3d Cir. 2011) (quoting *Campbell*, 510 U.S. at 590).

b. That is the case here. To start, there is plainly a market for the works at issue. Manufacturers sell licenses and subscriptions to use their maintenance-and-repair software, files, and documents. 4-JA-1067-68; 4-JA-1079; 4-JA-1361; 5-JA-1580. If third-party servicers wish to use manufacturers' software and documents to provide maintenance-and-repair services in competition with manufacturers, their technicians must therefore obtain the necessary training and pay a licensing fee. *E.g.*, 4-JA-1079-1080.

Beyond that, we have just shown that the copying of manufacturers' maintenance-related software and documents is commercially substitutive. "This is not a case where the copyist's work fills a market that the copyright owner will likely avoid, as is true for 'a lethal parody' or 'a scathing theater review.'" *Dr. Seuss Enterprises, L.P. v. ComicMix LLC*, 983 F.3d at 443, 460 (9th Cir. 2020) (quoting *Campbell*, 510 U.S. at 591-92). Rather, third-party servicers aim to take a greater share of the market for maintenance-and-repair services *from* manufacturers. *E.g.*, 5-JA-1439 (the point of the Exemption is to allow machine owners "to get faster and more affordable services from ISOs" rather than from manufacturers); 5-JA-1707 (district court noting that the exemption codified at § 117(c) "depriv[es] OEMs of licensing fees they would otherwise receive from repair services").

Allowing third-party servicers to copy manufacturers' service-related software tools and other digital materials without paying for them, so they may use them in their for-profit maintenance-and-repair businesses, therefore will, as a matter of "common sense" (*Campbell*, 510 U.S. at 591), have an adverse effect on the market for the software. Apart from depriving manufacturers of licensing revenue from the copiers themselves, many healthcare providers will stop paying for licenses and software subscriptions if they can obtain access to the protected works from lower-cost third-party servicers instead. Likewise, many will switch away from higher-cost OEM-affiliated

technicians, who must recoup the cost of training and licensing, electing instead to use third-party technicians who freeride on OEM innovations.

These market harms were not only acknowledged, but embraced, by the Librarian and petitioners throughout both rulemakings. The petitioners complained that manufacturers' training requirements, software licenses, and service contracts are "unnecessarily expensive" (4-JA-1044) and come at "undue expense" (4-JA-1042; 5-JA-1437). The Librarian was told repeatedly that "ISOs often charge much less than OEMs." 4-JA-1055; *accord* 3-JA-1022; 4-JA-1039; 4-JA-1057; 4-JA-1079. She also was told the reason why: Manufacturers require licensing fees for the "medical equipment software required for servicing of the medical equipment." 4-JA-1062; *accord* 3-JA-1024; 4-JA-1079; 5-JA-1434.

The higher prices resulting from licensing fees was thus presented as the very reason for the Exemption. But, again, that turns copyright law upside down. Manufacturers charge more because they, unlike third-party servicers, *actually innovate*. And they are granted a statutory monopoly for just that reason, so that they can recoup their enormous R&D investments and *continue* to innovate. *See Google*, 593 U.S. at 16-17.

Anyway, the point is simply that, in the Librarian's view, higher prices from a manufacturers' statutory copyright monopoly was a problem to over-

come—meaning, in effect, that substitutive market harm is the Exemption's *raison d'être*. Thus, the fourth factor weighs decisively against fair use.

2. The Librarian and district court erred in holding that there is no market to harm

a. The Librarian disagreed. She concluded that "most medical device and system software and data files generally have no independent value separate from being used with the equipment." 2-JA-631. Thus, although she acknowledged that "the record suggests that some system features on certain devices may be separately licensed through a subscription service," the Librarian determined that the copying at issue "is unlikely to harm the market for the embedded software" because "there is no indication that the software serves any function, or has any value, except for use with the medical device or system for which it was designed." *Id.*

That is a *non sequitur*. The question under the fourth factor is not whether the copyrighted material has a use, or can be sold in a market, *other than* its intended use or intended market. It is irrelevant that the materials are useful only in connection "with the medical device or system for which it was designed." The only questions under the fourth factor are (1) whether there is a market for buying or licensing the protected works, and (2) whether the author's position in that market is harmed by the copying. *Harper & Row*, 471 U.S. at 566; 4 Nimmer on Copyright § 13.05.

The evidence before the Librarian showed unequivocally that the answer to both questions here is *yes*. Transtate itself submitted a market analysis detailing the "dynamics" of the "medical equipment maintenance market." 4-JA-1132. In this market, manufacturers have a "large share" because of their "wide geographic presence and strong technical expertise." 4-JA-1133. But there has been an "emergence of ISOs dedicated to solely providing maintenance services" because they charge less. 4-JA-1135.

The evidence established further that, in the medical equipment maintenance market, manufacturers use encryption to "limit access to software and data files necessary to service [medical] equipment." 4-JA-1119. They sell "licenses to use the software," which also may be accessed by "an OEM technician" in lieu of an ISO. 4-JA-1079; *see also* 5-JA-1580 (manufacturers sell and lease certain software "functionalities" individually). As AdvaMed explained in both rulemakings, "there is a market for some medical device software modules as standalone works," which are "activated and maintained through a subscription model." 4-JA-1361; 5-JA-1580.

We made these points to the district court. But it concluded, like the Library, that "the software cannot be used without the equipment, and the equipment cannot be used without the software, so the market for the equipment and the software is one in the same." 5-JA-1697. But as we have shown, there *is* a market for the software separate from the equipment—as the Librar-

ian admitted but ignored. 2-JA-631 ("the record suggests that some system features on certain devices may be separately licensed through a subscription service"). The Library's ultimate conclusion to the contrary once again is "counter to the evidence before the agency." *State Farm*, 463 U.S. at 43.

b. Perhaps appreciating the insufficiency of the Librarian's answer on this point, the district court went on to assume our "premises as true," meaning that the works at issue are licensed and sold in the "separate market for diagnosis, maintenance, and repairs." 5-JA-1698. From there, it offered yet another explanation not furnished by the Librarian (and thus off the table). It reasoned that "the commercial value of the copyrighted materials in the latter market comes not from the copyrighted materials alone but rather relies on the application of labor, creative analytics and expertise." *Id.* On this ground, the district court made the stunning assertion that third-party servicers "arguably are creating a market by adding their own skill and expertise to provide a service using copyrighted materials." 5-JA-1699.

That reasoning once more turns copyright principles upside down. Consider again the singer/performance analogy. It may be true that the "commercial value" of a song "comes not from the copyrighted materials alone but rather relies on the" singer's interpretation and creativity to produce a sound. Sheet music has no value without a performance of its contents. But that observation has no relevance to the fourth fair-use factor, and it nowise

indicates that the author of the song is disentitled to copyright protection against exploitative performances.

In the context of the analogy, the fourth factor asks simply: (1) Is there a market for performances of the song? And (2) would allowing singers to copy the song's lyrics and tune, in unlicensed performances, have a "substantially adverse impact on the potential market for the original?" *Campbell*, 510 U.S. at 590. The answer to both questions is (as before) an obvious *yes*. And no one seriously could contend that the singer is not exploiting the market for the original and instead "creating a market" of her own. Quite the opposite: One would say that she is freeriding on the market that the *author* has created, by performing the song for commercial entertainment, without paying for a license. That's Copyright 101.

All of that holds true here. Again, the Librarian acknowledged this. She was clear that the purpose of the Exemption was to *overcome* manufacturers' copyright protection so that third-party servicers can put the works at issue to their intended uses, in competition with manufacturers, at lower prices. 2-JA-647. Depriving manufacturers of licensing revenue in the market for maintenance and repair (and thus "help[ing] to address the broader competitive concerns" in that market (*id.*)) is the *point* of the Exemption. *Cf.* 5-JA-1707 (district court noting that the exemption codified at § 117(c) "depriv[es]

OEMs of licensing fees they would otherwise receive from repair services"). There is thus no logical ground for denying market harm.

c. *Triad Systems* is once again instructive. There, "Triad invented, developed, and marketed its software to enable its customers and its own technicians to service Triad computers." 64 F.3d at 1337. The Ninth Circuit recognized that the third-party servicer in that case was "getting a free ride when it use[d] that software to perform precisely the same service" in competition with Triad, but without paying a licensing fee. *Id.* The court thus had no trouble concluding that "a finding of fair use is unwarranted" given the substitutive effect. *Id.* Because the defendant's "use of Triad's software [was] entirely commercial in nature" and substituted for Triad's own services, it was an infringing use, not a fair use—period. *Id.* at 1337.

That is this case exactly. For its part, the district court dismissed the Ninth Circuit's reasoning in *Triad Systems* as "sparse and thus hardly instructive," noting that it "predate[s] not only the DMCA's § 117(c) but also several key fair use decisions from the Supreme Court." 5-JA-1708-1709. But the district court did not point to any substantive inconsistencies between the Ninth Circuit's reasoning in *Triad Systems* and the Supreme Court's subsequent decisions. And none are apparent. Indeed, the Ninth Circuit addressed all the relevant considerations under contemporary doctrine: transformativeness, substitution, commerciality, market harm, and so on. As for the length

of the Ninth Circuit's decision, its fair-use analysis spans five paragraphs and is, on its own terms, complete and sound.

C. Second and third factors: There is no other "compelling justification" for finding the permitted uses noninfringing

Because the Exemption authorizes third-party servicers to put manufacturers' copyrighted works to commercial, non-transformative uses to compete at an unfair advantage, only "a particularly compelling justification" under the second and third fair-use factors could save the Exemption from invalidation. *Warhol*, 598 U.S. at 547. But the Librarian offered no justification, let alone a compelling one, for copying the works at issue—other than lowering prices for device maintenance and repair, which is no justification at all under settled copyright law.

a. Under the second factor, the Court must evaluate "the nature of the copyrighted work" (17 U.S.C. § 107(2)), including whether "it serves an artistic rather than a utilitarian function." *Google*, 593 U.S. at 20. No doubt, "computer programs differ from books, films, and many other 'literary works' in that such programs almost always serve functional purposes" rather than artistic, expressive ones. *Id.* at 21. Yet "[b]y defining computer programs in § 101, Congress chose to place this subject matter within the copyright regime." *Id.* at 23. And "unless a persuasive fair use justification is involved, authors of factual works, like authors of fiction, should be entitled to copy-

right protection of their protected expression." *Authors Guild*, 804 F.3d at 220. Put simply, "[t]he mere fact that the original is a factual work [does] not imply that others may freely copy it." *Id.*

Courts have recognized that a justification may exist where copying facilitates "a service important to the public." *Romanova v. Amilus Inc*, 138 F.4th 104, 116-17 (2d Cir. 2025) (Leval, J.) (collecting cases). But in each of those cases, the service was not substitutive or exploitative—it was instead transformative. *Id.* For example, in *Authors Guild v. HathiTrust*, 755 F.3d 87 (2d Cir. 2014), the service was conversion of copyrighted works into formats readable by the blind; and in *A.V. ex rel. Vanderhye v. iParadigms, LLC*, 562 F.3d 630 (4th Cir. 2009), the service was copying of student theses into a database to help universities detect plagiarism.

The same is true of the case on which the district court relied (5JA1682-84), *American Society for Testing & Materials v. Public.Resource.Org, Inc.*, which produced two opinions at 82 F.4th 1262 (D.C. Cir. 2023) and 896 F.3d 437 (D.C. Cir. 2018). The Court there concluded that the copiers' purpose (reporting legal standards to the public at large) was non-commercial and resembled "the purposes listed in the preamble paragraph of § 107," including "news reporting, teaching," and "research." *Warhol*, 598 U.S. at 529. As construed by the Court, those purposes were wholly different from (and not

substitutions for) the purposes of the original author, which was the creation of state-of-the-art industry standards.

These cases demonstrate that the second factor "favors fair use" only when, *because* the works are factual, "the secondary use transformatively provides valuable [new] information about the original, rather than replicating protected expression" and "substitute[ing] for the original." 4 Patry on Copyright § 10:138 (quoting *Authors Guild*, 804 F.3d at 220).

Not so here. There already is an established market for medical machine maintenance-and-repair services, independent of unauthorized copying. Copying merely permits ISOs to compete substitutively, at a lower price. In the copyright context, that is the *opposite* of justification. As the Supreme Court explained in *Google*, the purpose of copyright is "to encourage the production of works that others might reproduce more cheaply" by granting the author the right to exclude third parties from engaging in such reproduction, even though doing so generally will "raise prices." 593 U.S. at 16-17. But a manufacturer's "higher service rates cannot be said to violate the public interest" under copyright principles because a manufacturer "should be entitled to rely on [higher] service fees to recoup its investment costs in developing the software" and the machines that depend on it. *Advanced Computer Services*, 845 F. Supp. at 365.

b. Finally, the third factor directs courts to examine "the amount and substantiality of the portion used in relation to the copyrighted work as a whole." 17 U.S.C. § 107(3). This is not a justificative consideration, but rather a hurdle to overcome. When a copier takes all or a substantial portion of the original, fair use is less likely because substantial copying "is evidence of the qualitative value of the copied material, both to the originator and to the plagiarist who seeks to profit from marketing someone else's copyrighted expression." *Harper & Row*, 471 U.S. at 565. Here, the entire works are copied and used for commercial gain. There is thus no way in which the third factor could help to justify fair use in this case.

D. The Exemption purports to amend, and therefore is in conflict with, the plain language of 17 U.S.C. § 117(c)

The district court concluded its fair-use analysis with its own views on the purpose of 17 U.S.C. § 117(c)—views that, because they were not offered by the Librarian, were improper for the court to consider at all, much less base its decision on. *See* 5-JA-1704-10.

Section 117(c)'s text is explicit and narrow: It permits copying only of "a computer program," and then only when the copy "is made solely by virtue of the activation of a machine" and is "destroyed immediately after the maintenance or repair is completed." As both the Librarian and the district court acknowledged, that is "a narrower range of activities than those" covered by

the Exemption. JA1707. Service software tools are not copied by virtue of machine activation, and manuals and other written works needed for maintenance and repair are not computer programs at all. *See* JA1356.

Yet the district court, drawing on snippets of legislative history, took the position that § 117(c) reflects a broader "intent" to "ensure that maintenance and repairs [are] not monopolized by copyright owners of computer programs" and that "owners and lessees can maintain and repair their devices without being beholden to OEMs." JA1706-1707. Although the district court acknowledged that the "Exemption goes beyond" the statute by authorizing copying that § 117(c) does not, it concluded that the Exemption is "consistent with" the provision's broader "intent." JA1707.

That reasoning is misguided. "[A] broadly stated legislative purpose cannot trump more narrowly worded statutory text." *United States v. Hillie*, 39 F.4th 674, 688 (D.C. Cir. 2022). "[W]hatever degree of confidence about congressional purpose one derives from the legislative history, that purpose must find expression 'within the permissible limits of the language' before it can be given effect" by a court. *U.S. ex rel. Totten v. Bombardier Corp.*, 380 F.3d 488, 495 (D.C. Cir. 2004).

If § 117(c) is relevant here at all, it is only to show that Congress understood that copying to provide substitutive third-party maintenance-and-repair services is *not* fair use. Thus, when it made the policy decision to exempt copy-

ing for maintenance and repair that occurs as a consequence of activating a machine, it did so not by amending the fair use doctrine, but by adopting a simple, standalone carveout from the Act.

The district court's theory that Congress simply lacked the foresight to draft a "broader statutory exemption" because it "did not anticipate the need" for one in 1998 (5-JA-1707) is both irrelevant and wrong. Irrelevant, because it is not the district court's place to substitute its judgment for Congress's. Wrong, because use of licensed software in connection with maintenance and repairs was well known in 1998, as *Triad* demonstrates.

If Congress had wanted to draft a broader exception, it could have done so—but it did not. And even if there were ground to conclude today that § 117(c)'s scope is unduly narrow, it would be for Congress, not the Librarian or district court, to enlarge it.

II. THE COURT SHOULD VACATE THE EXEMPTION

When an APA plaintiff succeeds in showing that an agency has undertaken a final action that is inconsistent with law, arbitrary and capricious, or unsupported by evidence, "[t]he ordinary practice is to vacate unlawful agency action." *United Steel v. Mine Safety & Health Administration*, 925 F.3d 1279, 1287 (D.C. Cir. 2019) (citing 5 U.S.C. § 706). That ordinary practice is warranted here.

In proceedings below, the Library proposed that the district court instead issue a declaration that the Exemption is unlawful and otherwise enjoin the Library from implementing it. That would not suffice. The injuries arising from the Exemption are worked not just by the Librarian, but also by the private third parties violating plaintiffs' members' rights under the Exemption's authorization. As long as the Exemption stands, third-party servicers may utilize it as a rationale for infringing manufacturers' copyrights. Only the relief required expressly by 5 U.S.C. § 706(2)—an order setting the Exemption aside—will accord plaintiffs the full relief to which they are entitled.

CONCLUSION

The Court should reverse the decision below and remand with instructions to set aside the Medical Devices Exemption, 37 C.F.R. § 201.40(b)(17).

Respectfully submitted,

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Dated: November 7, 2025

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g)(1), undersigned counsel for appellant certifies that this brief:

(i) complies with the type-volume limitation of Circuit Rule 32 because it contains 12,994 words, including footnotes and excluding the parts of the brief exempted by Rule 32(f); and

(ii) complies with the typeface and type style requirements of Rule 32(a) because it is typeset in Century Supra font in 14 points.

Dated: November 7, 2025 /s/ *Michael B. Kimberly*

CERTIFICATE OF SERVICE

Undersigned counsel for appellant certifies that on this date, the foregoing document was served electronically via the Court's CM/ECF system upon all counsel of record.

Dated: November 7, 2025 /s/ *Michael B. Kimberly*

ADDENDUM
OF STATUTES AND REGULATIONS

17 U.S.C. § 1201(a) ..... Add. 1

17 U.S.C. § 117(c) ..... Add. 3

37 C.F.R. § 201.40(b)(17) ..... Add. 3

Section 1201(a) of Title 17 of the U.S. code specifies:

(a) Violations Regarding Circumvention of Technological Measures.

(1) (A) No person shall circumvent a technological measure that effectively controls access to a work protected under this title. The prohibition contained in the preceding sentence shall take effect at the end of the 2-year period beginning on the date of the enactment of this chapter.

(B) The prohibition contained in subparagraph (A) shall not apply to persons who are users of a copyrighted work which is in a particular class of works, if such persons are, or are likely to be in the succeeding 3-year period, adversely affected by virtue of such prohibition in their ability to make noninfringing uses of that particular class of works under this title, as determined under subparagraph (C).

(C) During the 2-year period described in subparagraph (A), and during each succeeding 3-year period, the Librarian of Congress, upon the recommendation of the Register of Copyrights, who shall consult with the Assistant Secretary for Communications and Information of the Department of Commerce and report and comment on his or her views in making such recommendation, shall make the determination in a rulemaking proceeding for purposes of subparagraph (B) of whether persons who are users of a copyrighted work are, or are likely to be in the succeeding 3-year period, adversely affected by the prohibition under subparagraph (A) in their ability to make noninfringing uses under this title of a particular class of copyrighted works. In conducting such rulemaking, the Librarian shall examine—

(i) the availability for use of copyrighted works;

(ii) the availability for use of works for nonprofit archival, preservation, and educational purposes;

(iii) the impact that the prohibition on the circumvention of technological measures applied to copyrighted works has on criticism, comment, news reporting, teaching, scholarship, or research;

(iv) the effect of circumvention of technological measures on the market for or value of copyrighted works; and

(v) such other factors as the Librarian considers appropriate.

(D) The Librarian shall publish any class of copyrighted works for which the Librarian has determined, pursuant to the rulemaking conducted under subparagraph (C), that noninfringing uses by persons who are users of a copyrighted work are, or are likely to be, adversely affected, and the prohibition contained in subparagraph (A) shall not apply to such users with respect to such class of works for the ensuing 3-year period.

(E) Neither the exception under subparagraph (B) from the applicability of the prohibition contained in subparagraph (A), nor any determination made in a rulemaking conducted under subparagraph (C), may be used as a defense in any action to enforce any provision of this title other than this paragraph.

(2) No person shall manufacture, import, offer to the public, provide, or otherwise traffic in any technology, product, service, device, component, or part thereof, that—

(A) is primarily designed or produced for the purpose of circumventing a technological measure that effectively controls access to a work protected under this title;

(B) has only limited commercially significant purpose or use other than to circumvent a technological measure that effectively controls access to a work protected under this title; or

(C) is marketed by that person or another acting in concert with that person with that person's knowledge for use in circumventing a technological measure that effectively controls access to a work protected under this title.

(3) As used in this subsection—

(A) to "circumvent a technological measure" means to descramble a scrambled work, to decrypt an encrypted work, or otherwise to avoid, bypass, remove, deactivate, or impair a technological measure, without the authority of the copyright owner; and

(B) a technological measure "effectively controls access to a work" if the measure, in the ordinary course of its operation, requires the application of information, or a process or a treatment, with the authority of the copyright owner, to gain access to the work.

Section 117(c) of Title 17 of the U.S. Code specifies:

(c) Machine Maintenance or Repair.—Notwithstanding the provisions of section 106, it is not an infringement for the owner or lessee of a machine to make or authorize the making of a copy of a computer program if such copy is made solely by virtue of the activation of a machine that lawfully contains an authorized copy of the computer program, for purposes only of maintenance or repair of that machine, if—

(1) such new copy is used in no other manner and is destroyed immediately after the maintenance or repair is completed; and

(2) with respect to any computer program or part thereof that is not necessary for that machine to be activated, such program or part thereof is not accessed or used other than to make such new copy by virtue of the activation of the machine.

Section 201.40(b)(17) of Title 37 of the Code of Federal Regulations specifies:

Exemptions to prohibition against circumvention.

(17) Computer programs that are contained in and control the functioning of a lawfully acquired medical device or system, and related data files, when circumvention is a necessary step to allow the diagnosis, maintenance, or repair of such a device or system. For purposes of this paragraph (b)(17):

(i) The "maintenance" of a device or system is the servicing of the device or system in order to make it work in accordance with its original specifications and any changes to those specifications authorized for that device or system; and

(ii) The "repair" of a device or system is the restoring of the device or system to the state of working in accordance with its original specifications and any changes to those specifications authorized for that device or system.