UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ADVANCED MEDICAL TECHNOLOGY ASSOCIATION, *et al.*, Plaintiffs, v. LIBRARY OF CONGRESS, *et al.*, Defendants.	Civil Action No. 22-499 (BAH) Judge Beryl A. Howell

MEMORANDUM OPINION

Pending before this Court, for the second time, are challenges to the Library of Congress's rule exempting parties accessing copyrighted software for the purpose of diagnosis, maintenance, and repair of medical devices from the proscription in the Digital Millennium Copyright Act of 1998 ("DMCA") barring the circumvention of technological protection measures ("TPMs") limiting access to copyrighted works. *See* Exemption to Prohibition on Circumvention of Copyright Protection Systems for Access Control Technologies, 89 Fed. Reg. 85,437, 85,441 (Oct. 28, 2024); Exemption to Prohibition on Circumvention of Copyright Protection Systems for Access Control Technologies, 86 Fed. Reg. 59,627, 59,628 (Oct. 28, 2021), codified at 37 C.F.R. § 201.40(b)(17) (hereinafter "Medical Device Exemption"). After the D.C. Circuit determined that the Library of Congress's rulemaking is subject to the Administrative Procedure Act ("APA") and remanded this dispute, *see Medical Imaging & Technology Alliance v. Library of Congress* ("*MITA II*"), 103 F.4th 830, 841-42 (D.C. Cir. 2024), the parties filed cross motions for summary judgment on plaintiffs' APA claims. *See* Pls.' Mot. for Summ. J. ("Pls.' MSJ"), ECF No. 33; Defs.' Mot. for Summ. J. ("Defs.' MSJ"), ECF No. 35. For the reasons explained below, plaintiffs Medical Imaging & Technology Alliance

and Advanced Medical Technology Association's motion for summary judgment is denied, and the Library and Librarian of Congress' motion for summary judgment is granted.

I. BACKGROUND

The statutory scheme, facts, and procedural history relevant to the pending motion are described below.

A. Statutory and Regulatory Background

The Copyright Act of 1976 prohibits the unauthorized reproduction of "original works of authorship fixed in any tangible medium of expression." 17 U.S.C. § 102(a). Such original works include computer programs and software. *See id.* §§ 102(a)(1), 109(b)(1)(A). While generally prohibiting the reproduction of original works, the Copyright Act also codifies the fair use doctrine, which allows reproduction of works for certain purposes such as "criticism, comment, news reporting, teaching . . ., scholarship, or research" upon "consider[ation]" of four factors:

> (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.

Id. § 107. "When those factors favor a finding of fair use, that use is 'not an infringement of copyright,'" so any party sued for a copyright violation based on that use will have a complete defense. *Green v. U.S. Dep't of Just.*, 111 F.4th 81, 89 (D.C. Cir. 2024) (quoting 17 U.S.C. § 107).

"In the 1990s, Congress anticipated that 'the movies, music, software, and literary works that are the fruit of American creative genius' could soon be accessed 'quickly and conveniently via the Internet.'" *Id.* (quoting S. Rep. No. 105-190, at 8 (1998)). Copyright owners would be reluctant to make their works available in digital form "without reasonable assurance" of

protection "against massive piracy." *Id.* (quoting S. Rep. No. 105-190, at 8). To address concerns about copyright protection in such an environment and to implement two World Intellectual Property Organization treaties, Congress in 1998 enacted the DMCA, which allows copyright owners to enforce "digital walls" used to protect their works from piracy. *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437, 458 (2007); *see MITA II*, 103 F.4th at 834; *Green*, 111 F.4th at 89. The DMCA provides a private right of action against anyone who "circumvent[s]" such digital walls, or "technological measure[s,] that effectively control[] access to a work protected" by copyright law. 17 U.S.C. § 1201(a)(1)(A) (the "anticircumvention provision"); *MITA II*, 103 F.4th at 833; *see also id.* § 1201(a)(3)(A) (defining "to circumvent a technological measure" as "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"). For example, a subscription-based streaming service might require a log-on code to access videos and encrypt the media to prevent copying as forms of "digital walls." *See Green*, 111 F.4th at 89. In this way, the DMCA "operate[s] as a prohibition against digital trespass." *Id.*

The DMCA includes, however, several exceptions to the anticircumvention provision within the statute itself for uses that promote public safety and security and productive, noninfringing uses. *See* H.R. Rep. No. 105-796, at 65-67 (1998). Circumvention of a technological protective measure ("TPM") is permitted for a school or library to determine whether to acquire a copyrighted product, for law enforcement purposes, to identify and analyze elements necessary to achieve interoperability of law enforcement purposes, to engage in encryption research and security testing of a computer, computer system or computer network, and, as necessary, both to limit minors' Internet access and to protect personally identifying information. 17 U.S.C. § 1201(d)-(j). In addition, the DMCA instructs the Librarian of

Congress, upon recommendation of the Register of Copyrights (in consultation with the Assistant Secretary for Communications and Information of the Department of Commerce), to engage in a triennial rulemaking process to identify additional exceptions. *Id.* § 1201(a)(1)(C)-(D).[1] Such a process allows the rules around digital access to copyrighted materials to reflect evolving "marketplace realities," preventing "diminution in the availability" of certain materials as necessary during limited periods of time. H.R. Rep. No. 105-551, pt. II, at 36 (1998).

Pursuant to that rulemaking process, the Librarian of Congress is instructed to determine whether users' ability to make noninfringing uses of copyrighted materials "are or are likely to be in the succeeding 3-year period, adversely affected by" the anticircumvention provision based on four described factors, plus leeway for other "appropriate" factors:

> (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.

17 U.S.C. § 1201(a)(1)(C). Upon making that determination, the Librarian may waive the anticircumvention provision for that class of works. *Id.* § 1201(a)(1)(D).

"Although the DMCA entrusts the Librarian with the ultimate decision, as a practical matter, the Register performs most of the rulemaking functions," *MITA II*, 103 F.4th at 834; H.R. Rep. 105-796, at 64, including soliciting proposed rules, providing notice of such rules, and

[1] The U.S. Office of Copyright, headed by the Register of Copyrights, is housed within the Library of Congress. *MITA II*, 103 F.4th at 833; 17 U.S.C. § 701(a) ("All administrative functions and duties under this title, except as otherwise specified, are the responsibility of the Register of Copyrights as director of the Copyright Office of the Library of Congress. The Register of Copyrights, together with the subordinate officers and employees of the Copyright Office, shall be appointed by the Librarian of Congress, and shall act under the Librarian's general direction and supervision.").

opening the rules to public comment, and in doing so, develops a comprehensive administrative record. *See, e.g.*, 86 Fed. Reg. at 59,628. Proponents seeking an exemption must demonstrate "(1) that uses affected by the prohibition on circumvention are or are likely to be noninfringing; and (2) that as a result of [a TPM], the prohibition is causing, or in the next three years is likely to cause, an adverse impact on those uses." *Id.* The Register is to recommend granting an exemption only when such a showing has been made by a preponderance of the evidence. *Id.*

This rulemaking process was intended as a "'fail-safe' to ensure that the anticircumvention provision leaves breathing room for noninfringing uses, including fair use, of copyrighted content." *Green*, 111 F.4th at 90 (quoting H.R. Rep. No. 105-551, at 36). During "the drafting of the DMCA," many voiced concerns that "if not carefully crafted," the DMCA "might 'create a "pay-per use" society' without adequate protection for noninfringing expression." *Id.* (quoting H.R. Rep. No. 105-551, at 26). Accordingly, "the statutory standard for triennial rulemaking borrows liberally from the doctrine of fair use." *Id.* at 101. The final rules "resemble a series of *ex ante* determinations as to which activities are likely to qualify as fair uses that would be adversely affected by the anticircumvention provision if not exempted." *Id.* While copyright infringement is closely related to circumvention of TPMs and the rulemaking process is intended to free from DMCA liability uses that would not be violations of copyrights, copyright infringement and circumvention of TPMs nonetheless remain distinct illegal acts with independent legal inquiries. *See Green*, 111 F.4th at 91; 17 U.S.C. § 1201(c) (DMCA provision clarifying that "[n]othing in this section shall affect rights, remedies, limitations, or defenses to copyright infringement, including fair use, under this title."); *see also id.* § 1201(a)(1)(E) (DMCA provision providing that "Neither the exception under subparagraph (B) from the applicability of the prohibition contained in subparagraph (A) [*i.e.*, the

anticircumvention provision,] 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."); *see also* David Nimmer, *A Riff on Fair Use in the Digital Millenium Copyright Act*, 148 U. PA. L. REV. 673, 698-99 & nn. 130-31 (2000) (noting that § 1201(a)(1)(E) and § 1201(c)(1) are redundant in this respect and summarizing that "a defendant whose usage wins exemption in pertinent rulemaking does not thereby gain any mileage in urging a fair use defense to copyright infringement").

B. Factual Background

The Medical Device Exemption at issue here was adopted as part of the Eighth Triennial Rulemaking in 2021 and subsequently renewed in 2024.

1. *Eighth Triennial Rulemaking*

In 2020, the Register of Copyrights published a notice of inquiry in the Federal Register, soliciting proposals for new exemptions. Notice of Inquiry and Request for Petitions, Exemptions to Permit Circumvention of Access Controls on Copyrighted Works, 85 Fed. Reg. 37,399 (June 22, 2020), AR at 45-49. After organizing those proposals into particular classes, the Register provided notice of the proposed rules and requested comment. Notice of Proposed Rulemaking, Exemptions to Permit Circumvention of Access Controls on Copyrighted Works, 85 Fed. Reg. 65,293, 65,302 (Oct. 15, 2020), AR at 50-67, ECF No. 24-1.

Two petitions were submitted by independent service-organizations ("ISOs") with memberships comprised of non-manufacturer, third-party service operators hired to repair equipment, seeking to expand existing exceptions "relating to diagnosis, repair, and modification of software-enabled devices." *See id.* at 65,306-07, AR at 63-64. The existing exemptions protected ISOs from DMCA liability when accessing computer programs operating "lawfully acquired motorized land vehicle[s]" when "circumvention is a necessary step to allow the

diagnosis, repair, or lawful modification of a vehicle function," and when accessing computer programs operating "lawfully acquired smartphone[s] or home appliance[s] or home system[s]," again when such "circumvention is a necessary step to allow the diagnosis, maintenance, or repair of such a device or system." *Id.*

The petitions sought an "exemption allowing circumvention of TPMs for purposes of diagnosis, modification, and repair of medical devices." *Id.* at 65,307, AR at 64. Many complex medical devices, such as MRI machines, are operated by computer software designed by original equipment manufacturers ("OEMs"). *See* Pls.' MSJ, Ex. D, Philips Long Comment Regarding Proposed Exemption ("Philips 2021 Cmt.") at 2-3, ECF No. 33-6, AR at 4132-33. The devices' software, in addition to performing their imaging or other basic functions, enables them to store and relay confidential patient information electronically. *See* Pls.' MSJ, Ex. B, Med. Imaging & Tech. All. Long Comment Regarding Proposed Exemption ("MITA 2021 Cmt.") at 5, 10, ECF No. 33-4, AR at 4099, 4104. Given the importance of these devices and their safety to patients and the healthcare community, the devices and their manufacturers are regulated by the FDA. *See, e.g.*, 21 C.F.R. pts. 801, 814 (requiring approvals before distribution); *id.* pt. 803 (requiring reports of serious malfunctions); *id.* pt. 820 (regarding quality system regulation). The devices' operating software is copyrighted, *see* 17 U.S.C. §§ 101, 102(a), and OEMs employ TPMs to guard against unauthorized access to both the original code and the confidential patient information generated by the device. *See* MITA 2021 Cmt. at 2, AR at 4096.

Hospitals and other owners of the devices may diagnose, repair, and maintain the devices themselves or hire outside services from the OEM or an ISO to do so. Although sometimes OEMs provide support to ISOs or allow limited licensing of their copyrighted documents and software, other times ISOs act without authorization from OEMs and must circumvent TPMs to

access the software and related data files in order to conduct maintenance or repairs. Pls.' MSJ, Ex. C, AdvaMed Long Comment Regarding Proposed Exemption ("AdvaMed 2021 Cmt.") at 8, ECF No. 33-5, AR 4017; *id.*, Ex. A, Section 1201 Rulemaking: Eighth Triennial Proceeding to Determine Exemptions to the Prohibition on Circumvention: Recommendation of the Register of Copyrights (Oct. 2021) ("2021 Reg. Rec.") at 225, ECF No. 33-3, AR at 1925. In the ISOs' view, the ability of healthcare providers easily and affordably to access repair services when needed is essential to their public health missions. *See* 2021 Reg. Rec. at 224, AR at 1924 ("[P]roponents point to instances where medical facilities have been unable to use equipment due to inadequate repair options, particularly during the COVID-19 pandemic." (citing submissions in the record)). In the OEMs' view, ISOs take advantage of the massive investment in research and development made by OEMs in developing the software and circumvent TPMs simply to benefit the ISOs' own commercial interests. *See, e.g.*, MITA 2021 Cmt. at 3, AR at 4097; Philips 2021 Cmt. at 6, AR at 4136.

The Register solicited three rounds of comment: one from proponents of the petitions or neutral parties, another from opponents, and a final reply round from the proponents or neutral parties. *See* 85 Fed. Reg. at 65,302, AR at 59. Medical Imaging & Technology Alliance ("MITA") and Advanced Medical Technology Association ("AdvaMed"), collectively "plaintiffs," participated in the second round, filing comments in opposition to the petitions. *See* MITA 2021 Cmt., AR at 4095-130; AdvaMed 2021 Cmt., AR at 4010-24. Both plaintiffs are non-profit member-based trade associations representing manufacturers of medical devices that advocate for policies and regulations to support their industry and promote patient care. Am. Compl. ¶¶ 21-22, ECF No. 32. As relevant here, their members manufacture software-enabled medical devices and rely on TPMs to protect their intellectual property. *Id.* ¶¶ 23-24.

Plaintiffs expressed their view during the rulemaking that the uses in the proposed medical device exemption for ISOs to conduct maintenance and repairs are not "fair uses." As support for this position, they first contended that the maintenance and repair uses were purely commercial and simply competed with OEMs also offering such services, not transforming the computer code in any way. *See* MITA 2021 Cmt. at 7-9, AR at 4101-03; AdvaMed 2021 Cmt. at 7-8, AR at 4016-17; *see also* Philips 2021 Cmt. at 7-8, AR at 4137-38. Second, they expressed concern about ISOs free riding on the investment of OEMs in developing the innovative equipment, which would discourage further creations. *See* MITA 2021 Cmt. at 9, AR at 4103; AdvaMed 2021 Cmt. at 8-9, AR at 4017-18. Third, plaintiffs pointed out that the proposed exemption could decrease the value of the devices and their copyrighted software on the market, especially given the cybersecurity risks at stake with circumvention of TPMs. *See* MITA 2021 Cmt. at 10-11, AR at 4104-05; AdvaMed 2021 Cmt. at 3, 8-9, 11-15, AR at 4012, 4017-18. 4020-24; *see also* Philips 2021 Cmt. at 9-10, 17, AR at 4139-40, 4147. Lastly, plaintiffs argued that the exemption would jeopardize patient safety and privacy given that ISOs are not carefully regulated and the devices, if not employed using the appropriate standards, could cause harm to patients through mechanical failure or burns. *See* MITA 2021 Cmt. at 3-5, AR at 4097-99; AdvaMed 2021 Cmt. at 3, 11-15, AR at 4012, 4020-24; Philips 2021 Cmt. at 17-19, AR at 4147-49.

The Register subsequently held a hearing regarding the proposed exemption, including participants expressing opposition. *See* Notice of Public Hearings, Exemptions to Permit Circumvention of Access Controls on Copyrighted Works, 86 Fed. Reg. 8560, 8561 (Feb. 8, 2021), AR at 68-69, 5627-5763; Section 1201 Rulemaking Hearing Tr. at 730 (Apr. 20, 2021),

AR 5628, ECF No. 24-6 (listing participants, including other representatives of opponents, though not plaintiffs).

2. *Final Rule Adopted*

Upon considering all of the viewpoints expressed, the Register recommended adopting the Medical Device Exemption in October 2021, concluding that "the prohibition on circumvention of TPMs is causing, or is likely to cause, an adverse impact on the noninfringing diagnosis, repair, and maintenance of medical devices and systems." 2021 Reg. Rec. at 229, AR 1929.

The Register determined that the Medical Device Exemption targeted noninfringing uses by examining the four statutory factors for "fair use," 17 U.S.C. § 107. *See* 2021 Reg. Rec. at 208-12, AR 1908-12. All four, in the Register's view, favored fair use. First, regarding "the purpose and character of the use," the Register determined that ISOs' services should be considered more transformative than commercial, given that they were not *commercializing* the embedded copyright software but rather restoring the device's functionality, and that diagnosis, maintenance and repair was considered "likely to be transformative," citing prior conclusions to that effect in other contexts. *See* 2021 Reg. Rec. at 209, AR at 1909. Second, regarding the nature of the copyrighted work, the Register observed that the copyrighted software was used for its "functional and informational" character, *i.e.*, operating medical equipment, not its expressive qualities. *See id.* at 2010, AR at 1910. Third, the amount and substantiality of the copyrighted work used was as much as "necessary to accomplish" the purpose of diagnosis, maintenance, or repair, which was "reasonable." *Id.* at 211, AR at 1911. Fourth, the Register considered the "effect of the use on the market for or value of the copyrighted work" and determined the effect of the use of the copyrighted software by ISOs for diagnosis, repair, and maintenance on the market for the software would be minimal because the device and system software was sold with

the equipment and has "no independent value separate from the devices." *Id.* The Register nonetheless acknowledged that reproduction of "copyrighted materials for use with other devices, or enabl[ing] permanent access to subscription-only services" could injure the market for the devices, but such uses were not covered by the exemption and thus "would remain prohibited." *Id.* at 212, AR at 1912.

The Register then turned to the statutory criteria for an exemption set out in 17 U.S.C. § 1201(a)(1)(C), leading to the conclusion that such noninfringing uses would be adversely affected by the DMCA anti-circumvention provision. *See* 2021 Reg. Rec. at 229, AR at 1929. As to the first factor, the availability for use of copyrighted works, the Register considered the proponents' concern about the inadequate availability of timely, cost-effective repair services during the COVID pandemic given the anticircumvention provision's restriction of the use of the device software and manuals, countered by the plaintiffs' assertions that OEMs offered robust service and repair options and that owners and lessees of devices can become authorized to conduct repairs, too, through particular programs. *See id.* at 224-226, AR at 1924-26. She concluded that the "factor favors an exemption because the prohibition on circumvention" does make "medical equipment software and manuals less available for use in noninfringing diagnosis, maintenance, and repair." *Id.* at 226, AR at 1926.

The Register determined that the second and third factors—the "availability for use of works for nonprofit archival, preservation, and educational purposes" and "the impact that the prohibition on the circumvention of technological measures . . . has on criticism, comment, news reporting, teaching, scholarship, or research," 17 U.S.C. § 1201(a)(1)(C)(ii)-(iii)—were not "especially relevant to the determination," though MITA argued that the commercial nature of the proponents' interest undercut the nonprofit purposes in these factors, 2021 Reg. Rec. at 226,

AR at 1926. The Register noted, however, the unaddressed gap in MITA's argument that "repair of medical devices and systems that are no longer supported by OEMs arguably preserves the availability for use of the equipment's software and servicing materials." *Id.*

Regarding the "effect of circumvention . . . on the market for or value of copyrighted works," 17 U.S.C. § 1201(a)(1)(C)(iv), the Register determined that this fourth factor did not "disfavor an exemption." 2021 Reg. Rec. at 227, AR at 1927. She reasoned that the "narrow proposed uses" by ISOs "and additional limitations on the scope of these activities limit any potential market harm" because repairs "support rather than displace the embedded computer programs" and the software and manuals have "no independent value separate from the equipment they operate or explain." *Id.*

Finally, the Register considered the public interest as a consideration under the fifth statutory factor, which gives the Librarian discretion to consider additional factors as deemed appropriate. *See* 2021 Reg. Rec. at 227-28, AR at 1927-28. She credited proponents' point that, without an exemption, OEMs could control the repair market and charge high prices and that an exemption "could help to address the[se] broader competitive concerns[,] recently highlighted by the Executive Branch." *Id.* (citing Exec. Order No. 14,036, Promoting Competition in the American Economy, 86 Fed. Reg. 36987, 36992 (July 14, 2021)). She also addressed plaintiffs' concerns about patient safety, given that ISOs do not adhere to "FDA Quality System Regulation (QSR) requirements." *Id.* at 228, AR at 1928. The FDA had submitted its own comment in the proceeding concluding that concerns about safety related to medical device servicing did not justify additional regulatory requirements on ISOs, and the Register emphasized that the Exemption requires no changes be made to the firmware. *See id.* at 229, AR at 1929. The

Register, therefore, recommended that the Librarian grant the requested Medical Device Exemption. *See id.* at 229, 232, AR at 1929, 1932.

The Librarian adopted the Medical Device Exemption in October 2021 based on the Register's reasoning. *See* 86 Fed. Reg. at 59,627, AR at 7-84. The final rule exempts from the anticircumvention provision "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 of system." 37 C.F.R. § 201.40(b)(17). The Exemption defines "maintenance" as 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," *id.* § 201.40(b)(17)(i), and "repair" as "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," *id.* § 201.40(b)(17)(ii). The Medical Device Exemption does not protect ISOs from liability for conduct violative of other provisions of the DMCA. *See id.* § 201.40(b).

3. *Ninth Triennial Rulemaking*

While this suit has been pending, the Librarian renewed the Medical Device Exemption in the next triennial rulemaking proceeding in 2024. The Register received petitions to renew the Exemption, *see, e.g.*, Petition to Renew a Current Exemption Under 17 U.S.C. § 1201, AR at 2623-31, ECF No. 46-5, and plaintiffs and others submitted comments in opposition, *see* Pls.' MSJ, Ex. F, MITA Comments in Response to Section 1201 Renewal Petition Regarding Medical Devices ("MITA 2024 Cmt."), ECF No. 33-8, AR at 2821-26; *id.*, Ex. G, AdvaMed Long Comment Regarding a Proposed Exemption Under 17 U.S.C. § 1201 ("AdvaMed 2024 Cmt."), ECF No. 33-9, AR at 2830-38; *id.*, Ex. H, Comments by Philips North America, LLC In

Response to Petitions to Renew DMCA Exemption Relating to Medical Devices ("Philips 2024 Cmt."), ECF No. 33-10, AR at 2782-820.

Plaintiffs and other opponents argued once again that the Exemption undermined FDA repair standards in a way that threatened patient safety and contradicted FDA policies on medical device cybersecurity. *See* MITA 2024 Cmt. at 6, AR at 2826, AR; AdvaMed 2024 Cmt. at 5-6, AR at 2834-35; Philips 2024 Cmt. at 8-9, AR at 2789-90. The Register pointed to her earlier analysis in the 2021 recommendation and further noted that the Exemption from DMCA liability does not absolve any user from compliance with other laws and regulations. *See* Pls.' MSJ, Ex. E, Register Recommendation for Section 1201 Rulemaking Oct. 2024 ("2024 Reg. Rec.") at 37, ECF No. 33-7, AR at 2093. This time, the opponents also argued that the Supreme Court's decision in *Andy Warhol Foundation for the Visual Arts, Inc. v. Goldsmith*, 598 U.S. 508 (2023), undermined the Register's prior fair use analysis. *See* MITA 2024 Cmt. at 2-6, AR at 2822-26; AdvaMed 2024 Cmt. at 6-8, AR at 2835-37; Philips 2024 Cmt. at 5-7, AR at 2787-89. The Register was not persuaded that *Warhol* changed the fair use analysis in this context and instead found this case reinforced that the first factor focuses on whether the use adds something new with a new purpose or character beyond the copyrighted work. *See* 2024 Reg. Rec. at 38, AR at 2094. The Register, determining that the analysis in the 2021 Recommendation was sound, likewise recommended renewal of the Medical Device Exemption, and the Librarian adopted that recommendation. *See* 89 Fed. Reg. at 85,437.[2]

[2] Given that the Librarian adopted the Register's reasoning in both rulemakings, *see* 86 Fed. Reg. at 59,627; 89 Fed. Reg. 85,445, the reasoning and conclusions in the Register's Recommendation are considered those of the Librarian of Congress. *See* Pls.' Mem. in Supp. of Pls.' MSJ ("Pls.' Mem.") at 16 n.1, ECF No. 33-1 ("Because the Librarian effectively adopted the Register's reasoning as her own in granting . . . and renewing the Exemption, we attribute the Register's analysis to the Librarian."); *see generally* Defs.' Mem. in Supp. of Defs.' MSJ & Defs.' Opp'n to Pls.' MSJ ("Defs.' Opp'n"), ECF No. 35-1.

C. Procedural Background

Plaintiffs filed a complaint in 2022 alleging that the Librarian's adoption of the Exemption in 2021 violated the APA, as arbitrary and capricious and not in accordance with the law, as well as contrary to the APA's procedural requirements because the Librarian failed to respond to critical comments. *See* Compl. ¶¶ 78-91, ECF No. 1. Given D.C. Circuit precedent at the time holding, however, that "the Library of Congress is not an 'agency' under the APA," *MITA II*, 103 F.4th at 842 (Childs, J., dissenting) (citing *Clark v. Libr. of Cong.*, 750 F.2d 89, 102-03 (D.C. Cir. 1984); *Ethnic Emps. of Libr. of Cong. v. Boorstin*, 751 F.2d 1405, 1416 n.15 (D.C. Cir. 1985); *Wash. Legal Found. v. U.S. Sent'g Comm'n*, 17 F.3d 1446, 1449 (D.C. Cir. 1994)), plaintiffs alternatively claimed that, if review under the APA were not available, the challenged exemption should be deemed *ultra vires* as outside the scope of her statutory authority and in violation of the separation of powers. *Id.* ¶¶ 92-101. Plaintiffs then sought summary judgment, Pls.' Mot. Summ. J., ECF No. 10, and the Library of Congress, as well as the Librarian herself ("defendants"), cross moved to dismiss, under Federal Rule of Civil Procedure 12(b)(6), Defs.' Mot. Dismiss, ECF No. 17. This Court resolved those motions by holding that plaintiffs' APA claims were barred by sovereign immunity because, based on binding precedent in this Circuit, the Library of Congress was not an "agency" under that statute, *see Medical Imaging & Technology Alliance v. Library of Cong.* ("*MITA I*"), No. 22-cv-499 (BAH), 2023 WL 2387760, *9-10 (D.D.C. 2023) (citing 5 U.S.C. §§ 701(b)(1), 551(1) (defining "agency" and excluding Congress); *Clark*, 750 F.3d. at 102-03; *Ethnic Emps.*, 751 F.2d at 1416 n.15; *Wash. Legal Found.*, 17 F.3d at 1449), and that plaintiffs failed to plead plausible *ultra vires* and constitutional claims in the alternative, *id*. at *11-15. On appeal, a split panel of the D.C. Circuit vacated that opinion, concluding that the DMCA and the Copyright Act provided for APA review of the triennial DMCA rules, despite the Library not being an "agency" for

which the APA itself provided review. *See MITA II*, 103 F.4th at 841-42; *see also id.* at 842-43 (Childs, J., dissenting) (reasoning that the Copyright Act could not waive sovereign immunity over the Librarian, even if it did intend to provide judicial review). On remand, this Court was instructed to consider the merits of the APA claims in the first instance. *See id.*

The D.C. Circuit issued its mandate just months before the Ninth Triennial Rulemaking, so the parties agreed that defendants could proceed with that rulemaking and plaintiffs could thereafter amend their complaint. *See* Joint Status Report at 3, ECF No. 31. Plaintiffs filed an amended complaint in November 2024, asserting three claims only under the APA (*i.e.*, that the Medical Device Exemption was contrary to statute, arbitrary and capricious, and procedurally flawed in failing to respond to critical comments). *See* Am. Compl. ¶¶ 86-107, ECF 32. Both parties subsequently cross-moved for summary judgment, which, after full briefing, are now ripe for consideration. *See* Pls.' Mem. in Supp. of Pls.' MSJ ("Pls.' Mem."), ECF No. 33-1; Defs.' Mem. in Supp. of Defs.' MSJ & Defs.' Opp'n to Pls.' MSJ ("Defs.' Opp'n"), ECF No. 35-1; Pls.' Opp'n to Defs.' MSJ and Pls.' Reply in Supp. of Pls.' MSJ ("Pls.' Opp'n"), ECF No. 41; Defs.' Reply in Supp. of Defs.' MSJ ("Defs.' Reply"), ECF No. 43. Plaintiffs challenge both the adoption of the Medical Device Exemption in the Eighth Rulemaking, as well as the renewal in the Ninth Rulemaking, which relied largely on the same reasoning as the original adoption. *See* Pls.' MSJ at 2.

II. LEGAL STANDARD

The APA provides for judicial review of "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704. The Act "instructs a reviewing court to set aside agency action found to be 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *Cigar Ass'n of Am. v. FDA*, 964 F.3d 56, 61 (D.C. Cir. 2020) (quoting 5

U.S.C. § 706(2)(A)). This standard "'requires agencies to engage in reasoned decisionmaking' and . . . to reasonably explain to reviewing courts the bases for the actions they take and the conclusions they reach." *Bhd. of Locomotive Eng'rs & Trainmen v. Fed. R.R. Admin.*, 972 F.3d 83, 115 (D.C. Cir. 2020) (quoting *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.* ("*Regents*"), 591 U.S. 1, 16 (2020)). The scope of arbitrary and capricious review is "narrow," such that "a court is not to substitute its judgment for that of the agency." *Judulang v. Holder*, 565 U.S. 42, 52-53 (2011) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). Rather, the court determines "whether the [agency's] decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Marsh v. Ore. Nat. Res. Council*, 490 U.S. 360, 378 (1989); *Indian River Cnty. v. U.S. Dep't of Transp.*, 945 F.3d 515, 527 (D.C. Cir. 2019) ("Agency action is arbitrary and capricious 'if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, [or] offered an explanation for its decision that runs counter to the evidence before the agency.'" (quoting *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43)). Judicial review is "limited to 'the grounds that the agency invoked when it took the action," *Regents*, 591 U.S. at 20 (quoting *Michigan v. EPA*, 576 U.S. 743, 758 (2015)), and the agency likewise "must defend its actions based on the reasons it gave when it acted," *id.* at 24.

A "party is entitled to summary judgment only if there is no genuine issue of material fact and judgment in the movant's favor is proper as a matter of law." *Soundboard Ass'n v. FTC*, 888 F.3d 1261, 1267 (D.C. Cir. 2018); FED. R. CIV. P. 56(a). In APA cases involving cross-motions for summary judgment, such as this one, "the district judge sits as an appellate tribunal," *Rempfer v. Sharfstein*, 583 F.3d 860, 865 (D.C. Cir. 2009) (quoting *Am. Bioscience, Inc. v.*

Thompson, 269 F.3d 1077, 1083 (D.C. Cir. 2001)), because the "entire case on review is a question of law," *id.* (quoting *Marshall Cnty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993)). The complaint "presents no factual allegations, but rather only arguments about the legal conclusion to be drawn about the agency action." *Id.* (quoting *Marshall Cnty.*, 988 F.2d at 1226); *see also Lacson v. Dep't of Homeland Sec.*, 726 F.3d 170, 171 (D.C. Cir. 2013) (noting that in an APA case, "determining the facts is generally the agency's responsibility, not" the court's). The review is limited to the administrative record as a result. *See CTS Corp. v. EPA*, 759 F.3d 52, 64 (D.C. Cir. 2014) ("[A] reviewing court 'should have before it neither more nor less information than did the agency when it made its decision.'" (quoting *Hill Dermaceuticals, Inc. v. FDA*, 709 F.3d 44, 47 (D.C. Cir. 2013)).

III. DISCUSSION

Plaintiffs challenge the Medical Device Exemption's adoption as contrary to law, arbitrary and capricious, and procedurally flawed, but all these APA claims fail. The Exemption addresses a class of users that are "adversely affected by the" anticircumvention provision "in their ability to make noninfringing uses under [Title 17] of a particular class of copyrighted works," as prescribed by the statute. 17 U.S.C. § 1201(a)(1)(C). The Librarian applied the law to the evidence in the record in a fair and principled way in adopting the Exemption and fully addressed all key points raised by opponents in the rulemaking process. While plaintiffs may perceive competitive harms resulting from the Exemption, they identify no violation of the APA to justify granting their desired relief. For those reasons, as further explained below, defendants' motion for summary judgment is granted and plaintiffs' motion is denied.

A. The Medical Device Exemption is Consistent with the Law and Justified by Reasoned Analysis.

Plaintiffs argue that the Medical Device Exemption is contrary to law by permitting uses of copyrighted materials that are not "fair uses," under 17 U.S.C. § 107, when the DMCA allows exemptions only for "noninfringing" uses. *See* Pls.' Mem. at 15-28. They assert that the Librarian erred in conducting the four-factor fair use inquiry by misapplying applicable precedent and legal principles, and that her analysis was arbitrary and capricious and unsupported by the evidence. *See id.* at 15, 28-30. Defendants respond that the Librarian's determination that "accessing copyrighted works in order to repair medical devices is likely noninfringing is consistent with the Copyright Act and based on reasoned decisionmaking." Defs.' Opp'n at 15. Defendants are correct: The Librarian's conclusion that the exempted uses are likely noninfringing, under 17 U.S.C. § 1201(a)(1)(C), is consistent with both the fair use doctrine, codified at § 107, as well as the DMCA, and her analysis in reaching that conclusion is well-reasoned and grounded in record evidence.

At the outset, before turning to review of the fair use component of the Librarian's decision, two clarifications are helpful regarding what is not at issue in the challenged action. First, as described *supra* Part I.A, any TPM exemption under § 1201(a)(1)(C) requires a determination by the Librarian that the exempted uses are or are likely to be noninfringing. *See* 86 Fed. Reg. at 59,628; 17 U.S.C. § 1201(a)(1)(C) (allowing exemptions for users of copyrighted works "who are . . . , or are likely to be . . . adversely affected" by the anticircumvention provision "in their ability to make noninfringing uses under this title of a particular class of copyrighted works"). The Librarian here deemed that use of embedded computer programs and related data files for diagnosis, maintenance, and repair of medical devices was noninfringing because they were fair uses under 17 U.S.C. § 107. *See supra* Parts I.A-I.B. The DMCA also

required the Librarian to conclude that the users would be adversely affected by the anticircumvention provision to warrant an exception, *see* 17 U.S.C. § 1201(a)(1)(C), and she did so, *see* 2021 Reg. Rec. at 229, AR at 1929; *supra* I.B. Plaintiffs do not challenge the latter part of the Librarian's analysis, which is consequently not at issue, with plaintiffs' critiques focused solely on her application of the four fair use factors. *See* Defs.' Opp'n at 15 n.5 ("Because Plaintiffs argue only that the uses contemplated by the Repair Exemption are not likely to be noninfringing because they are not a fair use of the copyrighted software, the Librarian's adverse effects analysis is not addressed here.").

Second, an APA review of the Librarian's fair use analysis is not *de novo* in the same manner as if a copyright claim and fair use defense were being presented in the first instance. "[F]air use is a mixed question of law and fact," involving the "determination of subsidiary factual questions" as part of the four factors, such as "how much of the copyrighted work was copied." *Google LLC v. Oracle Am., Inc.*, 593 U.S. 1, 24 (2021) (first passage quoting *Harper & Row Publishers, Inc. v. Nation Enters.*, 471 U.S. 539, 560 (1985), and third passage quoting *Oracle Am., Inc. v. Google LLC*, 886 F.3d 1179, 1196 (Fed. Cir. 2018)). In the APA review context, a level of deference is given to the Librarian's factual findings to the extent those findings are supported by substantial evidence, which "requires more than a scintilla, but . . . something less than a preponderance of the evidence. If that threshold is met, we must uphold the agency's judgment regarding the relevant facts,'" *Bloomberg L.P. v. SEC*, 45 F.4th 462, 475 (D.C. Cir. 2022) (quoting *Epsilon Elecs., Inc. v. Dep't of Treasury*, 857 F.3d 913, 925 (D.C. Cir. 2017) (internal quotations and citations omitted)), "even if we think the evidence tends to weigh against the agency's finding," *Epsilon Elecs., Inc.,* 857 F.3d at 925 (internal quotation and citation omitted). Due to this deference, the substantial evidence inquiry asks not "whether

record evidence could support the petitioner's view of the issue, but whether it supports the [Librarian's] ultimate decision." *Fla. Gas Transmission Co. v. FERC*, 604 F.3d 636, 645 (D.C. Cir. 2010). Plaintiffs nowhere dispute that this deferential standard applies to the Librarian's factual findings nor that this Court reviews the Librarian's analysis under the arbitrary and capricious standard.[3] Thus, these review standards are not at issue. Accordingly, in applying the arbitrary and capricious standard, the Court examines whether the Librarian "relie[d] on inappropriate factors, fail[ed] to consider important aspects of the problem, or ignore[d] relevant evidence." *Int'l Dark-Sky Ass'n, Inc. v. Fed. Commc'ns Comm'n*, 106 F.4th 1206, 1213 (D.C. Cir. 2024). "Within an agency's lawful authority, courts will uphold agency action that is 'reasonable and reasonably explained.'" *Id.* (quoting *Fed. Commc'ns Comm'n v. Prometheus Radio Project*, 592 U.S. 414, 417 (2021)).

Close examination of the Librarian's challenged action shows that she was well cognizant of the role of the fair use doctrine to mediate the trade-offs in copyright law of providing "the benefits of incentives to create against the costs of restrictions on copying," based on "judicial balancing" according to the "relevant circumstances." *Warhol*, 598 U.S. at (2023) (last two passages quoting *Google LLC v. Oracle Am.*, 593 U.S. 1, 19 (2021)). The four factors in § 107 guide this "equitable rule of reason," though these factors are "not exhaustive" and "indicate[], rather than dictate[] how" the doctrine should be applied. *Google*, 593 U.S. at 18-19. The Librarian's fair use analysis addressed each of the four factors, as discussed *seriatim*.

1. First Factor Under § 107: Purpose and Character of the Use

[3] Plaintiffs omit a "legal standard" section in their brief, but they do not contest defendants' framing of the question for the Court as "whether the Librarian (1) arbitrarily and capriciously made the relevant findings (2) and, in turn, whether her conclusion that the Repair Exemption was fair use was itself arbitrary and capricious." Defs.' Opp'n at 17.

The Librarian determined that the first statutory 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(1)—favored a finding of fair use. She considered the commercial nature of ISOs' diagnostic, maintenance, and repair activities but concluded they were outweighed by the transformative nature of those uses, which pursued a novel function going beyond the original purpose of the copyrighted materials. *See* 2021 Reg. Rec. at 209, AR at 1909. Plaintiffs argue that this conclusion was "dead wrong" because the ISOs' uses are "entirely commercial" and "not transformative," considering that ISOs are not permitted to make changes to the copyrighted work. Pls.' Mem. at 17-19. Defendants respond that because the use of copyrighted works for diagnosis, maintenance, or repair serves "a different function" than the original code does—by expanding its usefulness rather than replacing it—the Medical Device Exemption's uses are indeed transformative. Defs.' Opp'n at 19. Defendants are correct: The Librarian's conclusion that the first factor weighed in favor of fair use was both consistent with the law and fairly reasoned.

The first fair use factor inquires "whether the new work merely 'supersede[s] the objects' of the original creation . . . ('supplanting' the original), or instead adds something new, with a further purpose or different character." *Warhol*, 598 U.S. at 528 (quoting *Campbell v. Acuff-Rose Music, Inc.*, 510 U.S. 569, 579 (1994)). Given how slippery that standard has often seemed, the Supreme Court has distilled this factor into a balancing test considering the degree to which "the use of a copyrighted work has a further purpose or different character"—thereby making it "transformative"—and the commercial nature of the use. *See Warhol*, 598 U.S. at 529, 532; *id.* at 549-50 ("Fair use instead strikes a balance between original works and secondary uses based in part on objective indicia of the use's purpose and character, including whether the use is

commercial and, importantly, the reasons for copying."). As the balancing test suggests, commerciality, while relevant, "is not dispositive of the first factor." *Google*, 593 U.S. at 32. Noncommercial use "tips the scales in favor of fair use," but the "inverse is not necessarily true, as many common fair uses are indisputably commercial," such as news reporting. *Id.* Further, transformation is considered a matter of degree, but to qualify as a "transformative use" at all, the use of the original must "go beyond that required to qualify as a derivative" because the owner of a copyright still has a "right to derivative transformation of her work." *Warhol*, 598 U.S. at 529.

Regarding the transformative nature of the uses permitted by the Medical Device Exemption, the Librarian reasonably concluded that restoration of medical devices supports rather than supplants the underlying copyrighted material and thus that diagnosis, maintenance, and repair are transformative in nature. *See* 2021 Reg. Rec. at 209, AR at 1909 ("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 original embedded copyrighted computer programs and their related files make the medical devices run, instructing them on how to operate. When an ISO references the computer programs to conduct diagnosis, maintenance, or repair, the user does so to protect or fix those same devices; the ISO does not reproduce the code with a purpose to run other devices. Repair and maintenance of a device thus has a "different character," *Warhol*, 598 U.S. at 528 (quoting *Campbell*, 510 U.S. at 579), and "employ the [code] in a different manner," Pierre N. Leval, Commentary, *Toward a Fair Use Standard*, 103 HARV. L. REV. 1105, 1111 (1990), from how the code is originally used by the machine to operate the device. Far from superseding the latter, the former uses are essential to and completely supportive of the original copyrighted software's ability to operate

the medical devices. *See id.* As the Librarian observed, *see* 2021 Reg. Rec. at 209, AR at 1909, diagnosis, repair, and maintenance in no way "obviate[s] any need" for the original copyrighted software to operate the medical devices, *Midlevel-U, Inc. v. ACI Info. Grp.*, 989 F.3d 1205, 1222 (11th Cir. 2021) (explaining that an index of full-length blog articles was not transformative because the index "obviate[d] any need for an Index subscriber to visit [the] website [containing the original posts] directly").

To be sure, the Librarian credited plaintiffs' argument that the uses contemplated by the Medical Device Exemption are, in most cases, commercial, since ISOs generally conduct maintenance and repairs in order to make money. 2021 Reg. Rec. at 208-09, AR at 1908-09. Yet commercial use is not dispositive. "[S]uch uses must be addressed through a 'sensitive balancing of interests.'" *Id.* (quoting *Campbell*, 510 U.S. at 584-85). The Librarian reasonably determined that the transformative purpose of the uses contemplated by the Exemption—*i.e.*, to restore functionality of the device—outweighed the commercialized nature of the use, particularly because the commercialized nature of diagnosis, maintenance, and repairs does not actually threaten the commercial value of the underlying copyrighted software itself. *See id.* ("[T]he proposed activities are intended to restore a medical device or system's functionality, not to commercialize the embedded copyright software and other servicing materials.").[4] She therefore fairly concluded that the first factor leans in favor of fair use.

[4] Defendants make the astute point that although ISOs and OEMs both make money by repairing medical devices, engaging in diagnosis, maintenance, and repairs are not inherently commercial activities: The Medical Device Exemption applies just as much to ISOs seeking to earn a profit as "persons and non-profit medical facilities that own their own devices and repair them for their own personal or institutional use." Defs.' Opp'n at 20. Plaintiffs' only response is that the possibility of non-commercial uses under the Exemption is not a reason "the Librarian offered in the rulemaking, and it is therefore not a basis upon which the Court may uphold the Exemption." Pls.' Opp'n at 5 ("It is well established that an agency's action must be upheld, if at all, on the basis articulated by the agency itself." (quoting *EchoStar Satellite LLC v. FCC*, 457 F.3d 31, 36 (D.C. Cir. 2006))). This response mischaracterizes the record. As defendants point out, the Librarian did cite "declarations from non-ISO medical facility personnel discussing in-house repair services," indicating she considered this fact, which provides further support for her conclusion. Defs.' Reply at 6 (citing 2021 Reg. Rec. at 209 n.1154). In any event, whether

Plaintiffs point to several supposed flaws in the Librarian's reasoning and conclusion. To start, plaintiffs argue that the Librarian overlooked the commercial nature of the Medical Device Exemption uses and failed to balance the commercial nature against the transformative purposes—resting solely on the transformative aspect of the Exemption uses. *See* Pls.' Mem. at 18-19 (criticizing what they describe boldly as "outright disregard for the commercial nature of ISOs' use"); Pls.' Opp'n at 4-5. Contrary to plaintiffs' hyperbolic characterization, as just explained, the Librarian *did* acknowledge the commercial nature of the exempted uses but rightly recognized that commercial use is not dispositive and that "such uses must be addressed through a 'sensitive balancing of interests.'" 2021 Reg. Rec. at 208-09, AR at 1908-09 (quoting *Campbell*, 510 U.S. at 584-85)). She then explained how the Exemption's uses were also transformative, which controlled her conclusion. *Id.*

Plaintiffs go on to criticize the Librarian's transformative-use analysis, asserting, as their second argument, that because the Exemption's uses do not actually change or alter the copyrighted software in any way, such uses cannot be transformative. *See* Pls.' Mem. at 19. In plaintiffs' words: "ISOs—by their own admission—do not modify the copyrighted software *at all*. That is because modifying the software would likely lead to the system being considered remanufactured, which is to be avoided because it would then subject ISOs to a raft of burdensome FDA regulations." *Id.* (emphasis in original) (internal quotation marks and citation omitted); *see also* Pls.' Opp'n at 7. Plaintiffs insist that a use is only transformative when the copyrighted work is used "in a different context such that" the work "is transformed into a new

this non-commercial use point was sufficiently considered in evaluating the first factor ultimately makes no difference. Even if the uses targeted in the Exemption are considered purely commercial, the Librarian garnered substantial evidence to support the determination that they were transformative and thus concluding that the first factor weighs in favor of fair use.

creation." Pls.' Opp'n at 9 (quoting *Wall Data Inc. v. Los Angeles Cnty. Sheriff's Dep't*, 447 F.3d 769, 778 (9th Cir. 2006)).

While the general, colloquial understanding of the term "transformative" urged by plaintiffs may certainly be correct in some contexts, the legal meaning when "consider[ing]" the first fair use factor—*i.e.*, "the purpose and character of the use," under 17 U.S.C. § 107(1)—is more nuanced. The caselaw makes clear that the inquiry looks to the use's *purpose* when assessing the transformative quality, not merely the *content* of the copyrighted material copied. Thus, "even making an exact copy of a work may be transformative so long as the copy serves a different function than the original work." *Perfect 10, Inc. v. Amazon.com, Inc.*, 508 F.3d 1146, 1165 (9th Cir. 2007) (determining that Google's reproduction of copyrighted images as thumbnails in search results was a transformative use); *see also Authors Guild, Inc. v. HathiTrust*, 755 F.3d 87, 96 (2d Cir. 2014) ("[A] transformative work is one that serves a new and different function from the original work and is not a substitute for it."); *A.V. ex. rel. Vanderhye v. iParadigms, LLC*, 562 F.3d 630, 639 (4th Cir. 2009) ("The use of a copyrighted work need not alter or augment the work to be transformative in nature. Rather, it can be transformative in function or purpose without altering or actually adding to the original work.").

Two examples illustrate how a use can be transformative without making any changes to the content of the copyrighted work itself. News reporters, for instance, "must 'faithfully reproduce an original work without alteration.'" *Am. Soc'y for Testing & Materials v. Public.Resource.Org, Inc. (No. IV)* ("*ASTM IV*"), 82 F.4th 1262, 1268 (D.C. Cir. 2023) (quoting *Am. Soc'y for Testing & Materials v. Public.Resource.Org., Inc. (No. II)* ("*ASTM II*"), 896 F.3d 437, 450 (D.C. Cir. 2018)). Despite their verbatim reproduction of other ideas, news reports are a paradigmatic example of fair use because they are "transformative in function or purpose." *Id.*

(quoting *ASTM II*, 896 F.3d at 450); *see also* 17 U.S.C. § 107 (listing "news reporting" as an example of fair use). "[A] reporter's message ('this is what they said') is very different from the original message ('this is what you should believe')." *ASTM IV*, 82 F.4th at 1268. As a second example, the D.C. Circuit considered an analogous situation in *ASTM IV*, where standard-developing private organizations (such as the American Society for Testing and Materials and the American Society of Heating, Refrigerating, and Air-Conditioning Engineers) brought a copyright infringement suit against a non-profit organization that disseminated the "copyrighted standards, as incorporated into law" by posting them on its freely accessible website. *See id.* at 1265-66. In evaluating the defendant non-profit website owner's fair use defense, the court noted that while the plaintiff standard-developing organizations sought to advance the "industry by producing standards reflecting . . . best practices," the defendant's mission differed, seeking rather "to provide the public with a free and comprehensive repository of the law." *Id.* at 1268. In other words, defendant's "message ('this is the law') [wa]s very different from the plaintiffs' message ('these are the current best practices for the engineering of buildings and products')." *Id.* That the exempted uses do not contemplate modification of any copyrighted materials therefore in no way precludes the Librarian's conclusion of a transformative purpose.

Plaintiffs nonetheless insist, in their third argument, that the Medical Device Exemption allows for the copyrighted software to be used "for the very purpose for which, and precisely the manner in which, it was designed to be used." Pls.' Mem. at 22 (quoting *Triad Sys. Corp. v. Southeastern Exp. Co.*, 64 F.3d 1330, 1337 (9th Cir. 1995)). In plaintiffs' view, the general operating system software and related files are used under the Exemption just as they were originally intended: "[t]o operate the machine being serviced." *Id.* Plaintiffs' view of the Exempted uses' purpose is, however, too general. The previous examples cited are again helpful

here. In a broad sense, both the system software's original use in the device and its secondary use by ISOs to repair the device further the goal of operating the machine to take medical images. The same was true in *ASTM IV*; in a broad sense, both the standard-developing organizations in developing standards and the non-profit website in disseminating those standards intended to advance knowledge in the industry. Yet, a narrower sense of the purpose controlled the legal analysis. While the original copyrighted software operates the medical device, conveying the message "do this" (much like "these are the best practices" in *ASTM IV* or "this is what you should believe" in the news reporting example), ISOs engaging in diagnosis, maintenance, and repair use the operating code to understand what the machine was told to do, interpreting the message as "this is the instruction" or "this is what the machine was told to do" (much like "this is the law" in *ASTM IV* or "this is what was said" in the news reporting example). The ISOs or other providers employ those instructions to determine what problem exists in the device or to fix the device so that the device can operate or execute the code as intended.[5]

Plaintiffs contest such a narrower approach to the transformative-use inquiry, relying on *Warhol* to argue that the inquiry is "not satisfied by only marginal shifts in the purposes to which copied works are put." Pls.' Opp'n at 9-10; *see also id.* at 14. The Court in *Warhol* indeed observed that "an overbroad concept of transformative use, one that includes any further

[5] Plaintiffs separately argue that the Librarian's analysis was flawed because she "ignored" comments made by OEMs explaining how "all of the copyrighted works at issue . . . have as an original purpose the diagnosis, maintenance, and repair of a machine when its functionality becomes impaired," and instead "adopted the opposite conclusion by pure *ipse dixit*" without addressing those comments. Pls.' Opp'n at 13. Although not every such comment was explicitly called out, the Librarian plainly engaged with the specific reasoning. When later addressing the fourth fair use factor, for instance, the Librarian noted that the proposed uses are intended "merely to restore functionality so the equipment performs as intended," recognizing a distinction between the original purpose of getting the device to operate—take images or store data, etc.—and the secondary one of fixing the device to improve or maintain its operation, as the above discussion also demonstrates. 2021 Reg. Rec. at 212; *see also id.* at 209 ("Here, the proposed activities are intended to restore a medical device or system's functionality.").

purpose, or any different character, would narrow the copyright owner's exclusive right to create derivative works. To preserve that right, the degree of transformation required to make "'transformative' use of an original must go beyond that required to qualify as a derivative." 598 U.S. at 529. At the same time, however, the inquiry is context-specific and functional, looking specifically at "the reasons for copying." *Id.* at 550. As a result, even a derivative work "borrowing heavily from an original," *id.* at 538, can still be a fair use "if, among other things, the use has a purpose and character that is sufficiently distinct from the original," *id.* at 550. Thus, while copying part of a code to repair a device may be "derivative" of its use to operate that device, its purpose is sufficiently distinct to qualify as a fair use. Indeed, copying a portion of software code as contemplated in the Medical Device Exemption in no way provides "the public with a substantial substitute" for the original software in the device. *Warhol*, 598 U.S. at 531-32 (quoting *Authors Guild*, 804 F.3d at 207).

Plaintiffs then shift to contend that the main dispute here is not about the copying of the device's operating code but rather about the use of ancillary copyrighted materials like electronic manuals, machine specifications, error logs generated by the software, etc., all of which ancillary material may be encompassed by the Exemption's reference to "and related data files," 37 C.F.R. § 201.40(b)(17). Pls.' Mem. at 22 (quoting 2021 Reg. Rec. at 211, AR at 1911). In plaintiffs' view, these "other" materials "exist[] precisely for the purpose of performing service and maintenance" and have no other function. *Id.*; Pls.' Opp'n at 12 ("[T]his case is really only about ISOs' unauthorized use of operating manuals and machine specifications, diagnostic software and service tools, data reports and error logs, and the like."). According to plaintiffs, OEMs created such items for use in performing their own repairs. *See* Pls.' Mem. at 22.

ISOs' use of those materials still may be considered transformative. Regardless of whether OEMs created these items or developed code to generate these items with an ultimate goal of facilitating repairs in mind, their immediate original purpose was to help operate the device or to provide information about the general operation of the device. 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. That secondary function transforms the basic knowledge conveyed in the copyrighted materials into a distinct and meaningful output, which is considered transformative. *See Warhol*, 598 U.S. at 529 ("A use that has a further purpose or different character is said to be 'transformative.'" (quoting *Campbell*, 510 U.S. at 579)); *Seltzer v. Green Day, Inc.*, 725 F.3d 1170, 1176 (9th Cir. 2013) ("If . . . the secondary use adds value to the original—if the quoted matter is used as raw material, transformed in the creation of new information, . . . new insights and understandings—this is the very type of activity that the fair use doctrine intends to protect." (quoting Leval, *supra*, at 1111)).[6]

Another way to understand how ISOs, when using a medical device's operating software, manuals, or other "related data files," employ a purpose different from those items' original function is by recognizing that diagnosis, maintenance, and repair has a concrete "transformative" effect on the device by changing some aspect of how it works—or more accurately, in this context, from not working as intended and advertised, to doing so. Plaintiffs point out that the inquiry under the first fair use factor is whether the use transforms the copyrighted material itself—not some separate related object. *See* Pls.' Opp'n at 8. Plaintiffs'

[6] Indeed, in this respect, the uses permitted by the Medical Device Exemption are akin to "research," a fair use explicitly contemplated by § 107. Users use the error logs, manuals, or other materials to inform their thinking and then add their own ingenuity to achieve a novel product—a diagnosis or a repaired device.

effort, however, to separate the medical device from the copyright-protected operating software and other material embedded in or generated by the device is elusive. Although technically the hardware and software may be distinct, the device is simply a vessel for, or a reader of, the copyrighted material. Neither is operational or commercially valuable without the other. Given that the software has no use or value apart from the device, maintenance and repairs to device components (either physical or software) facilitate use of the software and thus has a transformative effect on the *use* of the software—the commercially valuable, overall product.[7] The Librarian's conclusion that all of the uses contemplated by the Exemption are transformative was thus not, as plaintiffs suggest, ill reasoned or legally infirm.

As their fourth critique, plaintiffs challenge the Librarian's reliance on a comparison to a prior rulemaking for her conclusion that the exempted uses are transformative here. At the outset, plaintiffs assert that "the Librarian gave no explanation—*none at all*—for her view that an ISO's use of software for maintenance services can be understood in any way to serve 'a further purpose or different character' than that for which the software was originally created." Pls.' Mem. at 20 (emphasis in original) (quoting *Warhol*, 598 U.S. at 532). They then ironically go on to protest a point she offered explicitly as an explanation for her view: her previous conclusion in a 2015 rulemaking that "diagnosis and repair are likely to be transformative uses,"

[7] Plaintiffs argue that the Librarian's reasoning was illogical because this point—that the fair use inquiry turns on whether the copyrighted material itself, not a separate object, is altered—was raised in the rulemaking process "but the Librarian proceeded (AR2094) as if it never had been raised." Pls.' Opp'n at 8. The Librarian never, however, explicitly reasoned that the medical device was altered, as plaintiffs concede. *Id.* ("The Librarian also *appeared to conclude* that an ISO's use of an OEM's copyrighted works for diagnosis, maintenance, and repair is transformative because to maintain or repair a machine is transformative *of the machine*." (first emphasis added; second emphasis in original)). The Librarian thus did not need to explicitly respond to plaintiffs' counterargument. In any case, to the extent the Librarian employed this reasoning, her later recognition that "most medical device and system software and data files generally have no independent value separate from being used with the equipment," 2021 Reg. Rec. at 212, responds to plaintiffs' point: The copyrighted material and the devices are, from functional and commercial perspectives, one in the same.

2021 Reg. Rec. at 209, AR 1909. *See* Pls.' Mem. at 20, 29. Plaintiffs raise two purported problems with relying on this previous determination: (1) that fair-use doctrine requires a case-by-case analysis, so extrapolation from other contexts is inappropriate; (2) that the cited prior rulemaking concerned "admittedly transformative uses" because it concerned 'diagnosis, repair, and *modification*' of electronic control units (ECUs) in automobiles." Pls.' Mem. at 21 (emphasis in original) (quoting Register of Copyrights, *Section 1201 Rulemaking: Sixth Triennial Proceeding to Determine Exemptions to the Prohibition on Circumvention*, Recommendation of the Register of Copyrights, at 234 (Oct. 8, 2015) ("2015 Reg. Rec."), available at https://cdn.loc.gov/copyright/1201/2015/registers-recommendation.pdf); *see also* Pls.' Opp'n at 7-8.

Neither contention demonstrates a flaw in the Librarian's reasoning. First, though the fair use inquiry is context-specific, as plaintiffs correctly note, the Librarian's task here was not to conduct a fair-use analysis for a particular ISO's use of a specific copyrighted work associated with a unique device. Rather, the Librarian was making an "*ex ante* determination[] as to which activities are likely to qualify as fair uses that would be adversely affected by the anticircumvention provision if not exempted." *Green*, 111 F.4th at 101. Such a categorical approach requires some degree of generalization. Moreover, for DMCA-authorized TPM exemptions to be principled and reasoned rather than arbitrary and capricious, the Librarian helpfully demonstrated consistency across exemptions with similar uses in different industries incorporating copyrighted software. Analogizing therefore to another context involving TPM exemptions for use in diagnosis, maintenance, and repair was therefore not only acceptable but showed exemplary thoroughness.[8]

[8] The Librarian reached the conclusion that using copyrighted materials for diagnosis, maintenance, and repair is a transformative purpose on several other occasions as well, undermining plaintiffs' argument that her

Second, although modification sometimes occurred with ECUs and modification is not contemplated with the Medical Device Exemption, the Librarian's reasoning in the cited 2015 rulemaking did not rest on that fact, nor did it need to, so that distinction does not undermine its relevance here. In the cited 2015 rulemaking, the Librarian separately addressed the transformative nature of modifications and the transformative nature of diagnosis and repair. *See* 2015 Reg. Rec. at 234-35. After addressing modifications, she noted that although the new uses may "coincide[] generally with the original use," which would normally weigh against fair use, 2015 Reg. Rec. at 234, "the proposed uses for *diagnosis and repair* would presumably *enhance the intended use* of the ECU computer programs," so the first factor favored fair use, *id.* at 235 (emphasis added). Thus, the Librarian "singled out diagnosis and repair separately" from modifications. Defs.' Reply at 10. Her reasoning there—that a use that does not substitute for the original but rather enhances and enables it—is equally appliable in the medical device context and provides a rational basis for the Librarian's conclusion here. Additionally, as previously explained, *see supra*, that a new use does not alter or change the original in any way does not foreclose a finding of a transformative purpose. The Librarian made no error in drawing this comparison.

Finally, plaintiffs argue that in the 2024 Ninth Triennial rulemaking, the Register rested on flawed reasoning and "disregarded the significance of [*Warhol* as] intervening precedent" since the prior 2021 rulemaking. Pls.' Mem. at 22. In *Warhol*, the Supreme Court considered a copyright claim brought by a photographer, who took an iconic photo of Prince in the 1980s,

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conclusion was arbitrary and capricious. *See* Defs.' Reply at 9 (citing Section *1201 Rulemaking: Seventh Triennial Rulemaking to Determine Exemptions to the Prohibition on Circumvention: Recommendation of the Acting Register of Copyrights*, at 202-03 (Oct. 2018), AR 1560-61 (regarding diagnosis, repair, and maintenance of home appliances, smartphones, video game consoles, computers, etc.); *Section 1201 Rulemaking: Eighth Triennial Rulemaking to Determine Exemptions to the Prohibition on Circumvention: Recommendation of the Register of Copyrights*, at 201-02 (Oct. 2021), AR 1901-02 (regarding software-enabled computer devices)).

against the Andy Warhol Foundation, for Warhol's use of that photo to develop silkscreen portraits of Prince, including one appearing in Vanity Fair in 1984. *See* 598 U.S. at 515. The Court held that the first fair use factor favored the photographer, not Warhol, because the derivative images were commercial and did not serve a "purpose distinct from the original" so they were not transformative. *Id.* at 542. Both the original photograph and the silkscreen, as used in the magazine, intended to illustrate the piece about Prince, and any differences in artistic depiction did not change that purpose. *See id.* at 545-46. The Court applied principles from *Campbell* and *Google*, and while clarifying certain points, *see id.* at 541 ("*Campbell* cannot be read to mean that § 107(1) weighs in favor of any use that adds some new expression, meaning, or message."), did not purport to change the inquiry or overturn any precedent. In plaintiffs' view, *Warhol* reinforced that there is "nothing transformative" about copying software and "putting it 'to the identical purpose as the original software.'" Pls.' Mem. at 22 (quoting *Oracle Int'l Corp. v. Rimini St., Inc.*, No. 14-cv-1699, 2023 WL 4706127, at *76 (D. Nev. July 24, 2023)).

This is not a situation, however, where relevant legal precedent was ignored or mistakenly overlooked but instead plaintiffs simply disagree with the Librarian's interpretation and application of *Warhol*. The Librarian explicitly addressed *Warhol* and explained how its "holding that uses which 'share the same or highly similar purposes' as the copyrighted work weigh against fair use" was consistent with, not a departure from, prior caselaw like *Campbell* and *Google* that she had relied upon in the prior rulemaking. 2024 Reg. Rec. at 38, AR at 2094. The Librarian even observed that the Eleventh Circuit declined to hear a case involving fair use decided by the district court prior to *Warhol*, intimating that the case did not necessarily require a different analysis. *See id.* n.178. As a result, the Librarian concluded that the prior analysis

remained valid, and 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," the Exemption targeted fair uses. *Id.* That conclusion is fairly reasoned and consistent with *Warhol*.

Relatedly, plaintiffs contend that the Librarian applied *Warhol* in an arbitrary way because she credited the commercial nature of reproduction in another context—for-profit educational materials—and denied them an exemption as a result but did not appropriately consider the commercial nature of the Exemption uses here. *See* Pls.' Mem. at 29-30. In both cases, however, the Librarian appropriately weighed the commercial use against the transformative purpose. The materials at issue in the proposed educational exemption were short clips from movies for the purpose of teaching learners in for-profit classes requiring "close analysis of film and media excerpts." 2024 Reg. Rec. at 52, AR at 2108. In doing that balancing, the Librarian commented that "the nature of this entity's uses . . . [wa]s unclear based on the evidence submitted" and cited concern that the movie clips were used not for criticism and comment but merely for explanation—"to show things that are shown in the movie." *Id.* at 60. In other words, she expressed concern that the use was not sufficiently transformative. Despite the similarly commercial nature of the Exemption uses here, the Librarian explained that the proposed activities had a different purpose: "intend[ing] to restore a medical device or system's functionality, not to commercialize the embedded copyright software." 2021 Reg. Rec. at 209, AR at 1909. The Librarian therefore weighed the two factors (commerciality and transformative purpose), applying the same framework in both cases, and simply came to two different conclusions based on the different factual scenarios. Such well-reasoned and fact-sensitive reasoning is not arbitrary and capricious.

In sum, 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.

2. Second Factor Under § 107: Nature of the Copyrighted Work

The Librarian concluded that the second factor, "the nature of the copyrighted work," 17 U.S.C. § 107(2), also favored fair use. *See* 2021 Reg. Rec. at 210, AR at 1910. She noted that "the computer programs and data embedded in medical devices and systems are not used for their expressive qualities, but rather for their functional and informational aspects that enable users to control and understand the operation of the equipment." *Id.* Plaintiffs argue that she "misses the point entirely" because although "used for a functional purpose," the software is "essentially a creative work." Pls.' Mem. at 27 (quoting *Advanced Comput. Servs. of Mich., Inc. v. MAI Sys. Corp.*, 845 F. Supp. 356, 365 (E.D. Va. 1994)). Despite nearly always being functional, computer programs are still awarded copyright protection, plaintiffs point out. *Id.*

Plaintiffs' defense of software used in medical devices as "creative work[s]" and critique of the Librarian's decision as somehow "miss[ing]" this important point are entirely misplaced in considering the second fair use factor. The proper question here is not whether a work should be covered by copyright—the whole fair use inquiry presumes the work is copyrightable and copyrighted—but rather how "close" the work is "to the core of intended copyright protection." *Campbell*, 510 U.S. at 586. Creative, artistic expressions like fictional short stories, memoirs, and movies are closer to the core of copyright and thus less amenable to fair use. *See id.* By contrast, "[t]he law generally recognizes a greater need to disseminate" factual works like news broadcasts and published speeches. *Harper & Row*, 471 U.S. at 563; *see also ASTM II*, 896 F.3d at 451 ("All of the works at issue here fall at the factual end of the fact-fiction spectrum, which

counsels in favor of finding fair use."). As the Librarian rightly recognized, 2021 Reg. Rec. at 210, AR at 1910, computer programs are generally "functional in nature," though that does not mean that this factor will automatically weigh in favor of fair use. *Google*, 593 U.S. at 27-28; *Teradyne, Inc. v. Astronics Test Sys., Inc.*, No. 20-cv-2713, 2023 WL 9284863, at *22 (C.D. Cal. Dec. 6, 2023) (recognizing that computer code involves creativity but is generally considered "functional and/or utilitarian"); *see, e.g.*, *Advanced Comput. Servs.*, 845 F. Supp. at 365 (describing a particular software as "a specially designed and crafted work which represents a substantial investment of time and labor" and concluding that the "software's nature . . . militates against a fair use finding"). The Librarian nonetheless reasonably concluded that in this case, the software code itself and the ancillary materials are informative, factual, and functional rather than expressive in nature, favoring fair use. *See* 2021 Reg. Rec. at 209, AR at 1909. Although the code may be innovative and "represent[] a substantial investment of time and labor," as plaintiffs assert, Pls.' Mem. at 27 (quoting *Advanced Comput. Servs.*, 845 F. Supp. at 365), the materials overall are not as close as other forms of copyrighted works to the core of copyright.[9]

Plaintiffs urge that the Librarian also went off-course when crediting "competitive concerns" with OEMs having exclusive control over—and thus an ability to charge exorbitant prices for—maintenance and repair of their devices. *See* Pls.' Mem. at 27 (citing 2021 Reg. Rec. at 228, AR at 1928). Plaintiffs explain that only public benefits that further the purposes of

[9] Plaintiffs suggest an unintended adverse consequence if the second factor is always interpreted to weigh in favor of fair use for computer programs just because they are "functional" in their purpose, cautioning that such an approach would undermine and even "eviscerate copyright protections for *all* software." Pls.' Opp'n at 19 (emphasis in original). Just like Chicken Little overreacted by mistakenly thinking the sky was falling after being hit on the head by an acorn, plaintiffs' concern is predicated on at least two incorrect assumptions: First, contrary to plaintiffs' suggestion, the second factor is not dispositive of the whole fair use inquiry and thus not every use of a copyrighted computer program would be justified by application of the fair use inquiry as a whole. Second, also contrary to plaintiffs' suggestion, the second factor as applied to any copyrighted software does not always weigh in the direction of fair use, and the Librarian made no such blanket statement otherwise. *See* 2021 Reg. Rec. at 210 (asserting merely that the copyrighted material at issue here is used for its "functional and informational aspects").

copyright, such as the development of art and science, are relevant to the fair use inquiry, not the financial interests of consumers. *See id.* at 27-28. This argument is entirely misplaced. While the Librarian did consider "competitive concerns" as part of its rulemaking process, she did not do so as part of the analysis for the second fair use factor or as part of the fair use analysis at all. Rather, she addressed these competitive concerns as part of the fifth factor of the "adverse effects" inquiry under the DMCA's § 1201(a)(1)(C)(v), which instructs the Librarian to take into account "other factors as the Librarian considers appropriate." *See* 2021 Reg. Rec. at 227-28, AR at 1927-28. The Librarian thus did not err in her analysis of the second factor or inappropriately set aside the principles and purpose of copyright law in favor of other considerations.

3. Third Factor Under § 107: Amount and Substantiality of Portions Used

The third statutory factor looks to "the amount and substantiality of the portion used in relation to the copyrighted work as a whole." 17 U.S.C. § 107(3). The Librarian concluded that this factor weighed in favor of fair use but ultimately "should be given little weight." 2021 Reg. Rec. at 211, AR at 1911. She reasoned that the amount of copyrighted material used under the Medical Device Exemption was "reasonable relative to the purpose" because sometimes repairs would only require a portion of the copyrighted works and where the entire versions were necessary, such use would be justified "to achieve a transformative purpose." *Id.* at 210-11, AR at 1910-11. Plaintiffs contend that the Librarian erred because the third factor should not have been given short shrift and copying works in their entirety "weighs strongly against fair use." Pls.' Mem. at 23 (citing *Triad Sys.*, 64 F.3d at 1337).

Contrary to plaintiffs' critique, "[c]opying a large[] amount of material" is not inherently problematic. *Google*, 593 U.S. at 33. As the Court in *Google* explained, "where the material

copied captures little of the material's creative expression or is central to a copier's valid purpose," that does not weigh against fair use. *Id.* The factor "will generally weigh in favor of fair use where . . . the amount of copying [i]s tethered to valid, and transformative, purpose." *Id.* at 34.

The Librarian's conclusion here was well-reasoned and consistent with this law. Sometimes diagnosis, repair, and maintenance will require copying large portions of the software code or other materials in their entirety, but because its purpose is transformative, this factor does not weigh against fair use. *See* 2021 Reg. Rec. at 210-11, AR 1910-11. Given that the Medical Device Exemption only allows copying as necessary to carry out the transformative purposes, any concern about ISOs copying "too much" is misplaced. Such copying would not only fall outside of the Exemption, subjecting the user to liability under the DMCA, but could also trigger the risk of separate liability for copyright infringement. *See* 2021 Reg. Rec. at 212, AR at 1912 (observing that if a "user were to reproduce and retain additional copies of any copyrighted materials" beyond the limited purposes set out, they would remain prohibited). The Librarian's decision to give this factor "little weight" was also reasonable, considering that the amount of material necessary to copy will vary with any particular use, and consistent with precedent advising that not every factor will be equally important. *See Kelly v. Arriba Soft Corp.*, 336 F.3d 811, 820-21 (9th Cir. 2003) ("If the secondary user only copies as much as is necessary for his or her intended use, then this factor will not weigh against him or her."); *Google*, 593 U.S. at 19 ("[S]ome factors may prove more important in some contexts than in others.").

4. Fourth Factor Under § 107: Effect on the Market for or Value of Copyrighted Work

The fourth and final factor considers "the effect of the use upon the potential market for or value of the copyrighted work." 17 U.S.C. § 107(4). The Librarian concluded that "diagnosis, maintenance, and repair of medical devices and systems is unlikely to harm the market for the embedded software and this factor favors fair use." 2021 Reg. Rec. at 212, AR at 1912. In particular, the Librarian reasoned that "most medical device and system software and data files generally have no independent value separate from being used with the equipment." *Id.* As a result, replication of those files—because they have no use without the device—will not harm the market for their sale, which is dependent on purchases of the actual devices. Plaintiffs argue that the Librarian erred because she failed to take into account that the Medical Device Exemption will (1) harm the "the service-and-repair market," (2) diminish the incentive for derivative innovations, and (3) "increase the potential for device malfunction and cybersecurity attacks, which undermines the value for medical devices and their software." Pls.' Mem. at 24-26. To the contrary, the Librarian considered all relevant facts, including these three considerations referenced by plaintiffs, and came to a conclusion consistent with those facts and the law.

The fourth factor examines "whether the secondary use 'usurps the market of the original work.'" *Authors Guild*, 755 F.3d at 99 (quoting *NXIVM Corp. v. Ross Inst.*, 364 F.3d 471, 482 (2d Cir. 2004)). The law instructs courts "to consider" not only "the amount of money that the copyright owner might lose" but also the "source of the loss," taking into account the "public benefits the copying will likely produce." *Google*, 593 U.S. at 35. For instance, while a critical review panning a copyrighted work may reduce demand for the original, such harm is not cognizable under copyright law. *See id.* Courts should also 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 by the defendant . . . would result in a substantially adverse impact on the potential market for the original." *ASTM II*, 896 F.3d at 452 (quoting *Campbell*, 510 U.S. at 590). In addition to the market for the original, the "enquiry 'must take account . . . of the harm to the market for derivative works.'" *Campbell*, 510 U.S. at 590 (quoting *Harper & Row*, 471 U.S. at 568).

Although the first and fourth fair use factors are distinct, there is "a positive association between the two." *Warhol*, 598 U.S. at 536 n.12. "A secondary use that is more different in purpose and character is less likely to usurp demand for the original work or its derivatives." *Id.* "In other words, under [the fourth factor,] any economic 'harm' caused by transformative uses does not count because such uses, by definition, do not serve as substitutes for the original work" and thus do not impact its market. *Authors Guild*, 755 F.3d at 99.

Here, the proper inquiry is whether the market for the "copyrighted work," 17 U.S.C. § 107(4), which encompasses the embedded operating software and the related materials like electronic manuals, error logs, design specification documents, will be harmed by copying those materials for diagnosis, maintenance and repairs. *See* Pls.' Opp'n at 15-16 (agreeing these are the copyrighted works at issue). As the Librarian found, however, the software and related data files have no value apart from the device themselves. *See* 2021 Reg. Rec. at 212, AR at 1912. These materials cannot be put into other equipment to operate those devices or uploaded to a computer to carry out other functions. Although the physical equipment is not the subject of the OEMs' copyrights, 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. Given that the Medical Device Exemption does not allow ISOs in any way to replace the need for the equipment, the Librarian fairly concluded that ISOs' use of the software and

related data files does not harm the original market for the purchase of the devices—*i.e.*, the package of the equipment and software.[10]

Plaintiffs first argue that the software and related data files *do* actually have commercial value apart from the equipment because they have independent value in the market for services and repairs. *See* Pls.' Mem. at 24. In this market, ISOs make a profit from using the software and manuals without any sale of equipment. According to plaintiffs, the Exemption harms the OEMs' position in this market by depriving them of direct services contracts or licensing fees they would otherwise receive. *See* Pls.' Opp'n at 15-17. Taking all of these premises as true, plaintiffs' conclusion that therefore the fourth factor must weigh against fair use does not follow.

Plaintiffs conflate the original market of devices—including their embedded software and programs and any files they generate—with the separate market for diagnosis, maintenance, and repairs. Yet, 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—the transformative process conducted by ISOs. That process does not compete with or replace the use of the copyrighted materials as they were originally provided in the initial sale, which is the market that the fourth factor instructs courts to consider. As defendants put it, "[p]laintiffs' focus on the market for the *repair* of the underlying software is . . . misplaced, because the market at issue here is the market for the software itself, a market that there is no indication that potential users of the exemption—ISOs and medical facilities—seek to enter," Defs.' Opp'n at 26 (emphasis in original), and the fourth factor only concerns itself with

[10] Plaintiffs point to *Campbell*, 510 U.S. at 591, as establishing a presumption of market harm in the case of a non-transformative commercial use of a copyrighted work. Pls.' Opp'n at 16. As covered *supra* Part III.A.1, however, the Exemption allows *transformative* commercial uses, so any presumption contemplated in *Campbell* would not apply.

"the harm that results because the secondary use serves as a substitute for the original work," *i.e.*, "market substitution," *Authors Guild*, 755 F.3d at 99 (second passage quoting *Campbell*, 510 U.S. at 591).[11]

Where, as here, the users in question are "not simply 'creating a market substitute,' but at least arguably" are "creating a market" by adding their own skill and expertise to provide a service using the copyrighted materials, the fourth factor favors fair use. *Teradyne*, 2023 WL 9284863, at *27-28 (holding that a defendant's use of plaintiff's code to develop new software compatible with existing computer programs used by the military was fair use); *see SOFA Ent., Inc. v. Dodger Prods., Inc.*, 709 F.3d 1273, 1280 (9th Cir. 2013) (observing that "[w]here the secondary use is not a substitute for the original and does not deprive the copyright holder of a derivative use" but is rather a complementary use, "the fourth factor weighs in favor of fair use"). The Librarian's distinction between the original device market and the service-and-repair market and her subsequent conclusion that the Exemption did not harm the original market was therefore reasonable. *See* 2021 Reg. Rec. at 212, AR at 1912 (recognizing that although some of software or materials could have independent value and thus may be accessible for instance via a

[11] Plaintiffs respond that defendants have "confused a copyrighted work with its use or performance." Pls.' Opp'n at 15. They explain that copyrighted works are often only marketable through a particular product or service that communicates the copyrighted work, such as a performance of the play—or in this case, repair of a device. While a script of the play (or the original copyrighted software) is also marketable itself, the fact of the performance does not mean the use is different enough to be fair use, *i.e.*, that the producing theatre need not pay licensing fees for the show. *See id.* Plaintiffs' analogy falls apart, though, because plaintiffs fail to acknowledge the transformative purpose in the repair context. Here, the relevant "use or performance" of the copyrighted software is the operation of the medical device—its originally intended purpose to take medical images—not the repair of the device. The use of the software to conduct a repair is less like performing the play and instead more akin to the use of a script for research to better understand the playwright: a transformative fair use with a different purpose. Understanding the playwright better could aid the performance of the play, just as repairing the device may aid the device's operation, but using the script for research—just like using the software and error logs to diagnose and repair problems—is a task fundamentally different from performing the script or operating the medical imaging device, which are the originally intended uses of the copyrighted material.

separate subscription service, where access is necessary to engage in repair, "it is not likely to harm the market for the software" (citation omitted)).

The implication of plaintiffs' argument here is that even in the secondary service-and-repair market, OEMs are entitled, by virtue of their copyright over their software, to a monopoly. Only OEMs, in plaintiffs' view, should be able to utilize their materials to support the functioning of their machines. "The copyright law, however, does not confer such a monopoly." *Sony Comput. Ent., Inc. v. Connectix Corp.*, 203 F.3d 596, 607 (9th Cir. 2000). In *Sony*, the video game manufacturer Sony sued the developer of a conversion software that allowed Sony's games to be played on computers rather than solely on Sony game consoles. *Id.* at 598. The Ninth Circuit recognized that "Sony understandably s[ought] control over the market for devices that play games Sony produces or licenses" but concluded that the "attempt to monopolize the market by making it impossible for others to compete runs counter to the statutory purpose of promoting creative expression and cannot constitute a strong equitable basis for resisting the invocation of the fair use doctrine." *Id.* at 607-08 (second passage quoting *Sega Enters. Ltd. v. Accolade, Inc.*, 977 F.2d 1510, 1523-24 (9th Cir. 1992)). The court thus held that the fourth factor favored the defendant. *Id.* Similarly, in *Gulfstream Aerospace Corp. v. Camp Systems International, Inc.*, 428 F. Supp. 2d 1369 (S.D. Ga. 2006), a court held that an aircraft manufacturer could not monopolize maintenance services for its aircraft by enforcing the copyright for its maintenance manuals against third-party maintenance service providers (whose customers had purchased the manuals). *See id.* at 1379-80 ("[W]hat Gulfstream seeks here is to use its claimed copyright in its manuals to gain a judicially-enforced monopoly in maintenance-tracking services for Gulfstream aircraft."). The court deemed the manufacturer's effort so "injurious to the free-market public policy advanced through antitrust and restraint-of-trade

laws" and contrary to the "purpose of copyright law" of "promot[ing] the progress of science and the useful arts" that the fourth factor weighed strongly in favor of the defendants and warranted a finding of fair use. *Id.* (last passage quoting U.S. CONST. art. I, § 8, cl. 8). Given the similar policy concerns at issue here (*i.e.*, OEMs monopolizing the market for repairs and extorting high prices out of essential services providers), plaintiffs cannot demonstrate a different outcome is so compelled.

Plaintiffs next argue that the Exemption will have a "chilling effect on further innovations, including that for derivative works" because it will be more difficult for manufacturers to recoup their cost of investment. Pls.' Mem. at 25. Yet, creators of the copyrighted software recoup their costs through sale of the medical devices containing the software. Plaintiffs do not explain why recouping costs through ongoing licensing or repairs is essential to protect the incentive to innovate. Moreover, reproduction of the copyrighted materials beyond that necessary to conduct diagnosis, repair, and maintenance would not fall within the scope of the Exemption and would further be subject to additional liability for copyright infringement, as the Librarian explained, so concerns about pervasive leakage of their innovative code without remedy appear to be unfounded. *See* 2021 Reg. Rec. at 212, AR at 1912.

Third, plaintiffs contend that the Medical Device Exemption diminishes the value of the devices and the software themselves because the circumvention of TPMs "creates unnecessary technical vulnerabilities that put patient safety in jeopardy" and "increase the potential for device malfunction and cybersecurity attacks." Pls.' Mem. at 24-25. The Librarian took these concerns seriously and requested the FDA's position in the rulemaking process. The FDA expressed in the 2021 cycle that the "available evidence was insufficient to conclude whether or not there is a

widespread public health concern relating to medical device servicing" and thus "did not justify imposing additional regulatory requirements on ISOs." 2021 Reg. Rec. at 229, AR at 1929; Letter from Suzanne Schwartz, Director of Office of Strategic Partnerships and Technology for FDA (Aug. 13, 2021) ("2021 FDA Letter"), AR at 8203, 8205, ECF No. 46-5. The FDA, in fact, noted that both OEMs and ISOs "provide high quality, safe, and effective medical device servicing" and "that the continued availability of ISOs to service and repair medical devices is critical to the functioning of the healthcare system in the United States." 2021 FDA Letter, AR at 8205. During the Ninth Triennial Rulemaking in 2024, FDA reiterated the same position. *See* Letter from Suzanne Schwartz (June 21, 2024) ("2024 FDA Letter"), AR at 4594, ECF No. 46-5 ("FDA's view is that . . . [the Exemption] would not necessarily and materially jeopardize the safety and effectiveness of medical devices in the United States with respect to cybersecurity. The ability to conduct maintenance and repair of devices to restore them or ensure they work in accordance with their original specifications and any changes to those specifications authorized for such devices or systems is critical to the continued safe and effective use of devices postmarket."). Contrary to plaintiffs' assertions, the Exemption's enabling of repairs by ISOs may actually increase the value of medical devices on the market because ISOs may be able to help "identify and address security vulnerabilities," as the FDA recognized, and they will be more easily maintained and repaired by a wider variety of users. 2021 FDA Letter, AR at 8205; 2021 Reg. Rec. at 229 n.1272, AR at 1929. The Librarian's consideration of input from the FDA demonstrates a careful and logic-driven, rather than biased or arbitrary, approach to all of the concerns raised during the rulemaking process.

Plaintiffs lodge a final attack on the Librarian's reasoning, criticizing her analogy to "simple consumer electronics" for the conclusion that broader access to software and manuals

will "'support rather than [undercut the value of] the embedded computer programs,' in effect helping rather than hurting the market.'" Pls.' Mem. at 26 (alteration in original) (quoting 2021 Reg. Rec. at 227, AR at 1927). Plaintiffs perceive the Librarian as failing to conduct a context-specific analysis, lumping medical devices together with dissimilar products. *See id.* Plaintiffs seize on a single sentence to mischaracterize the record. The Librarian simply noted when considering the fourth statutory factor, *see* 17 U.S.C. § 1201(a)(1)(C)(iv) ("the effect of circumvention of technological measures on the market for or value of copyrighted works"), following her thorough fair use analysis, that "[a]s with other software enabled devices, the functional software and manuals for medical devices and systems have no independent value separate from the equipment they operate or explain." 2021 Reg. Rec. at 227, AR at 1927. As explained, this observation is both relevant and accurate, and the analogy to other contexts is appropriate for consistent and sound rulemaking. *See supra* Part III.A.1. As a result, the Librarian reasonably concluded that the Exemption supports ongoing use of the devices and does not invite a threatening substitute to the medical imaging device market.[12]

* * *

The fair use doctrine has been referred to as "billowing white goo," "so flexible as virtually to defy definition," *Monge v. Maya Magazines*, 688 F.3d 1164, 1171 (9th Cir. 2012) (first passage quoting Jessica Litman, *Billowing White Goo*, 31 COLUM. J. L. & ARTS 587, 596

[12] Defendants raise an additional point in support of the Librarian's analysis for the fourth factor—her attention to the public benefits of the Exemption, in particular the benefits to consumers of increased competition for repair and maintenance services. *See* Defs.' Opp'n at 29. Plaintiffs retort that the only "public benefit" that may be considered as part of a fair use analysis is the promotion of the objectives of copyright (*e.g.*, innovation and creation). *See* Pls.' Opp'n at 17-18. As already discussed in connection with the second fair use factor, *see supra* Part III.A.2, the Librarian, however, did not consider the public benefits as part of her fair use analysis at all. She rather noted the public benefit as part of the fifth statutory factor under the adverse effects analysis, § 1201(a)(1)(C)(v), instructing the Librarian to consider other factors as appropriate. Whether the public benefit of a more competitive market is appropriately considered in a fair use analysis is thus of no matter here.

(2008), and second passage quoting *Princeton Univ. Press v. Mich. Doc. Servs., Inc.*, 99 F.3d 1381, 1392 (6th Cir. 1996)), and more charitably, as an "equitable rule of reason," *Google*, 593 U.S. at 18 (quoting *Stewart v. Abend*, 495 U.S. 207, 236 (1990)). This flexibility gave the Librarian ample leeway to exercise discretion in conducting a predictive analysis regarding whether uses of copyrighted materials would likely be noninfringing while still falling within the bounds of the law and reasoned decision making. Indeed, as the above discussion illustrates, plaintiffs' efforts to show that her analysis was such an unreasonable interpretation of the law, erroneous application of the facts, or irrational weighing of the equities to warrant judicial intervention all fail. In short, the Librarian appropriately applied the four fair use factors, as set out in 17 U.S.C. § 107 and relevant precedent, to the facts in the record to conclude that the diagnostic, maintenance, and repair uses permitted by the Medical Device Exemption are likely to be noninfringing. This conclusion is consistent with copyright law and supported by her reasoned explanation.

B. Librarian's Decision Is Fully Consistent with DMCA's Text and Purpose

In focusing narrowly on the specifics of the Librarian's fair use analysis, plaintiffs sidestep the Librarian's broader rulemaking context. As previously explained, however, the Librarian's task here was not to conduct a straightforward fair use analysis for a particular instance of reproduction but rather, pursuant to the DMCA's § 1201(a)(1)(C) rulemaking provision, to make a nuanced "*ex ante* determination[] as to which activities are" likely to be noninfringing, *Green*, 111 F.4th at 101, borrowing principles from the fair use doctrine. *See supra* Parts I.A, III.A. The context of the DMCA, then, including its significant reshaping of copyright law in the late 1990s, is important to understanding what should qualify as likely "noninfringing" activities. The text of the DMCA and the policies this law embodies provide further support for upholding the Librarian's conclusion.

As previously highlighted, § 1201(a)(1)(C) was enacted to ward off "the specter of moving our Nation towards a 'pay-per-use' society." Nimmer, *supra*, at 725 (quoting 144 CONG. REC. S1187 (Oct. 8, 1998) (remarks of Sen. Ashcroft)); *see also id.* n.282 (citing 144 CONG. REC. H7101 (Aug. 4, 1998) (remarks of Rep. Stearns) (noting the inclusion of language to "protect consumers from a 'pay-per-view' world in the digital area"); 144 CONG. REC. E2144 (Oct. 13, 1998) (remarks of Rep. Tauzin)). The House Commerce Committee expressed concern about an ironic "monopoly stranglehold on information" in the Information Age and intended for the DMCA to strike the right balance among the interests of content creators and information users with the fair use doctrine as a stalwart principle protecting the latter. *Id.* at 719 (quoting H.R. Rep. No. 105-551, pt. 2, at 25-26); H.R. Rep. 105-551, pt. 2, at 25 ("A computer revolution that has increased access to information also creates opportunities for the holders of copyrights to impose fees for, among other things, research and the use of excerpts from published works. And digital technology—whatever that means—could be exploited to erode fair use."). As the D.C. Circuit in *Green* observed, if the DMCA "entitled owners of information to 'lock up' all access—as it might in a fully digitized environment—would-be fair-users of information could be relegated to negotiating access on terms set by the monopoly rights-holders. . . . The Act's drafters sought to avoid such threat to fair uses by balancing the right against circumvention with access protections for certain non-infringing uses." 111 F.4th at 90.

Accordingly, courts have warned against an overbroad reading of the DMCA's anticircumvention provision and suggested a robust role for the Librarian's creation of exemptions. In *Philips Medical Systems Nederland B.V. v. TEC Holdings, Inc.*, No. 20-cv-21, 2023 WL 2064201 (W.D.N.C. Feb. 16, 2023), the court held that an ISO doing medical device maintenance and repairs was liable for circumvention of TPMs under the DMCA. *See id.* at *15-

17. The Medical Device Exemption had not yet been promulgated during the time of the challenged conduct in that case, and all parties agreed that this Exemption was not retroactive. *Id.* at *15. The court explained the concern in an environment without the Exemption: "Whereas the DMCA was originally enacted to protect copyright owners from digital piracy . . ., powerful corporations are now putting digital locks on their products as a tool to capture and retain a huge market share over the repair industry, reducing consumer choice and raising repair costs." *Id.* at *14. This could be "extremely problematic" for "consumers." *Id.* "Imagine the company you bought your vehicle from telling you that you may only get your vehicle repaired at the dealership. This cannot be what Congress intended when it passed the DMCA." *Id.* Indeed, Congress intended for the Librarian to use the "fail-safe" mechanism, H.R. Rep. No. 105-551, pt. 2, at 36, as she has, to protect important noninfringing users from circumvention liability.

Congress' particular intent to ensure that maintenance and repairs were not monopolized by copyright owners of computer programs is evinced by another provision of the DMCA exempting from copyright liability owners and lessees of machines making copies of computer programs for the purposes of maintenance and repair. *See* 17 U.S.C. § 117(c); DMCA, Pub. L. 105-304, 112 Stat. 2860, sec. 302 (1998). Specifically, that provision states:

> [I]t 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.

Id. This exemption, like others in the DMCA, "limit[s] copyright owners' rights in order to preserve copyright law's delicate balance." Nimmer, *supra*, at 704.

The Medical Device Exemption goes beyond the statutory provision. As the Librarian explained, "section 117(c) covers a narrower range of activities than those proposed here; any uses that involve loading or accessing software that are not necessary to activate the machine likely would not be protected under the statute." 2021 Reg. Rec. at 207, AR at 1907 (explaining in the context of consumer devices); *see also id.* at 212, AR at 1912 (concluding the same in the context of medical devices). At the same time, the Exemption is consistent with the intent expressed in § 117(c), which was enacted as Title III of the DMCA, titled "Computer Maintenance or Repair Copyright Exemption," to ensure that owners and lessees can maintain and repair their devices without being beholden to OEMs. *See* 144 CONG. REC. S11891 (Oct. 8, 1998) (statement of Sen. Leahy, original sponsor of DMCA and Member of DMCA Conference Committee remarking on DMCA Conference Report, that "Title III will provide a minor, yet important, clarification in section 117 of the Copyright Act to ensure that the lawful owner or lessee of a computer machine may authorize an independent service provider, a person unaffiliated with either the owner or lessee of the machine, to activate the machine for the sole purpose of servicing its hardware components."). That Congress did not anticipate the need for a broader statutory exemption to avoid potential adverse effects at the time of enactment in 1998 in no way suggests that Congress intended to set the boundaries of fair use or exemption from circumvention or copyright liability there. Congress simply addressed what it saw, at a minimum, as a then-present threat leering towards a pay-per-use society, where even owners and lessees of machines operating with copyrighted software would have to pay OEMs to obtain repairs of those machines. Despite depriving OEMs of licensing fees they would otherwise receive from repair services, Congress made the determination that such repair uses should be a

non-infringing use and, now, nearly thirty years later, the Medical Device Exemption is consistent with the policy expressed in § 117(c).

The specific context of DMCA rulemaking also helps explain why plaintiffs' heavy reliance on two cases from the 1990s—one from the district court in the Eastern District of Virginia and the other from the Ninth Circuit—that rejected fair use defenses by ISOs for repairs of computer equipment in traditional copyright infringement suits is unavailing. *See, e.g.*, Pls.' Mem. at 2, 24-25, 28-29; Pls.' Opp'n at 2 (discussing *Advanced Comput. Servs.*, 845 F. Supp. 356 and *Triad Sys.*, 64 F.3d 1330). As a general matter, as previously explained, whether a use is "likely noninfringing" so as to support an exemption to the DMCA under § 1201(a)(1)(C) and whether a particular use constitutes a "fair use" as a defense to a copyright infringement suit are two distinct questions. *See supra* Part I.A. Though both questions rely on the general fair use principles in copyright law, the first is a general predictive analysis conducted in the context of the DMCA, with its own unique purpose and priorities, and the second is a more narrowly focused fact-specific inquiry. Moreover, these decisions cited by plaintiffs predate not only the DMCA's § 117(c) but also several key fair use decisions from the Supreme Court that clarified certain aspects of the analysis, rendering plaintiffs' cases not only non-binding but also unpersuasive.

Looking first to *Advanced Computer Services*, while the facts there closely mirror the uses contemplated by the Medical Device Exemption here—use of operating and diagnostic computer software to conduct repairs—the district court's analysis is obsolete in light of newer caselaw. The court in *Advanced Computer Services* determined that the first factor "weigh[ed] substantially against a finding of fair use" because the contemplated uses were commercial, without considering the transformative property of the use. 846 F. Supp. at 365. As *Campbell*

and *Warhol* have since made clear, however, the commercial nature of a use is not dispositive of the first factor; the commercial quality must simply be weighed against the transformative nature. *See Warhol*, 598 U.S. at 532. That oversight also infected the court's analysis of the fourth factor since the court presumed the future harm to the market simply because the use was commercial. *See Advanced Comput. Servs.*, 846 F. Supp. at 366.

Considering next the Ninth Circuit's decision in *Triad Systems*, the facts are also analogous to situations covered by the Medical Device Exemption, but the court's analysis is sparse and thus hardly instructive. The dispute there involved an ISO that serviced computers made by plaintiff Triad using its licensed operating software and utilities, diagnostic, and auxiliary software. *See* 64 F.3d at 1333. The Ninth Circuit concluded that the ISOs were using the software "for the very purpose for which, and in precisely the manner in which, it was designed to be used," such that the copies "diminished the value of [its] copyright." *Id.* at 1337. The Ninth Circuit rejected the argument that the copyright did "not extend to the service market" because Triad "invented, developed, and marketed its software to enable its customers and its own technicians to service Triad computers"—not third parties. *Id.* That the Librarian made a different factual finding here—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—leading to the opposite conclusion, is not, however, arbitrary or irrational since the Librarian's factual finding is supported by substantial evidence, *see supra* Part III.A, with concomitant deference owed. These two cases, occurring in different factual and legal contexts,

do not bind the Librarian in her rulemaking or in her evaluation of the flexible, equitable inquiry that is the fair use doctrine.[13]

* * *

In sum, plaintiffs have identified no legitimate inconsistency between copyright law and the Medical Device Exemption, nor have they identified an error in reasoning or other shortcoming in the Librarian's analysis. They are not entitled to any relief from the rulemaking on any substantive ground claimed under the APA.

C. The Exemption's Promulgation was Procedurally Valid.

Plaintiffs additionally challenge the Librarian's rulemaking procedure, arguing that she failed to address significant comments of "central relevance to the Exemption," offering an independent basis for setting aside the exemption. Pls.' Mem. at 31. "A regulation will be deemed arbitrary and capricious, if the issuing agency failed to address significant comments raised during the rulemaking." *Ass'n of Priv. Sector Colls. & Univs. v. Duncan*, 681 F.3d 427, 441 (D.C. Cir. 2012). "An agency's obligation to respond, however, is not 'particularly demanding.'" *Id.* (quoting *Pub. Citizen, Inc. v. Fed. Aviation Admin.*, 988 F.2d 186, 197 (D.C. Cir. 1993)). The agency "need not address every comment,'" but rather "must respond in a reasoned manner to those that raise significant problems.'" *City of Waukesha v. EPA*, 320 F.3d 228, 257 (D.C. Cir. 2003) (quoting *Reytblatt v. Nuclear Reg. Comm'n*, 105 F.3d 715, 722 (D.C. Cir. 1997)). "Nevertheless, '[t]he failure to respond to comments is significant only insofar as it demonstrates that the agency's decision was not based on a consideration of the relevant factors.'" *Id.* (quoting *Tex. Mun. Power Agency v. EPA*, 89 F.3d 858, 876 (D.C. Cir. 1996)).

[13] Of course, other non-binding cases have come to the opposite conclusion on the fair use question in equally applicable contexts. *See Gulfstream Aerospace Corp.*, 428 F. Supp. 2d at 1380-81; *supra* Part III.A.4 (discussing *Gulfstream*). None of these cases mandates a particular outcome here.

The record here demonstrates that the Librarian explicitly addressed all of the topics of concern in the comments raised by plaintiffs.

1. *Comments Requesting Device-Specific Analysis*

Plaintiffs first contend that the Librarian "did not address comments calling for a device-specific analysis of the fair-use doctrine," instead grouping all medical devices together into a categorical analysis and comparing them to disparate products like consumer devices. Pls.' Mem. at 31-32. The Librarian did, though, consider the appropriate scope of a class, noting Congress's warning not to draw the boundaries of classes "too narrowly." 2021 Reg. Rec. at 9, AR at 1709. She explained that determining the appropriate scope for a class of items subject to an exemption may "involve consideration of the adverse effects an exemption may have on the market for or value of copyrighted works." *Id.* Classes may be refined by reference to the access controls put on them or the particular type of use or user. The Librarian subsequently explained why "medical devices and systems" was an appropriate scope for a class and should be evaluated separately from consumer devices, noting that they differ from consumer devices in terms of their function, TPMs, and software licenses. *Id.* at 199, AR at 1899. The data files and servicing materials to which the ISOs sought access were specific to medical devices and systems, and the record materials, including FDA reports, bearing on the adverse effects of the anticircumvention provision were specific to medical devices. *Id.* The Librarian then evaluated fair use for medical devices specifically. *See id.* at 209, AR at 1909. While she may have analogized to other forms of devices, she did not indiscriminately lump them together; she rather noted the particular ways in which they were similar as relevant to the analysis. *See id.* at 209, 211, AR at 1909, 1911 (comparing to other devices in particular contexts, such as observing that repair often has a transformative purpose). The Librarian thus did not ignore the comments plaintiffs identified.

2. *Comments Regarding Commercial Nature of Exemption Uses and Application of* Warhol

Plaintiffs next argue that the Librarian "disregarded commenters' observation that the purpose of the ISOs' proposed uses" was financial gain of for-profit companies—offering only "the *ipse dixit* that maintenance and repair of medical devices is somehow transformative." Pls.' Mem. at 32. To the contrary, the Librarian explicitly addressed the commercial interests of ISOs and concluded with careful reasoning—not *ipse dixit*—that this was outweighed by the transformative purpose. "Commerciality is not fatal to a fair use determination," she observed, rather "such uses must be addressed through a 'sensitive balancing of interests.'" 2021 Reg. Rec. at 209, AR at 1909 (quoting *Campbell*, 510 U.S. at 584-85). She then reasoned that the ISOs were not commercializing the embedded software itself and diagnosis and repair were likely transformative uses, invoking prior analysis in an analogous context for further support. *Id.* Nothing is arbitrary or deficient about that analysis.

Plaintiffs again insist that her analysis was insufficient because she did not change her position in the 2024 Rulemaking based on *Warhol*, which several commenters brought to her attention. Pls.' Mem. at 32-33, 34-35. As previously explained, the Librarian certainly considered *Warhol* and concluded that the Supreme Court in this decision did not change the framework for the first factor. *See supra* Part III.A.1. The Librarian then weighed the uses permitted by the Exemption's transformative purpose against their commercial nature, consistent with the long-standing framework that was also applied in *Warhol*. *See* 2021 Reg. Rec. at 209, AR at 1909; 2024 Reg. Rec. at 38, AR at 2094 ("[T]he 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."). Plaintiffs simply disagree with which way the Librarian came out, describing her response to *Warhol* as a "cursory brush-off." Pls.' Opp'n at

21. Not so. The Librarian applied the caselaw in a principled way, citing to prior holdings that were consistent with *Warhol* and circuit courts' analysis of all of the precedents to show that the analysis under *Warhol* did not fundamentally differ. *See* 2024 Reg. Rec. at 38, AR at 2094.

Plaintiffs further take issue with the Librarian's analysis of the DMCA statutory factors, contending that she did not respond adequately to opponents' arguments that the Medical Device Exemption did not service "nonprofit archival, preservation, and educational purposes," or "impact 'criticism, comment, news reporting, teaching, scholarship, or research," as enumerated considerations in the second and third factors in 17 U.S.C. § 1201(a)(1)(C)(ii)-(iii). Pls.' Mem. at 33. Again, plaintiffs' disagreement with the Librarian's conclusion does not exhibit her failure to consider the arguments. The Librarian explicitly noted this argument—*e.g.*, "MITA asserts that the 'commercial nature' of petitioners' interest runs contrary to the nonprofit nature of the purposes outlined in these factors." 2021 Reg. Rec. at 226, AR at 1926. She noted that those factors promote the nonprofit nature of services and that "repair of medical devices and systems that are no longer supported by OEMs arguably preserves the availability for use of the equipment's software and servicing materials," reflecting an archival and preservation purpose as contemplated in the statute. *Id.* at 226-27, AR at 1926-27. She concluded that, in any case, "these factors [were] not especially relevant to the determination." *Id*. at 227, AR at 1927. Not every statutory factor needs to weigh in favor of an exemption for the Librarian to grant one. *See* 17 U.S.C. § 1201(a)(1)(C) (merely instructing the Librarian to "examine" the four factors plus any "other factors" she "considers appropriate"). The Librarian's analysis here was therefore neither neglectful of plaintiffs' concerns nor otherwise flawed.

3. *Comments About Chilling Effect on Innovation or Negative Impact on Value of Copyrighted Software*

Third, plaintiffs purport that the Librarian "did not address opponents' concern for the Exemption's chilling effect on innovation or its negative impact on the value of the copyrighted software and medical devices," as relevant to the fourth fair use factor. Pls.' Mem. at 33. Commenters had expressed concerns that replication would diminish the value of copyrighted works by making the intellectual property public. *Id.* The Librarian clearly explained, however, that the Exemption would not chill any incentive to innovate because the Exemption would only allow uses of the software for the narrow purpose of maintenance, diagnosis, and repair, and additional reproductions for other purposes would "remain prohibited." 2021 Reg. Rec. at 212, AR at 1912. Plaintiffs dislike that response because "the point was that supposedly permissible uses will lead to impermissible ones, thus affecting the market for medical devices and their software," but the Librarian explicitly addressed that such uses would be illegal. Pls.' Mem. at 33-34. She need not have ventured further to speculate about how to reduce illegal activity when the DMCA and copyright law already provide ample protections.

Plaintiffs also take issue with the Librarian's response to concerns about the creation of unnecessary cybersecurity vulnerabilities through circumvention of TPMs and about the lack of regulation for ISOs working with medical devices. Pls.' Mem. at 34. Plaintiffs seem to have missed, however, the Librarian's acknowledgment of FDA comments addressing the safety of devices in light of ISO repairs, which did not express concern warranting additional regulation on ISOs. 2021 Reg. Rec. at 229, AR at 1929; *see also* 2021 FDA Letter; 2024 FDA Letter.

4. *Comments About New Congressional and FDA Cybersecurity Policies*

Lastly, plaintiffs contend that in the Ninth Triennial Rulemaking in 2024, the Librarian "disregarded comments showing that Congress and the FDA . . . set forth *new* cybersecurity

policies squarely at odds with the Exemption." Pls.' Mem. at 35 (emphasis added). They point to MITA's comment calling attention to new provisions enacted by Congress requiring OEMs to monitor, identify, and address post-market cybersecurity vulnerabilities, which must include circumvention of TPMs. *See id.* (citing MITA 2024 Cmt. at 6, AR at 4100, and Consolidated Appropriations Act, 2023, Pub. L. No. 117-328, § 3305, 136 Stat. 5832-34 (2022)). Moreover, the comments explained that the FDA had issued new guidance to OEMs to use TPMs to identify and mitigate cybersecurity vulnerabilities. *See id.* (citing MITA 2024 Cmt. at 6, AR at 4100, and FDA, *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, Guidance for Industry and FDA Staff* (Sept. 27, 2023), available at perma.cc/2YZR-XX55).

The Librarian did not ignore these new concerns. She sought updated guidance from the FDA, which concluded that despite the evolved cybersecurity landscape, the Exemption would not jeopardize the safety of medical devices. *See* 2024 FDA Letter, AR at 4594. These concerns were thus addressed and rejected clearly in the record.

The Librarian's 2021 and 2024 Rulemakings were thorough and procedurally sound, addressing all significant comments in a substantive and principled way.

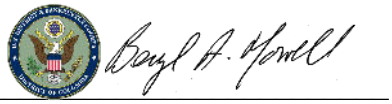
IV. CONCLUSION

The Exemption for medical devices and systems is consistent with copyright law and the DMCA and supported by the Librarian's thorough and well-reasoned explanations from the Eighth and Ninth Triennial Rulemaking procedures. The plaintiffs' arguments to the contrary, challenging both the substance of the Librarian's reasoning and her procedural thoroughness, all

fail. Consequently, plaintiffs' motion for summary judgment is denied, and defendants' cross-motion is granted.[14]

An order consistent with this Memorandum Opinion will be entered contemporaneously.

Date: July 21, 2025



BERYL A. HOWELL
United States District Judge

[14] Given that plaintiffs are not entitled to any relief, defendants' arguments about the appropriate scope of that relief, *see* Defs.' Opp'n at 36-38, are not addressed.