

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued May 15, 2026

Decided September 1, 2026

No. 25-5328

MEDICAL IMAGING & TECHNOLOGY ALLIANCE AND
ADVANCED MEDICAL TECHNOLOGY ASSOCIATION,
APPELLANTS

v.

LIBRARY OF CONGRESS AND TODD BLANCHE, IN HIS OFFICIAL
CAPACITY AS ACTING LIBRARIAN OF CONGRESS,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 1:22-cv-00499)

Michael B. Kimberly argued the cause and filed the briefs
for appellants.

Laura E. Myron, Attorney, U.S. Department of Justice,
argued the cause for appellees. With her on the brief were *Brett
A. Shumate*, Assistant Attorney General, and *Daniel Tenny*,
Attorney.

Before: MILLETT, CHILDS and PAN, *Circuit Judges*.

Opinion for the Court filed by *Circuit Judge* CHILDS.

CHILDS, *Circuit Judge*: In accordance with authority granted by Congress in the Digital Millennium Copyright Act (DMCA or the Act), the Librarian of Congress (Librarian) conducts a rulemaking every three years (triennial rulemaking) to consider requests for limited exemptions to the Act's copyright anticircumvention provision. *See* 17 U.S.C. § 1201(a)(1)(C). Appellants Advanced Medical Technology Association and Medical Imaging & Technology Alliance (together, Appellants) sued the Librarian and the Library of Congress (together, Appellees) challenging the Librarian's initial adoption and subsequent renewal of a medical device repair exemption. This exemption permits circumvention of technological protection measures (TPMs), allowing access to copyrighted "medical equipment computer programs and data files . . . that are used to support operation, mechanical, and electronic processes of the medical systems," JA628 (citation modified), for the sole purpose of the "diagnosis, maintenance, or repair" of a medical device, 37 C.F.R. § 201.40(b)(17). The district court denied Appellants' motion for summary judgment and granted summary judgment to Appellees, concluding that the medical device repair exemption was lawful under the DMCA. For the reasons explained below, we affirm the district court's decision.

I.

Both this court and the district court have fully recounted the background events giving rise to this litigation in several opinions. *See Med. Imaging & Tech. All. v. Libr. of Cong. (MITA I)*, No. 22-499, 2023 WL 2387760 (D.D.C. Mar. 7, 2023); *Med. Imaging & Tech. All. v. Libr. of Cong. (MITA II)*, 103 F.4th 830 (D.C. Cir. 2024); *Advanced Med. Tech. Ass'n v. Libr. of Cong. (MITA III)*, No. 22-499, 2025 WL 2029804 (D.D.C. July 21, 2025). We restate here only the information relevant to this appeal.

A.

1.

The Constitution grants Congress the power to provide copyright protection. *See* U.S. Const. art. I, § 8, cl. 8 (granting Congress the power “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries”). In accordance with this authority, Congress passed the Copyright Act of 1976, 17 U.S.C. § 101 *et seq.* The Copyright Act’s purpose, in broad terms, is “to increase and not to impede” creative and innovative activity while also ensuring creators “a fair return” for their contributions. *Harper & Row, Publishers, Inc. v. Nation Enters.*, 471 U.S. 539, 545–46 (1985) (explaining that (1) “copyright is intended to increase and not to impede the harvest of knowledge” and (2) “[t]he rights conferred by copyright are designed to assure contributors to the store of knowledge a fair return for their labors”). Through a bundle of exclusive rights, the Copyright Act protects “original works of authorship fixed in any tangible medium of expression, now known or later developed, from which they can be perceived, reproduced, or otherwise communicated, either directly or with the aid of a machine or device.” 17 U.S.C. § 102(a); *see also id.* §§ 101, 106; *Google LLC v. Oracle Am., Inc.*, 593 U.S. 1, 23 (2021) (“By defining computer programs in § 101, Congress chose to place this subject matter within the copyright regime.”). The Copyright Act remains the primary source of copyright law in the United States. *E.g., DeCarlo v. Archie Comic Publ’ns, Inc.*, 127 F. Supp. 2d 497, 505 (S.D.N.Y.), *aff’d*, 11 F. App’x 26 (2d Cir. 2001) (“Since the effective date of the Copyright Act of 1976, the exclusive source of rights arising from authorship of a work fixed in tangible form is that statute.”).

One limitation on copyright liability is fair use. 17 U.S.C. § 107 (providing that “fair use . . . is not an infringement of copyright”). Conceptually, the fair use doctrine permits certain types of otherwise infringing uses. It “permits and requires courts to avoid rigid application of the copyright statute when, on occasion, it would stifle the very creativity which that law is designed to foster.” *Campbell v. Acuff-Rose Music, Inc.*, 510 U.S. 569, 577 (1994) (citation modified) (quoting *Stewart v. Abend*, 495 U.S. 207, 236 (1990)). The statute identifies illustrative fair use purposes such as “criticism, comment, news reporting, teaching (including multiple copies for classroom use), scholarship, or research.” 17 U.S.C. § 107. Fair use operates as an affirmative defense to a claim of copyright infringement. See *Andy Warhol Found. for the Visual Arts, Inc. v. Goldsmith*, 598 U.S. 508, 526–27 (2023).

A fair use determination requires a case-by-case inquiry. *Harper & Row*, 471 U.S. at 549. Courts traditionally consider four non-exhaustive statutory factors in evaluating fair use:

(1) the purpose and character of the use, including whether [the] use is of a commercial nature or is for nonprofit educational purposes; (2) the nature of the copyrighted work; (3) the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and (4) the effect of the use upon the potential market for or value of the copyrighted work.

17 U.S.C. § 107.

In response to “the ease with which pirates could copy and distribute a copyrightable work in digital form,” Congress again utilized its copyright powers and passed the DMCA in 1998, which “backed with legal sanctions the efforts of copyright owners to protect their works from piracy behind digital walls such as encryption codes or password protections.” *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437, 458 (2007) (citation modified). “Those walls, also called [TPMs], limit access to and use of copyrighted work.” *Green v. U.S. Dep’t of Just.*, 111 F.4th 81, 89 (D.C. Cir. 2024). To protect TPMs, the DMCA contains an anticircumvention provision prohibiting a “person” from circumventing or overcoming a TPM which “effectively controls access to a” copyright-protected work. 17 U.S.C. § 1201(a)(1)(A).

However, “[t]he anticircumvention provision is subject to statutory and regulatory exemptions.” *Green*, 111 F.4th at 89. Critically, the DMCA authorizes the Librarian to issue limited three-year exemptions from the Act’s anticircumvention provision for persons “who are or are likely to be ‘adversely affected’ . . . in their ability to make noninfringing uses of copyrighted materials.” *Id.* at 90; *see also* 17 U.S.C. § 1201(a)(1)(C)–(D). The Librarian decides whether to grant an exemption by looking at an entire “class of copyrighted works,” not a single work. 17 U.S.C. § 1201(a)(1)(C). Additionally, the Librarian’s determination is prospective, looking ahead to the “succeeding 3-year period,” rather than focusing on assertedly infringing acts that have already occurred or will imminently occur. *Id.*

The Librarian grants exemptions by conducting triennial rulemakings and acting “upon the recommendation of the Register of Copyrights,” after the Register has “consult[ed]

with the Assistant Secretary for Communications and Information of the Department of Commerce.” 17 U.S.C. § 1201(a)(1)(C).¹ “The Register will recommend granting an exemption only when the preponderance of the evidence in the record shows that the conditions for granting an exemption have been met.” Exemption to Prohibition on Circumvention of Copyright Protection Systems for Access Control Technologies, 86 Fed. Reg. 59,627, 59,628 (Oct. 28, 2021) (citation modified). “The evidence must show that it is more likely than not that users of a copyrighted work will, in the

¹ Section 1201(a)(1)(C) provides:

During the 2-year period described in subparagraph (A), and during each succeeding 3-year period, the Librarian of Congress, upon the recommendation of the Register of Copyrights, who shall consult with the Assistant Secretary for Communications and Information of the Department of Commerce and report and comment on his or her views in making such recommendation, shall make the determination in a rulemaking proceeding for purposes of subparagraph (B) of whether persons who are users of a copyrighted work are, or are likely to be in the succeeding 3-year period, adversely affected by the prohibition under subparagraph (A) in their ability to make noninfringing uses under this title of a particular class of copyrighted works. In conducting such rulemaking, the Librarian shall examine—(i) the availability for use of copyrighted works; (ii) the availability for use of works for nonprofit archival, preservation, and educational purposes; (iii) the impact that the prohibition on the circumvention of technological measures applied to copyrighted works has on criticism, comment, news reporting, teaching, scholarship, or research; (iv) the effect of circumvention of technological measures on the market for or value of copyrighted works; and (v) such other factors as the Librarian considers appropriate.

succeeding three-year period, be adversely affected by the prohibition on circumvention in their ability to make noninfringing uses of a particular class of copyrighted works.” *Id.* (citation modified). The Register, and ultimately the Librarian, determine whether a given use is noninfringing by looking to the statutory fair-use factors previously detailed. *See* 17 U.S.C. § 107.

B.

The United States Copyright Office launched the eighth triennial rulemaking on June 22, 2020, and issued its notice of proposed rulemaking approximately four months later. *See* Exemptions to Permit Circumvention of Access Controls on Copyrighted Works, 85 Fed. Reg. 65,293, 65,293 (Oct. 15, 2020). The Copyright Office received many proposals for new exemptions to the DMCA’s anticircumvention provision from independent service organizations (ISOs). Because they “derive a ‘commercial benefit’ from medical equipment repair services,” JA627, these ISOs petitioned for (1) an exemption to circumvent “TPMs on software-enabled medical devices and systems for purposes of diagnosis, maintenance, and repair” and (2) “access to related data files stored on medical devices and systems, including manuals and servicing materials.” 86 Fed. Reg. at 59,635.

On October 19, 2021, the Register recommended that the Librarian grant “a new exemption allowing circumvention of TPMs restricting access to firmware and servicing materials on medical devices and systems for the purposes of diagnosis, maintenance, and repair.” JA651. In support of the recommendation for adopting the medical device repair exemption, the Register explained that the agency had “previously concluded that diagnosis and repair are likely to be transformative uses,” thus, “the first factor favors fair use.”

JA628. The Register then observed that the second factor also favors fair use because “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.” JA629. After giving the third factor “little weight . . . because the use is necessary to accomplish the transformative purposes of diagnosis, maintenance, and repair,” JA630, the Register decided that the fourth factor also favors fair use after “conclud[ing] that diagnosis, maintenance, and repair of medical devices and systems is unlikely to harm the market for the embedded software,” JA631. In summation, the Register considered the four statutory factors and determined that the proposed uses underlying the medical device repair exemption were “likely to be noninfringing fair uses.” JA631.

The Librarian accepted the Register’s recommendation, 86 Fed. Reg. at 59,637, and adopted the regulation in a final rule, *id.* at 59,627. The medical device repair exemption—which permits circumvention with respect to “[c]omputer programs that are contained in and control the functioning of a lawfully acquired medical device or system, and related data files, when circumvention is a necessary step to allow the diagnosis, maintenance, or repair of such a device or system”—was codified at 37 C.F.R. § 201.40(b)(15) (2021). *See also* 86 Fed. Reg. at 59,640.

C.

Appellants are trade associations representing manufacturers of various kinds of medical and digital devices. In February 2022, Appellants sued Appellees alleging that the Librarian violated the Administrative Procedure Act (APA), exceeded statutory authority, and exercised

unconstitutional rulemaking power in adopting the medical device repair exemption during the eighth triennial rulemaking. After Appellants and Appellees each moved for summary judgment, the district court ultimately granted Appellees' alternative motion to dismiss, concluding that (1) sovereign immunity barred the APA claims, *MITA I*, 2023 WL 2387760, at *9–11; (2) Appellants failed to plausibly allege how adoption of the medical device repair exemption was beyond the scope of the Librarian's designated powers, *id.* at *11–13; and (3) the Librarian's promulgation of rules under the DMCA was not an unconstitutional exercise of either legislative or executive authority, *id.* at *13–15. Appellants timely appealed in March 2023 and we subsequently reversed, holding that "DMCA rules are subject to the APA just like other copyright rules," and remanded for the district court "to assess the APA claims in the first instance." *MITA II*, 103 F.4th at 833.

Before we ruled in *MITA II*, the Copyright Office launched the ninth triennial rulemaking on June 8, 2023, and issued its notice of proposed rulemaking on October 19, 2023. Exemptions to Permit Circumvention of Access Controls on Copyrighted Works, 88 Fed. Reg. 72,013 (Oct. 19, 2023). Numerous entities petitioned for renewal of the medical device repair exemption. Appellants and others submitted opposition comments to the renewal. Of note, the opponents of the exemption argued that the United States Supreme Court's decision in *Andy Warhol Foundation for the Visual Arts v. Goldsmith* undermined the Librarian's rationale for adopting the medical device repair exemption. See JA1510; JA1514–17; JA1550–54; JA1559–60; JA1563–64. One opponent specified that in *Warhol*, the Court clarified that the use of a copyrighted work "for the same or highly similar purpose" as it was created "is non-transformative," an infringing use, "and not fair use under the Copyright Act." JA1510. A second one agreed opining that the medical device repair exemption failed

“the *Warhol* test” because the “original copyrighted work” and the “secondary use” “share[d] the *exact same purpose*.” JA1552.

On October 18, 2024, the Register recommended that the Librarian renew the medical device repair exemption. The Register considered the exemption opponents’ arguments regarding the applicability of other regulatory schemes and the *Warhol* decision. *See* JA810–12. Those arguments did not persuade the Register that “the Office’s analysis from the 2021 cycle” was now unsound. JA811. The Librarian accepted the Register’s renewal recommendation regarding the medical device repair exemption, Exemption to Prohibition on Circumvention of Copyright Protection Systems for Access Control Technologies, 89 Fed. Reg. 85,437, 85,445 (Oct. 28, 2024), and it was codified at 37 C.F.R. § 201.40(b)(17) (2024). *See also* 89 Fed. Reg. at 85,449.

On remand after *MITA II*, Appellants amended their complaint to allege only APA violations, adding allegations about the Librarian’s renewal of the medical device repair exemption in the ninth triennial rulemaking. Subsequently, both parties moved for summary judgment. The district court granted summary judgment in favor of Appellees and denied Appellants’ motion. Specifically, the district court found that the Librarian’s assessment of the medical device repair exemption was well reasoned and consistent with modern copyright law, particularly the fair-use doctrine. The district court rejected Appellants’ contention that the Librarian’s conclusions regarding the transformative nature of the ISOs’ use of copyrighted works was arbitrary or capricious. The district court further ruled that the Librarian’s analysis was consistent with the text and purpose of the DMCA and the 2021

and 2024 rulemakings had addressed all relevant comments. Appellants timely appealed.²

II.

Because the district court’s order “ended the litigation on the merits,” we have jurisdiction under 28 U.S.C. § 1291. *Budinich v. Becton Dickinson & Co.*, 486 U.S. 196, 199 (1988) (citation modified). We review the district court’s summary judgment decision *de novo* where it granted one motion and denied the other, and we review the Librarian’s decision for compliance with the APA. *Grossmont Hosp. Corp. v. Burwell*, 797 F.3d 1079, 1082 (D.C. Cir. 2015); *see also Insider Inc. v. Gen. Servs. Admin.*, 92 F.4th 1131, 1134 (D.C. Cir. 2024). We “will affirm summary judgment for the agency unless it violated the APA by taking action that is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” *Alignment Healthcare Inc. v. U.S. Dep’t of Health & Hum. Servs.*, 181 F.4th 1236, 1242 (D.C. Cir. 2026) (citation modified). “This standard examines whether the agency’s decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment.” *Id.* (citation modified). In conducting that review, we afford “no particular deference” to the district court’s review of an agency action under the APA. *NACS v. Bd. of Governors of*

² Soon after oral argument, the Copyright Office initiated the tenth triennial rulemaking. *See* Exemptions to Permit Circumvention of Access Controls on Copyrighted Works, 91 Fed. Reg. 34,795 (June 9, 2026) (setting August 24, 2026, as the deadline for submission of “written petitions for renewal of current exemptions,” and September 28, 2026, as the deadline for submission of “written comments in response to petitions for renewal” of current exemptions). The parties do not suggest that this ongoing rulemaking proceeding affects our resolution of this matter. Therefore, we need not address it.

Fed. Rsrv. Sys., 746 F.3d 474, 482 (D.C. Cir. 2014) (citation modified).

III.

Appellants' main argument on appeal is that the Librarian misapplied the statutory fair-use factors in adopting and renewing the medical device repair exemption. But this is not a copyright infringement case. Appellants bring claims for a violation of the APA, and that is how we must resolve this appeal. In that regard, Appellants assert that the record so poorly supports the Librarian's conclusion that the medical device repair exemption permits noninfringing use that the decision was "arbitrary, capricious, and not in accordance with law." Reply Br. 2. As such, the burden rests on Appellants to demonstrate that the Librarian's decision violates the Copyright Act or "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

After consideration of the Librarian's determination as to each of the four factors of the fair use analysis, we affirm the district court's determination that the Librarian's adoption of the medical device repair exemption was lawful, reasonable, and supported by "thorough and well-reasoned explanations from the Eighth and Ninth Triennial Rulemaking procedures." See JA1715.

Appellants argue that the primary purpose of the copyrighted software is repair and maintenance, and the Librarian erred in determining that the software is primarily for

clinical operational use. In both their challenge to the medical device repair exemption and the district court's grant of summary judgment, however, Appellants did not point to record evidence supporting this argument. The Librarian's decision, after all, creates an exemption to "medical equipment computer programs and data files . . . that are used to support operation, mechanical, and electronic processes of the medical systems," JA628 (citation modified). While that copyrighted material includes information relevant to the repair process, Appellants' argument turns centrally on the proposition that there is a distinct body of repair software independent from the clinical-operation software and that it occupies its own standalone market. Appellants, however, made no such record in the rulemaking process or before the district court. Nor have they shown that the Librarian's classification of the relevant software exemption was unreasoned or unsupported by the administrative record.

A.

We begin by assessing the Librarian's determination under the first fair-use factor, which concerns "the purpose and character of the use, including whether the use is of a commercial nature or is for nonprofit educational purposes." 17 U.S.C. § 107(1). "This factor considers the reasons for, and nature of, the copier's use of an original work." *Andy Warhol Found.*, 598 U.S. at 527–28. "The central question it asks is whether the new work merely supersedes the objects of the original creation . . . (supplanting the original), or instead adds something new, with a further purpose or different character." *Id.* at 528 (citation modified). While commerciality is a relevant element, it does not carry presumptive force against a finding of fair use. "[T]he more transformative the new work, the less will be the significance of other factors, like commercialism, that may weigh against a

finding of fair use.” *Campbell*, 510 U.S. at 579, 591; *see also Google*, 593 U.S. at 29 (explaining that a use is transformative if the copy adds “something new and important” (citing *Campbell*, 510 U.S. at 579)). However, “[i]f an original work and a secondary use share the same or highly similar purposes, and the secondary use is of a commercial nature, the first factor is likely to weigh against fair use, absent some other justification for copying.” *Andy Warhol Found.*, 598 U.S. at 532–33.

Appellants claim that ISOs use manufacturer-created repair software and data files in a commercially substitutive manner, thereby infringing Appellants’ copyrights. They further contend that, because the software’s purpose is to repair the machines and the ISOs’ purpose is *also* to repair them, the ISOs’ work is not transformative and is commercially substitutive of Appellants’ work. They state that “[a]ll third-party servicers do is put the works at issue to their intended uses in a commercial application,” Reply Br. 11, and claim that ISOs profit from the fees for the labor they perform in the same manner a licensed operator would.

Appellants’ challenge to the Librarian’s determination of transformativeness is rooted in their argument about the scope of the medical device repair exemption. Again, Appellants’ challenge relies on their argument that the copyrighted works at issue are separately licensed and created for the primary purpose of repair, and that the Librarian did not adequately assess that distinction in making its determination.

That argument is misplaced. The Librarian reasonably determined that the purpose and character of the secondary repair use favored fair use. In adopting the Register’s 2021 recommendation, the Librarian understood that ISOs requested an exemption for “medical equipment computer programs and

data files . . . that are used to support operation, mechanical, and electronic processes of the medical systems.” JA628 (citation modified); *see also* 86 Fed. Reg. at 59,637

To be sure, the Librarian did not address the proposed distinction between operating works and repair works. But that is because Appellants did not demonstrate before the agency the existence of this distinction that it now presses. At most, comments before the agency discuss the possible distinction only in vague terms and provide no supporting evidence. *See, e.g.*, JA1356, JA1361. In fact, in the Ninth Rulemaking, one of Appellants argued that both the original and secondary uses of the work were the same: “operating a medical device or system.” JA1563. The other argued that both uses “share the *exact same purpose*—to enable the device[s] to function.” JA1552. So the record amply supported the Librarian’s finding in the Ninth Rulemaking that “the original purpose of the software is to operate a device that functions as designed”—not to repair devices. JA812.

Moreover, Appellants were fully aware that the medical device repair exemption’s “proponents were clear that they sought [the] exemption for diagnostic software and data files” and this repair use is distinct from the general operational software. Appellants’ Br. 30 (citation modified).

As for transformativeness, ISOs put clinical operation software to a new use when it is used as a tool for repairing medical devices, transforming the machines from nonfunctional to functional devices—a use that is markedly different from the original, manufacturer-intended purpose. Since the primary use of the clinical operation software by ISOs was fundamentally different from the primary purpose of Appellants, the Librarian found that the ISOs’ use is not a substitutive use, but transformative.

Appellants argue that the ISOs' use of clinical operation software to repair devices results in a commercial benefit. But as the Register recommended and the Librarian agreed, that secondary use would not "commercialize *the embedded copyrighted [clinical operation] software* and other servicing materials" themselves. JA628 (emphasis added). The mere fact that a secondary use was primarily commercial in purpose does not presumptively preclude that purpose from favoring fair use. *See Andy Warhol Found.*, 598 U.S. at 531. ISOs are neither creating copies of the embedded software and reselling those copies for a profit, nor using those copies to create compatible hardware or identical software of their own and selling it to other manufacturers. The object of the transaction, which lends the use its commercial nature, is instead the labor and technical expertise of the operators. Appellants' analogy to selling tickets to a screening of an illegally downloaded film misses the mark. When a party illegally copies a film and sells tickets to a screening, it has not restored an otherwise nonfunctional or incomplete film to a viewable state. Rather, they have simply reproduced and commercialized a copy of the protected work *itself*.

Appellants' focus on the money exchanged for the repair service is not dispositive. In the 2021 recommendation during the eighth triennial rulemaking, the Register directly addressed this concern observing that Appellants "overstate[d] the significance of the commercial purpose element to the fair use analysis." JA628. In that same analysis, the Register also supported the distinction in purpose by citing earlier analogous exemptions and comments on the initial proposals and replies. *Id.* In short, calling the Register's analysis, which the Librarian adopted, an "illogical *ipse dixit*," Appellants' Br. 33, is simply a claim unsupported by the record. Appellants'

disagreement with the Librarian's reasoning does not render the conclusions at issue arbitrary or capricious.

Accordingly, on this record, the Librarian's conclusion that the ISOs' use of clinical operation software is fundamentally transformative in nature and weighs in favor of a finding of fair use did not violate the APA.

B.

Next, we turn to the Librarian's assessment under the second statutory fair-use factor, "the nature of the copyrighted work." 17 U.S.C. § 107(2). The second statutory fair use "factor calls for recognition that some works are closer to the core of intended copyright protection than others, with the consequence that fair use is more difficult to establish when the former works are copied." *Campbell*, 510 U.S. at 586. While not inherently dispositive, courts have held that some works "are closer to the core of intended copyright protection than others." *Campbell*, 510 U.S. at 586. Primarily factual works, by contrast, are more likely to succeed in establishing fair use. *Id.*

Here, both parties acknowledge that the computer programs at issue are functional works which serve to "enable users to control and understand the operation of the equipment." JA629; *see also* Appellants' Br. 52; Appellees' Br. 36. Both the clinical operation software and the repair software are inherently utilitarian rather than artistic and thus beyond the "core of intended copyright." *Campbell*, 510 U.S. at 586. Furthermore, the clinical operation software is not used for its "expressive qualities, but rather for its functional and informational aspects that enable users to control and understand the operation of the equipment." JA629. The Librarian adopted the Register's finding that the specific works

here “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.” JA629; 86 Fed. Reg. at 59,637. Appellants have not shown any error in this factual finding.

Appellants, however, contend that the commercial purpose of the software, and their arguments regarding a lack of transformativeness, should turn the second factor against fair use. *See* Appellants’ Br. 54. Yet this contention incorrectly assumes that the commerciality of the use defeats the possibility that the use may be transformative due to its effects on the market for maintenance and repair services. We know that the commerciality of a use is not dispositive of its purpose. *See Andy Warhol Found.*, 598 U.S. at 531. Additionally, we have already concluded that the Librarian did not err in determining that the use was transformative based on the record before the agency. *See supra* Section III. Similarly, in this rulemaking context, the Librarian did not err by following the general proposition that the software is functional and therefore favors fair use.

C.

Appellants’ challenge to the Librarian’s assessment under the third statutory factor likewise fails. This fair-use factor asks whether “the amount and substantiality of the portion used in relation to the copyrighted work as a whole,” 17 U.S.C. § 107(3), “are reasonable in relation to the purpose of the copying,” *Campbell*, 510 U.S. at 586. When assessing “the amount and substantiality of the portion used,” 17 U.S.C. § 107(3), the relevant analysis is the substance of the copy relative to the original work, not the infringing work, *Harper & Row*, 471 U.S. at 565. Put more plainly, “a taking may not be excused merely because it is insubstantial with respect to the

infringing work.” *Harper & Row*, 471 U.S. at 565. The Supreme Court has previously held that the third factor tends to favor fair use when the amount and substantiality are “tethered to a valid, and transformative, purpose.” *Google*, 593 U.S. at 34.

Appellants argue that the third factor turns against fair use because the copy uses the entire work. *See* Appellants’ Br. 55. But even the copying of the entirety of a work can be justified if the amount and portion copied is “central to a copier’s valid purpose.” *Google*, 593 U.S. at 33. Appellants make no developed argument in their briefing that the amount copied by the ISOs is too much relative to the purpose of repair. Appellants’ argument instead once again rests on mischaracterizing the scope of the medical device repair exemption. As stated previously, the Librarian did not err in finding that the copyrighted material at issue is clinical operation software and the exemption is confined to temporary access needed to repair those systems. *See supra* Section III. Because Appellants’ arguments presume that the exemption references a distinct and independent body of purely repair software, Appellants have offered no argument or analysis of the third factor in the context of clinical operation software that the Librarian, the Register, and the administrative record addressed. Additionally, the Register and Librarian accorded “little weight” to this factor. JA630; 86 Fed. Reg. at 59,637. Given the lack of meaningful alternative arguments, and the little weight accorded to this factor in the Librarian’s decision, the Appellants have not demonstrated that the Librarian erred in finding that the third factor favors fair use.

D.

As to the Librarian’s assessment of the fourth fair-use factor, we look to “the effect of the use upon the potential

market for or value of the copyrighted work.” 17 U.S.C. § 107(4). We “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.” *Campbell*, 510 U.S. at 590 (citation modified). Appellants claim that ISOs take market share away from higher-cost manufacturers and destroy the licensing market for the protected software. However, we have long recognized that copyright protections are not absolute. There are myriad exceptions in which unauthorized uses or reproductions of a given work do not infringe upon the rights of the copyright holder. But a use that usurps market demand for the original work is ordinarily an infringement. *Harper & Row*, 471 U.S. at 566–68. Note that this factor of fair use is concerned with market harm, specifically, to the original work and its derivatives. *Id.* at 568.

The Librarian adopted the Register’s view that the medical device repair exemption was “unlikely to harm the market for the embedded software,” JA631, 86 Fed. Reg. at 59,637, because “medical device and system software and data files are sold with the equipment and have no independent value separate from the devices,” JA630.

Appellants disagree, claiming market harm based upon loss of revenue from copiers, healthcare providers, and higher-cost manufacturer-affiliated technicians. But Appellants did not introduce evidence into the administrative record to prove their claims. In fact, one of the Appellants told the agency that “there is no independent market for the medical imaging device software beyond the devices themselves.” JA646 n.1261.

Again, the Librarian viewed the primary purpose of the software at issue was not facilitating maintenance and repair, but rather the operation of the original device wholesale. *See* JA811–12 (explaining that “repair supports—rather than displaces—the purpose of the embedded programs that control the device” (citation modified)). Since “[a] secondary use that is more different in purpose and character is less likely to usurp demand for the original work or its derivatives,” *Andy Warhol Found.*, 598 U.S. at 536 n.12, the Librarian’s determination points the fourth factor towards fair use. This conclusion is further reinforced when one considers the administrative record and the nature of the market effects alleged by Appellants. Appellants point to competition from ISOs in the repair services market as evidence that the fourth factor weighs against fair use. Now, while it is certainly the case that the medical device repair exemption enables competition in the maintenance and repair services market, that does not itself demonstrate an adverse effect on the market for the original device or its clinical operation software, which is the protected work. Courts have previously highlighted that not all lost revenue constitutes the type of harm copyright is intended to protect against. *See Campbell*, 510 U.S. at 592 (concluding that market harm to a work or its derivatives caused by a critical parody of the original can still be protected by fair use).

Here, the harm alleged by Appellants is the type that typically falls outside the realm of copyright protection because the secondary use cannot usurp or replace the market for the original. Recall that, per the Register’s 2021 recommendation, ISOs neither retain copies nor create competing works using those copies because, even with the medical device repair exemption, users would be prohibited from “reproduc[ing] and retain[ing] additional copies of any copyrighted materials for use with other devices.” JA631. The ISOs’ purpose is to “restore a medical device or system’s functionality, not to

commercialize the embedded copyrighted software and other servicing materials.” JA628. Because ISOs neither directly sell nor license the protected clinical operation software, nor use it to prepare commercialized derivative works such as their own machinery, it cannot be said to usurp the market for the *original* protected work. There is little in the administrative record to indicate that the exemption and subsequent repair services provided by ISOs have harmed the market for sophisticated medical technology. Appellants’ concerns are focused entirely on the secondary market of repair and maintenance services, services that require human input and expertise that the Librarian previously deemed transformative. Because the ISOs’ use does not replace or substitute for the original work, we agree with the district court that the Librarian did not err in finding that the fourth factor favors fair use.

In sum, we uphold the Librarian’s medical device repair exemption as consistent with the law, reasoned, and supported by the record. Accordingly, we affirm the district court’s grant of summary judgment to the Librarian and Library of Congress.

So ordered.