Med. Imaging & Tech. All. v. Libr. of Cong.
189 F.4th 1150 (D.C. Cir. 2026)

Year	2026
Court	United States Court of Appeals for the District of Columbia
Key Facts	This case concerns determinations made by the Librarian of Congress, based on recommendations from the Register of Copyrights, that using certain copyrighted works on medical devices to repair those devices is likely fair use. These determinations were made in the context of a triennial rulemaking to consider requests for temporary exemptions to section 1201 of the Digital Millenium Copyright Act ("DMCA"), which prohibits circumventing a "digital lock" (called a "technological protection measure" or "TPM") that controls access to a copyrighted work. In the eighth triennial rulemaking, two independent service organizations ("ISOs") petitioned for an exemption to circumvent TPMs to access medical device software and electronic service manuals for the purposes of diagnosis, maintenance, and repair. In October 2021, after analyzing the fair use factors (as well as five statutory factors to assess whether a use is or is likely to be "adversely affected" by section 1201), the Register recommended and the Librarian adopted a new "medical device repair exemption" that pertains 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." Plaintiffs Medical Imaging & Technology Alliance and Advanced Medical Technology Association ("Appellants") are "trade associations representing manufacturers of various kinds of medical and digital devices[]" that opposed the proposed exemption during the rulemaking and then sued the Library of Congress ("LOC"), arguing that the Librarian's decision violated the Administrative Procedures Act ("APA"). In 2024, after a prior D.C. Circuit opinion concluded that the APA applied to the LOC in this case and remanded to the district court to consider the APA claims, the Librarian renewed the medical device repair exemption—again opposed by Appellants—during the ninth triennial rulemaking. Appellants amended their claims to challenge the renewed exemption and both parties moved for summary judgment. The district court granted the LOC's motion, concluding 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." Appellants again appealed.
Issue	Whether using copyrighted software and data files that are contained in and control the functioning of medical devices to diagnose, maintain, and repair those devices constitutes fair use.
Holding	At the outset, the panel noted that "this is not a copyright infringement case" and its appellate review concerned whether the fair use analysis for the medical device repair exemption in the 1201 rulemakings violated the APA. The court observed that Appellants' argument that the "primary purpose of the copyrighted software is repair and maintenance" relies 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," but noted that they "made no such record in the rulemaking process or before the district court." On the first factor, the purpose and character of the use, the panel agreed with the district court's finding that the Librarian's transformativeness determination did not violate the APA. The court rejected Appellants' contention that the repair uses were substitutive, concluding that their assertion that "the copyrighted works at issue are separately licensed and created for the primary purpose of repair" was "misplaced" and unsupported by the administrative record. Rather, the court agreed with the determination that ISOs' secondary use was "fundamentally transformative" because

	it "put[s] 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." Regarding commerciality, the panel found that, even though repair services were commercial, ISOs did not "commercialize *the embedded copyrighted* [*clinical operation*] *software* and other servicing materials." The court explained that ISOs neither resold copies of the software nor used it to create compatible hardware or software and "[t]he object of the transaction, which lends the use its commercial nature, is instead the labor and technical expertise of the operators." Regarding the second factor, the nature of the copyrighted work, the court concluded that the Librarian's finding that this factor favored fair use was not erroneous. Both parties acknowledged the software was functional because "[b]oth the clinical operation software and the repair software are inherently utilitarian rather than artistic and thus beyond the 'core of intended copyright.'" And the Librarian did not err in finding that the works were used for their functional and informational aspects—that is, to understand the equipment for the purpose of repairing it—rather than for their expressive qualities. Next, the panel agreed that the Librarian did not err when determining the third factor, the amount and substantiality of the portion used in relation to the copyrighted work, favored fair use. Although the use involved copying the entire work, the court reasoned that Appellants did not prove that the amount copied was "too much relative to the purpose of repair" and its "argument instead once again rests on mischaracterizing the scope of the medical device repair exemption." The panel further noted that the Librarian appropriately afforded little weight to this factor. Finally, the court agreed that the fourth factor, the effect upon the potential market for or value of the original work, pointed towards fair use because the Librarian properly determined "that the medical device repair exemption was 'unlikely to harm the market for the embedded software,' . . . because 'medical device and system software and data files are sold with the equipment and have no independent value separate from the devices[.]'" The court rejected Appellants' market harm argument that pointed to increased competition in the repair services market, observing that "the primary purpose of the software at issue was not facilitating maintenance and repair, but rather the operation of the original device wholesale[,]" and "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." The panel concluded that using medical device software to fix a device's functionality, not to sell, license, or create derivatives of the underlying software, "cannot be said to usurp the market for the *original* protected work" and "[t]here 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." Accordingly, the court affirmed 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.'"
Tags	Computer Program
Outcome	Fair use found

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