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COMMENTS OF THE MEDICAL IMAGING AND TECHNOLOGY ALLIANCE IN REPONSE TO SECTION 1201 RENEWAL PETITION REGARDING MEDICAL DEVICES

As the leading trade association representing the manufacturers of medical imaging equipment, contrast agents, radiopharmaceuticals, and focused ultrasound devices, the Medical Imaging & Technology Alliance (MITA) hereby opposes the petitions to renew the 2021 exemption governing "Computer programs that control medical devices or systems, and related data files, for diagnosis, maintenance, or repair of the device or system" (the "2021 Exemption"). MITA submits these comments in response to the request for comments published by the Library of Congress in the Federal Register at 88 FR 37,486, *Exemptions To Permit Circumvention of Access Controls on Copyrighted Works*, Docket No. 2023-5.

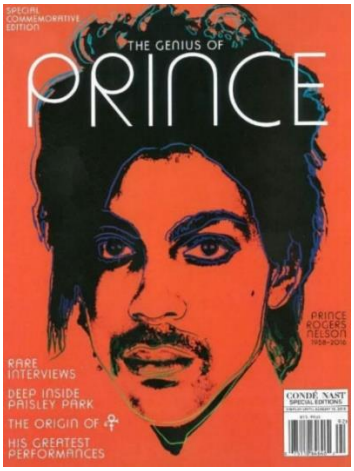
Developments in the law regarding copyright fair use undermine the Librarian's earlier (and unsupported) conclusion that fair use supports the 2021 Exemption. Legal developments from the U.S. Supreme Court, Congress, and the FDA undermine the legal foundation for the Librarian's 2021 Exemption and do not support exemption renewal.

Moreover, the patient safety risks remain just a serious today as they did during the earlier rulemaking. MITA's earlier comments[1] submitted during the previous rulemaking regarding patient safety risks and other concerns with the exemption are hereby incorporated by reference. In brief, medical devices are regulated by the U.S. Food and Drug Administration (FDA) *except when the device is being repaired by an independent service operator (ISO)*. These unregulated ISOs are not monitored by the FDA, nor are they required to have quality, safety, or regulatory controls in place to ensure that they return the device to safe and effective condition after servicing. The original equipment manufacturers, however, must register with the FDA, implement and maintain a quality management system to ensure consistent and controlled servicing processes, and file reports of device malfunctions involving injury or potential injury.

I. The U.S. Supreme Court Has Foreclosed the Librarian's Fair Use Reasoning

The U.S. Supreme Court recently decided *Andy Warhol Foundation for the Visual Arts v. Goldsmith* (No. 21-869, May 18, 2023). That case undermines the Librarian's fair use analysis in the 2021 Exemption and removes any doubt that the copying of medical imaging device software by ISOs to provide commercial repair and maintenance services is not fair use.

The *Warhol* decision addressed the scope of fair use in a case involving a photograph of the late musician known as Prince. The photograph was taken by independent photographer Lynn Goldsmith. Years later, the Andy Warhol Foundation used that photograph without Goldsmith's permission to generate a colorized and stylized rendering of the photograph. The Warhol Foundation sold the rendered photograph to Vanity Fair magazine for $10,000. Vanity Fair then used the rendering as a magazine cover to memorialize Prince after his death in 2016. The original photograph is shown below left; the rendered photograph as it appeared on the magazine cover appears below right.



[1]https://www.copyright.gov/1201/2021/comments/opposition/Class_12_Opp'n_Medical%20Imaging%20&%20Technology%20Alliance.pdf

The Supreme Court's ruling and reasoning in the *Warhol* case eviscerates the legal foundation for the Librarian's fair use analysis in the 2021 Exemption. The Digital Millennium Copyright Act (DMCA) authorizes the Librarian to promulgate exemptions to the DMCA's general anti-circumvention restriction only when the restriction would suppress "noninfringing uses . . . of a particular class of copyrighted works." 17 U.S.C. § 1201(a)(1)(C). Congress has delineated four factors for analyzing fair use. The first factor is the "purpose and character of the use, including whether such use is of a commercial nature." 17 U.S.C. § 107(1). In *Warhol*, the Court explained:

> This factor considers the reasons for, and nature of, the copier's use of an original work. ***The "central" question it asks is "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."*** In that way, the first factor relates to the problem of substitution—copyright's bête noire. ***The use of an original work to achieve a purpose that is the same as, or highly similar to, that of the original work is more likely to substitute for, or "'supplan[t],'" the work***.

Warhol, slip op. at 15 (emphasis added). The Court elaborated:

> Consider the "purposes" listed in the preamble paragraph of §107: "criticism, comment, news reporting, teaching . . . , scholarship, or research." Although the examples given are "'illustrative and not limitative,'" they reflect "the sorts of copying that courts and Congress most commonly ha[ve] found to be fair uses," and so may guide the first factor inquiry. *Campbell*, 510 U. S., at 577–578 (quoting §101). As the Court of Appeals observed, the "examples are easily understood," as they contemplate the use of an original work to "***serv[e] a manifestly different purpose from the [work] itself.***" 11 F. 4th, at 37. Criticism of a work, for instance, ordinarily does not supersede the objects of, or supplant, the work. ***Rather, it uses the work to serve a distinct end***.
>
> Not every instance will be clear cut, however. Whether a use shares the purpose or character of an original work, or instead has a further purpose or different character, is a matter of degree. Most copying has some further purpose, in the sense that copying is socially useful ex post. Many secondary works add something new. That alone does not render such uses fair. ***Rather, the first factor (which is just one factor in a larger analysis) asks "whether and to what extent" the use at issue has a purpose or character different from the original***. *Campbell*, 510 U. S., at 579

> (emphasis added). ***The larger the difference, the more likely the first factor weighs in favor of fair use. The smaller the difference, the less likely***.

Warhol, slip op. at 18 (emphasis added). The Court concluded with a distillation of its reasoning and an articulation of a new test for fair use:

> In sum, the first fair use factor considers ***whether the use of a copyrighted work has a further purpose or different character***, which is a matter of degree, and the degree of difference must be balanced against the commercial nature of the use. ***If 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.

Warhol, slip op. at 19-20 (emphasis added). Applying these factors, the Supreme Court concluded that the two photographs shared substantially the same commercial purpose, and that the Warhol Foundation's use of Goldsmith's photo was not fair use.

The 2021 Exemption also fails the *Warhol* test. The use of the copyrighted work (the medical device software) by third-party ISOs has exactly the same "purpose and character" as the original copyrighted work: enabling the functionality of the medical device. The "original work" (the device software before the ISO repair) and the "secondary use" (the exact same device software after the ISO repair) share the *exact same purpose*—to enable the device to function.

In support of the 2021 Exemption, the Librarian concluded that the ISOs' use of the software was "likely transformative." It was not. A transformative use of a copyrighted work is one that adds "new expression, meaning or message" by altering the content, context, or presentation of the work. *Google*, 141 S. Ct. at 1202. It asks "whether the copier's use adds something new, with a further purpose or different character," thus "altering the copyrighted work" with some new and different expression. *Id*.

The ISOs' proposed uses do not meet that definition in any conceivable respect; they "simply commandeer" the copyright holder's "software and us[e] it for the very purpose for which, and in precisely the manner in which, it was designed to be used." *Triad Systems*, 64 F.3d at 1337. In support of the 2021 Exemption, the ISOs themselves expressly disclaimed transformative use, explaining in their petitions that they did "not seek an exemption to modify medical devices or systems, or their software," in any way. *Register's Recommendation* 208. They wished only to copy the software and use it precisely as it was designed, angling to avoid FDA regulations. That is not a "fair" use.

The copyrighted work is not transformed—*at all*—during or after the maintenance or repair work. The ISOs specifically disclaimed any request for transformative use because such transformation would constitute "remanufacturing" under FDA regulations. The Librarian in the

2021 Exemption improperly conflated the medical device's *operational* restoration with the transformation of the copyrighted work itself. The copyrighted work is the device software. Repair or maintenance by an ISO does not transform the device software. The fact that the medical *device* was, in a loose sense, "transformed" from non-functional to functional as a result of the ISO accessing and copying the device *software* does not mean that the actual copyrighted work (the software) was transformed. It was not.

In concluding otherwise, the Librarian explained that she had "previously concluded that diagnosis and repair are likely to be transformative uses," pointing to prior rulemakings concerning exemptions for the service and repair of consumer products like cell phones and game consoles. But those rulemakings concerned uses that everyone agreed *were* transformative. In particular, the 2015 rulemaking cited in the Register's recommendation concerned "diagnosis, *modification*, and repair" of electronic control units in automobiles. The Librarian thus observed in 2015 that "copying the work" embedded in automobile ECUs would often lead to "creat[ing] new applications" and "modification of ECU computer programs" to allow new modes of "interoperation" among auto parts. She concluded, therefore, that "at least some of the proposed uses of ECU computer programs are likely to be transformative." Later, in the 2018 rulemaking, the Librarian cited to its 2015 analysis, but without acknowledging this crucial factor.

Beyond the entirely non-transformative nature of the use of the copyrighted work, the ISO's use of the medical device software is purely commercial. There is no debate that an ISO's use of device software for maintenance services is "entirely commercial in nature." *Triad Systems v. Southeastern Express*, 64 F.3d 1330, 1337 (9th Cir. 1995) (holding that using OEM software for maintenance is not fair use); *accord Advanced Computer Services of Michigan v. MAI Systems*, 845 F. Supp. 356, 364-66 (E.D. Va. 1994) (same). Such commercial use "tends to weigh against a finding of fair use" because "the user stands to profit from exploitation of the copyrighted material without paying the customary price." *Harper & Row Publishers, Inc. v. Nation Enterprises*, 471 U.S. 539, 562 (1985).

In the 2021 Exemption, the Librarian brushed aside the purely commercial nature of the ISOs' intended use, stating without elaboration that their plan to compete with OEMs for maintenance contracts "is not fatal to [the] fair use determination." While true that commercial use is not singularly dispositive of a fair-use assertion, it weighs strongly against fair use when the user acts with "*the intended purpose* of supplanting the copyright holder's commercially valuable right." *Harper & Row*, 471 U.S. at 562.

The *Warhol* case strongly reinforces that conclusion. Just as a magazine publisher's commercial use of a stylized photograph of a famous musician supplants the purpose of and displaces the use of the original photograph of that musician, so too does an ISO's use of medical imaging device software to provide commercial repair and maintenance services displace the right of OEMs to use their copyrighted software for the exact same purpose. The relevant use of the copyrighted works by OEMs is *diagnosis, maintenance, and repair of medical imaging equipment*; the relevant use of the copyrighted works by the ISOs is also for *diagnosis, maintenance, and repair of the equipment*. They are precisely the same. "A use that shares the

purpose of a copyrighted work" like this will merely "provide the public with a substantial substitute for matter protected by the copyright owner's interests in the original work or derivatives of it, which undermines the goal of copyright." *Warhol*, Slip. Op. at 19 (cleaned up).

II. Congressional and FDA Action Further Undermine the Renewal Petitions

Since the Librarian implemented the 2021 Exemption, Congress and the FDA have announced new policies on medical device cybersecurity that directly conflict with the 2021 Exemption. Specifically, FDA issued draft guidance in April 2022[2] that, when finalized, will create more stringent premarket expectations for medical device submission sponsors. Further, on December 29, 2022, the Consolidated Appropriations Act, 2023 was signed into law. Section 3305, "Ensuring Cybersecurity of Medical Devices," amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding section 524B, Ensuring Cybersecurity of Devices. This new law creates new cybersecurity requirements for medical device manufacturers that may be impeded by the hacking allowed under the exemption.

III. Conclusion

Developments in the law regarding copyright fair use undermine renewal of the 2021 Exemption. The *Warhol* case makes clear that commercial copying for the same commercial purpose fails the fair use test. That is exactly what the 2021 Exemption allows. The patient safety risks from unregulated and unmonitored ISO repairs are just as serious today as when the original exemption was proposed and issued in 2021. Moreover, actions by Congress and the FDA reinforce the importance of cybersecurity protections, which the 2021 Exemption undermines by legalizing hacking into lifesaving medical devices. For these reasons, the Librarian should not renew the 2021 Exemption.

[2] https://www.fda.gov/media/119933/download#page=44