UNITED STATES COPYRIGHT OFFICE

Long Comment Regarding a Proposed Exemption Under 17 U.S.C. § 1201

Please submit a separate comment for each proposed class.

NOTE: This form must be used in all three rounds of comments by all commenters not submitting short-form comments directly through regulations.gov, whether the commenter is supporting, opposing, or merely providing pertinent information about a proposed exemption.

When commenting on a proposed expansion to an existing exemption, you should focus your comments only on those issues relevant to the proposed expansion.

[ ] Check here if multimedia evidence is being provided in connection with this comment

Commenters can provide relevant multimedia evidence to support their arguments. Please note that such evidence must be separately submitted in conformity with the Office's instructions for submitting multimedia evidence, available on the Copyright Office website at https://www.copyright.gov/1201/2021.

ITEM A. COMMENTER INFORMATION

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ITEM B. PROPOSED CLASS ADDRESSED

Class 12: Computer Programs—Repair, and, in particular, the subset of Electronic Servicing Materials for Diagnosis, Maintenance, Repair of Medical Equipment

The Librarian of Congress is requested to exempt from the anti-circumvention provision of the Digital Millennium Copyright Act (17 U.S.C. § 1201) ("DMCA"), the circumvention of technological measures (also referred to herein as technological protective measures ("TPMs"))[1] undertaken by or on behalf of the owners or lessees of the medical systems and devices, for the purpose of accessing and using medical equipment servicing materials in the form of computer programs and data files (including databases and manuals) that are necessary for servicing (diagnosis, repair, and maintenance) of the medical devices and systems, thereby ensuring proper operation and compliance with manufacturer and governmental specifications; and where such circumvention does not constitute a violation of any other applicable law.

This exemption will allow owners and lessees of medical systems and medical devices, and their authorized agents, to access and use the servicing materials and perform servicing activities that are essential to the repair, diagnosis, and maintenance of their own medical equipment, without the threat of legal action should the need arise to actually or allegedly circumvent TPMs. This exemption will also alleviate the unintended consequences of the application of copyright law enacted for developers of software applications for stand-alone computers, to specialty medical equipment integrated with software.

ITEM C. REPLY COMMENT

I. Introduction

The Period 2 comments by Philips, MITA, and AdvaMed (hereinafter, collectively, "OEM Commenters") are the only comments filed in direct opposition to Transtate's (and Summit Imaging's) comments in support of an exemption under the anti-circumvention provisions of the DMCA for accessing medical device electronic servicing materials.[2,3] All three comments actually support the need for an exemption. Critically, the comments focus not on the purpose of the DMCA, but rather underscore that (a) original equipment manufacturers ("OEMs") believe that they are entitled to be the arbiters of who, if any one at all, gets to service their medical

[1] In using the terms "technological protective measure" and "TPM," Petitioner does not admit or concede that the technological measures discussed herein meet the definition of a "technological measure" that "effectively controls access to a protected work," as defined in 17 USC § 1201(a)(3)(B).

[2] "Transtate" refers to Petitioner Transtate Equipment Company, Inc. d/b/a Avante Diagnostic Imaging.
"Summit Imaging" refers to Petitioner Summit Imaging, Inc.
"Philips" refers to Opponent Philips North America LLC.
"MITA" refers to Opponent Medical Imaging & Technology Alliance.
"AdvaMed" refers to Opponent Advanced Medical Technology Association.

[3] "Electronic service materials" are defined in Transtate's Period 1 comments at 5 as "computer programs or modules thereof, electronic data files, including databases, and electronic manuals"

devices, as well as when, and under what conditions, and (b) the purpose of the OEMs' TPMs is to allow the OEMs to be the arbiters.

There is no dispute that the electronic servicing materials embedded or stored on medical devices and hidden behind TPMs include uncopyrightable (and hence unprotected) materials and works subject to fair use.[4] Even Philips acknowledges that it is obligated to make electronic service materials available for what it calls "basic servicing of Philips medical imaging systems,"[5] yet hides them behind TPMs, and thus, they are not available unless one obtains an Integrated Security Tool ("IST") key, at undue expense and with other burdens.[6]

To be clearer, Transtate's petition and Period 1 comments distinguish between two types of electronic servicing materials.[7] The **necessary electronic service materials** are those necessary for servicing (diagnosis, repair, and maintenance) of the medical devices and systems, **thereby ensuring proper operation and compliance with manufacturer and governmental specifications**.[8] The **unnecessary electronic service materials** are those **specialized materials OEMs include for their own benefit**. Transtate is seeking for all lawful possessors of medical devices and third party servicers working on behalf of the lawful possessors to be relieved of the DMCA guillotine should the need arise to circumvent the TPMs to access the necessary electronic service materials.[9] Further, no one is seeking access to remanufacture or modify the

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[4] Petitioner does not admit that any particular work is "protected" as that term is used in the DMCA, or that any particular work enjoys enforceable rights.

[5] Philips Period 2 comments at 4.

[6] The FDA mandates that Assembly, Installation, Adjustment, and Testing ("AIAT") information be made available "at a cost not to exceed the cost of publication and distribution." 21 U.S.C. § 1020.30(g). In its 2003 Guidance, the FDA elaborated:

> The agency has explained that manufacturers may charge for the cost of producing each additional package or unit of instructions. The charge can incorporate factors such as the cost of paper, labor, use of a copying machine, or other costs associated with each package the manufacturer provides under the performance standard. This principle should govern the calculation of the costs for all information subject to disclosure, whether printed, encoded in software, or any other format. For software, recoverable charges equivalent to printed materials would include such factors as the cost of the technical labor of producing such additional package or unit, computer disks, and packaging materials used to produce each additional unit of software. Using a reasonable set of factors should govern the calculation of the costs for any materials that are provided. *See* Ex. 28

Despite this, there are financial burdens far greater than the cost of "publication and distribution" placed on lawful possessors and third-party assistants by OEMs in order to access even its "basic" Level 0 access keys. *See*, declarations of Michael Spencer (Ex. 3 at ¶ 8), Abigail Lane Savage (Ex. 7 at ¶7),and Jacqueline Dickson (attached in Philips Period 2 comments at ¶¶ 7-9).

[7] Transtate Period 1 comments at 1-2.

[8] Maintenance and repair are similarly defined at 17 USC §§ 117(d)(1) and (2) as follows:

> (1) the "maintenance" of a machine is the servicing of the machine in order to make it work in accordance with its original specifications and any changes to those specifications authorized for that machine; and
> (2) the "repair" of a machine is the restoring of the machine to the state of working in accordance with its original specifications and any changes to those specifications authorized for that machine.

[9] 21 C.F.R. § 1020.30(b): "Assembler means any person engaged in the business of assembling, replacing, or installing one or more components into a diagnostic x-ray system or subsystem."

devices. The exemption can be easily tailored, as proposed by Petitioner, to not exempt those situations.

The Copyright Office is not requested to determine what electronic service materials should be considered necessary electronic materials required for the purposes of servicing medical devices. However, it should concern the Copyright Office that TPMs and the DMCA are purposefully being used to restrict access to unprotected materials, fair use materials, and information the FDA mandates be made available.[10]

Philips' self-serving statement that it makes materials available for "basic service" is misleading in several respects.[11] First, Philips alone determines what should be considered "basic service." Second, Philips alone determines what materials are needed for such "basic service." Third, Philips alone determines who has access to even these "basic" materials. Fourth, Philips does not explain or address the hurdles it places on non-Philips' persons and entities to obtain access, such as the short expiration times of access keys, the expense for the access keys, and the refusal to train. Fifth, the AIAT mandate to which Philips alleges it complies, applies only to ionizing radiation emitting devices, not all medical imaging devices, much less all medical devices. Regarding this last point, at footnote 2 of its Period 2 comments, Philips misrepresents the facts and fails to completely quote the January 2, 2014 letter from Mary S. Pastel, Sc.D., Deputy Director for Radiological Health, Food & Drug Administration, to Gail M. Rodriguez Ph.D., Executive Director, Medical Imaging & Technology Alliance. The letter concludes that (emphasis added): "The manufacturer of the original system is not required to disclose proprietary accessories or functions, additional documentation or enhanced software programs to third parties unless this information is part of the AIAT instructions specified in 21 CFR 1020.30(g) or part of the user information specified in 21 CFR 1020.30(h)." Thus, the Deputy Director is clarifying that in fact OEMs must disclose and make available proprietary accessories or functions, additional documentation and enhanced software programs to third parties if they are covered by the AIAT disclosure requirements. Tellingly, this is the opposite of the impression Philips attempts to make in its' footnote.

The OEM Commenters argue that providing lawful possessors and third-party assistants with CSIP Level 0 access allows for "basic servicing of the systems". This is not accurate. First, Level 0 documentation and software is not available on all medical systems and modalities. Further still, many medical systems are not properly set up to use Level 0 documentation and software without prior configuration. Even when Level 0 is available, it requires the purchase of thousands of dollars in hardware per engineer in order to properly service medical equipment. As a result, and in contradiction to the FDA mandate that certain information be made available "at a cost not to exceed the cost of publication and distribution," lawful possessors, independent

[10] 21 C.F.R. § 1020.30(g). *See also*, FDA Guidance Document (attached in Transtate Period 1 comments as Exhibit 28).
[11] Philips Period 2 comments at 5.

service organizations ("ISOs"), and third-party assistants are forced to expend financial resources even before they are granted a limited amount of access and information to service medical equipment.[12] This "basic" level access also requires a tedious multistep process and certificates expire on a monthly basis, requiring lawful possessors, ISOs, and third-party assistants to endure the process at least twelve times per year and often more. Accordingly, and despite what the OEM Commenters state, Level 0 documentation and software is not sufficient.

Further, the OEM Commenters completely ignore that they do not always make keys for devices they deem to have reached end of life. This is an obvious impediment to servicing older medical devices.

OEMS could eliminate the TPMs for these materials and use TPMs only for the specialized unnecessary electronic servicing materials, but they have not done so because the threat of liability for violation of the DMCA to access the necessary electronic servicing materials gives the OEMs (undue) control over the medical device servicing market and makes lawful possessors beholden to the OEMs, as discussed below.

The concerns raised by the OEM Commenters regarding safety and cybersecurity also are not a concern in connection with this exemption seeking process, and, in any event, are based on speculation.[13] The incidences noted by AdvaMed and MITA relate to hardware issues, not use of software issues. Cybersecurity is already the subject of many other laws[14] and is an area addressed by the FDA.[15] More importantly, the OEM Commenters' self-serving concerns are unwarranted. The FDA also looked at the issues of patient safety and regulation of ISO's in 2017, and concluded in its 2018 report that there was no evidence to warrant further regulation of ISO's.[16] Again, the OEM comments are based on speculation. They provide no evidence of an ISO modifying software or otherwise committing a malicious or even reckless act via software. And, in any event, whether or not ISO's are regulated has nothing to do with the fact that TPMs are being used to hide non-protectable and necessary electronic servicing materials that are subject to non-infringing uses[17], and information the FDA has mandated be made available.

Accordingly, the requested exemption for medical devices is warranted.

II. The OEM Commenters Confirm That TPMs Are Not Being Used, Or At Least Used Primarily, By OEMs To Protect Copyrighted Material

A. All Three OEM Commenters Make Similar Arguments

[12] *See* supra fn. 6.
[13] Philips Period 2 comments at 2, 18; MITA Period 2 comments at 5; and AdvaMed Period 2 comments at 6.
[14] The Computer Fraud and Abuse Act, 18 U.S.C. § 1030, is one example.
[15] 21 C.F.R. § 11.10.
[16] Ex. 22 at 25-26.
[17] Such infringing uses are Fair Use, Essential Steps, and Machine Maintenance and Repair, as discussed in Transtate's Period 1 Comments at 14-19, and infra in Sections E(1)-(2).

Philips, MITA, and AdvaMed raise the specter of "unregulated" and "untrusted" ISOs servicing medical devices, insinuating that ISOs are presumed untrustworthy, and cannot be entrusted with servicing of medical devices unless they pass some approval process imposed by the OEMs and/or the FDA.[18] The OEM Commenters also raise the specter that granting the exemption would endanger "patient safety."[19] They also raise the specter of an exemption enabling "hacking" and compromising cybersecurity of the medical devices.[20] But, these issues have already been addressed by the FDA, and, in any event, are irrelevant to the DMCA exemption request process.

B. The OEM Comments Are Not Relevant To The Purpose Of TPMs

The anti-circumvention provision of the DMCA was enacted for the purpose of protecting digital works in the then new digital media, *e.g*., the Internet and storage devices, given the much greater ease with which digital works could be easily reproduced and distributed. The provision was not enacted to regulate servicing of devices, be a mechanism for the OEMs to vet the technical qualifications of device servicing entities, to address patient safety concerns, for the OEMs to protect patient privacy, or to protect trade secrets. All of the OEMs' arguments regarding these issues are irrelevant and only serve to lay bare that the OEMs' main intent is to act as marketplace controllers and to be the sole arbiters regarding who should be allowed to service medical devices. And if this is not telling enough, the OEM Commenters direct all of their arguments against ISOs and do not mention any of these concerns with respect to the device owners and other lawful possessors who are in the same position as ISOs. The OEM Commenters do not explain why it is that the lawful possessors are somehow "trustworthy" but ISOs are not. It is clear the TPMs are used primarily, if not solely, to keep lawful medical device possessors beholden to the OEMs for servicing their devices and to eliminate ISOs from assisting the lawful possessors of the medical devices.

Indeed, the market for servicing medical devices is more accurately divided into OEMs and non-OEMs. The non-OEMs include (a) the lawful possessors such as hospitals and other medical facilities as well as refurbishers/remarketers, and (b) ISOs. The lack of or burdensome access to necessary electronic servicing materials is foremost an issue for the lawful possessors with in house servicing departments, whether they are staffed by employees or contractors, because of the unnecessary delays and costs in needing to rely on the OEMs for servicing, as outlined by Transtate's Period 1 declarants.[21]

Further, and as noted in Transtate's Period 1 comments, although some lawful possessors of medical devices can obtain some degree of access to the embedded servicing materials, it is at an

[18] Philips Period 2 Comments at 2 and 9-10.
[19] Philips Period 2 comments at 7; MITA Period 2 comments at 3-4, 9-10, 18, and 30; and AdvaMed Period 2 comments at 2, 9, and 11-12.
[20] Philips Period 2 comments at 2 and 9-10.
[21] *See* declarations of Melvin (Ex. 5 at ¶ 8); Kahler Ex. 6 at ¶¶ 13-16); and Grogan (Ex. 8 at ¶ 16).

undue expense, and the access is insufficient. And, the electronic servicing materials to which access is given are entirely within the discretion of the OEMs.

What the OEM Commenters fail to mention, is the fact that there are other OEMs, such as Del Medical, Cannon, and Toshiba[22] that do not use TPMs, and who do not prevent non-OEM servicing of their devices. There is no mention by the OEM Commenters that there is any, much less a significant, concern for privacy breaches, safety incidences, cybersecurity issues, or copyright infringement in connection with non-OEM servicing of such devices without TPMs. This is because these issues are overblown and unsupported in the record.

C. The Safety And ISO Regulation Issues Are The Purview Of The FDA Which, Already Determined Not To Regulate ISOs Because ISOs Are Not Only Trusted, But Vital.

The patient safety and regulation of non-OEM servicing of medical devices is the purview of the FDA. Even the OEM Commenters recognize this. In its May 2018 Report,[23] the FDA noted that (emphasis added):

- The currently available objective evidence is not sufficient to conclude whether or not there is a widespread public health concern related to servicing, including by third party servicers, of medical devices that would justify imposing additional/different, burdensome regulatory requirements at this time;
- Rather, the objective evidence indicates that many OEMs **and third party entities provide high quality, safe, and effective servicing of medical devices**;
- A majority of comments, complaints, and adverse event reports alleging that inadequate "servicing" caused or contributed to clinical adverse events and deaths actually pertain to "remanufacturing" **and not "servicing**"; and
- **The continued availability of third party entities to service and repair medical devices is critical to the functioning of the U.S. healthcare system**.

If the FDA, the agency responsible for patient safety and regulation of the manufacture and servicing of medical devices has determined that third party entities provide high quality, safe, and effective servicing of medical devices and that the availability of third party entities to service and repair medical devices is critical to the functioning of the U.S. healthcare system, it is to that agency that the OEM Commenters should raise their concerns. The OEM Commenters' attempt to involve the Copyright Office and the Registrar in these issues is simply inappropriate and an improper attempt to raise irrelevant issues for the sole purpose of maintaining their exclusionary behavior.

[22] Grogan Decl., Ex. 8 at ¶ 12.
[23] FDA Report on the Quality, Safety,and Effectiveness of Servicing of Medical Devices (May 2018), Ex. 22 at pg. i.

Further, patient and operator safety is covered by a myriad of laws and regulations. It is in no one's interest to jeopardize patient or operator safety. The OEM comments in that regard are simply without any basis in fact. If anything, access to the necessary electronic servicing materials will enhance such safety because it will enable lawful possessors and their trusted third party assistants to address problems quickly.[24] The exemption will enable access when the need arises and the OEMs refuse or greatly hinder access.

Indeed, the OEMs have their own safety issues. The Department of Health and Human Services reviews complaints and tracks responses to complaints. Attached as **Exhibit 30**, are a sampling of issues raised by the HHS with respect to complaints against Philips. Many involve software issues. This further underscores that the OEMs' invocation of patient safety is nothing more than a smokescreen.

D. The Cybersecurity Issues Raised By The OEM Commenters Are Covered By Other Statutes

The OEM Commenters arguments regarding the risk of malicious cybersecurity breaches or hacking to modify medical devices by exempting access to necessary electronic servicing materials is not relevant. Cybersecurity is both subject to multiple laws such as the Health Insurance Portability and Accountability Act of 1996, the Computer Fraud and Abuse Act of 1986 or regulations of the Food and Drug Administration, and various criminal statutes. The FDA also is active in this area.[25]

Aside from the fact that the OEM Commenters provide no evidence of malicious cybersecurity breaches committed by a non-OEM servicing entity, the exemption sought is for diagnosis, maintenance and repair, not remanufacture or alteration. One would still remain liable under all relevant laws for circumvention to perform acts other than servicing. Further, an exemption would not remove the TPMs, only liability for circumvention to service the medical devices under lawful conditions.

Bad actors will commit bad acts regardless of the laws meant to deter them. Circumvention of a TPM is a minimal concern for someone wishing to commit a malicious act. All the TPMs do in the present situation is make it more difficult and more expensive for lawful possessors to have

[24] As an example, after performing certain types of service on Philips' cath lab machines, including service permitted under Philips' "basic" access, you are required to calibrate the Interventional Work Station ("IWS"). Philips' "basic" access level does not permit access to this calibration. If IWS is not calibrated, it puts the patient's health and safety at risk. For example, without calibration, the images displayed through IWS may not be clear, necessitating taking multiple images, exposing the patient to unnecessary radiation. More significantly, lack of calibration may result in "image misregistration," where for example the location of a catheter that is being placed in a patient's body is not being accurately shown in the IWS image. This could cause major issues during surgery, resulting in injury or even death to the patient.

[25] *See* https://www.fda.gov/medical-devices/digital-health-center-excellence/cybersecurity.

their medical devices serviced. It also makes the lawful possessors more reliant on the OEMs for their servicing needs.[26]

E. Arguments Regarding the Commercial Motive of ISOs Are Misplaced

The OEM Commenters make much ado about the commercial motivation of ISOs. But that is easily dispensed with.

First, the petition requests an exemption for lawful possessors of the medical devices and the third party servicers performing services requested by the lawful possessors. As set forth in the declarations provided with Petitioner's Period 1 comments, lawful possessors such as hospitals invariably have in-house staff to perform the servicing to the extent they are able to do so.[27] This reduces cost and delays. Lawful possessors such as hospitals and medical facilities do rely on outside parties, whether OEMs or ISOs for some servicing. Some contract out of their in-house departments, i.e., they are staffed by contractors, not direct employees. These lawful possessors experience the same issues with the impediments imposed by the TPMs, namely high costs to obtain keys, higher servicing costs by OEMs, and no access to needed information such as error/failure codes and the like. Ultimately, the benefit of allowing circumvention is for the lawful possessors to get faster and more affordable services from ISOs.

To focus exclusively on ISOs, while ignoring hospitals and other lawful possessors, is a clear indication that the OEM Commenters are intent on trying to persuade the Copyright Office using unwarranted scare tactics rather than to focus on the merits of TPMs and access to protected works.

F. The Failure to Separate the Necessary and Unnecessary Electronic Servicing Materials is the OEM's Achilles' Heel

To the limited extent that the OEM Commenters mention a concern for protecting copyright protectable material, they conveniently fail to separate out the necessary electronic servicing materials from the unnecessary electronic service materials, which presumably are materials for the benefit of the OEMs. Because by definition there would be no need for anyone other than an OEM to access the unnecessary electronic servicing materials materials, there would be no risk of exposure of these materials because a non-OEM would not have a need to access these materials. At the same time, the lawful possessors and those assisting them would be able to more easily, quickly, and with less expense ensure compliance of the medical devices with governmental and manufacturer specifications.

IV. The Making Of Copies Of Necessary Servicing Materials In Order To Conduct Servicing Of Medical Devices Indeed Is Exempt From Infringement

[26] *See* declarations of Melvin (Ex. 5 at ¶ 8), Kahler (Ex. 6 at ¶¶ 13-16); and Grogan (Ex. 8 at ¶ 16).
[27] *Id*.

A. The Making Of A Copy Of A Computer Program Or Database In Order To Service A Medical Device Is Fair Use

i. The Purpose and Character of the Requested Use Supports Exemption

OEM Commenters argue that the lawful possessors, ISOs, and third-party assistants' requested uses are purely commercial and thus presumptively unfair,[28] however, they ignore the underlying non-commercial "purpose and character" of the proposed use, *i.e.*, that Transtate, lawful possessors and other third-party assistants' require access to the necessary electronic servicing materials for the purpose of adequately servicing medical devices used in furtherance of public health. The OEM Commenters also conveniently fail to mention that other lawful possessors (*i.e.*, hospitals and medical facilities) share similar "commercial" qualities.[29]

The OEM Commenters mischaracterize the emphasis on commercial use involved in consideration of the first factor for fair use. As articulated by Nimmer on Copyright, a less stark formulation of the same principle is that "commercial motivation and fair use can exist side by side," and considerations include "whether the alleged infringing use was primarily for public benefit or for private commercial gain"—which inclines against fair use in a commercial context, but leaves wide latitude for consideration of all the other factors that may outweigh this single fact under appropriate circumstances.[30] In other words, labeling a use as "commercial," should not end the analysis.[31] Accordingly, the mere fact that a use is educational and not for profit does not insulate it from a finding of infringement, any more than the commercial character of a use bars a finding of fairness." Because the fact that a given use is commercial does not necessarily negate fair use, any presumption that a commercial use is *ipso facto* unfair should be regarded as "rebutt[able] by the characteristics of a particular commercial use."[32]

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[28] *See* Phillips Period 2 Comments at pg. 7 citing *Leadsinger, Inc. v. BMG Music Pub.*, 512 F.3d 522, 530 (9th Cir. 2008) and *Disney Enters., Inc. v. VidAngel, Inc.*, 224 F.Supp.3d 957, 972 (C.D. Cal. 2016), for the conclusion that commercial use is presumptively unfair. However, the facts that represent "commercial use" in each of these cases are distinguishable from the facts at hand. In *Leadsinger, Inc. v. BMG Music Pub.*, a manufacturer of karaoke devices brought an action against music publishers seeking declaratory judgment that it was authorized to display lyrics to songs, either in print or displayed on a video screen, under the fair use doctrine. The court held that plaintiff's basic purpose—to sell its karaoke device for profit—was a commercial one. Similarly, in *Disney Enters., Inc. v. VidAngel, Inc.*, the plaintiffs were companies in the business of producing and distributing motion pictures and television programs and brought an action against an unauthorized provider of companies' copyrighted movies and television programs. Neither of these cases, nor the purposes for use of copyright protected materials articulated therein, is analogous to the type of use contemplated by Petitioner, that of service and repair of medical devices that directly impact the quality of public health.

[29] *See* supra at § E.

[30] *See* 4 Nimmer on Copyright § 13.05 (2020).

[31] *See* 4 Nimmer on Copyright § 13.05 (2020); *Campbell v. Acuff-Rose Music, Inc*., 510 U.S. 569, 584 (1994) ("The language of the statute makes clear that the commercial or nonprofit educational purpose of a work is only one element of the first factor enquiry into its purpose and character. Section 107(1) uses the term 'including' to begin the dependent clause referring to commercial use, and the main clause speaks of a broader investigation into "purpose and character'. . .).

[32] *See* 4 Nimmer on Copyright § 13.05 (2020).

In determining the purpose and character of the use, "the crux of the profit/non-profit distinction is not whether the sole motive of the use is monetary gain but whether the user stands to profit from exploitation of the copyrighted material without paying the customary price." *See, e.g., Harper & Row, Publrs. v. Nation Enters.*, 471 U.S. 539, 562, 105 S. Ct. 2218, 2231, 85 L. Ed. 2d 588, 608, 1985 U.S. LEXIS 17, *43, 225 U.S.P.Q. (BNA) 1073, 1081, 53 U.S.L.W. 4562, 11 Media L. Rep. 1969; *Weissmann v. Freeman*, 868 F.2d 1313, 1315, 1989 U.S. App. LEXIS 2387, *1, 10 U.S.P.Q.2D (BNA) 1014, 1015, Copy. L. Rep. (CCH) P26,390, 101 A.L.R. Fed. 91 (one academic's use of another academic's materials was a for-profit use); *Society of Holy Transfiguration Monastery, Inc*., 689 F.3d 29, 61 (1st Cir. 2012) ("In effect, the commercial-noncommercial distinction the law draws centers not on whether a user intends to line his own pockets, but rather on whether the user stands to profit from exploitation of the copyrighted material without paying the customary price. Profit, in this context, is thus not limited simply to dollars and coins; instead, it encompasses other non-monetary calculable benefits or advantages.").

Here, the request to access fair use of the necessary electronic servicing materials would involve a commercial setting only to ensure that the medical equipment complies with OEM and regulatory specifications.[33] Petitioner is not aware of anyone in the business of selling access to such servicing materials. Moreover, remarketers, such as Petitioner, pay in full for the medical equipment at issue, and are lawful owners of the medical devices with the software integrated in them. Servicing the medical equipment owned by lawful possessors is primarily for public benefit, as access to materials required for servicing is imperative in treating patients, and is especially critical during a pandemic such as the current COVID-19 crisis.[34] Petitioner does not and is not seeking to provide, or for others to provide, the copyrighted works to third-parties, but instead seeks access to effectively service products that are lawfully owned. Accordingly, the Petitioner's proposed use of copyrighted works is not commercial in the ordinary sense.

Petitioner does not dispute that it is a for-profit entity. However, the commercial nature of Petitioner's business model does not outweigh the noncommercial nature of its servicing and repair work.

ii. The Nature of the Original Work Supports Exemption

OEM Commenters seek to downplay this factor precisely because it weighs in favor of exemption. The more informational or functional the work, the broader the scope of the fair use defense. *See, e.g.*, 4 Nimmer on Copyright § 13.05[A][2][a]; *Leadsinger, Inc. v. BMG Music* Pub., 512 F.3d 522, 531 (9th Cir. 2008) *Leadsinger, Inc. v. BMG Music Publ'g*, 512 F.3d 522, 531 (9th Cir. 2007); *Stern v. Does*, 978 F. Supp. 2d 1031, 1046 (C.D. Cal. 2012), *aff'd*, 512 Fed. Appx. 701 (9th Cir.), *cert. denied*, 134 S. Ct. 423 (2013); *Cambridge Univ. Press v. Becker*, 863

[33] 21 C.F.R. §§ 1020.30(g)-(h)
[34] *See* declarations of Melvin (Ex. 5 at ¶ 7), Kahler (Ex. 6 at ¶ 16), and Lane-Savage (Ex. 7 at ¶¶ 17-19).

F. Supp. 2d 1190, 1225 (N.D. Ga. 2012), *rev'd on other grounds sub nom., Cambridge Univ. Press v. Patton*, 769 F.3d 1232 (11th Cir. 2014); *See Diamond v. Am-Law Corp*., 745 F.2d 142 (2d Cir. 1984) ("informational works may be more freely published"); *Consumers Union of U.S., Inc. v. General Signal Corp.*, 724 F.2d 1044, 1049 (2d Cir. 1983) ("Since the risk of restraining the free flow of information is more significant with informational work, the scope of permissible fair use is greater."), *cert. denied*, 469 U.S. 823, 105 S. Ct. 100, 83 L. Ed. 2d 45 (1984) (*but see later opinion*, 664 F. Supp. 753 (S.D.N.Y. 1987)).

The service software designed and blocked by OEMs is not creative nor fictional, expression; it is functional information required to safely service medical equipment. The software itself is not dictated by any creative expression, but by the specific technical needs of the machine. Indeed, because the copyrighted works held hostage by OEMs are integrated with functional medical equipment (*i.e*., the hardware), access to this information is necessary to engage in diagnosis, repair, and lawful modification of medical device functions.[35] Petitioner seeks access and use of this functional information in order to obtain diagnostic data. Accordingly, the second factor supports fair use.

iii. The Amount And Substantiality Of The Portion Used In Relation To The Copyrighted Work As A Whole Weighs In Favor Of An Exemption

The amount of use of the servicing materials would not be substantial and would be limited to those instances where circumvention was essential for critical diagnoses, maintenance, and repairs. As explained above, only the portion of the works containing necessary electronic service materials are at issue under the proposed exemption. Accordingly, granting Petitioner's proposed exemption does not require use of the entire copyrighted works.

OEM Commenters argue that granting Petitioner's exemption requires use of its entire copyrighted works, providing little evidence to support this assertion, but the OEM Commenters do not address the fact that use of its works are part and parcel of a lawful possessor's ownership of the medical equipment it services. The OEM Commenters also do not admit that in certain instances, access to proprietary information, additional documentation or enhanced software programs is required.[36] OEM Commenters also falsely state that the current access level provides

[35] Opponent Medical Imaging & Technology Alliance ("MITA") cites *Allen-Myland, Inc. v. IBM* as an exemplar where copying computer code was not found to be fair use despite the computer code's informational nature, however the facts and holding are distinguishable from the facts at hand. In *Allen-Myland, Inc. v. IBM*, the court declined to find a fair use of computer code because the plaintiff copied code to build a library of different versions of the microcode in order to discover how to support various configurations and learn how to use IBM's system to achieve its commercial purposes without paying IBM. In this instance, Petitioner's purpose is not to create an internal inventory, it is to repair, service, and diagnose the medical equipment it owns.

[36] *See., e*.g., January 2, 2014 letter from Mary S. Pastel, Sc.D., Deputy Director for Radiological Health, Food & Drug Administration, to Gail M. Rodriguez Ph.D., Executive Director, Medical Imaging & Technology Alliance.

information necessary for basic repair and maintenance, but the OEM Commenters do not define, extrapolate, or provide evidence of their interpretation of "basic."[37]

The attempt to drag safety and cybersecurity cautions into their arguments also fail, given that the FDA has weighed in and concluded ISOs like Petitioner are "critical" to a safe and functioning medical care industry. Moreover, Petitioner and other ISOs like it already receive some degree of training directly from OEMs, and are skilled and trained in repair and diagnosis of medical equipment, so long as they are empowered with the appropriate level of access needed to do so. If the OEMs cared solely about safety, they would provide even more training, not less. The OEM Commenters arguments that granting the exemption requires use of its entire copyrighted works is misleading and misses the point. The third fair use factor supports an exemption.

iv. The Effect Of The Use Upon The Potential Market For Or Value Of The Copyrighted Work Is Minimal

The OEM Commenters argue that the fourth factor weighs against Petitioner because as a third-party ISO it is inherently commercial.[38] Instead, of responding to the valid concerns provided from lawful possessors, and those acting at their behest, the OEM Commenters attempt to focus on the potential for safety and hacking harm by allowing **third parties** access to service medical devices. This argument ignores the plight of in-house hospital employees attempting to service their own medical equipment.[39]

Medical equipment software is effectively useless outside of the equipment it inhabits, with no separate market for reselling or distributing the software apart from the devices. The servicing materials required are only useful for the particular medical equipment in which they are embedded. Moreover, OEM Commenters concede that they already license some of their copyrighted materials to some ISOs,[40] which causes no harm to the secondary market. Petitioner is seeking access for lawful possessors, and those acting at their behest, to the necessary electronic servicing materials to ensure proper operation and servicing activities on medical systems and devices. Access to the computer programs and data files comprising the necessary electronic servicing materials is needed to replace the unprotected electrical and mechanical parts on the medical device. Again, the TPMs do not provide a means for maintaining the device's hardware without also accessing the software. There is no other need to otherwise copy or access the computer programs and data files.

OEMs would still be free to sell medical devices and computer programs. Accordingly, the necessary servicing materials used by lawful possessors, ISOs, and third-party assistants does not

[37] *See also* supra at pg. 5.
[38] Philips Period 2 comments at10; AdvaMed Period 2 comments at 7; and MITA Period 2 comments at 8.
[39] *See* declarations of Melvin (Ex. 5 at ¶ 4), Kahler (Ex. 6 at ¶ 5), and Grogan (Ex. 8 at ¶¶ 6-7).
[40] Dickson Decl. at para. 4.

affect the market for or value of the computer programs and data files involved. Therefore, the fourth factor weighs in favor of a finding of fair use.

B. The Making Of A Copy Of A Computer Program Or Database In Order To Service A Medical Device At The Request Of An Owner Of The Device Is An Essential Step In The Use Of The Device

OEM Commenters raise the issue that a copy of the computer program or data base is not necessary for the activation of the medical device, but it is necessary to service or diagnose the medical device.[41] The OEM Commenters also claim that the owners of the medical devices are not the owners of the copies of the electronic materials embedded in the devices stating the software is only licensed. However, this ignores that the issue of ownership is a fact-based inquiry.[42] The Copyright Act provides for two basic manners for distributing copies of works: (a) by sale or other transfer of ownership, or (b) by rental, lease, or lending.[43] Yet the OEM Commenters nowhere describe how they are distributing their works via the rental, lease, or lending, or that the machine sale documents include these words or concepts. Rather, they rely on "licensing" which is an intellectual property right concept, not a concept associated with the transfer of tangible property, and in this case, the copies of sofware and data files stored or embedded on a machine.

Indeed, even assuming that the software in the owned machines was only considered rented, leased, or lent, there is no sensical explanation as to how one returns the embedded copies of the works. Presumably they could, if they knew how, delete all of the software by somehow reimaging the drives of the machines, but then the machines would cease to function. They would no longer constitute the purchased machine. This surely is not contemplated by anyone in the purchase of the medical devices. Rather, the expectation is that the medical devices can be maintained and repaired thoughout their useful lives.

Philips even concedes that its "customers purchase a limited license to use Philips' CSIP materials **to service their own Philips imaging systems**."[44] Yet, Philips fails to address why these materials, which include "documentation and software to support planned maintenance activities and to execute common corrective maintenance activities," are not essential in the use

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[41] AdvaMed Period 2 comments at 7-8; MITA Period 2 comments at 13; and Philips Period 2 comments at 12-13.
[42] *See* Raymond Nimmer, The Law of Computer Technology § 1.18[1] p. 1–103 (1992) ("Ownership of a copy should be determined based on the actual character, rather than the label, of the transaction by which the user obtained possession. Merely labeling a transaction as a lease or license does not control. If a transaction involves a single payment giving the buyer an unlimited period in which it has a right to possession, the transaction is a sale. In this situation, the buyer owns the copy regardless of the label the parties use for the contract. Course of dealing and trade usage may be relevant, since they establish the expectations and intent of the parties. The pertinent issue is whether, as in a lease, the user may be required to return the copy to the vendor after the expiration of a particular period. If not, the transaction conveyed not only possession, but also transferred ownership of the copy.")
[43] 17 U.S.C. §106(3).
[44] Dickson Decl. at para. 4.

of the medical device.[45] Instead Philips misconstrues Petitioner's comments relating to use as an essential step by relying on the 2018 Recommendation regarding motor vehicle telematics and entertainment system to assert that software is licensed, not owned.[46]

Philips' arguments ignores the nature and context of the Register's concerns in its 2018 Recommendation. First, the Recommendations noted that most of the concerns "primarily relate to accessing entertainment works through vehicle entertainment systems and related subscription services, not to repairing more functional software installed to facilitate vehicle operation."[47] In its 2018 Recommendation, the Register also distinguished the 2015 rulemaking favoring exemption for vehicle repair "because the activities were personal, noncommercial, and would 'enhance the intended use' of the vehicle programs."[48] Again, Philips does not address how the TPM protected necessary electronic servicing materials do not enhance the use of the medical devices. Instead, Philips is attempting to categorize its software licenses with subscription services such as Sirius XM, which were of concern in the 2018 Recommendation.[49] These arguments also ignore that a potential harm from medical devices that are not properly serviced and maintained is loss of human life.

To rebut Petitioner's evidence of servicing harm during the COVID-19 pandemic, Philips (the only OEM to address this issue) provides that its own records do not show a reduction in service capabilities.[50] This over-simplification of the argument ignores the potential harm to life from medical equipment that is not properly maintained.[51] It also avoids addressing the current effect to taxpayers and patients resulting from costs for maintaining medical devices from purchasing access keys and paying higher service charges by OEMs.[52] By ignoring the current harms to both patient safety and medical costs, OEM Commenters are minimizing the current market harm from its broadly applied use of TPMs.

Petitioner is not seeking an exemption to access the same types of software that were of concern in the 2018 Recommendation. Rather, Petitioner is seeking access to fairly use the necessary electronic servicing materials embedded in medical equipment as an essential step in the servicing and repair activities associated with the medical equipment. This software cannot be separated from the medical equipment. The medical device is rendered useless without the software. This is distinguishable from motor vehicle telematics and entertainment system software where, as the Register notes, "diagnostic data is still available through the online

[45] *Id*.
[46] Philips Period 2 comments at 12.
[47] 2018 Recommendation, Ex. 29 at 215.
[48] *Id*. at 203.
[49] *Id*. at 216.
[50] Philips Period 2 comments at pg. 14.
[51] *See* FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices, Published May 2018, Ex. 25; *see also* Peloso Decl., Ex. 15 at ¶¶ 11-13.
[52] Kahler Decl., Ex. 6 at ¶ 16; *see also* Lane-Savage Decl., Ex. 7 at ¶ 21.

diagnostics port."[53] Here, OEMs are using TPMs to prevent both ISOs and medical device owners from accessing diagnostic data.[54]

C. Hardware Maintenance And Repair 17 U.S.C. § 117(C) Is Applicable To Effect Maintenance Or Repair Of A Medical Device

The necessary electronic servicing materials are not "additional"—they are an included and necessary part of the medical equipment.

In relying on *Storage Tech. Corp. v. Custom Hardware Eng'g & Consulting, Inc*,[55] the OEM Commenters mischaracterize and cherry pick their supporting arguments. In this case, the court stated that "Congress's clearest indication of what it considered to be 'necessary for the machine to be activated,' is found not in section 117(c), but in section 117(d) which defines repair and maintenance in terms of allowing the system to work "in accordance with its original specifications and any changes to those specifications authorized for that machine." The court continued, stating that "the service provider must be able to cause the machine to boot up in order to determine if it 'works in accordance with its original specifications.'" The court concluded that "in some instances, it may be difficult to determine whether particular software is necessary to make the computer function and to ascertain whether the computer is working properly." Accordingly, it found that where the maintenance code was "so entangled with the functional code that the entire code must be loaded into RAM for the machine to function at all", loading the maintenance code was necessary for the Management or Control Unit "to be turned on."[56]

The OEM Commenters conflate the concepts and incorrectly emphasize the element of turning on the device with the underlying purpose of the statute: function. The necessary electronic servicing materials on medical equipment are so entangled with the devices, that they must be accessible in order to conduct diagnosis and repair in a safe manner. In order to determine if the medical equipment functions in accordance with its original and updated specifications, use of servicing computer programs and data files comprising the necessary electronic servicing materials is required.

Indeed, attached as **Exhibits 31 and 32**, are copies of the certified registrations for two versions of the Allura software embedded in Philips x-ray machines. Each registration is for a complete software package that includes aspects of the code for both running and maintaining the machines. The entire package is invoked when operating and maintaining the machines.

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[53] *Id*. at 213.
[54] *See* declarations of Spencer (Ex. 3 at ¶ 6), Melvin (Ex. 5 at ¶ 5), Kahler (Ex. 6 at ¶ 6), Lane-Savage (Ex. 7 at ¶ 22), and Grogan (Ex. 8 at ¶ 6).
[55] *Storage Tech. Corp. v. Custom Hardware Eng'g & Consulting, Inc*., 421 F.3d 1307, 1314 (Fed. Cir. 2005).
[56] Notably, the court in *Storage Tech. Corp.* held that the Defendant-Appellant service company came within the safe harbor for software copying done solely for purposes of maintenance or repair and found the district court erred in finding that it was unlikely to prevail on its defense to copyright infringement. *Storage Tech. Corp. v. Custom Hardware Eng'g & Consulting, Inc.*, 421 F.3d 1307, 1317 (Fed. Cir. 2005).

Transtate is not aware of any ISO or lawful possessor that modifies the necessary servicing computer programs and data. Instead, they simply seek to access and use them for repair and servicing activities. Transtate is not aware of anyone who makes copies of the necessary electronic materials, outside of fair use loading of them into random access memory for execution purposes. Accordingly, and because the necessary electronic servicing materials are necessary to conduct servicing activities, the proposed use is exempt from infringement under Section 117.

CONCLUSION

The OEM Commenters' argument that granting Petitioner's exemption will expose the public to serious dangers associated with the modification of medical devices has already been dispelled by the FDA. The OEM Commenters' further argument that the current access and use of documentation and software is sufficient to perform servicing activities is self-serving and not supported. As concluded by the many declarants supporting Petitioner's Period 1 comments and the proposed exemption, this is not the case. Finally, the OEM Commenters' argument that the Copyright Office granting the proposed exemption will threaten entire copyrighted works, proprietary information and trade secrets is not supported. The Petitioner seeks a tailored exemption, which would grant access only to the electronic service materials necessary for servicing (diagnosis, repair, and maintenance) of medical devices and systems. As a result, the OEM Commenters arguments fail.

For the aforementioned reasons, Petitioner's proposed exemption should be granted.